Women's Health Initiative
2009 Annual Progress Report

Data as of: August 14, 2009

Prepared by
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1. Overview

1.0 Preliminary Remarks

This report documents the experience of the WHI Extension Study (ES) activities through August 14, 2009, the fourth year of this phase, summarizing consent and follow-up response rates, study outcomes and performance. In addition, this report describes efforts using core resources for biomarker and intermediate endpoint studies, ancillary studies with particular focus on those using the biospecimen repository, and a summary of publications.

The current Principal Investigators and sponsoring institutions are presented in Table 1.1. Several changes in site leadership are occurring at this time. Dr. Margery Gass has been named the Executive Director of the North American Menopause Society and is therefore leaving the Cincinnati Field Center. Her replacement is Dr. Michael Thomas. Dr. Haleh Sangi-Haghpeykar, PhD will be the new Principal Investigator at Baylor College of Medicine, replacing Dr. Aleksander Rajkovic, who has moved to Pittsburgh. Dr. Erin LeBlanc will be the new PI at Portland-Kaiser Foundation Research Institute, replacing Dr. Yvonne Michael. We thank Drs. Gass, Rajkovic, and Michael for their service to WHI and welcome our new colleagues.

Data presentations on consent, response rates, vital status and outcome rates for each study component are provided with limited additional explanation as these follow the same conventions as have been previously described. A few comments are presented below as orientation to the new presentation on aging related analyses.

1.1 Extension Study Follow-up

The ES study follow-up plan entails annual mailed contacts to obtain self-reported outcomes (Form 33–*Medical History Update*), hormone therapy use (Form 150–*Hormone Use Update*) among HT trial participants, and quality of life (Form 151–*Activities of Daily Living*). A one time collection of historical diagnoses of Parkinson's disease and diabetes (Form 134–*Addendum to Medical History Update*) was also collected during the first ES follow-up year.

The annual contact is administered through up to three mailings from the CCC over a five month period followed by FC follow-up of non-responders after seven months. Currently follow-up for Year 4 has been initiated for over 83% of enrolled participants. Response rates to Form 33–*Medical History Update,* viewed as the primary indicator of response, indicate that participation rates remain high in year 4, with 82.5% responding to the first mailing and 91.9% responding to mailings overall (Table 1.5). Response rates remain somewhat lower in the clinical trial components than in the observational study.

Field Centers are responsible for data collection from women who cannot be followed by mail and from non-responders to the three CCC mailings. In year 4 so far, 6.9% have required Field Center follow-up and of these, 91.9% have provided a Form 33 giving a total estimated response rate of 97.4% (Table 1.6, page 1-19).

Response rates for Form 151 are lower generally than for other instruments because Field Center follow-up for this form is optional. Responses to Form 134 are also low in Year 2 and beyond because this form was to be collected only in Year 1; later response rates represent

only activities for participants who did not respond in Year 1. Differences between study components are generally small.

1.2 Outcomes

The list of potential outcomes being investigated for the WHI-ES has changed somewhat from WHI. The most important changes were:

- Outpatient stroke is adjudicated (not adjudicated during WHI)
- Hip fracture continues to be adjudicated but no other fractures (during WHI other fractures were adjudicated for Clinical Trial participants)
- Hospitalizations of a single night are no longer investigated, unless they occur in conjunction with a self-report of a designated WHI-ES outcome
- Angina and CHF are no longer adjudicated with the beginning of the Extension in 2005. In 2009, plans were developed to resume adjudication of CHF in HT participants from 2005 forward, in preparation for the next extension period from 2010 to 2015.
- VTE events continue to be adjudicated for former HT participants. In 2009, plans were developed to adjudicate VTE in all Black and Hispanic participants from 2005 forward, also in preparation for the next extension period.

For each outcome type, only the first occurrence since the beginning of WHI is investigated. A complete list of adjudicated outcomes for the WHI-ES may be found in the WHI-ES protocol.

Outcomes adjudication for the WHI-ES is centralized. Field Centers collect documents from self- or proxy-reported cases and forward them to the CCC. The CCC forwards purported cases of designated WHI outcomes to an adjudicator specific to the disease category. Outcomes identified from other hospitalizations are first reviewed by CCC outcomes staff and then either forwarded to an appropriate adjudicator, or closed administratively. Adjudicators are divided into committees responsible for cardiovascular events (which include VTE but not stroke), stroke, hip fractures, fatal events, and cancer. The cancer committee consists of trained cancer coders at the CCC. All other committees consist of physician adjudicators, many of whom were local physician adjudicators during WHI. There is a large overlap between the fatal events committee and the cardiovascular committee. Every case is reviewed by a single adjudicator. QA procedures require a second adjudication of at least 10% of the cases by another adjudicator from the same committee.

A tabulation of all designated outcomes currently available based on the current procedures for adjudication are presented by age and race/ethnicity for each CT components in Sections 2 through 4, for OS participants in Section 5 and for CT participants combined in Section 6. Additional tables of self-reported outcomes in women who did not report a prevalent condition at baseline are also provided in each section.

Agreement rates between self-report and confirmed outcomes occurring during the WHI extension are provided in Tables 7.1 and 7.2. Because there is not always a one-to-one correspondence between self-reported and adjudicated outcomes, the agreement is presented in two ways.

Table 7.1 presents the final status of all self-reports. A self-report for a particular outcome is considered closed if all adjudications associated with the outcome are closed. In the rare situation where a self-report of a specific event is associated with several adjudication cases, perhaps because of several associated hospitalizations, the original event would not be considered closed in this table, even if the original event has been confirmed. This is a reason for discrepancies between numbers in these tables and other tables in this report.

If a self-report is closed, it is considered "confirmed" if any of the associated adjudication cases confirms the exact outcome. If this is not the case, we examine whether a related outcome has been found. All cardiovascular outcomes are considered related, all cancers are considered related, and all fractures are considered related. If no related outcome is confirmed, we determine whether any outcome has been confirmed. For the denied cases, we separate those that are denied for administrative reasons (e.g. no release of information [ROI] obtained) from those where the records indicate that no outcomes occurred.

Table 7.2 examines the source for confirmed outcomes to determine if a centrally confirmed case was investigated as a result of a self-report for the exact outcome, a related outcome, an unrelated outcome, or a hospitalization.

1.3 Aging Outcomes-WHI Extension

Reports summarizing the data acquired to date from Form 151, the Aging Outcomes Questionnaire, are shown in Section 8. Form 151 is mailed annually to participants in the WHI Extension with Form 33. If no form is returned, no telephone follow-up is required to solicit this information. Nonetheless, response rates have been excellent. Only 1.8% of women have never completed a Form 151. These data provide an overall picture of the co-morbidity, self-rated health, perceived quality of life and functional status of our aging cohort.

Table 8.1 shows the distribution by current age and race/ethnicity among WHI participants known to be alive on August 14, 2009. Thirty percent of the WHI Extension Study cohort has reached their ninth decade, with 32,473 women aged 80-89 and 2,385 women aged 90 and older.

Co-morbidity is quite common in the Extension Study cohort. Based on self-reported outcomes (including DVT, pulmonary embolism, treated diabetes, treated hypertension, hysterectomy, osteoarthritis, intestinal polyps, and lupus) through August 14, 2009, nearly 46% of women have reported 4 or more outcomes (Table 8.2). Only 3.1% of women have reported no outcomes. The burden of self-reported co-morbidity appears to be highest in African American and Native American women and lowest in Asian women with similar percentages occurring among white and Hispanic/Latino women. For adjudicated outcomes (Table 8.3), 76.4% of women have none of our WHI-adjudicated outcomes, 20.7% have one such outcome, and 2.8% of women have had two or more adjudicated outcomes. Women over 80 years are two to three times as likely to have experienced at least one adjudicated outcome compared to younger women. Event rates for adjudicated outcomes are more similar across race/ethnicity groups than rates of self-reported outcomes. The combined self-reported and adjudicated outcomes that have occurred as of August 14, 2009, (Table 8.4) shows that 88% of WHI women have two or more diagnoses to date.

Self-reported aging outcomes items are shown by age on April 1, 2005 (the beginning of the WHI Extension), in Table 8.5 and by race/ethnicity in Table 8.6. Overall, 37.6% of women report their health status as "excellent or very good" and women ages 80 and older espouse this category 23-30% of the time. Nearly 94% of women report their quality of life as good and this holds for 89% of women in their 90s. Prevalence rates of ADL disabilities and instrumental activities of daily living increase dramatically with age. Difficulty with grocery shopping is the most common limitation. Difficulty with bathing, dressing, and taking medications becomes much more common in age groups 80 and above.

The need for nursing care doubles across each age category: whereas less than 2% of women less than 65 years (1.6%) require nursing care, one-fifth of women over 90 years (22%) need care. Twice as many (61.8%) women over 90 years report living alone compared to the overall cohort (31.4%).

Under geriatric conditions, we report the percent of women who fell two or more times per year on average between April 1, 2002, and March 31, 2005. About 5% of women below age 80 are frequent fallers, compared to 7.8% of women ages 80-89 and 18.4% of women ages 90 and above. Incontinence, dizziness, and hearing and vision impairments are common in all age groups.

Figure 8.1 shows change in Rand-36 Physical Function scores according to age on April 1, 2005. There are clear differences amongst the age groups in levels of physical function with women younger than 70 having very high levels of physical function that hold over the 5 years of the extension. For women 70-90, levels of physical function are lower initially and fall slightly over the 5 years of the Extension. For the few women in their 90s on April 1, 2005, we observe a precipitous drop in physical function scores over this period.

These data illustrate the schism between accumulated morbidity and perceived health and quality of life in our older cohort. Many older women have multiple diagnoses, but the vast majority still report a high quality of life.

1.4 Data Quality and Study Performance Reports

Reports summarizing Field Center activities (Tables 9.1 to 9.5) are produced monthly and posted on the staff website for investigators and Field Center staff use. The Performance Monitoring Committee also uses these reports to monitor study activities.

The current status of outcomes processing by FCs is somewhat variable. Most Centers are considered up-to-date in their efforts. Ten FCs have been identified by the Performance Monitoring Committee (PMC) as having backlog, four of which are considered to be significant. The PMC has contacted the Principal Investigators from each of these sites to discuss their circumstances and develop a catch-up plan.

Participants return questionnaires to the CCC by mail for scanning. Forms that cannot be scanned are key-entered. CCC staff also review all the returned forms for comments the participant many have written on the form and indicate which forms need to be reviewed by Field Center staff (Table 9.6).

The current status of outcomes adjudication indicates that outcomes processing by FCs is excellent (Table 9.7), with timeliness of documenting and forwarding cases better than it ever was during WHI. All adjudications are up-to-date with the flow of cases (Table 9.8). For stroke, additional adjudicators were engaged in the process during the previous year and since then the backlog of over 950 cases has been reduced to a normal flow. Adjudication of other hospitalizations is a lower priority, however thanks to some streamlining activities even this backlog has been reduced considerably.

A current outcomes priority is to SEER-code the non-primary cancers that up to now mostly have been adjudicated only for fact of cancer. In late 2007, the EC approved a proposal to extend the SEER-ICD-02 cancer coding to include non-primary cancers rather than just primary cancers. CCC cancer coders began coding these 9,307 non-primary cancer cases, and have hired additional coders to assist in this workload.

1.5 Specimen Repository

The current inventory of the WHI specimen repository is described in Tables 10.1–*CT Outcomes Cases with Blood* and 10.2–*OS Outcomes Cases with Blood* and Table 10.3–*CT and OS Outcomes with DNA Available*. These tabulations show the estimated volume of each type of specimen (serum, EDTA plasma, citrate plasma) available according to the primary outcomes of interest in the clinical trial and observational study components separately. Table 10.4 tabulates the number of funded studies using these specimens by outcome type and specimen type. Specimen availability is not shown for women who have not experienced one of these outcomes because of the large supply of potential controls. RBCs collected on all participants at baseline, CT Year 1, and OS Year 3 are not shown and urine samples, collected at the three bone mineral densitometry Centers, are also not shown. These samples have yet to receive much use for scientific purposes.

The WHI specimen resources have been divided into three accounts, (1) that which is available to WHI investigators now to support core or ancillary study activities, (2) that which is reserved for Broad Agency Announcement awardees (see Table 11.2); and (3) that which is reserved for use by WHI investigators at the end of the Extension Follow-up period. Tabulation for each of these accounts is available upon request.

1.6 Core, Broad Agency Announcement Activities, and Ancillary Studies

WHI investigators are involved in numerous activities funded by the program designed to further explicate the results of the clinical trials, to expand the scope of our understanding of intervention effects, and to identify and evaluate biomarkers of disease through use of the WHI repository. These core studies are summarized briefly in Table 11.1.

In 2006 and 2008, the NHLBI released a Broad Agency Announcement (BAA) to the larger scientific community, requesting proposals designed to use WHI specimens. The 12 awardees announced in January 2007 and 10 awardees announced in January 2009 are listed in Table 11.2.

WHI investigators and their colleagues, as well as investigators without WHI connections, continue to propose ancillary studies to use WHI resources. Together these efforts are aimed to maximize the use of these resources to provide insight into the causes and mechanisms of disease. A summary of all proposed ancillary studies and associated status is found in Table

11.3 with a detailed listing in Table 11.4. For brevity, the following acronyms are used to refer to some of the larger Core/Ancillary Studies.

W8	NBS - Nutrient Biomarker Study
W25	WHI-CACS - WHI Coronary Artery Calcium Study
M5	SHARe - SNP Health Association Resource
M6	PAGE - Population Architecture of Genes and Environment
M24	WHISP – WHI Sequencing Project
AS39	WHIMS - WHI Memory Study
AS62	WHISE - WHI Sight Exam
AS103	WHISCA - WHI Study of Cognitive Aging
AS105	CAREDS - Carotenoids in Age-Related Eye Disease Study
AS130	BBDS - Benign Breast Disease Study
AS183	WHIMS-MRI - WHI Magnetic Resonance Imaging Study
AS218	NPAAS-Nutrition and Physical Activity Assessment Study
AS233	WHIMS Extension
AS244	WHIMS ECHO - Epidemiology of Cognitive Health
AS262	WHIMS-Y – WHIMS in Younger Women

Participant enrollments to ancillary studies requiring a separate consent are tabulated by Field Center and shown in Table 11.5. More than 34,000 participants were involved in ancillary studies during WHI and over 29,000 during the Extension Study. Table 11.6 provides the distribution of enrollments per participant. Approximately 17% of ES participants are enrolled in one or more ancillary study, and of these, the majority participate in only one.

A detailed progress report from the WHI Memory Study (WHIMS) Coordinating Center for the studies associated with cognition and dementia is provided in the Appendix.

1.7 Publications

WHI investigators remain engaged in the publication process. To date, 1103 manuscript proposals have been received and 831 approved for development by the Publications and Presentations committee. Of these, 431 have been published or are in press, including 56 since the last report (Table 12.1). A full listing of approved manuscript proposals in provided in Table 12.2.

Table 1.1
WHI Centers and Principal Investigators

Principal Investigator	Institution	Location
Shirley Beresford, PhD	Fred Hutchinson Cancer Research Center	Seattle, WA
Robert Brunner, PhD	University of Nevada	Reno, NV
Robert Brzyski, MD	University of Texas	San Antonio, TX
Bette Caan, PhD	Kaiser Foundation Research Institute	Oakland, CA
Rowan Chlebowski, MD, PhD	University of California, Los Angeles	Torrance, CA
J. David Curb, MD	University of Hawaii	Honolulu, HI
Charles Eaton, MD	Memorial Hospital of Rhode Island	Pawtucket, RI
Gerardo Heiss, MD MPH	University of North Carolina, Chapel Hill	Chapel Hill, NC
Barbara Howard, PhD	MedStar Research Institute	Washington, D.C.
Allan Hubbell, MD	University of California, Irvine	Irvine, CA
Rebecca Jackson, MD	Ohio State University	Columbus, OH
Karen Johnson, MD, MPH	University of Tennessee	Memphis, TN
Jane Kotchen, MD, MPH	Medical College of Wisconsin	Milwaukee, WI
Lewis Kuller, MD, DrPH	University of Pittsburgh	Pittsburgh, PA
Dorothy Lane, MD, MPH	Research Foundation SUNY, Stony Brook	Stony Brook, NY
Norman Lasser, MD, PhD	University of Medicine and Dentistry	Newark, NJ
Erin LeBlanc, M.D.	Oregon Health & Science University	Portland, OR
Cora Lewis, MD, MSPH	University of Alabama at Birmingham	Birmingham, AL
Marian Limacher, MD	University of Florida	Gainesville/ Jacksonville, FL
JoAnn Manson, MD, DrPH	Brigham and Women's Hospital	Boston, MA
Karen Margolis, MD	University of Minnesota	Minneapolis, MN
Lisa Martin, MD, FACC	George Washington University	Washington, DC
Lauren Nathan, MD	University of California, Los Angeles	Los Angeles, CA
Mary-Jo O'Sullivan, MD	University of Miami	Miami, FL
Judith Ockene, PhD	University of Massachusetts	Worcester, MA
Larry Phillips, MD	Emory University	Atlanta, GA
Lynda Powell, PhD	Rush University Medical Center	Chicago, IL
Haleh Sangi-Haghpeykar, PhD	Baylor College of Medicine	Houston, TX
John Robbins, MD	University of California, Davis	Sacramento, CA
Gloria Sarto, MD	University of Wisconsin	Madison, WI
Michael Simon, MD	Wayne State University	Detroit, MI
Marcia Stefanick, PhD	Stanford University	San Jose, CA
Michael Thomas, MD	University of Cincinnati	Cincinnati, OH
Cyndi Thomson, PhD, RD	University of Arizona	Tucson/ Phoenix, AZ
Linda Van Horn, PhD, RD	Northwestern University	Chicago/ Evanston, IL
Mara Vitolins, PhD	Wake Forest University	Winston-Salem/Greensboro, NC
Jean Wactawski-Wende, PhD	State University of New York, Buffalo	Buffalo, NY
Robert Wallace, MD	University of Iowa	Iowa City/ Bettendorf, IA
Sylvia Wassertheil-Smoller, PhD	Albert Einstein College of Medicine	Bronx, NY
Garnet Anderson, PhD Ross Prentice, PhD	Clinical Coordinating Center, Fred Hutchinson Cancer Research Center	Seattle, WA
Sally Shumaker, PhD	WHI Memory Study Coordinating Center, Wake Forest University	Winston-Salem, NC

Table 1.2
Consent Status by Study Component and Arm

Data as of: August 14, 2009

WHI Enrollment	Enrolled in WHI	Eligible for extension[1]	Consented N	Consented %
Hormone Therapy	27347	25194	20433	81.1
With Uterus	16608	15408	12788	83.0
E+P	8506	7878	6545	83.1
Placebo	8102	7530	6243	82.9
Without Uterus	10739	9786	7645	78.1
E-alone	5310	4851	3778	77.9
Placebo	5429	4935	3867	78.4
Dietary Modification	48835	45560	37858	83.1
Intervention	19541	18207	14769	81.1
Comparison	29294	27353	23089	84.4
Calcium and Vitamin D	36282	34447	29862	86.7
Active	18176	17280	15025	87.0
Placebo	18106	17167	14837	86.4
Clinical Trial Total	68132	63332	52176	82.4
Observational Study	93676	86744	63230	72.9
Total	161808	150076	115406	76.9

[1] Eligibility defined as alive at the beginning of consent and willing to be contacted.

Table 1.3
Consent Status by Age and Race/Ethnicity

Data as of: August 14, 2009

WHI Enrollment	Enrolled in WHI	Eligible for extension[1]	Consented N	Consented %
Clinical Trial	68132	63332	52176	82.4
Age				
50-54	9188	8754	7237	82.7
55-59	14661	13940	11724	84.1
60-69	31389	29290	24528	83.7
70-79	12894	11348	8687	76.6
Race/Ethnicity				
American Indian	292	260	185	71.2
Asian/Pacific Islander	1519	1414	1105	78.1
Black	6983	6423	4769	74.2
Hispanic	2875	2686	1791	66.7
White	55525	51682	43680	84.5
Unknown	938	867	646	74.5
Observational Study	93676	86744	63230	72.9
Age				
50-54	12381	11969	8995	75.2
55-59	17329	16565	12732	76.9
60-69	41200	38502	28582	74.2
70-79	22766	19708	12921	65.6
Race/Ethnicity				
American Indian	421	372	217	58.3
Asian/Pacific Islander	2671	2444	1291	52.8
Black	7635	6868	3585	52.2
Hispanic	3609	3333	1598	47.9
White	78016	72504	55766	76.9
Unknown	1324	1223	773	63.2

[1] Eligibility defined as alive at the beginning of consent and willing to be contacted.

Table 1.4
Extension Consent Summary by Field Center

Data as of: August 14, 2009

	DM			HT			CaD			CT			OS		
	Eligible	Consent	%	Eligible	Consent	%	Eligible	Consent	%	Eligible	Consent	%	Eligible	Consent	%
Atlanta	1329	1068	80.4	534	441	82.6	834	722	86.6	1611	1298	80.6	2311	1831	79.2
Bettendorf	470	400	85.1	708	624	88.1	658	596	90.6	1051	922	87.7	1404	1110	79.1
Birmingham	1237	955	77.2	705	579	82.1	887	762	85.9	1695	1334	78.7	2303	1343	58.3
Bowman	1024	808	78.9	567	425	75.0	652	539	82.7	1408	1091	77.5	2083	1569	75.3
Brigham	1643	1429	87.0	770	664	86.2	1024	939	91.7	2206	1906	86.4	2841	2310	81.3
Buffalo	1057	1001	94.7	631	577	91.4	921	883	95.9	1490	1395	93.6	2042	1733	84.9
Chapel Hill	1061	943	88.9	586	488	83.3	719	650	90.4	1447	1264	87.4	1972	1584	80.3
Chi-Rush	872	627	71.9	495	353	71.3	785	604	76.9	1226	880	71.8	1881	1029	54.7
Chicago	1121	952	84.9	518	443	85.5	759	687	90.5	1493	1266	84.8	1754	1369	78.1
Cincinnati	967	881	91.1	495	444	89.7	859	803	93.5	1298	1176	90.6	2076	1616	77.8
Columbus	1072	898	83.8	558	454	81.4	845	732	86.6	1456	1199	82.3	2098	1705	81.3
Des Moines	478	400	83.7	865	624	72.1	807	638	79.1	1237	938	75.8	1513	1091	72.1
Detroit	914	707	77.4	470	360	76.6	806	650	80.6	1220	938	76.9	1911	1416	74.1
Gainesville	1289	1182	91.7	875	800	91.4	852	798	93.7	1935	1771	91.5	2565	2176	84.8
GWU-DC	1069	929	86.9	525	453	86.3	814	746	91.6	1443	1245	86.3	2132	1681	78.8
Honolulu	1006	804	79.9	372	283	76.1	628	523	83.3	1280	1003	78.4	1897	984	51.9
Houston	845	636	75.3	427	269	63.0	573	437	76.3	1160	829	71.5	1906	1403	73.6
Irvine	1104	943	85.4	550	452	82.2	881	779	88.4	1509	1274	84.4	2062	1665	80.7
L.A.	1156	912	78.9	554	410	74.0	971	803	82.7	1559	1213	77.8	2056	1615	78.6
La Jolla	1525	976	64.0	682	329	48.2	1080	721	66.8	1986	1194	60.1	3188	1884	59.1
Madison	1032	929	90.0	622	563	90.5	867	801	92.4	1484	1343	90.5	1855	1420	76.5
Medlantic	1027	880	85.7	544	448	82.4	782	694	88.7	1367	1157	84.6	2036	1456	71.5
Memphis	1164	866	74.4	663	483	72.9	839	661	78.8	1558	1148	73.7	2250	1249	55.5
Miami	1009	729	72.2	544	387	71.1	500	378	75.6	1377	987	71.7	1254	695	55.4

Table 1.4 (continued)
Extension Consent Summary by Field Center

Data as of: August 14, 2009

	DM			HT			CaD			CT			OS		
	Eligible	Consent	%	Eligible	Consent	%	Eligible	Consent	%	Eligible	Consent	%	Eligible	Consent	%
Milwaukee	1084	973	89.8	683	589	86.2	953	876	91.9	1531	1352	88.3	2113	1586	75.1
Minneapolis	1262	1097	86.9	793	654	82.5	1045	949	90.8	1877	1606	85.6	2576	1949	75.7
Nevada	980	849	86.6	572	480	83.9	923	816	88.4	1362	1163	85.4	1957	1551	79.3
Newark	1269	1011	79.7	490	393	80.2	836	713	85.3	1600	1277	79.8	2369	1686	71.2
New Brunswick	375	328	87.5	368	330	89.7	436	402	92.2	657	580	88.3	779	651	83.6
NY-City	1223	1003	82.0	698	560	80.2	827	718	86.8	1767	1435	81.2	2710	1526	56.3
Oakland	1022	903	88.4	583	512	87.8	628	577	91.9	1468	1296	88.3	1895	1480	78.1
Pawtucket	1892	1676	88.6	898	780	86.9	1328	1217	91.6	2488	2187	87.9	3395	2685	79.1
Pittsburgh	1096	1005	91.7	595	540	90.8	804	754	93.8	1528	1395	91.3	1733	1381	79.7
Portland	1111	950	85.5	592	524	88.5	827	750	90.7	1523	1323	86.9	2082	1565	75.2
San Antonio	873	621	71.1	658	448	68.1	793	584	73.6	1261	875	69.4	1709	962	56.3
Seattle	1097	904	82.4	686	542	79.0	804	682	84.8	1681	1358	80.8	1515	1070	70.6
Stanford	1226	1071	87.4	633	558	88.2	948	866	91.4	1639	1445	88.2	2465	2045	83.0
Stonybrook	936	801	85.6	473	400	84.6	572	509	89.0	1266	1083	85.5	1915	1467	76.6
Torrance	745	554	74.4	288	206	71.5	507	405	79.9	916	673	73.5	1385	877	63.3
Tucson	1387	1077	77.6	714	508	71.1	1007	816	81.0	1929	1461	75.7	2544	1650	64.9
UC Davis	1358	1135	83.6	642	542	84.4	1033	904	87.5	1790	1488	83.1	2107	1393	66.1
Worcester	1153	1045	90.6	568	514	90.5	833	778	93.4	1553	1408	90.7	2105	1772	84.2
Total	45560	37858	83.1	25194	20433	81.1	34447	29862	86.7	63332	52176	82.4	86744	63230	72.9

Table 1.5
Response Rates to CCC Annual Mailings, Extension Year 1

Data as of: August 14, 2009

	1st Mailing Period				2nd Mailing Period						3rd Mailing Period					
Study	Form	Sent Mail 1	Response		Past 2nd mailing period	Sent Mail 2		Response		Cumulative Response	Past 3rd mailing period	Sent Mail 3		Response		Cumulative Response
Total	33	113981	96608	84.8%	113981	17826	15.6%	8717	48.9%	92.4%	113981	7883	6.9%	2903	36.8%	95.0%
	134	113991	95149	83.5%	113991	19196	16.8%	9588	50.0%	91.9%	113991	8315	7.3%	3042	36.6%	94.6%
	150	20240	15903	78.6%	20240	4496	22.2%	1904	42.4%	88.0%	20240	2247	11.1%	737	32.8%	91.6%
	151	81906	67510	82.4%	81906	14826	18.1%	7200	48.6%	91.2%	81906	6559	8.0%	2374	36.2%	94.1%
HT	33	20235	15887	78.5%	20235	4503	22.3%	1903	42.3%	87.9%	20235	2243	11.1%	734	32.7%	91.5%
	134	20237	15707	77.6%	20237	4680	23.1%	1999	42.7%	87.5%	20237	2311	11.4%	736	31.9%	91.1%
	150	20240	15903	78.6%	20240	4496	22.2%	1904	42.4%	88.0%	20240	2247	11.1%	737	32.8%	91.6%
	151	20241	15875	78.4%	20241	4520	22.3%	1917	42.4%	87.9%	20241	2258	11.2%	747	33.1%	91.6%
DM	33	37611	30715	81.7%	37611	7216	19.2%	3430	47.5%	90.8%	37611	3257	8.7%	1153	35.4%	93.9%
	134	37614	30339	80.7%	37614	7589	20.2%	3648	48.1%	90.4%	37614	3407	9.1%	1189	34.9%	93.5%
	150	6060	4655	76.8%	6060	1473	24.3%	615	41.8%	87.0%	6060	763	12.6%	235	30.8%	90.8%
	151	37618	30564	81.3%	37618	7390	19.6%	3573	48.4%	90.8%	37618	3293	8.8%	1178	35.8%	93.9%
CaD	33	29670	24166	81.5%	29670	5746	19.4%	2673	46.5%	90.5%	29670	2633	8.9%	943	35.8%	93.6%
	134	29673	23898	80.5%	29673	6008	20.3%	2819	46.9%	90.0%	29673	2735	9.2%	964	35.3%	93.3%
	150	12815	10148	79.2%	12815	2771	21.6%	1187	42.8%	88.5%	12815	1365	10.7%	469	34.4%	92.1%
	151	29678	24078	81.1%	29678	5846	19.7%	2756	47.1%	90.4%	29678	2657	9.0%	963	36.2%	93.7%
OS	33	62195	54662	87.9%	62195	7578	12.2%	3991	52.7%	94.3%	62195	3147	5.1%	1251	39.8%	96.3%
	134	62200	53708	86.4%	62200	8447	13.6%	4581	54.2%	93.7%	62200	3375	5.4%	1347	39.9%	95.9%
	151	30107	25724	85.4%	30107	4391	14.6%	2329	53.0%	93.2%	30107	1771	5.9%	683	38.6%	95.5%

Table 1.5 (continued for year 2)
Response Rates to CCC Annual Mailings, Extension Year 2

Data as of: August 14, 2009

	1st Mailing Period				2nd Mailing Period						3rd Mailing Period					
Study	Form	Sent Mail 1	Response		Past 2nd mailing period	Sent Mail 2		Response		Cumulative Response	Past 3rd mailing period	Sent Mail 3		Response		Cumulative Response
Total	33	112945	95639	84.7%	112945	18499	16.4%	7847	42.4%	91.6%	112945	6282	5.6%	2185	34.8%	93.6%
	134[1]	1414	550	38.9%	1414	778	55.0%	126	16.2%	47.8%	1414	429	30.3%	63	14.7%	52.3%
	150	19782	15709	79.4%	19782	4167	21.1%	1552	37.3%	87.3%	19782	1561	7.9%	468	30.0%	89.6%
	151	112991	95499	84.5%	112991	18693	16.5%	7987	42.7%	91.6%	112991	6323	5.6%	2212	35.0%	93.6%
HT	33	19780	15694	79.3%	19780	4182	21.1%	1564	37.4%	87.3%	19780	1563	7.9%	472	30.2%	89.6%
	134[1]	332	63	19.0%	332	237	71.4%	32	13.5%	28.6%	332	148	44.6%	11	7.4%	31.9%
	150	19782	15709	79.4%	19782	4167	21.1%	1552	37.3%	87.3%	19782	1561	7.9%	468	30.0%	89.6%
	151	19785	15701	79.4%	19785	4195	21.2%	1569	37.4%	87.3%	19785	1567	7.9%	473	30.2%	89.7%
DM	33	36972	30737	83.1%	36972	6651	18.0%	2750	41.4%	90.6%	36972	2229	6.0%	767	34.4%	92.7%
	134[1]	376	87	23.1%	376	249	66.2%	23	9.2%	29.3%	376	144	38.3%	21	14.6%	34.8%
	150	5931	4657	78.5%	5931	1321	22.3%	478	36.2%	86.6%	5931	502	8.5%	154	30.7%	89.2%
	151	36981	30703	83.0%	36981	6703	18.1%	2793	41.7%	90.6%	36981	2238	6.1%	768	34.3%	92.7%
CaD	33	29172	24141	82.8%	29172	5309	18.2%	2139	40.3%	90.1%	29172	1823	6.3%	609	33.4%	92.2%
	134[1]	351	77	21.9%	351	236	67.2%	22	9.3%	28.2%	351	146	41.6%	15	10.3%	32.5%
	150	12538	10066	80.3%	12538	2529	20.2%	958	37.9%	87.9%	12538	940	7.5%	286	30.4%	90.2%
	151	29173	24109	82.6%	29173	5350	18.3%	2165	40.5%	90.1%	29173	1832	6.3%	613	33.5%	92.2%
OS	33	62122	53853	86.7%	62122	8997	14.5%	4018	44.7%	93.2%	62122	2995	4.8%	1102	36.8%	94.9%
	134[1]	805	416	51.7%	805	365	45.3%	79	21.6%	61.5%	805	179	22.2%	32	17.9%	65.5%
	151	62155	53746	86.5%	62155	9125	14.7%	4108	45.0%	93.1%	62155	3025	4.9%	1124	37.2%	94.9%

[1] Required only in Extension study Follow-up Year 1. Year 2 and 3 responses reflect data collected from Year 1 non-respondents.

Table 1.5 (continued for year 3)
Response Rates to CCC Annual Mailings, Extension Year 3

Data as of: August 14, 2009

	1st Mailing Period				2nd Mailing Period						3rd Mailing Period					
Study	Form	Sent Mail 1	Response		Past 2nd mailing period	Sent Mail 2		Response		Cumulative Response	Past 3rd mailing period	Sent Mail 3		Response		Cumulative Response
Total	33	111075	92912	83.7%	111075	17976	16.2%	7626	42.4%	90.5%	111075	8266	7.4%	2608	31.6%	92.9%
	134[1]	237	35	14.8%	237	160	67.5%	8	5.0%	18.1%	237	136	57.4%	11	8.1%	22.8%
	150	19363	15165	78.3%	19363	4012	20.7%	1489	37.1%	86.0%	19363	2018	10.4%	576	28.5%	89.0%
	151	111073	92849	83.6%	111073	18055	16.3%	7676	42.5%	90.5%	111073	8319	7.5%	2643	31.8%	92.9%
HT	33	19367	15144	78.2%	19367	4032	20.8%	1509	37.4%	86.0%	19367	2011	10.4%	575	28.6%	89.0%
	134[1]	81	7	8.6%	81	64	79.0%	2	3.1%	11.1%	81	57	70.4%	4	7.0%	16.1%
	150	19363	15165	78.3%	19363	4012	20.7%	1489	37.1%	86.0%	19363	2018	10.4%	576	28.5%	89.0%
	151	19366	15170	78.3%	19366	4012	20.7%	1492	37.2%	86.0%	19366	2011	10.4%	579	28.8%	89.0%
DM	33	36412	29759	81.7%	36412	6528	17.9%	2682	41.1%	89.1%	36412	3113	8.6%	1012	32.5%	91.9%
	134[1]	79	2	2.5%	79	63	79.8%	3	4.8%	6.3%	79	55	69.6%	5	9.1%	12.7%
	150	5825	4469	76.7%	5825	1292	22.2%	465	36.0%	84.7%	5825	666	11.4%	198	29.7%	88.1%
	151	36411	29757	81.7%	36411	6540	18.0%	2692	41.2%	89.1%	36411	3126	8.6%	1023	32.7%	91.9%
CaD	33	28672	23416	81.7%	28672	5135	17.9%	2130	41.5%	89.1%	28672	2415	8.4%	753	31.2%	91.7%
	134[1]	84	4	4.8%	84	68	81.0%	4	5.9%	9.5%	84	60	71.4%	1	1.7%	10.7%
	150	12278	9743	79.4%	12278	2444	19.9%	918	37.6%	86.8%	12278	1210	9.9%	347	28.7%	89.7%
	151	28671	23427	81.7%	28671	5130	17.9%	2134	41.6%	89.2%	28671	2414	8.4%	754	31.2%	91.8%
OS	33	61123	52468	85.8%	61123	8717	14.3%	3904	44.8%	92.2%	61123	3813	6.2%	1224	32.1%	94.2%
	134[1]	108	27	25.0%	108	60	55.6%	4	6.7%	28.7%	108	49	45.4%	5	10.2%	33.3%
	151	61122	52395	85.7%	61122	8792	14.4%	3951	44.9%	92.2%	61122	3851	6.3%	1243	32.3%	94.2%

[1] Required only in Extension study Follow-up Year 1. Year 2 and 3 responses reflect data collected from Year 1 non-respondents.

Table 1.5 (continued for year 4)
Response Rates to CCC Annual Mailings, Extension Year 4

Data as of: August 14, 2009

	1st Mailing Period				2nd Mailing Period						3rd Mailing Period					
Study	Form	Sent Mail 1	Response		Past 2nd mailing period	Sent Mail 2		Response		Cumulative Response	Past 3rd mailing period	Sent Mail 3		Response		Cumulative Response
Total	33	96211	79370	82.5%	81798	14347	17.5%	6002	41.8%	89.7%	81798	6066	7.4%	1814	29.9%	91.9%
	150	14030	10858	77.4%	10903	2468	22.6%	887	35.9%	85.0%	10903	1081	9.9%	276	25.5%	87.5%
	151	96211	79354	82.5%	81798	14384	17.6%	6064	42.2%	89.8%	81798	6061	7.4%	1858	30.7%	92.0%
HT	33	14030	10834	77.2%	10903	2487	22.8%	893	35.9%	84.8%	10903	1089	10.0%	271	24.9%	87.3%
	150	14030	10858	77.4%	10903	2468	22.6%	887	35.9%	85.0%	10903	1081	9.9%	276	25.5%	87.5%
	151	14030	10841	77.3%	10903	2487	22.8%	908	36.5%	85.0%	10903	1083	9.9%	279	25.8%	87.5%
DM	33	26401	21405	81.1%	20309	3984	19.6%	1609	40.4%	88.2%	20309	1657	8.2%	459	27.7%	90.4%
	150	4210	3232	76.8%	3339	790	23.7%	279	35.3%	84.1%	3339	334	10.0%	79	23.7%	86.4%
	151	26401	21401	81.1%	20309	3998	19.7%	1625	40.7%	88.2%	20309	1658	8.2%	461	27.8%	90.5%
CaD	33	20802	16798	80.8%	15969	3183	19.9%	1250	39.3%	87.7%	15969	1360	8.5%	377	27.7%	90.1%
	150	8943	6999	78.3%	6987	1537	22.0%	552	35.9%	85.4%	6987	679	9.7%	177	26.1%	88.0%
	151	20802	16794	80.7%	15969	3189	20.0%	1273	39.9%	87.8%	15969	1353	8.5%	380	28.1%	90.2%
OS	33	59990	50351	83.9%	53925	8672	16.1%	3777	43.6%	90.9%	53925	3660	6.8%	1165	31.8%	93.1%
	151	59990	50336	83.9%	53925	8698	16.1%	3815	43.9%	91.0%	53925	3658	6.8%	1197	32.7%	93.2%

Table 1.6
Response Rates to Field Center Follow-up and Cumulative Response--Extension Study Follow-up Year 1

Data as of: August 14, 2009

Study	Form	Eligible for FC Follow-up	Respondents		Total Estimated Response Rate
Total	33	5434	4982	91.7%	98.3%
	134	6093	4970	81.6%	97.9%
	150	1614	1150	71.3%	96.8%
	151	4875	1667	34.2%	94.7%
HT	33	1542	1326	86.0%	97.5%
	134	1677	1302	77.6%	97.0%
	150	1614	1150	71.3%	96.8%
	151	1631	602	36.9%	94.0%
DM	33	2174	1876	86.3%	98.4%
	134	2365	1839	77.8%	98.0%
	150	541	390	72.1%	96.7%
	151	2282	736	32.3%	95.4%
CaD	33	1718	1477	86.0%	98.2%
	134	1876	1457	77.7%	97.8%
	150	947	672	71.0%	96.9%
	151	1810	621	34.3%	95.4%
OS	33	2241	2230	99.5%	98.4%
	134	2609	2271	87.0%	98.0%
	151	1505	525	34.9%	94.2%

Table 1.6 (continued for year 2)
Response Rates to Field Center Follow-up and Cumulative Response--Extension Study Follow-up Year 2

Data as of: August 14, 2009

Study	Form	Eligible for FC Follow-up	Respondents		Total Estimated Response Rate
Total	33	7007	6719	95.9%	98.4%
	134[1]	1406	432	30.7%	43.9%
	150	2009	1678	83.5%	96.5%
	151	7448	4539	60.9%	96.5%
HT	33	1943	1838	94.6%	97.3%
	134[1]	393	138	35.1%	36.9%
	150	2009	1678	83.5%	96.5%
	151	2042	1296	63.5%	94.7%
DM	33	2649	2534	95.7%	98.3%
	134[1]	518	173	33.4%	36.6%
	150	633	543	85.8%	96.7%
	151	2804	1749	62.4%	96.2%
CaD	33	2165	2055	94.9%	98.1%
	134[1]	416	151	36.3%	38.7%
	150	1189	993	83.5%	96.7%
	151	2295	1463	63.8%	96.1%
OS	33	3031	2930	96.7%	98.8%
	134[1]	622	168	27.0%	50.7%
	151	3252	1923	59.1%	97.1%

[1] Required only in Extension Study Follow-up Year 1. Year 2 and 3 responses reflect data collected from Year 1 non-respondents.

Table 1.6 (continued for year 3)
Response Rates to Field Center Follow-up and Cumulative Response--Extension Study Follow-up Year 3

Data as of: August 14, 2009

Study	Form	Eligible for FC Follow-up	Respondents		Total Estimated Response Rate
Total	33	7758	7423	95.7%	97.9%
	134[1]	1383	108	7.8%	7.7%
	150	2142	1760	82.2%	95.7%
	151	8155	4994	61.2%	95.8%
HT	33	2067	1951	94.4%	96.6%
	134[1]	335	36	10.8%	8.5%
	150	2142	1760	82.2%	95.7%
	151	2164	1312	60.6%	93.5%
DM	33	2893	2770	95.8%	97.8%
	134[1]	462	41	8.9%	7.1%
	150	688	581	84.5%	95.8%
	151	3007	1880	62.5%	95.4%
CaD	33	2300	2167	94.2%	97.6%
	134[1]	368	36	9.8%	7.5%
	150	1261	1048	83.1%	96.0%
	151	2391	1472	61.6%	95.2%
OS	33	3471	3333	96.0%	98.3%
	134[1]	692	45	6.5%	8.2%
	151	3681	2245	61.0%	96.5%

[1] Required only in Extension Study Follow-up Year 1. Year 2 and 3 responses reflect data collected from Year 1 non-respondents.

Table 1.6 (continued for year 4)
Response Rates to Field Center Follow-up and Cumulative Response--Extension Study Follow-up Year 4

Data as of: August 14, 2009

Study	Form	Eligible for FC Follow-up	Respondents		Total Estimated Response Rate
Total	33	2441	2242	91.9%	97.4%
	150	302	230	76.2%	94.0%
	151	2593	1401	54.0%	95.2%
HT	33	298	258	86.6%	95.0%
	150	302	230	76.2%	94.0%
	151	309	157	50.8%	91.2%
DM	33	450	410	91.1%	96.9%
	150	107	94	87.9%	95.1%
	151	479	254	53.0%	93.5%
CaD	33	355	318	89.6%	96.4%
	150	191	150	78.5%	94.4%
	151	374	205	54.8%	93.4%
OS	33	1800	1675	93.1%	97.7%
	151	1917	1060	55.3%	95.7%

Table 2.1
Hormone Therapy Component Age–and Race/Ethnicity

Data as of: August 14, 2009

HT Participants	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age				
Overall	**27,347**			
50-54	3,420	125%	13%	10%
55-59	5,413	99%	20%	20%
60-69	12,360	100%	45%	45%
70-79	6,154	90%	23%	25%
Without Uterus	**10,739**			
50-54	1,396	113%	13%	10%
55-59	1,917	78%	18%	20%
60-69	4,851	88%	45%	45%
70-79	2,575	84%	24%	25%
With Uterus	**16,608**			
50-54	2,024	135%	12%	10%
55-59	3,496	116%	21%	20%
60-69	7,509	111%	45%	45%
70-79	3,579	95%	22%	25%
Race/Ethnicity				
Overall	**27,347**			
American Indian	130		<1%	
Asian	527		2%	
Black	2,738		10%	
Hispanic	1,537		6%	
White	22,030		81%	
Unknown	385		1%	
Without Uterus	**10,739**			
American Indian	75		1%	
Asian	164		2%	
Black	1,616		15%	
Hispanic	651		6%	
White	8,084		75%	
Unknown	149		1%	
With Uterus	**16,608**			
American Indian	55		<1%	
Asian	363		2%	
Black	1,122		7%	
Hispanic	886		5%	
White	13,946		84%	
Unknown	236		1%	

Table 2.2
Lost-to-Follow-up and Vital Status: HT Participants by Hysterectomy Status

Data as of: August 14, 2009
Extension Participants Only

	Without Uterus (N=7,645)		With Uterus (N=12,788)		HT Participants (N=20,433)	
	N	%	N	%	N	%
Vital Status/Participation						
Deceased	425	5.6	650	5.1	1075	5.3
Alive: Current Participation[1]	6885	90.1	11634	91.0	18519	90.6
Alive: Recent Participation[2]	155	2.0	239	1.9	394	1.9
Alive: Past/Unknown Participation[3]	1	<0.1	5	<0.1	6	<0.1
Stopped Follow-Up[4]	95	1.2	157	1.2	252	1.2
Lost to Follow-Up[5]	84	1.1	103	0.8	187	0.9

Data as of: September 12, 2005
Events through Study Closeout

	Without Uterus (N=10,739)		With Uterus (N=16,608)		HT Participants (N=27,347)	
	N	%	N	%	N	%
Vital Status/Participation						
Deceased	727	6.8	918	5.5	1645	6.0
Alive: Current Participation[6]	9302	86.6	14897	89.7	24199	88.5
Alive: Recent Participation[7]	89	0.8	78	0.5	167	0.6
Alive: Past/Unknown Participation[8]	4	<0.1	4	<0.1	8	<0.1
Stopped Follow-Up[4]	475	4.4	538	3.2	1013	3.7
Lost to Follow-Up[5]	142	1.3	173	1.0	315	1.2

[1] Participants who have filled in a Form 33 within the last 15 months.
[2] Participants who last filled in a Form 33 between 15 and 24 months ago.
[3] Participants without a Form 33 within the last 24 months, who have been located (as indicated on Form 23) within the last 6 months.
[4] Participants with codes 5 (no follow-up) or 8 (absolutely no follow-up) on Form 7 or 9.
[5] Participants not in any of the above categories.
[6] Participants who have filled in a Form 33 within the last 9 months.
[7] Participants who last filled in a Form 33 between 9 and 18 months ago.
[8] Participants without a Form 33 within the last 18 months, who have been located (as indicated on Form 23) within the last 6 months.

Table 2.3
Verified Outcomes (Annualized Percentages) by Age for Hormone Therapy

Data as of: August 14, 2009

Outcomes	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	27347		3420		5413		12360		6154	
Mean follow-up (months)	130.2		137.3		134.5		130.3		122.0	
Cardiovascular										
CHD[1]	1444	(0.49%)	71	(0.18%)	159	(0.26%)	669	(0.50%)	545	(0.87%)
CHD death[2]	442	(0.15%)	16	(0.04%)	37	(0.06%)	177	(0.13%)	212	(0.34%)
Total MI[3]	1131	(0.38%)	57	(0.15%)	133	(0.22%)	535	(0.40%)	406	(0.65%)
Clinical MI	1098	(0.37%)	56	(0.14%)	131	(0.22%)	518	(0.39%)	393	(0.63%)
CABG/PTCA	1693	(0.57%)	87	(0.22%)	231	(0.38%)	847	(0.63%)	528	(0.84%)
Carotid artery disease	295	(0.10%)	8	(0.02%)	33	(0.05%)	162	(0.12%)	92	(0.15%)
Stroke	992	(0.33%)	39	(0.10%)	89	(0.15%)	450	(0.34%)	414	(0.66%)
Non-disabling stroke[4]	555	(0.19%)	30	(0.08%)	60	(0.10%)	246	(0.18%)	219	(0.35%)
Fatal/disabling stroke[4]	374	(0.13%)	6	(0.02%)	23	(0.04%)	171	(0.13%)	174	(0.28%)
Unknown status from stroke[4]	63	(0.02%)	3	(0.01%)	6	(0.01%)	33	(0.02%)	21	(0.03%)
PVD	301	(0.10%)	14	(0.04%)	37	(0.06%)	155	(0.12%)	95	(0.15%)
DVT	563	(0.19%)	38	(0.10%)	79	(0.13%)	263	(0.20%)	183	(0.29%)
Pulmonary embolism	414	(0.14%)	29	(0.07%)	54	(0.09%)	197	(0.15%)	134	(0.21%)
Coronary disease[5]	3283	(1.11%)	179	(0.46%)	404	(0.67%)	1545	(1.15%)	1155	(1.85%)
DVT/PE	788	(0.27%)	48	(0.12%)	103	(0.17%)	384	(0.29%)	253	(0.40%)
Total cardiovascular disease	4964	(1.67%)	269	(0.69%)	608	(1.00%)	2343	(1.75%)	1744	(2.79%)
Cancer										
Breast cancer	1271	(0.43%)	127	(0.32%)	233	(0.38%)	606	(0.45%)	305	(0.49%)
Invasive breast cancer	1028	(0.35%)	97	(0.25%)	190	(0.31%)	478	(0.36%)	263	(0.42%)
Non-invasive breast cancer	257	(0.09%)	31	(0.08%)	45	(0.07%)	136	(0.10%)	45	(0.07%)
Ovarian cancer	107	(0.04%)	5	(0.01%)	21	(0.03%)	60	(0.04%)	21	(0.03%)
Endometrial cancer[6]	143	(0.05%)	15	(0.04%)	29	(0.05%)	67	(0.05%)	32	(0.05%)
Colorectal cancer	417	(0.14%)	27	(0.07%)	47	(0.08%)	204	(0.15%)	139	(0.22%)
Other cancer[7]	1751	(0.59%)	129	(0.33%)	256	(0.42%)	837	(0.62%)	529	(0.85%)
Total cancer	3514	(1.18%)	292	(0.75%)	568	(0.94%)	1682	(1.25%)	972	(1.55%)
Fractures										
Hip fracture	646	(0.22%)	8	(0.02%)	42	(0.07%)	234	(0.17%)	362	(0.58%)
Deaths										
Cardiovascular deaths	817	(0.28%)	29	(0.07%)	62	(0.10%)	323	(0.24%)	403	(0.64%)
Cancer deaths	1072	(0.36%)	53	(0.14%)	125	(0.21%)	522	(0.39%)	372	(0.59%)
Other known cause	603	(0.20%)	26	(0.07%)	67	(0.11%)	242	(0.18%)	268	(0.43%)
Unknown cause	97	(0.03%)	6	(0.02%)	10	(0.02%)	38	(0.03%)	43	(0.07%)
Not yet adjudicated	261	(0.09%)	12	(0.03%)	22	(0.04%)	105	(0.08%)	122	(0.19%)
Total death	2850	(0.96%)	126	(0.32%)	286	(0.47%)	1230	(0.92%)	1208	(1.93%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Study.
[2] "CHD death" includes definite and possible CHD death.
[3] "Total MI" includes clinical MI and evolving Q-wave MI; Q-wave MI is not collected in the WHI Extension Study.
[4] Non-disabling stroke includes Glasgow scales 1 and 2; fatal/disabling includes Glasgow scales 3-5 and death within 1 month of stroke; and unknown status includes Glasgow scale 6 and status not yet known.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA; Q-wave MI, angina, and congestive heart failure are not collected in the WHI Extension Study.
[6] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[7] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.

Table 2.4
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Hormone Therapy

Data as of: August 14, 2009

Outcomes	Race/Ethnicity: American Indian/ Alaskan Native		Asian/Pacific Islander		Black/African American		Hispanic/ Latino		White		Unknown	
Number randomized	130		527		2738		1537		22030		385	
Mean follow-up (months)	120.6		122.4		126.4		119.8		131.7		123.4	
Cardiovascular												
CHD[1]	5	(0.38%)	19	(0.35%)	141	(0.49%)	39	(0.25%)	1218	(0.50%)	22	(0.56%)
CHD death[2]	2	(0.15%)	8	(0.15%)	65	(0.23%)	9	(0.06%)	355	(0.15%)	3	(0.08%)
Total MI[3]	4	(0.31%)	16	(0.30%)	91	(0.32%)	32	(0.21%)	968	(0.40%)	20	(0.51%)
Clinical MI	4	(0.31%)	15	(0.28%)	90	(0.31%)	30	(0.20%)	940	(0.39%)	19	(0.48%)
CABG/PTCA	7	(0.54%)	21	(0.39%)	128	(0.44%)	61	(0.40%)	1452	(0.60%)	24	(0.61%)
Carotid artery disease	1	(0.08%)	1	(0.02%)	11	(0.04%)	3	(0.02%)	276	(0.11%)	3	(0.08%)
Stroke	6	(0.46%)	13	(0.24%)	125	(0.43%)	28	(0.18%)	806	(0.33%)	14	(0.35%)
Non-disabling stroke[4]	3	(0.23%)	8	(0.15%)	69	(0.24%)	17	(0.11%)	451	(0.19%)	7	(0.18%)
Fatal/disabling stroke[4]	3	(0.23%)	5	(0.09%)	46	(0.16%)	7	(0.05%)	309	(0.13%)	4	(0.10%)
Unknown status from stroke[4]	0	(0.00%)	0	(0.00%)	10	(0.03%)	4	(0.03%)	46	(0.02%)	3	(0.08%)
PVD	2	(0.15%)	5	(0.09%)	32	(0.11%)	3	(0.02%)	258	(0.11%)	1	(0.03%)
DVT	3	(0.23%)	3	(0.06%)	56	(0.19%)	8	(0.05%)	490	(0.20%)	3	(0.08%)
Pulmonary embolism	3	(0.23%)	1	(0.02%)	53	(0.18%)	4	(0.03%)	349	(0.14%)	4	(0.10%)
Coronary disease[5]	12	(0.92%)	42	(0.78%)	341	(1.18%)	117	(0.76%)	2726	(1.13%)	45	(1.14%)
DVT/PE	6	(0.46%)	3	(0.06%)	87	(0.30%)	10	(0.07%)	676	(0.28%)	6	(0.15%)
Total cardiovascular disease	22	(1.68%)	59	(1.10%)	524	(1.82%)	151	(0.98%)	4151	(1.72%)	57	(1.44%)
Cancer												
Breast cancer	3	(0.23%)	27	(0.50%)	113	(0.39%)	39	(0.25%)	1076	(0.45%)	13	(0.33%)
Invasive breast cancer	3	(0.23%)	21	(0.39%)	93	(0.32%)	31	(0.20%)	871	(0.36%)	9	(0.23%)
Non-invasive breast cancer	0	(0.00%)	7	(0.13%)	20	(0.07%)	9	(0.06%)	217	(0.09%)	4	(0.10%)
Ovarian cancer	0	(0.00%)	2	(0.04%)	8	(0.03%)	0	(0.00%)	95	(0.04%)	2	(0.05%)
Endometrial cancer[6]	1	(0.08%)	1	(0.02%)	10	(0.03%)	6	(0.04%)	123	(0.05%)	2	(0.05%)
Colorectal cancer	1	(0.08%)	10	(0.19%)	33	(0.11%)	15	(0.10%)	349	(0.14%)	9	(0.23%)
Other cancer[7]	7	(0.54%)	34	(0.63%)	127	(0.44%)	59	(0.38%)	1502	(0.62%)	22	(0.56%)
Total cancer	12	(0.92%)	73	(1.36%)	280	(0.97%)	113	(0.74%)	2991	(1.24%)	45	(1.14%)
Fractures												
Hip fracture	3	(0.23%)	6	(0.11%)	14	(0.05%)	10	(0.07%)	608	(0.25%)	5	(0.13%)
Deaths												
Cardiovascular deaths	4	(0.31%)	13	(0.24%)	112	(0.39%)	16	(0.10%)	665	(0.28%)	7	(0.18%)
Cancer deaths	5	(0.38%)	24	(0.45%)	86	(0.30%)	42	(0.27%)	903	(0.37%)	12	(0.30%)
Other known cause	4	(0.31%)	5	(0.09%)	46	(0.16%)	13	(0.08%)	525	(0.22%)	10	(0.25%)
Unknown cause	0	(0.00%)	2	(0.04%)	18	(0.06%)	3	(0.02%)	73	(0.03%)	1	(0.03%)
Not yet adjudicated	2	(0.15%)	6	(0.11%)	23	(0.08%)	3	(0.02%)	225	(0.09%)	2	(0.05%)
Total Death	15	(1.15%)	50	(0.93%)	285	(0.99%)	77	(0.50%)	2391	(0.99%)	32	(0.81%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Study.
[2] "CHD death" includes definite and possible CHD death.
[3] "Total MI" includes clinical MI and evolving Q-wave MI; Q-wave MI is not collected in the WHI Extension Study.
[4] Non-disabling stroke includes Glasgow scales 1 and 2; fatal/disabling includes Glasgow scales 3-5 and death within 1 month of stroke; and unknown status includes Glasgow scale 6 and status not yet known.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA; Q-wave MI, angina, and congestive heart failure are not collected in the WHI Extension Study.
[6] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[7] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.

Table 2.5
Verified Outcomes (Annualized Percentages) for HT Participants Without and With Uterus

Data as of: August 14, 2009

Outcomes	Without Uterus		With Uterus	
Number randomized	10739		16608	
Mean follow-up (months)	127.9		131.6	
Cardiovascular				
CHD[1]	666	(0.58%)	778	(0.43%)
CHD death[2]	224	(0.20%)	218	(0.12%)
Total MI[3]	512	(0.45%)	619	(0.34%)
Clinical MI	497	(0.43%)	601	(0.33%)
CABG/PTCA	778	(0.68%)	915	(0.50%)
Carotid artery disease	149	(0.13%)	146	(0.08%)
Stroke	442	(0.39%)	550	(0.30%)
Non-disabling stroke[4]	231	(0.20%)	324	(0.18%)
Fatal/disabling stroke[4]	177	(0.15%)	197	(0.11%)
Unknown status from stroke[4]	34	(0.03%)	29	(0.02%)
PVD	136	(0.12%)	165	(0.09%)
DVT	227	(0.20%)	336	(0.18%)
Pulmonary embolism	163	(0.14%)	251	(0.14%)
Coronary disease[5]	1557	(1.36%)	1726	(0.95%)
DVT/PE	323	(0.28%)	465	(0.26%)
Total cardiovascular disease	2262	(1.98%)	2702	(1.48%)
Cancer				
Breast cancer	429	(0.37%)	842	(0.46%)
Invasive breast cancer	350	(0.31%)	678	(0.37%)
Non-invasive breast cancer	82	(0.07%)	175	(0.10%)
Ovarian cancer	28	(0.02%)	79	(0.04%)
Endometrial cancer[6]	0	N/A	143	(0.08%)
Colorectal cancer	171	(0.15%)	246	(0.14%)
Other cancer[7]	688	(0.60%)	1063	(0.58%)
Total cancer	1268	(1.11%)	2246	(1.23%)
Fractures				
Hip fracture	241	(0.21%)	405	(0.22%)
Deaths				
Cardiovascular deaths	393	(0.34%)	424	(0.23%)
Cancer deaths	438	(0.38%)	634	(0.35%)
Other known cause	231	(0.20%)	372	(0.20%)
Unknown cause	40	(0.03%)	57	(0.03%)
Not yet adjudicated	109	(0.10%)	152	(0.08%)
Total death	1211	(1.06%)	1639	(0.90%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Study.
[2] "CHD death" includes definite and possible CHD death.
[3] "Total MI" includes clinical MI and evolving Q-wave MI; Q-wave MI is not collected in the WHI Extension Study.
[4] Non-disabling stroke includes Glasgow scales 1 and 2; fatal/disabling includes Glasgow scales 3-5 and death within 1 month of stroke; and unknown status includes Glasgow scale 6 and status not yet known.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA; Q-wave MI, angina, and congestive heart failure are not collected in the WHI Extension Study.
[6] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[7] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.

Table 2.6
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for HT Participants Who Did Not Report a Prevalent Condition at Baseline

Data as of: August 14, 2009

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	27347		3420		5413		12360		6154	
Mean follow-up (months)	130.2		137.3		134.5		130.3		122.0	
Hospitalizations										
Ever	16651	(5.61%)	1517	(3.88%)	2719	(4.48%)	7810	(5.82%)	4605	(7.36%)
Two or more	10509	(3.54%)	774	(1.98%)	1532	(2.52%)	4974	(3.71%)	3229	(5.16%)
Other										
Diabetes (treated)	3199	(1.14%)	462	(1.23%)	638	(1.11%)	1493	(1.18%)	606	(1.02%)
Gallbladder disease[1, 2]	2117	(1.01%)	282	(0.98%)	443	(1.01%)	988	(1.05%)	404	(0.92%)
Hysterectomy	948	(0.52%)	92	(0.39%)	199	(0.50%)	468	(0.57%)	189	(0.51%)
Glaucoma[2]	3203	(1.32%)	287	(0.88%)	548	(1.09%)	1519	(1.40%)	849	(1.70%)
Osteoporosis[2]	6115	(2.55%)	477	(1.46%)	962	(1.92%)	2955	(2.74%)	1721	(3.52%)
Osteoarthritis[3]	6431	(3.48%)	843	(2.82%)	1341	(3.15%)	2943	(3.66%)	1304	(4.11%)
Rheumatoid arthritis[2]	1698	(0.70%)	211	(0.66%)	341	(0.69%)	764	(0.70%)	382	(0.75%)
Intestinal polyps	5402	(1.96%)	625	(1.65%)	1073	(1.85%)	2663	(2.14%)	1041	(1.88%)
Lupus	362	(0.12%)	41	(0.11%)	75	(0.12%)	166	(0.12%)	80	(0.13%)
Kidney stones[2, 3]	769	(0.36%)	94	(0.34%)	143	(0.33%)	346	(0.35%)	186	(0.40%)
Cataracts[2, 3]	8650	(4.55%)	505	(1.82%)	1345	(3.12%)	4578	(5.25%)	2222	(6.96%)
Pills for hypertension	9237	(4.36%)	1099	(3.46%)	1838	(3.91%)	4252	(4.55%)	2048	(5.16%)

Outcomes	Race/Ethnicity: Am Indian/ Alaskan Native		Asian/Pacific Islander		Black/African American		Hispanic/ Latino		White		Unknown	
Number randomized	130		527		2738		1537		22030		385	
Mean follow-up (months)	120.6		122.4		126.4		119.8		131.7		123.4	
Hospitalizations												
Ever	78	(5.97%)	239	(4.45%)	1658	(5.75%)	709	(4.62%)	13744	(5.68%)	223	(5.63%)
Two or more	57	(4.36%)	126	(2.34%)	1051	(3.64%)	369	(2.40%)	8776	(3.63%)	130	(3.28%)
Other												
Diabetes (treated)	17	(1.49%)	65	(1.31%)	475	(1.87%)	272	(1.92%)	2324	(1.00%)	46	(1.25%)
Gallbladder disease[1, 2]	13	(1.50%)	32	(0.76%)	187	(0.84%)	129	(1.28%)	1730	(1.02%)	26	(0.93%)
Hysterectomy	3	(0.56%)	9	(0.24%)	65	(0.55%)	45	(0.51%)	815	(0.53%)	11	(0.45%)
Glaucoma[2]	16	(1.50%)	60	(1.36%)	410	(1.79%)	190	(1.46%)	2480	(1.26%)	47	(1.49%)
Osteoporosis[2]	32	(2.96%)	141	(3.19%)	349	(1.46%)	338	(2.69%)	5162	(2.66%)	93	(2.90%)
Osteoarthritis[3]	41	(4.62%)	130	(3.42%)	640	(3.64%)	442	(4.14%)	5079	(3.40%)	99	(3.85%)
Rheumatoid arthritis[2]	15	(1.49%)	30	(0.68%)	272	(1.20%)	220	(1.72%)	1126	(0.57%)	35	(1.09%)
Intestinal polyps	28	(2.32%)	84	(1.72%)	571	(2.12%)	248	(1.69%)	4408	(1.96%)	63	(1.74%)
Lupus	2	(0.15%)	4	(0.07%)	40	(0.14%)	25	(0.16%)	289	(0.12%)	2	(0.05%)
Kidney stones[2, 3]	9	(0.98%)	25	(0.63%)	82	(0.39%)	62	(0.55%)	583	(0.33%)	8	(0.27%)
Cataracts[2, 3]	44	(4.98%)	143	(4.09%)	790	(4.19%)	450	(4.10%)	7110	(4.64%)	113	(4.42%)
Pills for hypertension	53	(5.69%)	164	(4.35%)	798	(5.52%)	545	(4.72%)	7571	(4.24%)	106	(4.04%)

[1] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[2] Data not collected for WHI Extension Study.
[3] These outcomes have not been self-reported on all versions of Form 33 during WHI follow-up. The annualized percentages are corrected for the different amounts of follow-up.

Table 2.7
Selected Medication Use after Stopping of the HT Intervention

Data as of: August 14, 2009

	Without Uterus				With Uterus			
	E-alone		Placebo		E+P		Placebo	
	N	%	N	%	N	%	N	%
Use after stopping but before closeout[1]								
Number due for medication collection					7463		7063	
% missing medication information					20.3%		21.0%	
Estrogen	N/A		N/A		385	6.5	301	5.4
Osteoporosis[2]	N/A		N/A		739	12.4	949	17.0
SERM	N/A		N/A		124	2.1	118	2.1
Use during extension[3]								
Number in extension	3778		3867		6545		6243	
Extension Year 1								
Any prescription hormone	219	6.6	122	3.7	240	4.2	177	3.2
E-alone use	154	4.7	92	2.7	151	2.6	122	2.2
E+P use	18	0.5	16	0.5	110	1.9	43	0.8
Non-prescription (natural) hormone	92	2.8	84	2.5	172	3.0	155	2.8
Osteoporosis[4]	572	17.6	688	21.0	1275	22.6	1457	26.9
SERM	72	2.2	95	2.9	222	3.9	167	3.0
Extension Year 2								
Any prescription hormone	181	5.5	112	3.4	214	3.7	133	2.4
E-alone use	132	4.0	100	3.0	150	2.6	121	2.2
E+P use	24	0.7	19	0.6	85	1.5	42	0.8
Non-prescription (natural) hormone	60	1.8	66	2.0	118	2.1	123	2.2
Osteoporosis[4]	567	17.4	668	20.1	1275	22.3	1428	26.2
SERM	78	2.4	100	3.0	193	3.3	174	3.2
Extension Year 3								
Any prescription hormone	154	4.8	110	3.4	201	3.6	138	2.6
E-alone use	116	3.6	98	3.0	138	2.4	106	1.9
E+P use	18	0.6	20	0.6	65	1.1	38	0.7
Non-prescription (natural) hormone	53	1.7	47	1.4	122	2.2	108	2.0
Osteoporosis[4]	509	16.2	611	18.9	1223	21.8	1352	25.4
SERM	68	2.1	88	2.7	198	3.5	157	2.9
Extension Year 4								
Any prescription hormone	144	5.3	82	3.0	168	3.5	139	3.0
E-alone use	101	3.6	78	2.8	120	2.4	101	2.1
E+P use	19	0.7	12	0.4	59	1.2	30	0.6
Non-prescription (natural) hormone	43	1.6	36	1.3	104	2.1	77	1.7
Osteoporosis[4]	440	16.3	504	18.3	1042	21.7	1160	25.3
SERM	57	2.1	66	2.4	154	3.2	136	2.9

[1] Collected at annual visits 1, 3, 6, and 9. Insufficient data available on the E-alone participants.
[2] Bisphosphonate or calcitonin.
[3] Use at any time during the extension year.
[4] Bisphosphonate, calcitonin, or PTH.

Table 3.1
Dietary Modification Component Age–and Race/Ethnicity – Specific Recruitment

Data as of: August 14, 2009

	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age	**48,835**			
50-54	6,961	149%	14%	10%
55-59	11,037	118%	23%	20%
60-69	22,715	108%	47%	45%
70-79	8,122	70%	17%	25%
Race/Ethnicity	**48,835**			
American Indian	202		<1%	
Asian	1,105		2%	
Black	5,262		11%	
Hispanic	1,845		4%	
White	39,762		81%	
Unknown	659		1%	

Table 3.2
Lost-to-Follow-up and Vital Status: DM Participants

Data as of: August 14, 2009
Extension Participants Only

	DM Participants (N=37,858)	
	N	%
Vital Status/Participation		
Deceased	1554	4.1
Alive: Current Participation[1]	35297	93.2
Alive: Recent Participation[2]	508	1.3
Alive: Past/Unknown Participation[3]	5	<0.1
Stopped Follow-Up[4]	274	0.7
Lost to Follow-Up[5]	220	0.6

Data as of: September 12, 2005
Events through Study Closeout

	DM Participants (N =48,835)	
	N	%
Vital Status/Participation		
Deceased	2404	4.9
Alive: Current Participation[6]	44116	90.3
Alive: Recent Participation[7]	235	0.5
Alive: Past/Unknown Participation[8]	5	<0.1
Stopped Follow-Up[4]	1553	3.2
Lost to Follow-Up[5]	522	1.1

1 Participants who have filled in a Form 33 within the last 15 months.
2 Participants who last filled in a Form 33 between 15 and 24 months ago.
3 Participants without a Form 33 within the last 24 months, who have been located (as indicated on Form 23) within the last 6 months.
4 Participants with codes 5 (no follow-up) or 8 (absolutely no follow-up) on Form 7 and 9.
5 Participants not in any of the above categories.
6 Participants who have filled in a Form 33 within the last 9 months.
7 Participants who last filled in a Form 33 between 9 and 18 months ago.
8 Participants without a Form 33 within the last 18 months, who have been located (as indicated on Form 23) within the last 6 months.

Table 3.3
Nutrient Intake Monitoring

Data as of: August 15, 2008

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
24 Hr Recall, post-baseline	226	23.0	9.2	262	32.1	7.6	9.2	0.8	<.01
24 Hr Recall, Year 3 Cohort	787	24.8	8.5	1183	33.0	7.6	8.3	0.4	<.01
24 Hr Recall, Year 6 Cohort	766	26.6	9.1	1167	33.9	7.8	7.3	0.4	<.01
24 Hr Recall, Year 9 Cohort	154	28.5	8.6	264	35.2	8.4	6.7	0.9	<.01
24 Hr Recall, Ext. Year 1 Cohort	281	30.4	9.4	392	34.4	9.2	4.0	0.7	<.01
Total Energy (kcal)									
24 Hr Recall, post-baseline	226	1519.8	418.2	262	1652.8	516.5	133.0	43.0	<.01
24 Hr Recall, Year 3 Cohort	787	1431.8	391.6	1183	1589.9	489.3	158.1	20.8	<.01
24 Hr Recall, Year 6 Cohort	766	1388.8	391.0	1167	1544.2	482.1	155.4	20.8	<.01
24 Hr Recall, Year 9 Cohort	154	1406.7	384.6	264	1516.8	452.9	110.2	43.5	0.02
24 Hr Recall, Ext. Year 1 Cohort	281	1419.1	457.4	392	1578.7	533.7	159.7	39.3	<.01
Total Fat (g)									
24 Hr Recall, post-baseline	226	39.6	21.9	262	60.5	26.9	20.9	2.2	<.01
24 Hr Recall, Year 3 Cohort	787	39.8	18.7	1183	59.9	25.6	20.0	1.1	<.01
24 Hr Recall, Year 6 Cohort	766	41.5	20.0	1167	59.7	26.1	18.1	1.1	<.01
24 Hr Recall, Year 9 Cohort	154	45.1	18.6	264	60.9	26.3	15.9	2.4	<.01
24 Hr Recall, Ext. Year 1 Cohort	281	48.9	24.7	392	62.2	30.9	13.3	2.2	<.01
Saturated Fat (g)									
24 Hr Recall, post-baseline	226	12.9	7.9	262	20.1	9.6	7.2	0.8	<.01
24 Hr Recall, Year 3 Cohort	787	12.4	6.8	1183	19.7	9.3	7.3	0.4	<.01
24 Hr Recall, Year 6 Cohort	766	13.1	7.1	1167	19.5	9.7	6.4	0.4	<.01
24 Hr Recall, Year 9 Cohort	154	14.5	6.8	264	20.6	10.2	6.1	0.9	<.01
24 Hr Recall, Ext. Year 1 Cohort	281	15.6	9.3	392	20.8	13.4	5.2	0.9	<.01
Polyunsaturated Fat (g)									
24 Hr Recall, post-baseline	226	8.3	5.0	262	12.6	7.3	4.3	0.6	<.01
24 Hr Recall, Year 3 Cohort	787	8.7	4.6	1183	12.2	6.9	3.6	0.3	<.01
24 Hr Recall, Year 6 Cohort	766	8.8	4.6	1167	12.3	6.2	3.5	0.3	<.01
24 Hr Recall, Year 9 Cohort	154	9.6	4.4	264	12.2	5.7	2.7	0.5	<.01
24 Hr Recall, Ext. Year 1 Cohort	281	10.8	7.0	392	13.2	8.3	2.4	0.6	<.01

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.

Table 3.4
Verified Outcomes (Annualized Percentages) by Age for Dietary Modification

Data as of: August 14, 2009

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	48835		6961		11037		22715		8122	
Mean follow-up (months)	134.5		142.7		139.1		133.2		124.6	
Cancer										
Breast cancer	2865	(0.52%)	353	(0.43%)	662	(0.52%)	1359	(0.54%)	491	(0.58%)
Invasive breast cancer	2325	(0.42%)	262	(0.32%)	540	(0.42%)	1117	(0.44%)	406	(0.48%)
Non-invasive breast cancer	575	(0.11%)	94	(0.11%)	130	(0.10%)	258	(0.10%)	93	(0.11%)
Ovarian cancer	245	(0.04%)	26	(0.03%)	47	(0.04%)	124	(0.05%)	48	(0.06%)
Endometrial cancer[1]	406	(0.07%)	51	(0.06%)	94	(0.07%)	203	(0.08%)	58	(0.07%)
Colorectal cancer	687	(0.13%)	46	(0.06%)	116	(0.09%)	338	(0.13%)	187	(0.22%)
Other cancer[2]	2840	(0.52%)	250	(0.30%)	500	(0.39%)	1450	(0.57%)	640	(0.76%)
Total cancer	6658	(1.22%)	692	(0.84%)	1337	(1.04%)	3275	(1.30%)	1354	(1.61%)
Cardiovascular										
CHD[3]	1960	(0.36%)	107	(0.13%)	246	(0.19%)	949	(0.38%)	658	(0.78%)
CHD death[4]	554	(0.10%)	27	(0.03%)	45	(0.04%)	260	(0.10%)	222	(0.26%)
Total MI[5]	1578	(0.29%)	84	(0.10%)	212	(0.17%)	762	(0.30%)	520	(0.62%)
Clinical MI	1525	(0.28%)	78	(0.09%)	205	(0.16%)	736	(0.29%)	506	(0.60%)
CABG/PTCA	2515	(0.46%)	131	(0.16%)	355	(0.28%)	1369	(0.54%)	660	(0.78%)
Carotid artery disease	398	(0.07%)	17	(0.02%)	46	(0.04%)	215	(0.09%)	120	(0.14%)
Stroke	1535	(0.28%)	69	(0.08%)	168	(0.13%)	733	(0.29%)	565	(0.67%)
PVD	349	(0.06%)	17	(0.02%)	48	(0.04%)	179	(0.07%)	105	(0.12%)
Coronary disease[6]	4795	(0.88%)	272	(0.33%)	653	(0.51%)	2443	(0.97%)	1427	(1.69%)
Total cardiovascular disease	6471	(1.18%)	353	(0.43%)	864	(0.68%)	3257	(1.29%)	1997	(2.37%)
Fractures										
Hip fracture	879	(0.16%)	19	(0.02%)	63	(0.05%)	377	(0.15%)	420	(0.50%)
Deaths										
Cardiovascular deaths	1089	(0.20%)	44	(0.05%)	85	(0.07%)	478	(0.19%)	482	(0.57%)
Cancer deaths	1668	(0.30%)	105	(0.13%)	246	(0.19%)	840	(0.33%)	477	(0.57%)
Other known cause	859	(0.16%)	39	(0.05%)	87	(0.07%)	377	(0.15%)	356	(0.42%)
Unknown cause	117	(0.02%)	5	(0.01%)	12	(0.01%)	54	(0.02%)	46	(0.05%)
Not yet adjudicated	403	(0.07%)	18	(0.02%)	29	(0.02%)	192	(0.08%)	164	(0.19%)
Total death	4136	(0.76%)	211	(0.25%)	459	(0.36%)	1941	(0.77%)	1525	(1.81%)

[1] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.

[2] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.

[3] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Study.

[4] "CHD death" includes definite and possible CHD death.

[5] "Total MI" includes clinical MI and evolving Q-wave MI is not collected in the WHI Extension Study.

[6] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA; Q-wave MI, angina, and congestive heart failure are not collected in the WHI Extension Study.

Table 3.5
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Dietary Modification

Data as of: August 14, 2009

Outcome	Race/Ethnicity											
	American Indian/Alaskan Native		Asian/Pacific Islander		Black/African American		Hispanic/ Latino		White		Unknown	
Number randomized	202		1105		5262		1845		39762		659	
Mean follow-up (months)	126.8		129.9		128.3		122.3		136.2		126.2	
Cancer												
Breast cancer	6	(0.28%)	64	(0.53%)	249	(0.44%)	67	(0.36%)	2447	(0.54%)	32	(0.46%)
Invasive breast cancer	4	(0.19%)	48	(0.40%)	189	(0.34%)	54	(0.29%)	2004	(0.44%)	26	(0.38%)
Non-invasive breast cancer	2	(0.09%)	16	(0.13%)	63	(0.11%)	15	(0.08%)	473	(0.10%)	6	(0.09%)
Ovarian cancer	1	(0.05%)	6	(0.05%)	15	(0.03%)	8	(0.04%)	212	(0.05%)	3	(0.04%)
Endometrial cancer[1]	0	(0.00%)	4	(0.03%)	25	(0.04%)	9	(0.05%)	362	(0.08%)	6	(0.09%)
Colorectal cancer	4	(0.19%)	12	(0.10%)	78	(0.14%)	20	(0.11%)	565	(0.13%)	8	(0.12%)
Other cancer[2]	7	(0.33%)	44	(0.37%)	218	(0.39%)	56	(0.30%)	2482	(0.55%)	33	(0.48%)
Total cancer	16	(0.75%)	121	(1.01%)	555	(0.99%)	151	(0.80%)	5740	(1.27%)	75	(1.08%)
Cardiovascular												
CHD[3]	4	(0.19%)	25	(0.21%)	210	(0.37%)	36	(0.19%)	1660	(0.37%)	25	(0.36%)
CHD death[4]	0	(0.00%)	5	(0.04%)	82	(0.15%)	11	(0.06%)	444	(0.10%)	12	(0.17%)
Total MI[5]	4	(0.19%)	23	(0.19%)	150	(0.27%)	29	(0.15%)	1353	(0.30%)	19	(0.27%)
Clinical MI	4	(0.19%)	23	(0.19%)	145	(0.26%)	28	(0.15%)	1307	(0.29%)	18	(0.26%)
CABG/PTCA	8	(0.37%)	23	(0.19%)	233	(0.41%)	58	(0.31%)	2168	(0.48%)	25	(0.36%)
Carotid artery disease	2	(0.09%)	1	(0.01%)	24	(0.04%)	3	(0.02%)	362	(0.08%)	6	(0.09%)
Stroke	6	(0.28%)	24	(0.20%)	201	(0.36%)	39	(0.21%)	1244	(0.28%)	21	(0.30%)
PVD	3	(0.14%)	3	(0.03%)	67	(0.12%)	5	(0.03%)	266	(0.06%)	5	(0.07%)
Coronary disease[6]	17	(0.80%)	56	(0.47%)	582	(1.03%)	119	(0.63%)	3963	(0.88%)	58	(0.84%)
Total cardiovascular disease	27	(1.26%)	83	(0.69%)	785	(1.40%)	162	(0.86%)	5333	(1.18%)	81	(1.17%)
Fractures												
Hip fracture	2	(0.09%)	10	(0.08%)	22	(0.04%)	14	(0.07%)	823	(0.18%)	8	(0.12%)
Deaths												
Cardiovascular deaths	4	(0.19%)	15	(0.13%)	161	(0.29%)	20	(0.11%)	875	(0.19%)	14	(0.20%)
Cancer deaths	7	(0.33%)	24	(0.20%)	140	(0.25%)	44	(0.23%)	1430	(0.32%)	23	(0.33%)
Other known cause	10	(0.47%)	9	(0.08%)	90	(0.16%)	18	(0.10%)	721	(0.16%)	11	(0.16%)
Unknown cause	1	(0.05%)	1	(0.01%)	17	(0.03%)	2	(0.01%)	91	(0.02%)	5	(0.07%)
Not yet adjudicated	0	(0.00%)	1	(0.01%)	36	(0.06%)	6	(0.03%)	355	(0.08%)	5	(0.07%)
Total death	22	(1.03%)	50	(0.42%)	444	(0.79%)	90	(0.48%)	3472	(0.77%)	58	(0.84%)

[1] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[2] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.
[3] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Study.
[4] "CHD death" includes definite and possible CHD death.
[5] "Total MI" includes clinical MI and evolving Q-wave MI; Q-wave MI is not collected in the WHI Extension Study.
[6] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA; Q-wave MI, angina, and congestive heart failure are not collected in the WHI Extension Study.

Table 3.6
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for DM Participants Who Did Not Report a Prevalent Condition at Baseline

Data as of: August 14, 2009

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	48835		6961		11037		22715		8122	
Mean follow-up (months)	134.5		142.7		139.1		133.2		124.6	
Hospitalizations										
Ever	29294	(5.35%)	3135	(3.79%)	5693	(4.45%)	14350	(5.69%)	6116	(7.25%)
Two or more	18095	(3.31%)	1569	(1.90%)	3178	(2.48%)	9100	(3.61%)	4248	(5.04%)
Other										
DVT[1]	755	(0.14%)	49	(0.06%)	107	(0.09%)	372	(0.15%)	227	(0.28%)
Pulmonary embolism	564	(0.10%)	43	(0.05%)	85	(0.07%)	295	(0.12%)	141	(0.17%)
Diabetes (treated)	5372	(1.02%)	792	(0.98%)	1233	(1.00%)	2524	(1.05%)	823	(1.03%)
Gallbladder disease[2, 3]	3830	(0.99%)	573	(0.92%)	902	(0.98%)	1802	(1.04%)	553	(0.95%)
Hysterectomy	1990	(0.64%)	289	(0.61%)	483	(0.62%)	959	(0.68%)	259	(0.56%)
Glaucoma[3]	5318	(1.20%)	567	(0.83%)	1098	(1.05%)	2589	(1.28%)	1064	(1.59%)
Osteoporosis[3]	10221	(2.35%)	1129	(1.65%)	1969	(1.90%)	5021	(2.54%)	2102	(3.25%)
Osteoarthritis[4]	12354	(3.64%)	1919	(3.08%)	2964	(3.37%)	5663	(3.85%)	1808	(4.30%)
Rheumatoid arthritis[3]	2849	(0.64%)	399	(0.59%)	631	(0.61%)	1319	(0.65%)	500	(0.73%)
Intestinal polyps	10452	(2.05%)	1463	(1.82%)	2475	(2.04%)	5081	(2.19%)	1433	(1.91%)
Lupus	627	(0.12%)	97	(0.12%)	147	(0.12%)	298	(0.12%)	85	(0.10%)
Kidney stones[3, 4]	1319	(0.34%)	175	(0.31%)	281	(0.32%)	654	(0.36%)	209	(0.34%)
Cataracts[3, 4]	15485	(4.40%)	1157	(2.02%)	2859	(3.23%)	8462	(5.21%)	3007	(6.95%)
Pills for hypertension	15847	(4.13%)	2173	(3.26%)	3639	(3.76%)	7509	(4.42%)	2526	(5.02%)

Outcomes	Race/Ethnicity: Am Indian/ Alaskan Native		Asian/Pacific Islander		Black/African American		Hispanic/ Latino		White		Unknown	
Number randomized	202		1105		5262		1845		39762		659	
Mean follow-up (months)	126.8		129.9		128.3		122.3		136.2		126.2	
Hospitalizations												
Ever	110	(5.15%)	481	(4.02%)	3047	(5.42%)	868	(4.62%)	24426	(5.41%)	362	(5.22%)
Two or more	71	(3.33%)	234	(1.96%)	1903	(3.38%)	494	(2.63%)	15186	(3.37%)	207	(2.99%)
Other												
DVT[1]	3	(0.15%)	1	(0.01%)	84	(0.15%)	13	(0.07%)	642	(0.15%)	12	(0.18%)
Pulmonary embolism	3	(0.14%)	1	(0.01%)	66	(0.12%)	6	(0.03%)	481	(0.11%)	7	(0.10%)
Diabetes (treated)	27	(1.36%)	136	(1.20%)	902	(1.80%)	273	(1.54%)	3957	(0.90%)	77	(1.17%)
Gallbladder disease[2, 3]	14	(1.06%)	60	(0.66%)	304	(0.71%)	152	(1.25%)	3250	(1.03%)	50	(0.99%)
Hysterectomy	5	(0.50%)	33	(0.43%)	132	(0.53%)	59	(0.59%)	1749	(0.66%)	12	(0.31%)
Glaucoma[3]	30	(1.71%)	108	(1.12%)	763	(1.70%)	201	(1.29%)	4152	(1.13%)	64	(1.16%)
Osteoporosis[3]	43	(2.46%)	272	(2.87%)	679	(1.47%)	409	(2.72%)	8678	(2.43%)	140	(2.57%)
Osteoarthritis[4]	52	(4.20%)	287	(3.30%)	1256	(3.71%)	507	(3.96%)	10075	(3.62%)	177	(4.10%)
Rheumatoid arthritis[3]	23	(1.40%)	49	(0.51%)	506	(1.13%)	222	(1.44%)	1998	(0.55%)	51	(0.92%)
Intestinal polyps	55	(2.77%)	221	(2.02%)	1157	(2.20%)	341	(1.90%)	8538	(2.04%)	140	(2.19%)
Lupus	5	(0.24%)	10	(0.08%)	90	(0.16%)	21	(0.11%)	491	(0.11%)	10	(0.15%)
Kidney stones[3, 4]	9	(0.61%)	27	(0.32%)	137	(0.34%)	58	(0.42%)	1071	(0.34%)	17	(0.34%)
Cataracts[3, 4]	61	(4.51%)	306	(3.93%)	1510	(4.07%)	537	(4.11%)	12867	(4.47%)	204	(4.52%)
Pills for hypertension	59	(4.26%)	327	(4.05%)	1545	(5.46%)	623	(4.47%)	13102	(4.00%)	191	(4.08%)

[1] Inpatient DVT only.
[2] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[3] Data not collected for WHI Extension Study.
[4] These outcomes have not been self-reported on all versions of Form 33 during WHI follow-up. The annualized percentages are corrected for the different amounts of follow-up.

Table 4.1
Calcium and Vitamin D Component Age – and Race/Ethnicity – Specific Recruitment

Data as of: August 14, 2009

	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age	**36,282**			
50-54	5,153	118%	14%	10%
55-59	8,269	95%	23%	20%
60-69	16,519	84%	46%	45%
70-79	6,341	58%	17%	25%
Race/Ethnicity	**36,282**			
American Indian	149		<1%	
Asian	721		2%	
Black	3,315		9%	
Hispanic	1,502		4%	
White	30,155		83%	
Unknown	440		1%	

Table 4.2
Lost-to-Follow-up and Vital Status: CaD Participants

Data as of: August 14, 2009
Extension Participants Only

	CaD Participants (N = 29,862)	
	N	%
Vital Status/Participation		
Deceased	1285	4.3
Alive: Current Participation[1]	27699	92.8
Alive: Recent Participation[2]	436	1.5
Alive: Past/Unknown Participation[3]	4	<0.1
Stopped Follow-Up[4]	238	0.8
Lost to Follow-Up[5]	200	0.7

Data as of: September 12, 2005
Events through Study Closeout

	CaD Participants (N = 36,282)	
	N	%
Vital Status/Participation		
Deceased	1551	4.3
Alive: Current Participation[6]	32652	90.0
Alive: Recent Participation[7]	1099	3.0
Alive: Past/Unknown Participation[8]	27	0.1
Stopped Follow-Up[4]	684	1.9
Lost to Follow-Up[5]	269	0.7

[1] Participants who have filled in a Form 33 within the last 15 months.
[2] Participants who last filled in a Form 33 between 15 and 24 months ago.
[3] Participants without a Form 33 within the last 24 months, who have been located (as indicated on Form 23) within the last 6 months.
[4] Participants with codes 5 (no follow-up) or 8 (absolutely no follow-up) on Form 7 or 9.
[5] Participants not in any of the above categories.
[6] Participants who have filled in a Form 33 within the last 9 months.
[7] Participants who last filled in a Form 33 between 9 and 18 months ago.
[8] Participants without a Form 33 within the last 18 months, who have been located (as indicated on Form 23) within the last 6 months.

Table 4.3
Verified Outcomes (Annualized Percentages) by Age for Calcium and Vitamin D

Data as of: August 14, 2009

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number of participants	36282		5153		8269		16519		6341	
Mean follow-up (months)	124.1		131.0		128.5		123.1		115.5	
Fractures										
Hip fracture	676	(0.18%)	14	(0.02%)	64	(0.07%)	264	(0.16%)	334	(0.55%)
Cancer										
Colorectal cancer	473	(0.13%)	33	(0.06%)	70	(0.08%)	232	(0.14%)	138	(0.23%)
Breast cancer	1893	(0.50%)	227	(0.40%)	440	(0.50%)	890	(0.53%)	336	(0.55%)
Invasive breast cancer	1526	(0.41%)	170	(0.30%)	359	(0.41%)	720	(0.42%)	277	(0.45%)
Non-invasive breast cancer	392	(0.10%)	58	(0.10%)	85	(0.10%)	182	(0.11%)	67	(0.11%)
Ovarian cancer	166	(0.04%)	19	(0.03%)	40	(0.05%)	78	(0.05%)	29	(0.05%)
Endometrial cancer[1]	259	(0.07%)	35	(0.06%)	61	(0.07%)	119	(0.07%)	44	(0.07%)
Other cancer[2]	2024	(0.54%)	170	(0.30%)	352	(0.40%)	1014	(0.60%)	488	(0.80%)
Total cancer	4587	(1.22%)	469	(0.83%)	925	(1.04%)	2211	(1.30%)	982	(1.61%)
Cardiovascular										
CHD[3]	1458	(0.39%)	75	(0.13%)	184	(0.21%)	704	(0.42%)	495	(0.81%)
CHD death[4]	405	(0.11%)	17	(0.03%)	38	(0.04%)	168	(0.10%)	182	(0.30%)
Total MI[5]	1174	(0.31%)	61	(0.11%)	152	(0.17%)	588	(0.35%)	373	(0.61%)
Clinical MI	1125	(0.30%)	57	(0.10%)	147	(0.17%)	564	(0.33%)	357	(0.58%)
CABG/PTCA	1877	(0.50%)	101	(0.18%)	266	(0.30%)	1000	(0.59%)	510	(0.84%)
Carotid artery disease	317	(0.08%)	13	(0.02%)	40	(0.05%)	175	(0.10%)	89	(0.15%)
Stroke	1109	(0.30%)	53	(0.09%)	126	(0.14%)	508	(0.30%)	422	(0.69%)
PVD	285	(0.08%)	10	(0.02%)	43	(0.05%)	142	(0.08%)	90	(0.15%)
Coronary disease[6]	3507	(0.93%)	199	(0.35%)	490	(0.55%)	1751	(1.03%)	1067	(1.75%)
Total cardiovascular disease	4769	(1.27%)	263	(0.47%)	660	(0.75%)	2349	(1.39%)	1497	(2.45%)
Deaths										
Cardiovascular deaths	797	(0.21%)	31	(0.06%)	67	(0.08%)	331	(0.20%)	368	(0.60%)
Cancer deaths	1178	(0.31%)	84	(0.15%)	169	(0.19%)	596	(0.35%)	329	(0.54%)
Other known cause	616	(0.16%)	26	(0.05%)	73	(0.08%)	265	(0.16%)	252	(0.41%)
Unknown cause	91	(0.02%)	5	(0.01%)	12	(0.01%)	41	(0.02%)	33	(0.05%)
Not yet adjudicated	291	(0.08%)	17	(0.03%)	25	(0.03%)	127	(0.07%)	122	(0.20%)
Total death	2973	(0.79%)	163	(0.29%)	346	(0.39%)	1360	(0.80%)	1104	(1.81%)

[1] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[2] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.
[3] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Study.
[4] "CHD death" includes definite and possible CHD death.
[5] "Total MI" includes clinical MI and evolving Q-wave MI; Q-wave MI is not collected in the WHI Extension Study.
[6] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA; Q-wave MI, angina, and congestive heart failure are not collected in the WHI Extension Study.

Table 4.4
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Calcium and Vitamin D

Data as of: August 14, 2009

Outcome	Race/Ethnicity: American Indian/Alaskan Native		Asian/Pacific Islander		Black/African American		Hispanic/ Latino		White		Unknown	
Number of participants	149		721		3315		1502		30155		440	
Mean follow-up (months)	118.5		118.5		119.2		114.8		125.4		115.8	
Fractures												
Hip fracture	3	(0.20%)	8	(0.11%)	12	(0.04%)	7	(0.05%)	645	(0.20%)	1	(0.02%)
Cancer												
Colorectal cancer	2	(0.14%)	7	(0.10%)	47	(0.14%)	12	(0.08%)	399	(0.13%)	6	(0.14%)
Breast cancer	4	(0.27%)	37	(0.52%)	151	(0.46%)	47	(0.33%)	1635	(0.52%)	19	(0.45%)
Invasive breast cancer	3	(0.20%)	26	(0.37%)	116	(0.35%)	38	(0.26%)	1326	(0.42%)	17	(0.40%)
Non-invasive breast cancer	1	(0.07%)	12	(0.17%)	37	(0.11%)	11	(0.08%)	329	(0.10%)	2	(0.05%)
Ovarian cancer	0	(0.00%)	6	(0.08%)	11	(0.03%)	6	(0.04%)	141	(0.04%)	2	(0.05%)
Endometrial cancer[1]	1	(0.07%)	3	(0.04%)	12	(0.04%)	6	(0.04%)	233	(0.07%)	4	(0.09%)
Other cancer[2]	5	(0.34%)	34	(0.48%)	134	(0.41%)	46	(0.32%)	1785	(0.57%)	20	(0.47%)
Total cancer	11	(0.75%)	82	(1.15%)	342	(1.04%)	110	(0.77%)	3992	(1.27%)	50	(1.18%)
Cardiovascular												
CHD[3]	5	(0.34%)	12	(0.17%)	132	(0.40%)	34	(0.24%)	1256	(0.40%)	19	(0.45%)
CHD death[4]	1	(0.07%)	3	(0.04%)	52	(0.16%)	9	(0.06%)	333	(0.11%)	7	(0.16%)
Total MI[5]	5	(0.34%)	11	(0.15%)	91	(0.28%)	29	(0.20%)	1022	(0.32%)	16	(0.38%)
Clinical MI	5	(0.34%)	11	(0.15%)	88	(0.27%)	28	(0.19%)	978	(0.31%)	15	(0.35%)
CABG/PTCA	6	(0.41%)	18	(0.25%)	144	(0.44%)	58	(0.40%)	1628	(0.52%)	23	(0.54%)
Carotid artery disease	1	(0.07%)	1	(0.01%)	14	(0.04%)	3	(0.02%)	293	(0.09%)	5	(0.12%)
Stroke	7	(0.48%)	21	(0.30%)	114	(0.35%)	29	(0.20%)	921	(0.29%)	17	(0.40%)
PVD	2	(0.14%)	5	(0.07%)	40	(0.12%)	2	(0.01%)	234	(0.07%)	2	(0.05%)
Coronary disease[6]	11	(0.75%)	35	(0.49%)	352	(1.07%)	106	(0.74%)	2962	(0.94%)	41	(0.97%)
Total cardiovascular disease	18	(1.22%)	57	(0.80%)	483	(1.47%)	138	(0.96%)	4015	(1.27%)	58	(1.37%)
Deaths												
Cardiovascular deaths	2	(0.14%)	12	(0.17%)	102	(0.31%)	19	(0.13%)	652	(0.21%)	10	(0.24%)
Cancer deaths	2	(0.14%)	24	(0.34%)	86	(0.26%)	35	(0.24%)	1018	(0.32%)	13	(0.31%)
Other known cause	7	(0.48%)	7	(0.10%)	46	(0.14%)	13	(0.09%)	535	(0.17%)	8	(0.19%)
Unknown cause	0	(0.00%)	1	(0.01%)	17	(0.05%)	2	(0.01%)	69	(0.02%)	2	(0.05%)
Not yet adjudicated	1	(0.07%)	2	(0.03%)	23	(0.07%)	4	(0.03%)	259	(0.08%)	2	(0.05%)
Total death	12	(0.82%)	46	(0.65%)	274	(0.83%)	73	(0.51%)	2533	(0.80%)	35	(0.82%)

[1] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[2] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.
[3] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Study.
[4] "CHD death" includes definite and possible CHD death.
[5] "Total MI" includes clinical MI and evolving Q-wave MI; Q-wave MI is not collected in the WHI Extension Study.
[6] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA; Q-wave MI, angina, and congestive heart failure are not collected in the WHI Extension Study.

Table 4.5
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for CaD Participants Who Did Not Report a Prevalent Condition at Baseline

Data as of: August 14, 2009

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	36282		5153		8269		16519		6341	
Mean follow-up (months)	124.1		131.0		128.5		123.1		115.5	
Hospitalizations										
Ever	21034	(5.60%)	2205	(3.92%)	4089	(4.62%)	10098	(5.96%)	4642	(7.61%)
Two or more	12541	(3.34%)	1038	(1.84%)	2226	(2.51%)	6167	(3.64%)	3110	(5.10%)
Other										
DVT[1]	552	(0.15%)	36	(0.07%)	89	(0.10%)	255	(0.16%)	172	(0.29%)
Pulmonary embolism	403	(0.11%)	34	(0.06%)	68	(0.08%)	210	(0.12%)	91	(0.15%)
Diabetes (treated)	4020	(1.12%)	616	(1.12%)	894	(1.05%)	1881	(1.16%)	629	(1.08%)
Gallbladder disease[2, 3]	2485	(0.94%)	367	(0.88%)	602	(0.95%)	1157	(0.99%)	359	(0.84%)
Hysterectomy	1319	(0.60%)	179	(0.55%)	332	(0.61%)	625	(0.63%)	183	(0.53%)
Glaucoma[3]	3730	(1.23%)	401	(0.86%)	770	(1.06%)	1773	(1.31%)	786	(1.62%)
Osteoporosis[3]	7136	(2.38%)	736	(1.58%)	1362	(1.90%)	3451	(2.57%)	1587	(3.35%)
Osteoarthritis[4]	8835	(3.76%)	1354	(3.20%)	2099	(3.43%)	4008	(3.99%)	1374	(4.40%)
Rheumatoid arthritis[3]	1879	(0.62%)	267	(0.58%)	435	(0.61%)	834	(0.61%)	343	(0.69%)
Intestinal polyps	7419	(2.12%)	1050	(1.93%)	1724	(2.04%)	3538	(2.26%)	1107	(2.04%)
Lupus	454	(0.12%)	68	(0.12%)	111	(0.13%)	194	(0.11%)	81	(0.13%)
Kidney stones[3, 4]	819	(0.30%)	111	(0.28%)	180	(0.28%)	383	(0.31%)	145	(0.32%)
Cataracts[3, 4]	11122	(4.62%)	818	(2.09%)	2096	(3.42%)	5937	(5.44%)	2271	(7.26%)
Pills for hypertension	12069	(4.49%)	1646	(3.57%)	2781	(4.07%)	5584	(4.78%)	2058	(5.44%)

Outcomes	Race/Ethnicity: American Indian/ Alaskan Native		Asian/Pacific Islander		Black/African American		Hispanic/ Latino		White		Unknown	
Number randomized	149		721		3315		1502		30155		440	
Mean follow-up (months)	118.5		118.5		119.2		114.8		125.4		115.8	
Hospitalizations												
Ever	79	(5.37%)	311	(4.37%)	1880	(5.71%)	672	(4.68%)	17849	(5.66%)	243	(5.72%)
Two or more	55	(3.74%)	152	(2.14%)	1140	(3.46%)	349	(2.43%)	10709	(3.40%)	136	(3.20%)
Other												
DVT[1]	6	(0.42%)	1	(0.01%)	58	(0.18%)	10	(0.07%)	471	(0.15%)	6	(0.14%)
Pulmonary embolism	4	(0.27%)	0	(0.00%)	39	(0.12%)	4	(0.03%)	350	(0.11%)	6	(0.14%)
Diabetes (treated)	20	(1.46%)	89	(1.33%)	559	(1.90%)	254	(1.88%)	3040	(1.00%)	58	(1.46%)
Gallbladder disease[2, 3]	10	(1.03%)	39	(0.72%)	169	(0.67%)	121	(1.27%)	2118	(0.96%)	28	(0.93%)
Hysterectomy	3	(0.49%)	20	(0.43%)	78	(0.55%)	44	(0.55%)	1163	(0.61%)	11	(0.45%)
Glaucoma[3]	20	(1.66%)	59	(1.03%)	472	(1.81%)	177	(1.47%)	2969	(1.16%)	33	(0.97%)
Osteoporosis[3]	30	(2.48%)	156	(2.71%)	409	(1.52%)	299	(2.57%)	6160	(2.45%)	82	(2.44%)
Osteoarthritis[4]	48	(5.10%)	172	(3.28%)	793	(3.96%)	416	(4.22%)	7282	(3.71%)	124	(4.41%)
Rheumatoid arthritis[3]	17	(1.52%)	29	(0.51%)	304	(1.17%)	152	(1.28%)	1349	(0.53%)	28	(0.83%)
Intestinal polyps	39	(2.87%)	121	(1.85%)	721	(2.34%)	243	(1.76%)	6208	(2.11%)	87	(2.23%)
Lupus	4	(0.28%)	3	(0.04%)	53	(0.16%)	17	(0.12%)	372	(0.12%)	5	(0.12%)
Kidney stones[3, 4]	7	(0.65%)	18	(0.34%)	73	(0.30%)	46	(0.43%)	667	(0.29%)	8	(0.25%)
Cataracts[3, 4]	51	(5.16%)	178	(3.87%)	909	(4.21%)	440	(4.39%)	9409	(4.69%)	135	(4.79%)
Pills for hypertension	45	(4.82%)	215	(4.35%)	1038	(6.05%)	536	(4.84%)	10113	(4.35%)	122	(4.52%)

[1] Inpatient DVT only.
[2] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[3] Data not collected for WHI Extension Study.
[4] These outcomes have not been self-reported on all versions of Form 33 during WHI follow-up. The annualized percentages are corrected for the different amounts of follow-up.

Table 5.1
Observational Study Age and Race/Ethnicity Specific Recruitment

Data as of: August 14, 2009

	Total Enrolled	Distribution
Age	**93,676**	
50-54	12,381	13%
55-59	17,329	18%
60-69	41,200	44%
70-79	22,766	24%
Race/Ethnicity	**93,676**	
American Indian	421	<1%
Asian	2,671	3%
Black	7,635	8%
Hispanic	3,609	4%
White	78,016	83%
Unknown	1,324	1%

Table 5.2
Lost-to-Follow-up and Vital Status: OS Participants

Data as of: August 14, 2009
Extension Participants Only

	OS Participants (N=63,230) N	%
Vital Status/Participation		
Deceased	2939	4.6
Alive: Current Participation[1]	58741	92.9
Alive: Recent Participation[2]	838	1.3
Alive: Past/Unknown Participation[3]	11	<0.1
Stopped Follow-Up[4]	398	0.6
Lost to Follow-Up[5]	303	0.5

Data as of: September 12, 2005
Events through Study Closeout

	OS Participants (N =93,676) N	%
Vital Status/Participation		
Deceased	6260	6.7
Alive: Current Participation[1]	78092	83.4
Alive: Recent Participation[2]	4818	5.1
Alive: Past/Unknown Participation[3]	51	0.1
Stopped Follow-Up[4]	2347	2.5
Lost to Follow-Up[5]	2105	2.2

[1] Participants who have filled in a Form 33 within the last 15 months.
[2] Participants who last filled in a Form 33 between 15 and 24 months ago.
[3] Participants without a Form 33 within the last 24 months, who have been located (as indicated on Form 23) within the last 6 months.
[4] Participants with codes 5 (no follow-up) or 8 (absolutely no follow-up) on Form 7 or 9.
[5] Participants not in any of the above categories.

Table 5.3
Verified Outcomes (Annualized Percentages) by Age for OS Participants

Data as of: August 14, 2009

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number enrolled	93676		12381		17329		41200		22766	
Mean follow-up (months)	124.9		132.7		131.5		125.1		115.3	
Cardiovascular										
CHD[1]	3552	(0.36%)	124	(0.09%)	286	(0.15%)	1503	(0.35%)	1639	(0.75%)
CHD death[2]	1180	(0.12%)	28	(0.02%)	58	(0.03%)	414	(0.10%)	680	(0.31%)
Clinical MI	2738	(0.28%)	102	(0.07%)	242	(0.13%)	1214	(0.28%)	1180	(0.54%)
Angina[3]	2837	(0.29%)	124	(0.09%)	318	(0.17%)	1320	(0.31%)	1075	(0.49%)
CABG/PTCA	4340	(0.45%)	183	(0.13%)	480	(0.25%)	2152	(0.50%)	1525	(0.70%)
Carotid artery disease	764	(0.08%)	38	(0.03%)	71	(0.04%)	340	(0.08%)	315	(0.14%)
Congestive heart failure[3]	2305	(0.24%)	81	(0.06%)	174	(0.09%)	886	(0.21%)	1164	(0.53%)
Stroke	2865	(0.29%)	83	(0.06%)	219	(0.12%)	1180	(0.27%)	1383	(0.63%)
PVD	751	(0.08%)	20	(0.01%)	70	(0.04%)	334	(0.08%)	327	(0.15%)
Coronary disease[4]	8384	(0.86%)	353	(0.26%)	833	(0.44%)	3739	(0.87%)	3459	(1.58%)
Total cardiovascular disease	11780	(1.21%)	469	(0.34%)	1125	(0.59%)	5160	(1.20%)	5026	(2.30%)
Cancer										
Breast cancer	5368	(0.55%)	625	(0.46%)	938	(0.49%)	2499	(0.58%)	1306	(0.60%)
Invasive breast cancer	4469	(0.46%)	502	(0.37%)	765	(0.40%)	2076	(0.48%)	1126	(0.51%)
Non-invasive breast cancer	947	(0.10%)	130	(0.09%)	180	(0.09%)	446	(0.10%)	191	(0.09%)
Ovarian cancer	480	(0.05%)	46	(0.03%)	93	(0.05%)	219	(0.05%)	122	(0.06%)
Endometrial cancer[5]	734	(0.07%)	68	(0.05%)	127	(0.07%)	339	(0.08%)	200	(0.09%)
Colorectal cancer	1200	(0.12%)	67	(0.05%)	124	(0.07%)	551	(0.13%)	458	(0.21%)
Other cancer[6]	5521	(0.57%)	388	(0.28%)	729	(0.38%)	2624	(0.61%)	1780	(0.81%)
Total cancer	12542	(1.29%)	1145	(0.84%)	1907	(1.00%)	5852	(1.36%)	3638	(1.66%)
Fractures										
Hip fracture	1868	(0.19%)	42	(0.03%)	110	(0.06%)	642	(0.15%)	1074	(0.49%)
Deaths										
Cardiovascular deaths	2545	(0.26%)	60	(0.04%)	137	(0.07%)	864	(0.20%)	1484	(0.68%)
Cancer deaths	3620	(0.37%)	213	(0.16%)	397	(0.21%)	1624	(0.38%)	1386	(0.63%)
Other known cause	2123	(0.22%)	93	(0.07%)	154	(0.08%)	784	(0.18%)	1092	(0.50%)
Unknown cause	361	(0.04%)	19	(0.01%)	33	(0.02%)	133	(0.03%)	176	(0.08%)
Not yet adjudicated	922	(0.09%)	25	(0.02%)	78	(0.04%)	360	(0.08%)	459	(0.21%)
Total death	9571	(0.98%)	410	(0.30%)	799	(0.42%)	3765	(0.88%)	4597	(2.10%)

[1] "CHD" includes clinical MI and CHD death.
[2] "CHD death" includes definite and possible CHD death.
[3] Angina and CHF are not verified outcomes in the WHI Extension Study. Reported statistics represent experience during the original program.
[4] "Coronary disease" includes clinical MI, CHD death, angina, congestive heart failure, and CABG/PTCA; angina and congestive heart failure are not collected in the WHI Extension Study.
[5] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[6] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.

Table 5.4
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for OS Participants

Data as of: August 14, 2009

Outcomes	Race/Ethnicity: American Indian/Alaskan Native		Asian/Pacific Islander		Black/African American		Hispanic/ Latino		White		Unknown	
Number enrolled	421		2671		7635		3609		78016		1324	
Mean follow-up (months)	110.9		112.8		109.9		105.6		127.9		118.0	
Cardiovascular												
CHD[1]	21	(0.54%)	54	(0.22%)	300	(0.43%)	64	(0.20%)	3064	(0.37%)	49	(0.38%)
CHD death[2]	11	(0.28%)	18	(0.07%)	136	(0.19%)	18	(0.06%)	979	(0.12%)	18	(0.14%)
Clinical MI	12	(0.31%)	41	(0.16%)	196	(0.28%)	53	(0.17%)	2400	(0.29%)	36	(0.28%)
Angina[3]	18	(0.46%)	40	(0.16%)	250	(0.36%)	80	(0.25%)	2415	(0.29%)	34	(0.26%)
CABG/PTCA	23	(0.59%)	57	(0.23%)	267	(0.38%)	104	(0.33%)	3830	(0.46%)	59	(0.45%)
Carotid artery disease	4	(0.10%)	7	(0.03%)	32	(0.05%)	13	(0.04%)	696	(0.08%)	12	(0.09%)
Congestive heart failure[3]	16	(0.41%)	22	(0.09%)	235	(0.34%)	42	(0.13%)	1956	(0.24%)	34	(0.26%)
Stroke	13	(0.33%)	66	(0.26%)	242	(0.35%)	61	(0.19%)	2436	(0.29%)	47	(0.36%)
PVD	3	(0.08%)	4	(0.02%)	79	(0.11%)	8	(0.03%)	644	(0.08%)	13	(0.10%)
Coronary disease[4]	51	(1.31%)	116	(0.46%)	719	(1.03%)	191	(0.60%)	7198	(0.87%)	109	(0.84%)
Total cardiovascular disease	62	(1.59%)	187	(0.75%)	1004	(1.44%)	259	(0.82%)	10098	(1.21%)	170	(1.31%)
Cancer												
Breast cancer	15	(0.39%)	117	(0.47%)	329	(0.47%)	120	(0.38%)	4733	(0.57%)	54	(0.41%)
Invasive breast cancer	14	(0.36%)	99	(0.39%)	265	(0.38%)	100	(0.31%)	3945	(0.47%)	46	(0.35%)
Non-invasive breast cancer	1	(0.03%)	19	(0.08%)	69	(0.10%)	21	(0.07%)	828	(0.10%)	9	(0.07%)
Ovarian cancer	1	(0.03%)	5	(0.02%)	21	(0.03%)	17	(0.05%)	434	(0.05%)	2	(0.02%)
Endometrial cancer[5]	1	(0.03%)	11	(0.04%)	25	(0.04%)	11	(0.03%)	672	(0.08%)	14	(0.11%)
Colorectal cancer	4	(0.10%)	24	(0.10%)	113	(0.16%)	26	(0.08%)	1019	(0.12%)	14	(0.11%)
Other cancer[6]	17	(0.44%)	104	(0.41%)	342	(0.49%)	94	(0.30%)	4889	(0.59%)	75	(0.58%)
Total cancer	38	(0.98%)	247	(0.98%)	786	(1.12%)	262	(0.82%)	11059	(1.33%)	150	(1.15%)
Fractures												
Hip fracture	5	(0.13%)	18	(0.07%)	41	(0.06%)	16	(0.05%)	1767	(0.21%)	21	(0.16%)
Deaths												
Cardiovascular deaths	17	(0.44%)	48	(0.19%)	255	(0.36%)	50	(0.16%)	2137	(0.26%)	38	(0.29%)
Cancer deaths	13	(0.33%)	71	(0.28%)	270	(0.39%)	79	(0.25%)	3147	(0.38%)	40	(0.31%)
Other known cause	25	(0.64%)	36	(0.14%)	171	(0.24%)	69	(0.22%)	1800	(0.22%)	22	(0.17%)
Unknown cause	1	(0.03%)	5	(0.02%)	59	(0.08%)	13	(0.04%)	279	(0.03%)	4	(0.03%)
Not yet adjudicated	6	(0.15%)	6	(0.02%)	75	(0.11%)	16	(0.05%)	801	(0.10%)	18	(0.14%)
Total death	62	(1.59%)	166	(0.66%)	830	(1.19%)	227	(0.71%)	8164	(0.98%)	122	(0.94%)

[1] "CHD" includes clinical MI and CHD death.
[2] "CHD death" includes definite and possible CHD death.
[3] Angina and CHF are not verified outcomes in the WHI Extension Study. Reported statistics represent experience during the original program.
[4] "Coronary disease" includes clinical MI, CHD death, angina, congestive heart failure, and CABG/PTCA; angina and congestive heart failure are not collected in the WHI Extension Study.
[5] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[6] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin.

Table 5.5
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for OS Participants Who Did Not Report a Prevalent Condition at Baseline

Data as of: August 14, 2009

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	93676		12381		17329		41200		22766	
Mean follow-up (months)	124.9		132.7		131.5		125.1		115.3	
Hospitalizations										
Ever	53159	(5.45%)	5011	(3.66%)	8100	(4.26%)	24216	(5.64%)	15832	(7.24%)
Two or more	31436	(3.22%)	2382	(1.74%)	4207	(2.22%)	14374	(3.35%)	10473	(4.79%)
Other										
DVT[1]	1088	(0.12%)	69	(0.05%)	142	(0.08%)	505	(0.12%)	372	(0.18%)
Pulmonary embolism	817	(0.08%)	67	(0.05%)	115	(0.06%)	380	(0.09%)	255	(0.12%)
Diabetes (treated)	7561	(0.80%)	1005	(0.75%)	1412	(0.77%)	3460	(0.84%)	1684	(0.80%)
Gallbladder disease[2,3]	5690	(0.96%)	835	(0.97%)	1153	(0.99%)	2549	(0.99%)	1153	(0.85%)
Hysterectomy	4331	(0.44%)	604	(0.44%)	861	(0.45%)	1989	(0.46%)	877	(0.40%)
Glaucoma[3]	8516	(1.27%)	852	(0.89%)	1379	(1.06%)	3910	(1.33%)	2375	(1.57%)
Osteoporosis[3]	20767	(3.22%)	2110	(2.25%)	3384	(2.65%)	9540	(3.40%)	5733	(4.02%)
Osteoarthritis[4]	20521	(3.61%)	2845	(2.88%)	4017	(3.22%)	9151	(3.81%)	4508	(4.29%)
Rheumatoid arthritis[3]	4607	(0.69%)	638	(0.68%)	885	(0.69%)	1898	(0.65%)	1186	(0.77%)
Intestinal polyps	17527	(1.99%)	2251	(1.73%)	3556	(2.00%)	8151	(2.11%)	3569	(1.89%)
Lupus	1265	(0.13%)	169	(0.12%)	247	(0.13%)	564	(0.13%)	285	(0.13%)
Kidney stones[3,4]	2327	(0.39%)	292	(0.36%)	436	(0.39%)	996	(0.38%)	603	(0.43%)
Cataracts[3,4]	27206	(5.36%)	1735	(2.15%)	4109	(3.74%)	14089	(6.20%)	7273	(8.10%)
Pills for hypertension	27433	(3.91%)	3323	(2.91%)	5008	(3.36%)	12297	(4.09%)	6805	(4.91%)

Outcomes	Race/Ethnicity: American Indian/ Alaskan Native		Asian/Pacific Islander		Black/African American		Hispanic/ Latino		White		Unknown	
Number randomized	421		2671		7635		3609		78016		1324	
Mean follow-up (months)	110.9		112.8		109.9		105.6		127.9		118.0	
Hospitalizations												
Ever	239	(6.14%)	978	(3.90%)	3982	(5.69%)	1484	(4.67%)	45772	(5.51%)	704	(5.41%)
Two or more	149	(3.83%)	439	(1.75%)	2234	(3.19%)	731	(2.30%)	27477	(3.31%)	406	(3.12%)
Other												
DVT[1]	4	(0.11%)	5	(0.02%)	92	(0.14%)	17	(0.05%)	958	(0.12%)	12	(0.10%)
Pulmonary embolism	3	(0.08%)	4	(0.02%)	56	(0.08%)	9	(0.03%)	739	(0.09%)	6	(0.05%)
Diabetes (treated)	61	(1.81%)	231	(0.97%)	1009	(1.62%)	426	(1.44%)	5714	(0.71%)	120	(0.96%)
Gallbladder disease[2,3]	31	(1.32%)	81	(0.46%)	377	(0.79%)	232	(1.21%)	4892	(0.98%)	77	(0.95%)
Hysterectomy	21	(0.54%)	84	(0.33%)	264	(0.38%)	191	(0.60%)	3702	(0.45%)	69	(0.53%)
Glaucoma[3]	45	(1.64%)	253	(1.36%)	997	(2.01%)	312	(1.34%)	6787	(1.20%)	122	(1.32%)
Osteoporosis[3]	92	(3.37%)	630	(3.53%)	1078	(2.10%)	739	(3.26%)	17902	(3.31%)	326	(3.69%)
Osteoarthritis[4]	75	(3.48%)	632	(3.57%)	1548	(3.81%)	864	(4.15%)	17105	(3.57%)	297	(3.74%)
Rheumatoid arthritis[3]	38	(1.39%)	98	(0.53%)	664	(1.35%)	385	(1.68%)	3333	(0.59%)	89	(0.98%)
Intestinal polyps	62	(1.75%)	409	(1.82%)	1326	(2.07%)	527	(1.77%)	14993	(2.00%)	210	(1.80%)
Lupus	8	(0.21%)	23	(0.09%)	126	(0.18%)	64	(0.20%)	1028	(0.12%)	16	(0.12%)
Kidney stones[3,4]	18	(0.73%)	41	(0.25%)	266	(0.57%)	125	(0.59%)	1832	(0.37%)	45	(0.54%)
Cataracts[3,4]	105	(4.91%)	685	(4.93%)	1951	(4.86%)	905	(4.63%)	23165	(5.45%)	395	(5.69%)
Pills for hypertension	115	(4.59%)	680	(3.83%)	1904	(5.52%)	1038	(4.34%)	23288	(3.79%)	408	(4.43%)

[1] Inpatient DVT only.
[2] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[3] Data not collected for WHI extension study.
[4] These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

Table 5.6
First Reported Verified Outcomes Before and After AV-3[1] for OS Participants

Data as of: August 14, 2009

Outcome	Number of Events	
	Before AV-3	After AV-3
Cardiovascular		
CHD[2]	761	2791
CHD death[3]	178	1002
Clinical MI	640	2098
Angina	1270	1567
CABG/PTCA	1166	3174
Carotid artery disease	225	539
Congestive heart failure	719	1586
Stroke	596	2269
PVD	198	553
Coronary disease[4]	2586	5798
Total cardiovascular disease	3471	8309
Cancer		
Breast cancer	1605	3763
Invasive breast cancer	1340	3129
Non-invasive breast cancer	271	676
Ovarian cancer	136	344
Endometrial cancer	214	520
Colorectal cancer	332	868
Other cancer[5]	1412	4109
Total cancer	3623	8919
Fractures		
Hip fracture	294	1574
Deaths		
Cardiovascular deaths	372	2173
Cancer deaths	618	3002
Deaths: other known cause	225	1898
Deaths: unknown cause	59	302
Deaths: not yet adjudicated	0	922
Total death	1274	8297

[1] AV-3 date is the blood draw date for participants with an AV-3 blood draw and the OS enrollment date plus 3 years for participants without an AV-3 blood draw. All participants have been enrolled for at least 3 years.
[2] "CHD" includes clinical MI and CHD death.
[3] "CHD death" includes definite and possible CHD death.
[4] "Coronary disease" includes clinical MI, CHD death, angina, congestive heart failure, and CABG/PTCA; angina and congestive heart failure are not collected in the WHI Extension Study.
[5] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.

Table 5.7
Counts of Participants with Self-Reported Outcomes Before and After AV-3[1]
for OS Participants Who Did Not Report a Prevalent Condition at Baseline

Data as of: August 14, 2009

	Number of Events	
Outcome	**Before AV-3**	**After AV-3**
Ever hospitalized	19160	33999
DVT[2]	227	861
Pulmonary embolism	130	687
Diabetes (treated)	1694	5642
Gallbladder disease[3, 4]	2137	3553
Hysterectomy	1359	2972
Glaucoma[4]	2755	5761
Osteoporosis[4]	8703	12064
Osteoarthritis[5]	6339	14182
Rheumatoid arthritis[4]	1723	2884
Intestinal polyps	4397	13130
Lupus	348	917
Kidney stones[4, 5]	646	1681
Cataracts[4, 5]	9145	18061
Pills for hypertension	8141	19292

[1] AV-3 date is the blood draw date for participants with an AV-3 blood draw and the OS enrollment date plus 3 years for participants without an AV-3 blood draw. All participants have been enrolled for at least 3 years.
[2] Inpatient DVT only.
[3] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[4] Not collected on Form 33 after March 31, 2005.
[5] These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

Table 6.1
Verified Outcomes (Annualized Percentages) by Age for CT Participants

Data as of: August 14, 2009

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	68132		9188		14661		31389		12894	
Mean follow-up (months)	132.9		141.1		137.8		132.1		123.5	
Cardiovascular										
CHD[1]	3028	(0.40%)	160	(0.15%)	356	(0.21%)	1416	(0.41%)	1096	(0.83%)
CHD death[2]	891	(0.12%)	38	(0.04%)	70	(0.04%)	382	(0.11%)	401	(0.30%)
Total MI[3]	2403	(0.32%)	128	(0.12%)	302	(0.18%)	1134	(0.33%)	839	(0.63%)
Clinical MI	2326	(0.31%)	122	(0.11%)	294	(0.17%)	1096	(0.32%)	814	(0.61%)
Angina[4]	2414	(0.32%)	129	(0.12%)	331	(0.20%)	1215	(0.35%)	739	(0.56%)
CABG/PTCA	3743	(0.50%)	197	(0.18%)	508	(0.30%)	1960	(0.57%)	1078	(0.81%)
Carotid artery disease	620	(0.08%)	21	(0.02%)	74	(0.04%)	332	(0.10%)	193	(0.15%)
Congestive heart failure[4]	1750	(0.23%)	81	(0.07%)	172	(0.10%)	746	(0.22%)	751	(0.57%)
Stroke	2232	(0.30%)	87	(0.08%)	222	(0.13%)	1038	(0.30%)	885	(0.67%)
PVD	570	(0.08%)	28	(0.03%)	78	(0.05%)	289	(0.08%)	175	(0.13%)
Coronary disease[5]	7179	(0.95%)	402	(0.37%)	933	(0.55%)	3501	(1.01%)	2343	(1.77%)
Total cardiovascular disease	9643	(1.28%)	506	(0.47%)	1220	(0.72%)	4677	(1.35%)	3240	(2.44%)
Cancer										
Breast cancer	3735	(0.49%)	431	(0.40%)	813	(0.48%)	1769	(0.51%)	722	(0.54%)
Invasive breast cancer	3027	(0.40%)	325	(0.30%)	665	(0.39%)	1433	(0.41%)	604	(0.46%)
Non-invasive breast cancer	753	(0.10%)	110	(0.10%)	157	(0.09%)	358	(0.10%)	128	(0.10%)
Ovary cancer	322	(0.04%)	27	(0.02%)	66	(0.04%)	166	(0.05%)	63	(0.05%)
Endometrial cancer[6]	501	(0.07%)	57	(0.05%)	112	(0.07%)	248	(0.07%)	84	(0.06%)
Colorectal cancer	967	(0.13%)	60	(0.06%)	146	(0.09%)	476	(0.14%)	285	(0.21%)
Other cancer[7]	4089	(0.54%)	323	(0.30%)	679	(0.40%)	2034	(0.59%)	1053	(0.79%)
Total cancer	9110	(1.21%)	859	(0.79%)	1727	(1.03%)	4430	(1.28%)	2094	(1.58%)
Fractures										
Hip fracture	1365	(0.18%)	26	(0.02%)	98	(0.06%)	539	(0.16%)	702	(0.53%)
Deaths										
Cardiovascular deaths	1701	(0.23%)	62	(0.06%)	127	(0.08%)	701	(0.20%)	811	(0.61%)
Cancer deaths	2437	(0.32%)	141	(0.13%)	333	(0.20%)	1209	(0.35%)	754	(0.57%)
Other known cause	1308	(0.17%)	58	(0.05%)	131	(0.08%)	554	(0.16%)	565	(0.43%)
Unknown cause	196	(0.03%)	11	(0.01%)	19	(0.01%)	83	(0.02%)	83	(0.06%)
Not yet adjudicated	592	(0.08%)	25	(0.02%)	45	(0.03%)	268	(0.08%)	254	(0.19%)
Total death	6234	(0.83%)	297	(0.27%)	655	(0.39%)	2815	(0.81%)	2467	(1.86%)

[1] "CHD" includes clinical MI and CHD death.
[2] "CHD death" includes definite and possible CHD death.
[3] "Total MI" includes clinical MI and evolving Q-wave MI.
[4] Angina and CHF are not verified outcomes in the WHI Extension Study. Reported statistics represent experience during the original program.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[6] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[7] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.

Table 6.2
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for CT Participants

Data as of: August 14, 2009

Outcome	Race/Ethnicity					
	American Indian/Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	292	1519	6983	2875	55525	938
Mean follow-up (months)	124.1	127.7	127.3	121.0	134.6	125.1
Cardiovascular						
CHD[1]	8 (0.27%)	43 (0.27%)	298 (0.40%)	65 (0.22%)	2574 (0.41%)	40 (0.41%)
CHD death[2]	2 (0.07%)	12 (0.07%)	127 (0.17%)	17 (0.06%)	719 (0.12%)	14 (0.14%)
Total MI[3]	7 (0.23%)	38 (0.24%)	205 (0.28%)	53 (0.18%)	2068 (0.33%)	32 (0.33%)
Clinical MI	7 (0.23%)	37 (0.23%)	200 (0.27%)	51 (0.18%)	2001 (0.32%)	30 (0.31%)
Angina[4]	12 (0.40%)	30 (0.19%)	298 (0.40%)	80 (0.28%)	1964 (0.32%)	30 (0.31%)
CABG/PTCA	14 (0.46%)	40 (0.25%)	322 (0.43%)	100 (0.34%)	3224 (0.52%)	43 (0.44%)
Carotid artery disease	3 (0.10%)	2 (0.01%)	34 (0.05%)	5 (0.02%)	567 (0.09%)	9 (0.09%)
Congestive heart failure[4]	5 (0.17%)	17 (0.11%)	244 (0.33%)	49 (0.17%)	1411 (0.23%)	24 (0.25%)
Stroke	9 (0.30%)	35 (0.22%)	277 (0.37%)	59 (0.20%)	1822 (0.29%)	30 (0.31%)
PVD	5 (0.17%)	7 (0.04%)	86 (0.12%)	7 (0.02%)	459 (0.07%)	6 (0.06%)
Coronary disease[5]	26 (0.86%)	92 (0.57%)	798 (1.08%)	200 (0.69%)	5973 (0.96%)	90 (0.92%)
Total cardiovascular disease	39 (1.29%)	131 (0.81%)	1084 (1.46%)	261 (0.90%)	8009 (1.29%)	119 (1.22%)
Cancer						
Breast cancer	8 (0.27%)	84 (0.52%)	323 (0.44%)	89 (0.31%)	3193 (0.51%)	38 (0.39%)
Invasive breast cancer	6 (0.20%)	63 (0.39%)	253 (0.34%)	73 (0.25%)	2602 (0.42%)	30 (0.31%)
Non-invasive breast cancer	2 (0.07%)	22 (0.14%)	73 (0.10%)	18 (0.06%)	630 (0.10%)	8 (0.08%)
Ovary cancer	1 (0.03%)	8 (0.05%)	20 (0.03%)	8 (0.03%)	280 (0.04%)	5 (0.05%)
Endometrial cancer[6]	1 (0.03%)	5 (0.03%)	32 (0.04%)	13 (0.04%)	442 (0.07%)	8 (0.08%)
Colorectal cancer	5 (0.17%)	19 (0.12%)	100 (0.13%)	27 (0.09%)	801 (0.13%)	15 (0.15%)
Other cancer[7]	12 (0.40%)	71 (0.44%)	297 (0.40%)	102 (0.35%)	3562 (0.57%)	45 (0.46%)
Total cancer	25 (0.83%)	177 (1.10%)	737 (0.99%)	226 (0.78%)	7842 (1.26%)	103 (1.05%)
Fractures						
Hip fracture	5 (0.17%)	14 (0.09%)	33 (0.04%)	19 (0.07%)	1284 (0.21%)	10 (0.10%)
Deaths						
Cardiovascular deaths	8 (0.27%)	26 (0.16%)	234 (0.32%)	32 (0.11%)	1382 (0.22%)	19 (0.19%)
Cancer deaths	10 (0.33%)	43 (0.27%)	198 (0.27%)	74 (0.26%)	2083 (0.33%)	29 (0.30%)
Other known cause	11 (0.36%)	12 (0.07%)	116 (0.16%)	27 (0.09%)	1124 (0.18%)	18 (0.18%)
Unknown cause	1 (0.03%)	3 (0.02%)	32 (0.04%)	5 (0.02%)	149 (0.02%)	6 (0.06%)
Not yet adjudicated	2 (0.07%)	7 (0.04%)	56 (0.08%)	9 (0.03%)	512 (0.08%)	6 (0.06%)
Total death	32 (1.06%)	91 (0.56%)	636 (0.86%)	147 (0.51%)	5250 (0.84%)	78 (0.80%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.
[2] "CHD death" includes definite and possible CHD death.
[3] "Total MI" includes clinical MI and evolving Q-wave MI.
[4] Angina and CHF are not verified outcomes in the WHI Extension Study. Reported statistics represent experience during the original program.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[6] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[7] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.

Table 6.3
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for CT Participants Who Did Not Report a Prevalent Condition at Baseline

Data as of: August 14, 2009

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	68132		9188		14661		31389		12894	
Mean follow-up (months)	132.9		141.1		137.8		132.1		123.5	
Hospitalizations										
Ever	41040	(5.44%)	4109	(3.80%)	7496	(4.45%)	19771	(5.72%)	9664	(7.28%)
Two or more	25482	(3.38%)	2076	(1.92%)	4184	(2.48%)	12486	(3.61%)	6736	(5.08%)
Other										
DVT[1]	1125	(0.15%)	74	(0.07%)	156	(0.10%)	532	(0.16%)	363	(0.28%)
Pulmonary embolism	800	(0.11%)	60	(0.06%)	115	(0.07%)	407	(0.12%)	218	(0.17%)
Diabetes (treated)	7450	(1.03%)	1061	(1.01%)	1609	(0.99%)	3510	(1.07%)	1270	(1.01%)
Gallbladder disease[2, 3]	5248	(0.98%)	746	(0.92%)	1195	(0.99%)	2463	(1.03%)	844	(0.91%)
Hysterectomy	2677	(0.61%)	341	(0.55%)	626	(0.60%)	1304	(0.65%)	406	(0.54%)
Glaucoma[3]	7570	(1.24%)	745	(0.83%)	1457	(1.05%)	3664	(1.32%)	1704	(1.61%)
Osteoporosis[3]	14702	(2.45%)	1453	(1.62%)	2636	(1.92%)	7143	(2.62%)	3470	(3.39%)
Osteoarthritis[4]	16798	(3.60%)	2458	(3.02%)	3848	(3.31%)	7683	(3.79%)	2809	(4.21%)
Rheumatoid arthritis[3]	4012	(0.66%)	538	(0.61%)	866	(0.63%)	1823	(0.66%)	785	(0.73%)
Intestinal polyps	14174	(2.02%)	1869	(1.78%)	3174	(1.98%)	6911	(2.17%)	2220	(1.89%)
Lupus	902	(0.12%)	131	(0.12%)	205	(0.12%)	417	(0.12%)	149	(0.11%)
Kidney stones[3, 4]	1877	(0.35%)	241	(0.32%)	379	(0.32%)	898	(0.36%)	359	(0.37%)
Cataracts[3, 4]	21575	(4.46%)	1468	(1.95%)	3732	(3.18%)	11651	(5.23%)	4724	(6.97%)
Pills for hypertension	22323	(4.18%)	2889	(3.30%)	4846	(3.76%)	10470	(4.43%)	4118	(5.06%)

Outcomes	Race/Ethnicity: Am Indian/ Alaskan Native		Asian/Pacific Islander		Black/African American		Hispanic/ Latino		White		Unknown	
Number randomized	292		1519		6983		2875		55525		938	
Mean follow-up (months)	124.1		127.7		127.3		121.0		134.6		125.1	
Hospitalizations												
Ever	166	(5.50%)	671	(4.15%)	4106	(5.54%)	1337	(4.61%)	34239	(5.50%)	521	(5.33%)
Two or more	114	(3.78%)	335	(2.07%)	2554	(3.45%)	739	(2.55%)	21443	(3.44%)	297	(3.04%)
Other												
DVT[1]	6	(0.21%)	3	(0.02%)	124	(0.17%)	20	(0.07%)	959	(0.16%)	13	(0.14%)
Pulmonary embolism	5	(0.17%)	3	(0.02%)	84	(0.11%)	9	(0.03%)	689	(0.11%)	10	(0.10%)
Diabetes (treated)	38	(1.39%)	187	(1.23%)	1190	(1.81%)	460	(1.70%)	5468	(0.91%)	107	(1.16%)
Gallbladder disease[2, 3]	22	(1.14%)	86	(0.70%)	420	(0.74%)	243	(1.27%)	4403	(1.01%)	74	(1.05%)
Hysterectomy	7	(0.53%)	42	(0.40%)	177	(0.55%)	90	(0.55%)	2340	(0.62%)	21	(0.37%)
Glaucoma[3]	40	(1.62%)	153	(1.17%)	1008	(1.71%)	338	(1.39%)	5932	(1.17%)	99	(1.27%)
Osteoporosis[3]	66	(2.66%)	389	(3.01%)	911	(1.49%)	639	(2.73%)	12488	(2.53%)	209	(2.70%)
Osteoarthritis[4]	79	(4.34%)	395	(3.37%)	1644	(3.68%)	802	(4.03%)	13626	(3.56%)	252	(4.06%)
Rheumatoid arthritis[3]	32	(1.36%)	74	(0.57%)	683	(1.16%)	358	(1.50%)	2788	(0.55%)	77	(0.98%)
Intestinal polyps	71	(2.55%)	285	(1.93%)	1505	(2.18%)	496	(1.79%)	11631	(2.01%)	186	(2.07%)
Lupus	7	(0.23%)	14	(0.09%)	120	(0.16%)	42	(0.15%)	708	(0.11%)	11	(0.11%)
Kidney stones[3, 4]	15	(0.71%)	47	(0.40%)	190	(0.35%)	100	(0.47%)	1501	(0.34%)	24	(0.34%)
Cataracts[3, 4]	92	(4.70%)	428	(4.08%)	2003	(4.12%)	828	(4.07%)	17931	(4.53%)	293	(4.59%)
Pills for hypertension	94	(4.74%)	460	(4.16%)	2038	(5.47%)	976	(4.50%)	18491	(4.06%)	264	(4.04%)

[1] Inpatient DVT only.
[2] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[3] Data not collected for WHI extension study.
[4] These outcomes have not been self-reported on all versions of Form 33 during WHI follow-up. The annualized percentages are corrected for the different amounts of follow-up.

Table 6.4
First Reported Verified Outcomes Before and After AV-1[1] for CT Participants

Data as of: August 14, 2009

Outcome	Number of Events	
	Before AV-1	After AV-1
Cardiovascular		
CHD[2]	215	2813
CHD death[3]	44	847
Clinical MI	181	2145
Angina	300	2114
CABG/PTCA	252	3491
Carotid artery disease	63	557
Congestive heart failure	114	1636
Stroke	143	2089
PVD	33	537
Coronary disease[4]	611	6568
Total cardiovascular disease	839	8804
Cancer		
Breast cancer	201	3534
Invasive breast cancer	158	2869
Non-invasive breast cancer	43	710
Ovarian cancer	20	302
Endometrial cancer	40	461
Colorectal cancer	79	888
Other cancer[5]	274	3815
Total cancer	607	8503
Fractures		
Hip fracture	50	1315
Deaths		
Cardiovascular deaths	73	1628
Cancer deaths	53	2384
Deaths: other known cause	17	1291
Deaths: unknown cause	5	191
Deaths: not yet adjudicated	0	592
Total death	148	6086

[1] AV-1 date is the blood draw for participants with an AV-1 blood draw and the CT randomization date plus 1 year for participants without an AV-1 blood draw. All participants have been enrolled for at least 1 year.
[2] "CHD" includes clinical MI and CHD death.
[3] "CHD death" includes definite and possible CHD death.
[4] "Coronary disease" includes clinical MI, CHD death, angina, congestive heart failure, and CABG/PTCA; angina and congestive heart failure are not collected in the WHI Extension Study.
[5] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.

Table 6.5
Counts of Participants with Self-Reported Outcomes Before and After AV-1[1]
for CT Participants Who Did Not Report a Prevalent Condition at Baseline

Data as of: August 14, 2009

	Number of Events	
Outcome	**Before AV-1**	**After AV-1**
Ever hospitalized	5492	35548
DVT[2]	90	1035
Pulmonary embolism	48	752
Diabetes (treated)	561	6636
Gallbladder disease[3,4]	606	4642
Hysterectomy	158	1833
Glaucoma[4]	767	6803
Osteoporosis[4]	1502	13200
Osteoarthritis[5]	1248	15550
Rheumatoid arthritis[4]	587	3425
Intestinal polyps	956	13218
Lupus	75	827
Kidney stones[4,5]	128	1749
Cataracts [4,5]	1660	19915
Pills for hypertension	2190	20133

[1] AV-1 date is the blood draw date for participants with an AV-1 blood draw and the CT randomization date plus 1 year for participants without an AV-1 blood draw. All participants have been enrolled for at least 1 year.
[2] Inpatient DVT only.
[3] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[4] Not collected on Form 33 after March 31,2005.
[5] These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

Table 6.6
Verified Other Cancers (Annualized Percentages): CT and OS Participants

Data as of: August 14, 2009

	CT		OS	
Number of participants	68132		93676	
Mean follow-up time (months)	132.9		124.9	
Ppts with other cancer	4089	(0.54%)	5521	(0.57%)
Accessory sinus	1	(<0.01%)	1	(<0.01%)
Adrenal gland	1	(<0.01%)	7	(<0.01%)
Anus	20	(<0.01%)	34	(<0.01%)
Appendix	11	(<0.01%)	12	(<0.01%)
Biliary tract, parts of (other/unspecified)	54	(0.01%)	58	(0.01%)
Bladder	226	(0.03%)	278	(0.03%)
Bones/joints/articular cartilage (limbs)	4	(<0.01%)	8	(<0.01%)
Bones/joints/articular cartilage (other)	6	(<0.01%)	2	(<0.01%)
Brain	97	(0.01%)	104	(0.01%)
Cervix	51	(0.01%)	48	(<0.01%)
Central Nervous System (excludes brain)	0	(0.00%)	3	(<0.01%)
Connective/subcutaneous/soft tissues	37	(<0.01%)	45	(<0.01%)
Endocrine glands, related structures	6	(<0.01%)	7	(<0.01%)
Esophagus	30	(<0.01%)	33	(<0.01%)
Eye and adnexa	22	(<0.01%)	18	(<0.01%)
Genital organs	53	(0.01%)	53	(0.01%)
Kidney	184	(0.02%)	231	(0.02%)
Larynx	19	(<0.01%)	13	(<0.01%)
Leukemia	208	(0.03%)	292	(0.03%)
Liver	43	(0.01%)	53	(0.01%)
Lung	866	(0.11%)	1125	(0.12%)
Lymph nodes	12	(<0.01%)	9	(<0.01%)
Lymphoma, Hodgkins	19	(<0.01%)	25	(<0.01%)
Lymphoma, Non-Hodgkins	394	(0.05%)	539	(0.06%)
Melanoma of the skin	542	(0.07%)	702	(0.07%)
Multiple myeloma	144	(0.02%)	141	(0.01%)
Oral (mouth)	25	(<0.01%)	19	(<0.01%)
Palate	8	(<0.01%)	13	(<0.01%)
Pancreas	211	(0.03%)	255	(0.03%)
Parotid gland (Stensen's duct)	11	(<0.01%)	25	(<0.01%)
Peripheral nerves and autonomic nervous system	1	(<0.01%)	5	(<0.01%)
Pyriform sinus	1	(<0.01%)	4	(<0.01%)
Respiratory system, intrathoracic, other	11	(<0.01%)	19	(<0.01%)
Salivary glands, major (other/unspecified)	4	(<0.01%)	11	(<0.01%)
Stomach	58	(0.01%)	82	(0.01%)
Thyroid	107	(0.01%)	158	(0.02%)
Tongue, part of (other/unspecified)	24	(<0.01%)	25	(<0.01%)
Urinary organs (other/unspecified)	19	(<0.01%)	37	(<0.01%)
Uterus, not otherwise specified	45	(0.01%)	86	(0.01%)
Other/unknown site of cancer	269	(0.04%)	375	(0.04%)
Other/unknown cancers reported on death form	365	(0.05%)	714	(0.07%)

Table 6.7
Locally Verified Other Fractures (Annualized Percentages): CT and OS Participants

Data as of: August 14, 2009

	CT		OS	
Number of participants	68132		93676	
Mean follow-up time (months)	132.9		124.9	
Self-Reports				
Elbow	779	(0.10%)	1031	(0.11%)
Foot	2737	(0.36%)	3416	(0.35%)
Hand	696	(0.09%)	761	(0.08%)
Hip	1460	(0.19%)	2037	(0.21%)
Knee	1008	(0.13%)	1348	(0.14%)
Lower arm	3838	(0.51%)	4814	(0.49%)
Lower leg	3019	(0.40%)	3697	(0.38%)
Pelvis	749	(0.10%)	1221	(0.13%)
Tailbone	258	(0.03%)	373	(0.04%)
Upper arm	1895	(0.25%)	2337	(0.24%)
Upper leg	523	(0.07%)	756	(0.08%)
Spine	2161	(0.29%)	3131	(0.32%)
Other	2994	(0.40%)	3321	(0.34%)
Total fracture	16456	(2.18%)	21239	(2.18%)

Data as of: August 18, 2006
Events through Intervention Closeout

	CT		OS	
Number of participants	68132		6365	
Mean follow-up time (months)	96.1		97.6	
Locally verified				
Ppts with other fractures[1]	8335	(1.53%)	773	(1.49%)
Ankle	1352	(0.25%)	128	(0.25%)
Carpal bone(s) in wrist	192	(0.04%)	13	(0.03%)
Clavicle or collar bone	147	(0.03%)	14	(0.03%)
Elbow, not otherwise specified	31	(0.01%)	1	(<0.01%)
Humerus, shaft/unspecified	86	(0.02%)	7	(0.01%)
Humerus, upper end	842	(0.15%)	69	(0.13%)
Lower end of humerus	104	(0.02%)	10	(0.02%)
Metacarpal bone(s)	272	(0.05%)	27	(0.05%)
Patella	358	(0.07%)	29	(0.06%)
Pelvis	361	(0.07%)	51	(0.10%)
Radius or ulna	2227	(0.41%)	208	(0.40%)
Sacrum and coccyx	107	(0.02%)	12	(0.02%)
Scapula	37	(0.01%)	6	(0.01%)
lShaft of femur	113	(0.02%)	9	(0.02%)
Tarsal/metatarsal bones	1291	(0.24%)	128	(0.25%)
Tibia and fibula	640	(0.12%)	32	(0.06%)
Tibial plateau	176	(0.03%)	10	(0.02%)
Upper radius/ulna	381	(0.07%)	34	(0.07%)
Vertebral	828	(0.15%)	121	(0.23%)
Unknown other fracture	0	(0.00%)	0	(0.00%)

[1] "Other fractures" excludes non-vertebral fractures indicated as pathological.

Table 6.8
Cause of Death (Annualized Percentages): CT and OS Participants

Data as of: August 14, 2009

	CT		OS	
Number Randomized	68132		93676	
Mean Follow-up Time (months)	132.9		124.9	
Total death	6234	(0.83%)	9571	(0.98%)
Adjudicated death	5642	(0.75%)	8649	(0.89%)
Centrally adjudicated death	5603	(0.74%)	2640	(0.27%)
Locally adjudicated death (final)	1	(<0.01%)	5889	(0.60%)
Temporary adjudicated death	0	(0.00%)	0	(0.00%)
Identified by NDI search	38	(0.01%)	120	(0.01%)
Cardiovascular				
Atherosclerotic cardiac	891	(0.12%)	1180	(0.12%)
CHD deaths locally adjudicated before 10/99	0	(0.00%)	82	(0.01%)
Definite CHD deaths	426	(0.06%)	491	(0.05%)
Possible CHD deaths	465	(0.06%)	607	(0.06%)
Cerebrovascular	430	(0.06%)	662	(0.07%)
Pulmonary embolism	53	(0.01%)	59	(0.01%)
Other cardiovascular	302	(0.04%)	543	(0.06%)
Unknown cardiovascular	25	(<0.01%)	101	(0.01%)
Total cardiovascular deaths	1701	(0.23%)	2545	(0.26%)
Cancer				
Breast cancer	175	(0.02%)	519	(0.05%)
Ovarian cancer	156	(0.02%)	255	(0.03%)
Endometrial cancer	39	(0.01%)	62	(0.01%)
Colorectal cancer	221	(0.03%)	294	(0.03%)
Other cancer	1718	(0.23%)	2307	(0.24%)
Unknown cancer site	128	(0.02%)	183	(0.02%)
Total cancer deaths	2437	(0.32%)	3620	(0.37%)
Accident/injury				
Homicide	9	(<0.01%)	12	(<0.01%)
Accident	169	(0.02%)	194	(0.02%)
Suicide	18	(<0.01%)	31	(<0.01%)
Other injury	8	(<0.01%)	26	(<0.01%)
Total accidental deaths	204	(0.03%)	263	(0.03%)
Other				
Other known cause	1104	(0.15%)	1860	(0.19%)
Unknown cause	788	(0.10%)	1283	(0.13%)
Total deaths – other causes	1892	(0.25%)	3143	(0.32%)

Table 7.1
Agreement of the Central Adjudications with Self-Reports

Data as of: August 14, 2009

	Participants with a self-report[1]	Closed		Confirmed		Denied – related outcome found[2]		Denied – unrelated outcome found		Denied – no outcome found		Administrative denials	
		N	%[3]	N	(%)[3]	N	(%)[3]	N	(%)[3]	N	(%)[3]	N	(%)[3]
Cardiovascular													
Clinical MI	1339	1295	97%	918	(71%)	79	(6%)	7	(1%)	288	(22%)	3	(0%)
CABG	646	638	99%	566	(89%)	23	(4%)	1	(0%)	48	(8%)	0	(0%)
PTCA	2008	1965	98%	1620	(82%)	112	(6%)	15	(1%)	218	(11%)	0	(0%)
Carotid artery disease	408	393	96%	304	(77%)	37	(9%)	0	(0%)	46	(12%)	6	(2%)
Stroke/TIA[4]	2097	1899	91%	1163	(61%)	0	(0%)	0	(0%)	731	(38%)	5	(0%)
PVD	463	451	97%	256	(57%)	20	(4%)	15	(3%)	159	(35%)	1	(0%)
DVT[5]	187	176	94%	121	(69%)	9	(5%)	14	(8%)	31	(18%)	1	(1%)
Pulmonary embolism[5]	112	109	97%	92	(84%)	1	(1%)	5	(5%)	11	(10%)	0	(0%)
Cancers													
Breast cancer	2258	2191	97%	2132	(97%)	7	(0%)	0	(0%)	51	(2%)	1	(0%)
Ovarian cancer	241	236	98%	163	(69%)	62	(26%)	1	(0%)	10	(4%)	0	(0%)
Endometrial cancer	270	261	97%	239	(92%)	14	(5%)	1	(0%)	7	(3%)	0	(0%)
Cervical cancer	41	29	71%	3	(10%)	24	(83%)	0	(0%)	2	(7%)	0	(0%)
Colorectal cancer	607	589	97%	501	(85%)	46	(8%)	0	(0%)	40	(7%)	2	(0%)
Melanoma	439	377	86%	322	(85%)	20	(5%)	0	(0%)	25	(7%)	10	(3%)
Lung cancer	748	695	93%	592	(85%)	41	(6%)	0	(0%)	61	(9%)	1	(0%)
Liver cancer	134	81	60%	18	(22%)	33	(41%)	0	(0%)	29	(36%)	1	(1%)
Bone cancer	70	49	70%	0	(0%)	30	(61%)	1	(2%)	18	(37%)	0	(0%)
Lymphoma/Hodgkin's	295	270	92%	240	(89%)	18	(7%)	0	(0%)	10	(4%)	2	(1%)
Leukemia	193	172	89%	146	(85%)	10	(6%)	0	(0%)	16	(9%)	0	(0%)
Meningioma	19	11	58%	0	(0%)	4	(36%)	0	(0%)	7	(64%)	0	(0%)
Other cancer[6]	1466	1008	69%	0	(0%)	859	(85%)	0	(0%)	132	(13%)	17	(2%)
Fractures													
Hip fracture	1348	1292	96%	1082	(84%)	0	(0%)	0	(0%)	206	(16%)	4	(0%)
Upper leg fracture[7]	430	421	98%	0	(0%)	198	(47%)	0	(0%)	222	(53%)	1	(0%)

[1] Excludes duplicates and prior conditions.
[2] All cardiovascular outcomes are considered related, all cancers are considered related and all fractures are considered related.
[3] Percentages between parentheses' are relative to "closed".
[4] Stroke and TIA have a combined self-report. Only stroke is monitored.
[5] HRT participants only.
[6] Any cancer other than those listed above, excluding non-melanoma skin cancer.
[7] Upper leg fractures are only investigated for possible occurrence of hip fracture.

Table 7.2
Source of Outcomes Identified by Central Adjudications

Data as of: August 14, 2009

	Centrally confirmed	Reason for central investigation					
		Self-report same outcome		Self-report related outcome[1]		Self-report unrelated outcome[2]	
	N	N	%	N	%	N	%
Cardiovascular							
Clinical MI	1459	920	63%	411	28%	128	9%
CABG	625	566	91%	49	8%	10	2%
PTCA	1754	1625	93%	115	7%	14	1%
Carotid artery disease	350	306	87%	4	1%	40	11%
Stroke	1362	1223	90%	0	0%	139	10%
PVD	386	258	67%	81	21%	47	12%
DVT	154	121	79%	11	7%	22	14%
Pulmonary embolism	119	92	77%	7	6%	20	17%
Cancers							
Breast cancer	2149	2134	99%	8	<1%	6	<1%
Ovarian cancer	182	163	90%	6	3%	13	7%
Endometrial cancer	306	239	78%	59	19%	8	3%
Cervical cancer	4	3	75%	0	0%	1	25%
Colorectal cancer	522	487	93%	10	2%	25	5%
Melanoma	333	323	97%	9	3%	1	<1%
Lung cancer	646	594	92%	31	5%	21	3%
Liver cancer	22	18	82%	3	14%	1	5%
Lymphoma/Hodgkin's	298	243	82%	43	14%	12	4%
Leukemia	174	147	84%	15	9%	12	7%
Other cancer	936	0	0%	884	94%	50	5%
Fractures							
Hip fracture	1309	1086	83%	181	14%	42	3%

[1] All cardiovascular outcomes are considered related, all cancers are considered related and all fractures are considered related.

[2] Includes self-report of hospitalizations.

Table 8.1
Current Age[1] Distribution by Race/Ethnicity for Active[2] CT and OS Extension Study Participants

Data as of: August 14, 2009

Age group on August 14, 2009	Total		Race/Ethnicity											
			American Indian/ Alaskan Native		Asian/Pacific Islander		Black/African American		Hispanic/ Latino		White		Unknown	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
<65	10599	9.2	52	12.9	233	9.7	1047	12.5	481	14.2	8647	8.7	139	9.8
65-69	18457	16.0	96	23.9	488	20.4	1744	20.9	837	24.7	15072	15.2	220	15.5
70-79	51492	44.6	167	41.5	1021	42.6	3850	46.1	1510	44.6	44353	44.6	591	41.6
80-89	32473	28.1	83	20.6	608	25.4	1587	19.0	535	15.8	29232	29.4	428	30.2
90+	2385	2.1	4	1.0	46	1.9	126	1.5	26	0.8	2142	2.2	41	2.9

[1] Age on August 14, 2009
[2] Vital status is alive with current participation on August 14, 2009

Table 8.2
Counts (Percentages) of Participants with Self-Reported Outcomes by Age at the Beginning of the Extension and Race/Ethnicity for CT and OS Extension Study Participants

Data as of: August 14, 2009

Outcome	Total		Age on April 1, 2005 60-64		65-69		70-79		80-89		90+	
Number enrolled	115406		18278		26786		51913		18362		67	
Mean follow-up	146.5		149.2		147.9		145.4		144.9		161.6	
Number of outcomes[1] reported at baseline and during follow-up	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
0	3589	3.1	1409	7.7	1176	4.4	871	1.7	131	0.7	2	3.0
1	11770	10.2	3445	18.8	3786	14.1	3853	7.4	681	3.7	5	7.5
2	21241	18.4	4514	24.7	5947	22.2	8663	16.7	2110	11.5	7	10.4
3	26329	22.8	4046	22.1	6272	23.4	12054	23.2	3944	21.5	13	19.4
4+	52477	45.5	4864	26.6	9605	35.9	26472	51.0	11496	62.6	40	59.7

Outcome	Race/Ethnicity American Indian/ Alaskan Native		Asian/Pacific Islander		Black/African American		Hispanic/ Latino		White		Unknown	
Number enrolled	402		2396		8354		3389		99446		1419	
Mean follow-up (months)	144.8		144.2		145.2		143.2		146.8		144.0	
Number of outcomes[1] reported at baseline and during follow-up	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
0	9	2.2	104	4.3	126	1.5	109	3.2	3194	3.2	47	3.3
1	26	6.5	312	13.0	560	6.7	357	10.5	10370	10.4	145	10.2
2	51	12.7	508	21.2	1311	15.7	568	16.8	18570	18.7	233	16.4
3	82	20.4	573	23.9	1832	21.9	736	21.7	22801	22.9	305	21.5
4+	234	58.2	899	37.5	4525	54.2	1619	47.8	44511	44.8	689	48.6

[1] Self-reported outcomes include DVT, pulmonary embolism, diabetes (treated), hypertension (treated), hysterectomy, osteoarthritis, intestinal polyps, lupus, gallbladder disease, glaucoma, osteoporosis, kidney stones, cataracts, and rheumatoid arthritis. Data for gallbladder disease, glaucoma, osteoporosis, kidney stones, cataracts, and rheumatoid arthritis not collected for WHI Extension Study.

Table 8.3
Counts (Percentages) of Participants with Adjudicated Outcomes by Age at the Beginning of the Extension and Race/Ethnicity for CT and OS Extension Study Participants

Data as of: August 14, 2009

	Total		Age on April 1, 2005 <65		65-69		70-79		80-89		90+	
Number enrolled	115406		18278		26786		51913		18362		67	
Mean follow-up (months)	146.5		149.2		147.9		145.4		144.9		161.6	
Number of outcomes[1] since WHI enrollment	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
0	88136	76.4	15816	86.5	22031	82.2	38528	74.2	11727	63.9	34	50.7
1	23932	20.7	2333	12.8	4387	16.4	11776	22.7	5411	29.5	25	37.3
2	3044	2.6	119	0.7	347	1.3	1473	2.8	1100	6.0	5	7.5
3	269	0.2	10	0.1	20	0.1	128	0.2	108	0.6	3	4.5
4+	25	0.0	0	0.0	1	<0.1	8	<0.1	16	0.1	0	0.0

	Race/Ethnicity: American Indian/ Alaskan Native		Asian/Pacific Islander		Black/African American		Hispanic/ Latino		White		Unknown	
Number enrolled	402		2396		8354		3389		99446		1419	
Mean follow-up (months)	144.8		144.2		145.2		143.2		146.8		144.0	
Number of outcomes[1] since WHI enrollment	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
0	321	79.9	1979	82.6	6517	78.0	2841	83.8	75347	75.8	1131	79.7
1	74	18.4	387	16.2	1631	19.5	504	14.9	21084	21.2	252	17.8
2	6	1.5	28	1.2	184	2.2	44	1.3	2750	2.8	32	2.3
3	1	0.2	2	0.1	20	0.2	0	0.0	242	0.2	4	0.3
4+	0	0.0	0	0.0	2	0.0	0	0.0	23	0.0	0	0.0

[1] Adjudicated outcomes include incident reports of coronary disease (clinical MI, (possible) evolving Q-wave MI, CHD death, and CABG/PTCA), stroke, PVD, cancer (all), and hip fracture.

Table 8.4

Counts (Percentages) of Participants Reporting Any (Self-reported or Adjudicated) Outcomes by Age at the Beginning of the Extension and Race/Ethnicity for CT and OS Extension Study Participants

Data as of: August 14, 2009

	Total		Age on April 1, 2005 <65		65-69		70-79		80-89		90+	
Number enrolled	115406		18278		26786		51913		18362		67	
Mean follow-up (months)	146.5		149.2		147.9		145.4		144.9		161.6	
Number of outcomes[1] reported at baseline[2] and during follow-up	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
0	3179	2.8	1283	7.0	1050	3.9	746	1.4	99	0.5	1	1.5
1	10407	9.0	3231	17.7	3394	12.7	3276	6.3	500	2.7	6	9.0
2	19009	16.5	4275	23.4	5552	20.7	7479	14.4	1699	9.3	4	6.0
3	24119	20.9	4020	22.0	6048	22.6	10853	20.9	3190	17.4	8	11.9
4+	58692	50.9	5469	29.9	10742	40.1	29559	56.9	12874	70.1	48	71.6

	Race/Ethnicity: American Indian/ Alaskan Native		Asian/Pacific Islander		Black/African American		Hispanic/ Latino		White		Unknown	
Number enrolled	402		2396		8354		3389		99446		1419	
Mean follow-up (months)	144.8		144.2		145.2		143.2		146.8		144.0	
Number of outcomes[1] reported at baseline[2] and during follow-up	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
0	9	2.2	94	3.9	110	1.3	99	2.9	2822	2.8	45	3.2
1	22	5.5	298	12.4	512	6.1	330	9.7	9110	9.2	135	9.5
2	53	13.2	463	19.3	1185	14.2	539	15.9	16568	16.7	201	14.2
3	64	15.9	535	22.3	1643	19.7	695	20.5	20896	21.0	286	20.2
4+	254	63.2	1006	42.0	4904	58.7	1726	50.9	50050	50.3	752	53.0

[1] Self-reported outcomes include first report (baseline or incident) of DVT, pulmonary embolism, diabetes (treated), hypertension (treated), hysterectomy, osteoarthritis, intestinal polyps, lupus, gallbladder disease, glaucoma, osteoporosis, kidney stones, cataracts, and rheumatoid arthritis. Adjudicated outcomes include incident reports of coronary disease (clinical MI, (possible) evolving Q-wave MI, CHD death, and CABG/PTCA), stroke, PVD, cancer (all), and hip fracture. Data for gallbladder disease, glaucoma, osteoporosis, kidney stones, cataracts, and rheumatoid arthritis is not collected for the WHI Extension Study.

[2] Only reports of DVT, pulmonary embolism, diabetes (treated), hypertension (treated), hysterectomy, osteoarthritis, intestinal polyps, lupus, gallbladder disease, glaucoma, osteoporosis, kidney stones, cataracts, and rheumatoid arthritis at baseline are counted.

Table 8.5
Distribution of Aging Indicators Collected During the WHI Extension Study Stratified by Age at the Beginning of the Extension for CT and OS Extension Study Participants

Data as of: August 14, 2009

	Total (N = 115,406)		Age on April 1, 2005 <65 (N = 18,278)		65-69 (N = 26,786)		70-79 (N = 51,913)		80-89 (N = 18,362)		90+ (N = 67)	
	N	%	N	%	N	%	N	%	N	%	N	%
Never completed Form 151	2085	1.8	217	1.2	275	1.0	862	1.7	729	4.0	2	3.0
Perceived Health Status												
Excellent	6396	5.7	1714	9.5	2052	7.7	2232	4.4	395	2.2	3	4.8
Very good	36112	31.9	7101	39.3	10023	37.8	15298	30.0	3674	20.9	16	25.8
Good	49237	43.5	7024	38.9	10931	41.3	23172	45.5	8085	46.0	25	40.3
Fair	18415	16.3	1946	10.8	3058	11.5	8836	17.3	4559	25.9	16	25.8
Poor	3004	2.7	271	1.5	433	1.6	1432	2.8	866	4.9	2	3.2
Quality of Life												
Worst, 0-3	493	0.4	39	0.2	79	0.3	194	0.4	181	1.0	0	0.0
Halfway, 4-6	6862	6.1	798	4.4	1122	4.2	3093	6.1	1842	10.5	7	11.3
Best, 7-10	105842	93.5	17218	95.4	25297	95.5	47701	93.6	15571	88.5	55	88.7
Functional Capacity, ADL Dependencies												
None[1]	94548	83.5	16772	92.9	24097	91.0	42428	83.2	11224	63.8	27	42.9
Eating	1755	1.6	131	0.7	222	0.8	767	1.5	628	3.6	7	11.1
Dressing	4397	3.9	284	1.6	564	2.1	1993	3.9	1542	8.8	14	22.2
Transferring	2802	2.5	212	1.2	343	1.3	1230	2.4	1006	5.7	11	17.5
Bathing	6191	5.5	363	2.0	690	2.6	2685	5.3	2430	13.8	23	36.5
Grocery Shopping	16796	14.8	1091	6.0	2122	8.0	7680	15.1	5868	33.4	35	55.6
Taking Medication	6320	5.6	313	1.7	579	2.2	2742	5.4	2662	15.1	24	38.1
Performance Measures, Rand-36 Scale												
0-25	15315	13.6	1241	6.9	2144	8.1	7160	14.1	4740	27.3	30	49.2
25-50	19361	17.2	1831	10.2	3367	12.7	9689	19.1	4461	25.7	13	21.3
51-75	28583	25.4	3533	19.6	6210	23.5	14251	28.1	4576	26.4	13	21.3
76-100	49357	43.8	11413	63.3	14701	55.6	19671	38.7	3567	20.6	5	8.2
Independence												
Supportive Services Availability	36800	32.6	4276	23.7	7164	27.1	17199	33.8	8123	46.6	38	61.3
Supportive Services Use	10714	16.1	393	5.0	903	6.7	4566	14.3	4815	36.2	37	71.2
Need for nursing care	6671	5.9	284	1.6	789	3.0	3219	6.3	2365	13.4	14	22.2
Use of walking aid [2]	19009	16.8	1101	6.1	2244	8.5	8730	17.2	6893	39.4	41	65.1
Lives alone[3]	15492	31.4	1631	21.8	2957	24.1	7552	33.4	3331	47.8	21	61.8
Geriatric Conditions[3]	**(N =52,176)**		**(N =8,024)**		**(N =12,866)**		**(N =23,805)**		**(N =7,443)**		**(N =38)**	
Cognitive Impairment[4]	524	5.9	0	0.0	3	50.0	215	4.0	300	8.6	6	28.6
Falls[5]	2849	5.5	375	4.7	628	4.9	1258	5.3	581	7.8	7	18.4
Incontinence	37667	76.2	5487	73.2	9166	74.8	17436	77.0	5554	79.6	24	66.7
Low BMI (<18.5 kg/m^2)	366	0.7	41	0.5	73	0.6	165	0.7	87	1.2	0	0.0
Dizziness	11340	23.0	1437	19.2	2437	19.9	5429	24.0	2027	29.2	10	27.8
Vision Impairment	11713	23.9	1486	19.9	2412	19.9	5605	25.0	2200	32.1	10	27.8
Hearing Impairment	15288	31.1	1385	18.5	2742	22.5	7634	33.9	3511	50.7	16	44.4

[1] No limitations or need for help reported at any follow-up visit.
[2] Cane, crutches, walker, or wheelchair.
[3] Data not collected during WHI Extension Study; limited to WHI-CT participants.
[4] Limited to WHI HT participants 65 years and older at baseline.
[5] Two or more falls per year between April 1, 2002 and March 31, 2005.

Table 8.6
Distribution of Aging Indicators Collected During the WHI Extension Study Stratified by Race/Ethnicity for CT and OS WHI Extension Study Participants

Data as of: August 14, 2009

	Race/Ethnicity											
	American Indian/ Alaskan Native (N = 402)		Asian/Pacific Islander (N = 2,396)		Black/African American (N = 8,354)		Hispanic/ Latino (N = 3,389)		White (N = 99,446)		Unknown (N = 1,419)	
	N	%	N	%	N	%	N	%	N	%	N	%
Never completed Form	14	3.5	65	2.7	226	2.7	101	3.0	1653	1.7	26	1.8
Perceived Health Status												
Excellent	20	5.2	111	4.8	188	2.3	122	3.7	5897	6.0	58	4.2
Very good	112	28.9	671	28.8	1554	19.2	762	23.2	32633	33.4	380	27.3
Good	145	37.4	1117	48.0	4069	50.1	1478	45.0	41782	42.8	646	46.4
Fair	92	23.7	367	15.8	2042	25.2	786	24.0	14857	15.2	271	19.5
Poor	19	4.9	60	2.6	261	3.2	133	4.1	2495	2.6	36	2.6
Quality of Life												
Worst, 0-3	1	0.3	6	0.3	19	0.2	16	0.5	444	0.5	7	0.5
Halfway, 4-6	33	8.5	123	5.3	609	7.5	311	9.5	5679	5.8	107	7.7
Best, 7-10	354	91.2	2200	94.5	7488	92.3	2953	90.0	91571	93.7	1276	91.8
Functional Capacity, ADL Dependencies												
None[1]	294	75.8	2027	87.0	6399	78.8	2718	82.9	81980	83.9	1130	81.1
Eating	6	1.5	17	0.7	164	2.0	69	2.1	1473	1.5	26	1.9
Dressing	23	5.9	55	2.4	399	4.9	116	3.5	3740	3.8	64	4.6
Transferring	16	4.1	38	1.6	257	3.2	94	2.9	2344	2.4	53	3.8
Bathing	30	7.7	58	2.5	634	7.8	142	4.3	5247	5.4	80	5.7
Grocery Shopping	83	21.4	266	11.4	1572	19.4	497	15.2	14148	14.5	230	16.5
Taking Medication	25	6.5	90	3.9	515	6.3	172	5.3	5426	5.6	92	6.6
Performance Measures, Rand-36 Scale												
0-25	78	20.2	210	9.0	1389	17.3	375	11.6	13070	13.4	193	14.0
25-50	75	19.4	284	12.2	1636	20.4	527	16.3	16602	17.1	237	17.2
51-75	84	21.8	605	26.0	2011	25.0	814	25.2	24725	25.4	344	24.9
76-100	149	38.6	1224	52.7	2995	37.3	1519	47.0	42865	44.1	605	43.9
Independence												
Supportive Services Availability	170	44.2	969	41.7	2727	33.9	1088	33.5	31344	32.2	502	36.3
Supportive Services Use	49	17.1	158	11.2	888	16.1	260	11.4	9217	16.5	142	15.3
Need for nursing care	17	4.4	48	2.1	325	4.0	107	3.3	6102	6.2	72	5.2
Use of walking aid[2]	93	24.1	266	11.4	1995	24.7	451	13.8	15934	16.3	270	19.4
Lives alone[3]	59	33.7	192	18.3	1620	36.8	395	25.1	13046	31.4	180	29.8
Geriatric Conditions[3]	**(N =185)**		**(N =1,105)**		**(N =4,769)**		**(N =1,791)**		**(N =43,680)**		**(N =646)**	
Cognitive Impairment[4]	0	0.0	23	15.0	109	19.5	30	15.1	352	4.5	10	9.4
Falls[5]	15	8.1	38	3.4	181	3.8	72	4.0	2501	5.7	42	6.5
Incontinence	133	76.0	719	68.4	2614	59.2	1048	66.6	32739	78.7	414	68.0
Low BMI (<18.5 kg/m^2)	0	0.0	21	1.9	19	0.4	9	0.5	314	0.7	3	0.5
Dizziness	44	25.4	226	21.5	1143	26.0	418	26.7	9363	22.6	146	24.1
Vision Impairment	55	32.0	312	29.8	1193	27.5	453	29.4	9544	23.1	156	26.1
Hearing Impairment	49	28.5	332	31.6	938	21.4	453	29.0	13320	32.2	196	32.5

[1] No limitations or need for help reported at any follow-up visit.

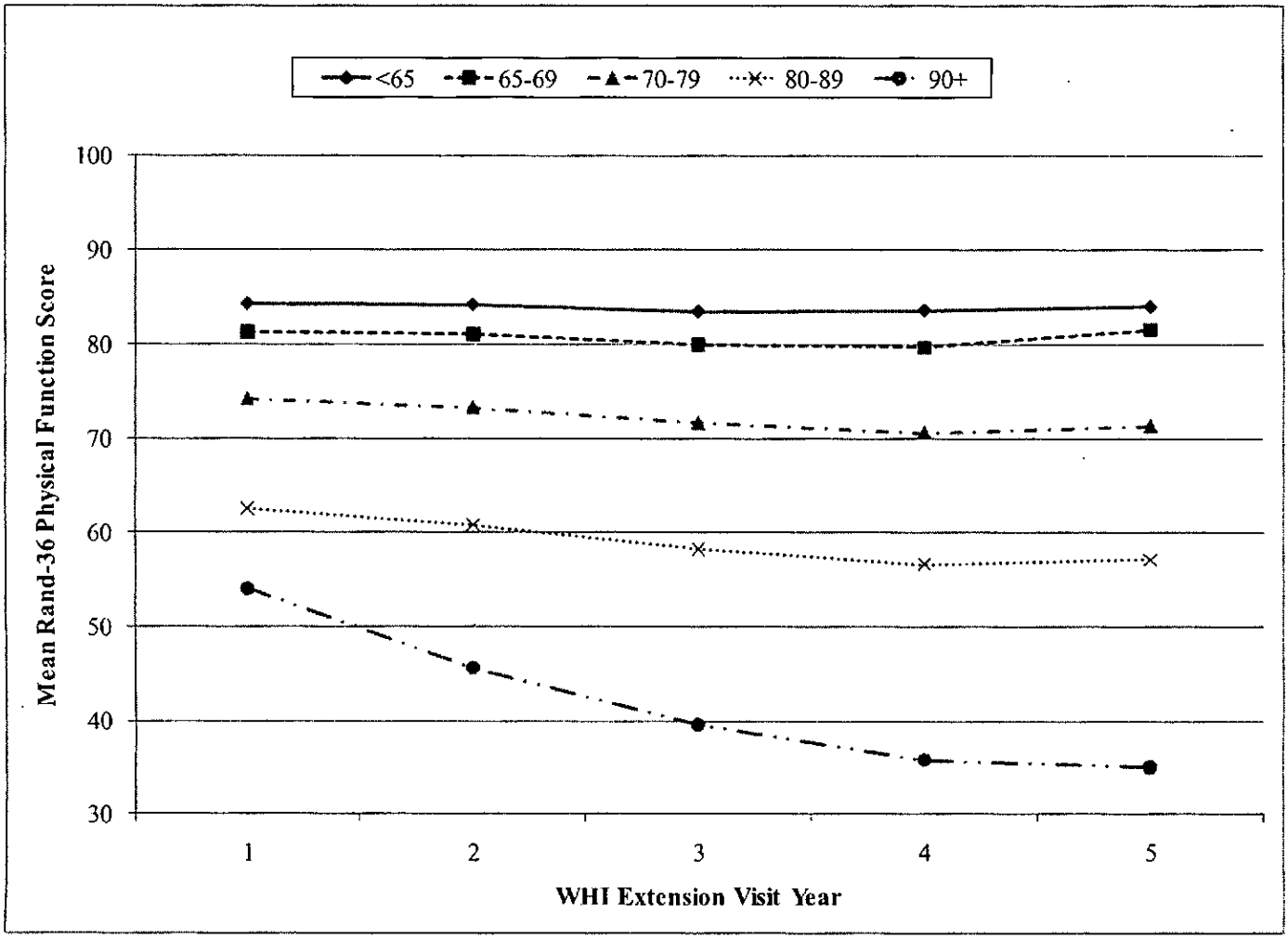
[2] Cane, crutches, walker, or wheelchair.

[3] Data not collected during WHI Extension Study; limited to WHI-CT participants.

[4] Limited to WHI HT participants 65 years and older at baseline.

[5] Two or more falls per year between April 1, 2002 and March 31, 2005.

Figure 8.1
Mean Rand-36 Physical Function Score Over Time by Age[1] at the Beginning of the Extension



[1] Age on April 1, 2005.

Table 9.1
Form 33/33D - Medical History Update/(Detail) Workload

Data as of 9-30-09

	Form 33 - Medical History Update 6-1-08 thru 5-31-09						Ppts on FC Mail003-Due for FC Collection Data as of 09/30/09		Form 33D - Medical History Update (Detail) 10-1-08 thru 9-30-09 [1 & 2]							
	Total		CCC Mailings Not Collected		Outstanding Info Errors (Cum)				# Due	Missing		Incomplete		Average Collected per Month last 12 mo	Form 33D Workload (miss + incomp)	
	# Due[1]	% Collected	#	%	#	%	#	% of Due		#	%	#	%	#	# cases	# months
Atlanta	2,997	96.9	352	11.7	6	0.2	4	0.1	423	26	6.1	16	4.0	35	42	1.2
Birmingham	2,561	94.4	485	18.9	1	0.0	14	0.5	427					36		
Bowman	2,529	94.2	287	11.3	6	0.3	38	1.5	380	20	5.3			37	20	0.5
Brigham	4,087	97.7	297	7.3			11	0.3	631	4	0.6			53	4	0.1
Buffalo	2,909	96.3	229	7.9	4	0.1	37	1.3	457	5	1.1	3	0.7	38	8	0.2
ChapelHill	2,719	96.0	298	11.0	5	0.2	17	0.6	397	4	1.0	3	0.8	40	7	0.2
Chicago-Rush	1,810	92.3	258	14.3	8	0.5	60	3.3	269	18	6.7	3	1.2	24	21	0.9
Chicago	2,489	96.9	211	8.5	3	0.1	20	0.8	425	12	2.8	1	0.2	39	13	0.3
Cincinnati	2,697	92.3	275	10.2	6	0.2	82	3.0	410	31	7.6	1	0.3	35	32	0.9
Columbus	2,744	97.4	175	6.4	8	0.3	20	0.7	449	9	2.0	1	0.2	39	10	0.3
Detroit	2,250	94.6	211	9.4	35	1.6	72	3.2	315	48	15.2	7	2.6	23	55	2.4
Gainesville	3,771	93.9	550	14.6	9	0.3	108	2.9	599	51	8.5			47	51	1.1
GWU-DC	2,818	93.8	259	9.2	18	0.7	96	3.4	353	18	5.1	6	1.8	30	24	0.8
Honolulu	1,915	96.9	180	9.4	2	0.1	12	0.6	190	2	1.1	6	3.2	17	8	0.5
Houston	2,138	93.2	194	9.1	3	0.2	53	2.5	318	18	5.7			26	18	0.7
IC-Bettendorf	1,942	98.2	105	5.4	4	0.2	3	0.2	336	10	3.0	1	0.3	30	11	0.4
IC-Des Moines	1,935	98.0	100	5.2	5	0.3	16	0.8	271	10	3.7			24	10	0.4
Irvine	2,807	93.1	200	7.1	27	1.0	81	2.9	331	69	20.8			24	69	2.9
LA	2,674	94.3	189	7.1			73	2.7	379	34	9.0			31	34	1.1
LaJolla	2,947	92.8	281	9.5	31	1.1	118	4.0	408	35	8.6			38	35	0.9
Madison	2,636	96.2	144	5.5	6	0.2	31	1.2	376	17	4.5	4	1.1	34	21	0.6
Medlantic	2,509	93.7	526	21.0	3	0.1	76	3.0	366	10	2.7	5	1.4	32	15	0.5
Memphis	2,250	96.6	286	12.7	22	1.0	8	0.4	349	15	4.3			28	15	0.5
Miami	1,629	90.9	320	19.6	19	1.3	79	4.8	268	17	6.3			23	17	0.8
Milwaukee	2,813	95.2	146	5.2	23	0.9	71	2.5	409	39	9.5	2	0.5	34	41	1.2

Table 9.1 (continued)
Form 33/33D - Medical History Update/(Detail) Workload

Data as of 9-30-09

	Form 33 - Medical History Update 6-1-08 thru 5-31-09						Ppts on FC Mail003-Due for FC Collection Data as of 09/30/09		Form 33D - Medical History Update (Detail) 10-01-08 thru 09-30-09 [1 & 2]							
	Total		CCC Mailings Not Collected		Outstanding Info Errors (Cum)				# Due	Missing		Incomplete		Average Collected per Month last 12 mo	Form 33D Workload (miss + incomp)	
	# Due[1]	% Collected	#	%	#	%	#	% of Due		#	%	#	%	#	# cases	# months
Minneapolis	3,433	98.4	164	4.8	8	0.2	5	0.1	487	32	6.6	1	0.2	44	33	0.8
Nevada	2,542	94.7	286	11.3	2	0.1	56	2.2	462	7	1.5	7	1.5	40	14	0.4
Newark	2,850	90.6	312	10.9	58	2.2	132	4.6	421	88	20.9	4	1.2	30	92	3.0
New Brunswick	1,163	94.8	182	15.6	7	0.6	27	2.3	174	18	10.3	2	1.3	13	20	1.5
NYC	2,824	91.3	372	13.2	3	0.1	99	3.5	421	5	1.2	1	0.2	35	6	0.2
Oakland	2,652	97.5	218	8.2			21	0.8	320	2	0.6	4	1.3	29	6	0.2
Pawtucket	4,616	95.8	447	9.7	9	0.2	26	0.6	773	19	2.5	2	0.3	64	21	0.3
Pittsburgh	2,612	94.5	284	10.9	11	0.4	79	3.0	449	18	4.0	5	1.2	39	23	0.6
Portland	2,739	93.3	267	9.7	9	0.4	70	2.6	350	25	7.1	2	0.6	29	27	0.9
San Antonio	1,761	95.2	277	15.7	6	0.4	31	1.8	167	16	9.6	2	1.3	17	18	1.1
Seattle	2,314	97.3	172	7.4	9	0.4	40	1.7	368	20	5.4	3	0.9	30	23	0.8
Stanford	3,328	97.9	239	7.2	8	0.2	14	0.4	498			6	1.2	41	6	0.1
StonyBrook	2,447	96.1	262	10.7	7	0.3	15	0.6	389	9	2.3			33	9	0.3
Torrance	1,486	94.0	136	9.2	20	1.4	31	2.1	226	4	1.8	1	0.5	19	5	0.3
Tucson	2,942	92.6	374	12.7	2	0.1	88	3.0	438	5	1.1	10	2.3	37	15	0.4
UCDavis	2,707	93.5	244	9.0	19	0.8	60	2.2	401	22	5.5	1	0.3	34	23	0.7
Worcester	3,023	97.8	241	8.0	21	0.7	9	0.3	529	42	7.9			41	42	1.0
All FCs	110,015	95.1	11,035	10.0	453	0.4	2,003	1.8	16,409	854	5.2	110	0.7	1,389	964	0.7

1 - Excludes absolutely no contact and deceased participants

2 - Form 33Ds due, missing, and incomplete in the last 12 months

Table 9.2
Outcomes Processing Workload

Data as of 9/30/09

							Closed Cases	Outcomes Workload			Deaths (Ext)			
	Open Cases	No Docs Request	No Docs Receive	No Docs Process	≥ 1 Doc Process	Open > 12 Mos	Avg # per Mo for last 12 Mo	Est # Months to Process Open Cases	Est Workload for Open cases and Form 33D		Cum[1]	Open		# Open cases with Deaths
	#	#	#	#	#	#			# cases	# months	#	#	%	
Atlanta	58	1	48	9		15	35	1.7	100	2.9	142	5	3.5	6
Birmingham	27		23	4		1	41	0.7	27	0.7	145	4	2.8	10
Bowman	81	42	28	11		7	30	2.7	101	3.3	128	20	15.6	24
Brigham	58	24	34				48	1.2	62	1.3	139	12	8.6	24
Buffalo	130	22	75	33		4	41	3.2	138	3.4	222	46	20.7	60
ChapelHill	29		18	11			34	0.9	36	1.0	125	2	1.6	1
Chicago-Rush	57	9	44	4		1	18	3.1	78	4.0	78	10	12.8	16
Chicago	94	35	41	18			40	2.4	107	2.7	154	19	12.3	32
Cincinnati	37	2	35				35	1.1	69	2.0	91	18	19.8	24
Columbus	83	3	80				47	1.8	93	2.0	164	13	7.9	19
Detroit	70	33	16	21		3	12	6.1	125	8.5	92	20	21.7	20
Gainesville	106	57	32	17		1	48	2.2	157	3.3	173	32	18.5	19
GWU-DC	71	6	57	8		5	31	2.3	95	3.1	103	12	11.7	14
Honolulu	4	1	2	1			13	0.3	12	0.8	56			
Houston	53	10	33	10		1	23	2.3	71	3.0	88	6	6.8	8
IC-Bettendorf	113	36	57	20			30	3.8	124	4.1	94	20	21.3	34
IC-Des Moines	75	37	23	15			25	3.1	85	3.5	83	14	16.9	23
Irvine	97	22	70	5		8	17	5.6	166	8.5	103	20	19.4	19
LA	90		66	24		14	20	4.4	124	5.5	128	28	21.9	34
LaJolla	120	51	49	20		4	32	3.8	155	4.7	141	35	24.8	41
Madison	49		26	23		2	31	1.6	70	2.2	134	11	8.2	12
Medlantic	55		42	13			30	1.8	70	2.3	112	13	11.6	15
Memphis	35	2	33				34	1.0	50	1.6	155	11	7.1	22
Miami	91	41	26	24		1	20	4.6	108	5.3	70	16	22.9	23
Milwaukee	49	26	23				27	1.8	90	3.0	123	20	16.3	21

Table 9.2 (continued)
Outcomes Processing Workload

Data as of 9/30/09

							Closed Cases	Outcomes Workload			Deaths (Ext)			
	Open Cases	No Docs Request	No Docs Receive	No Docs Process	≥ 1 Doc Process	Open > 12 Mos	Avg # per Mo for last 12 Mo	Est # Months to Process Open Cases	Est Workload for Open cases and Form 33D		Cum[1]	Open		# Open cases with Deaths
	#	#	#	#	#	#			# cases	# months	#	#	%	
Minneapolis	57	10	26	21			38	1.5	90	2.3	128	13	10.2	24
Nevada	96	12	69	15		5	41	2.4	110	2.7	190	10	5.3	23
Newark	170	15	154	1		16	25	6.9	262	9.9	104	41	39.4	68
New Brunswick	63	22	33	8			15	4.2	83	5.8	73	12	16.4	15
NYC	85	4	70	11			32	2.7	91	2.9	128	12	9.4	15
Oakland	36	5	23	8			34	1.0	42	1.3	134	11	8.2	16
Pawtucket	113		111	2			68	1.7	134	2.0	273	35	12.8	52
Pittsburgh	67	14	50	3		1	47	1.4	90	2.0	159	23	14.5	32
Portland	69	54	12	3		2	33	2.1	96	3.0	135	11	8.1	9
San Antonio	24	4	13	7			11	2.3	42	3.4	72	7	9.7	8
Seattle	79	38	24	17			31	2.5	102	3.3	121	26	21.5	38
Stanford	55	13	22	20			40	1.4	61	1.5	172	9	5.2	15
StonyBrook	88	7	80	1		2	40	2.2	97	2.5	117	11	9.4	16
Torrance	76	3	73			8	20	3.9	81	4.2	68	6	8.8	8
Tucson	80	7	45	28		3	42	1.9	95	2.3	190	24	12.6	38
UCDavis	120	97	5	18		9	32	3.8	143	4.4	168	13	7.7	33
Worcester	60	12	42	6			41	1.5	102	2.5	160	10	6.3	10
All FCs	3,070	777	1,833	460		113	1,350	2.3	4,034	3.0	5,435	681	12.5	941

1 - Deaths from Form 120-Initial Notification of Death, Ver. 8

Table 9.3
Closure Codes for Closed Outcomes Cases

Data as of 9/30/09

	Form 33 - Medical History Update	Forwarded to CCC C-9		Not Adjudicated C-10		Duplicate C-11		No Doc in 12 Months C-12		No ROI C-13		Admin C-14	
	#	#	%	#	%	#	%	#	%	#	%	No	%
Atlanta	1,673	1,467	87.7	88	5.3	59	3.5	53	3.2	6	0.4		
Birmingham	1,670	1,531	91.7	119	7.1	19	1.1					1	0.1
Bowman	1,226	1,073	87.5	75	6.1	46	3.8	1	0.1	31	2.5		
Brigham	2,084	1,750	84.0	179	8.6	144	6.9	1	0.0	9	0.4	1	0.0
Buffalo	1,896	1,643	86.7	140	7.4	90	4.7	2	0.1	20	1.1		
ChapelHill	1,383	1,346	97.3	22	1.6	12	0.9			3	0.2		
Chicago-Rush	971	682	70.2	187	19.3	64	6.6	24	2.5	12	1.2	2	0.2
Chicago	1,707	1,450	84.9	130	7.6	81	4.7	12	0.7	30	1.8	4	0.2
Cincinnati	1,628	1,447	88.9	85	5.2	95	5.8	1	0.1				
Columbus	1,905	1,693	88.9	170	8.9	31	1.6	1	0.1	8	0.4	2	0.1
Detroit	942	769	81.6	110	11.7	39	4.1	4	0.4	19	2.0	1	0.1
Gainesville	2,497	2,166	86.7	247	9.9	77	3.1	3	0.1	4	0.2		
GWU-DC	1,194	965	80.8	133	11.1	83	7.0	7	0.6	6	0.5		
Honolulu	643	578	89.9	38	5.9	26	4.0	1	0.2				
Houston	1,082	898	83.0	109	10.1	34	3.1	19	1.8	22	2.0		
IC-Bettendorf	1,307	1,153	88.2	81	6.2	63	4.8	1	0.1	8	0.6	1	0.1
IC-Des Moines	1,093	934	85.5	95	8.7	53	4.8	4	0.4	3	0.3	4	0.4
Irvine	935	749	80.1	97	10.4	26	2.8	35	3.7	26	2.8	2	0.2
LA	999	787	78.8	133	13.3	35	3.5	35	3.5	9	0.9		
LaJolla	1,513	1,208	79.8	177	11.7	101	6.7	16	1.1	11	0.7		
Madison	1,415	1,239	87.6	97	6.9	64	4.5	8	0.6	7	0.5		
Medlantic	1,255	1,090	86.9	113	9.0	41	3.3	5	0.4	5	0.4	1	0.1
Memphis	1,296	1,146	88.4	126	9.7	17	1.3			5	0.4	2	0.2
Miami	759	631	83.1	81	10.7	40	5.3	2	0.3	4	0.5	1	0.1
Milwaukee	1,331	1,231	92.5	80	6.0	17	1.3			3	0.2		

Table 9.3 (continued)
Closure Codes for Closed Outcomes Cases

Data as of 9/30/09

	Form 33 - Medical History Update	Forwarded to CCC C-9		Not Adjudicated C-10		Duplicate C-11		No Doc in 12 Months C-12		No ROI C-13		Admin C-14	
	#	#	%	#	%	#	%	#	%	#	%	No	%
Minneapolis	1,495	1,338	89.5	98	6.6	42	2.8			17	1.1		
Nevada	1,882	1,489	79.1	221	11.7	162	8.6	6	0.3	4	0.2		
Newark	1,403	1,112	79.3	220	15.7	37	2.6	4	0.3	30	2.1		
New Brunswick	691	616	89.1	22	3.2	11	1.6	33	4.8	8	1.2	1	0.1
NYC	1,386	1,248	90.0	77	5.6	34	2.5	3	0.2	24	1.7		
Oakland	1,283	1,145	89.2	72	5.6	50	3.9	4	0.3	12	0.9		
Pawtucket	2,869	2,563	89.3	208	7.2	68	2.4	3	0.1	27	0.9		
Pittsburgh	2,203	1,973	89.6	89	4.0	135	6.1	5	0.2	1	0.0		
Portland	1,354	1,103	81.5	111	8.2	103	7.6	19	1.4	11	0.8	6	0.4
San Antonio	422	362	85.8	33	7.8	11	2.6	5	1.2			11	2.6
Seattle	1,304	1,080	82.8	139	10.7	67	5.1	6	0.5	12	0.9		
Stanford	1,667	1,407	84.4	184	11.0	67	4.0			9	0.5		
StonyBrook	1,992	1,580	79.3	204	10.2	198	9.9	2	0.1	3	0.2	5	0.3
Torrance	771	643	83.4	94	12.2	30	3.9	3	0.4	1	0.1		
Tucson	1,828	1,492	81.6	136	7.4	111	6.1	33	1.8	54	3.0	2	0.1
UCDavis	1,545	1,336	86.5	134	8.7	56	3.6	4	0.3	15	1.0		
Worcester	1,834	1,616	88.1	185	10.1	31	1.7			2	0.1		
All FCs	60,333	51,729	85.7	5,139	8.5	2,570	4.3	365	0.6	481	0.8	47	0.1

Table 9.4
Participant Follow-up Status[1]

Data as of 9/30/09

	# Participants	Full		Partial/Custom		Proxy		Lost		No Follow-up		Absolutely No Contact		Deceased	
		#	%	#	%	#	%	#	%	#	%	#	%	#	%
Atlanta	3,129	2,621	83.8	335	10.7	21	0.7	1	0.0			8	0.3	143	4.6
Birmingham	2,677	2,418	90.3	76	2.8	4	0.1	1	0.0	17	0.6	13	0.5	148	5.5
Bowman	2,660	2,356	88.6	97	3.6	3	0.1	3	0.1	63	2.4	4	0.2	134	5.0
Brigham	4,216	3,870	91.8	163	3.9	32	0.8			3	0.1	6	0.1	142	3.4
Buffalo	3,128	2,701	86.3	105	3.4	37	1.2	9	0.3	19	0.6	27	0.9	230	7.4
ChapelHill	2,848	2,609	91.6	39	1.4	49	1.7			7	0.2	14	0.5	130	4.6
Chicago-Rush	1,909	1,638	85.8	135	7.1			26	1.4			32	1.7	78	4.1
Chicago	2,635	2,117	80.3	313	11.9	28	1.1	5	0.2	10	0.4	6	0.2	156	5.9
Cincinnati	2,792	2,559	91.7	94	3.4	20	0.7	17	0.6			8	0.3	94	3.4
Columbus	2,904	2,605	89.7	122	4.2	2	0.1	1	0.0			8	0.3	166	5.7
Detroit	2,354	2,004	85.1	224	9.5	4	0.2	9	0.4			20	0.8	93	4.0
Gainesville	3,947	3,253	82.4	447	11.3	16	0.4	34	0.9	11	0.3	11	0.3	175	4.4
GWU-DC	2,926	2,643	90.3	102	3.5	13	0.4	37	1.3	6	0.2	19	0.6	106	3.6
Honolulu	1,987	1,829	92.0	71	3.6	2	0.1	2	0.1	6	0.3	21	1.1	56	2.8
Houston	2,232	1,989	89.1	118	5.3	10	0.4	12	0.5			14	0.6	89	4.0
Iowa City-Bettendorf	2,032	1,770	87.1	131	6.4	21	1.0			4	0.2	9	0.4	97	4.8
Iowa City - Des Moines	2,029	1,761	86.8	145	7.1	17	0.8	1	0.0	5	0.2	16	0.8	84	4.1
Irvine	2,939	2,537	86.3	192	6.5	3	0.1	64	2.2	1	0.0	37	1.3	105	3.6
LA	2,828	2,465	87.2	138	4.9			51	1.8	4	0.1	41	1.4	129	4.6
LaJolla	3,078	2,659	86.4	213	6.9	13	0.4	41	1.3	7	0.2	4	0.1	141	4.6
Madison	2,763	2,456	88.9	119	4.3	37	1.3			8	0.3	7	0.3	136	4.9
Medlantic	2,613	2,086	79.8	349	13.4	17	0.7	33	1.3	9	0.3	7	0.3	112	4.3
Memphis	2,397	2,028	84.6	141	5.9	42	1.8					29	1.2	157	6.5
Miami	1,682	1,360	80.9	204	12.1	12	0.7	27	1.6	8	0.5	1	0.1	70	4.2
Milwaukee	2,938	2,645	90.0	100	3.4	19	0.6	30	1.0	2	0.1	18	0.6	124	4.2

Table 9.4 (continued)
Participant Follow-up Status[1]

Data as of 9/30/09

	# Participants	Full		Partial/Custom		Proxy		Lost		No Follow-up		Absolutely No Contact		Deceased	
		#	%	#	%	#	%	#	%	#	%	#	%	#	%
Minneapolis	3,555	3,217	90.5	157	4.4	27	0.8	1	0.0	15	0.4	6	0.2	132	3.7
Nevada	2,714	2,357	86.8	119	4.4	11	0.4	17	0.6	8	0.3	2	0.1	200	7.4
Newark	2,963	2,669	90.1	114	3.8	3	0.1	50	1.7	1	0.0	21	0.7	105	3.5
New Brunswick	1,231	904	73.4	221	18.0	17	1.4	6	0.5	5	0.4	4	0.3	74	6.0
NYC	2,961	2,754	93.0	32	1.1	2	0.1	27	0.9	2	0.1	14	0.5	130	4.4
Oakland	2,776	2,537	91.4	45	1.6	35	1.3	5	0.2	4	0.1	11	0.4	139	5.0
Pawtucket	4,872	4,442	91.2	26	0.5	78	1.6			37	0.8	7	0.1	282	5.8
Pittsburgh	2,776	2,412	86.9	152	5.5	25	0.9	6	0.2	9	0.3	11	0.4	161	5.8
Portland	2,888	2,603	90.1	83	2.9	2	0.1	33	1.1	5	0.2	26	0.9	136	4.7
San Antonio	1,837	1,593	86.7	123	6.7	6	0.3	16	0.9	6	0.3	17	0.9	76	4.1
Seattle	2,428	2,044	84.2	208	8.6	27	1.1	10	0.4	2	0.1	14	0.6	123	5.1
Stanford	3,490	3,078	88.2	199	5.7	15	0.4	3	0.1	1	0.0	15	0.4	179	5.1
StonyBrook	2,550	2,299	90.2	112	4.4	1	0.0	7	0.3			10	0.4	121	4.7
Torrance	1,550	1,285	82.9	155	10.0	1	0.1	23	1.5	14	0.9	4	0.3	68	4.4
Tucson	3,111	2,499	80.3	315	10.1	21	0.7	43	1.4	30	1.0	11	0.4	192	6.2
UCDavis	2,881	2,442	84.8	209	7.3	9	0.3	30	1.0	8	0.3	13	0.5	170	5.9
Worcester	3,180	2,931	92.2	20	0.6	56	1.8	5	0.2			2	0.1	166	5.2
All FCs	115,406	101,045	87.6	6,463	5.6	758	0.7	686	0.6	337	0.3	568	0.5	5,549	4.8

1 - Follow-up Status from Form 9-WHI ES Participation Status, Ver. 8; Lost calculated by WHIX (see April 4, 2007, upgrade notes); Deceased from Form 120-Initial Notification of Death (all versions)

Table 9.5
Form Collection: Forms 150 and 151

Data as of 9/30/09

Collections for 06-01-08 thru 05-31-09	Form 150- Hormone Use Update (HT)				Form 151 - Activities of Daily Living			
	Total		CCC Mailings Not Collected		Total		CCC Mailings Not Collected	
	# Due[1]	% Collected	#	%	# Due[1]	% Collected	#	%
Atlanta	421	96.7	65	15.4	2,986	95.3	141	4.7
Birmingham	547	91.6	131	23.9	2,522	94.1	149	5.9
Bowman	404	92.8	68	16.8	2,528	94.1	150	5.9
Brigham	639	96.7	71	11.1	4,077	93.1	280	6.9
Buffalo	524	94.3	58	11.1	2,908	95.9	119	4.1
Chapel Hill	462	92.2	79	17.1	2,717	89.4	287	10.6
Chicago-Rush	329	89.4	78	23.7	1,808	92.1	142	7.9
Chicago	407	95.6	47	11.5	2,489	95.4	115	4.6
Cincinnati	421	89.3	57	13.5	2,698	92.2	210	7.8
Columbus	430	96.3	40	9.3	2,747	97.4	71	2.6
Detroit	337	91.1	50	14.8	2,250	94.4	125	5.6
Gainesville	766	90.7	142	18.5	3,768	92.9	267	7.1
GWU-DC	434	90.1	63	14.5	2,818	91.0	253	9.0
Honolulu	267	94.0	41	15.4	1,915	90.6	180	9.4
Houston	256	86.7	43	16.8	2,137	93.0	149	7.0
IC-Bettendorf	587	97.6	44	7.5	1,940	95.0	97	5.0
IC-Des Moines	589	98.1	32	5.4	1,936	95.1	94	4.9
Irvine	421	87.9	53	12.6	2,808	93.1	194	6.9
LA	380	91.1	39	10.3	2,670	94.2	154	5.8
LaJolla	319	88.7	38	11.9	2,947	92.4	225	7.6
Madison	540	93.7	47	8.7	2,636	96.2	100	3.8
Medlantic	426	90.1	122	28.6	2,505	93.5	162	6.5
Memphis	435	96.6	74	17.0	2,230	96.6	76	3.4
Miami	376	81.6	135	35.9	1,617	90.4	156	9.6
Milwaukee	555	93.2	39	7.0	2,811	95.0	140	5.0

Table 9.5 (continued)
Form Collection: Forms 150 and 151

Data as of 9/30/09

Collections for 06-01-08 thru 05-31-09	Form 150- Hormone Use Update (HT)				Form 151 - Activities of Daily Living			
	Total		CCC Mailings Not Collected		Total		CCC Mailings Not Collected	
	# Due[1]	% Collected	#	%	# Due[1]	% Collected	#	%
Minneapolis	631	97.0	48	7.6	3,434	95.4	159	4.6
Nevada	446	93.3	69	15.5	2,542	94.7	135	5.3
Newark	372	85.2	62	16.7	2,848	89.3	304	10.7
New Brunswick	307	90.2	70	22.8	1,156	94.4	65	5.6
NYC	529	85.3	119	22.5	2,823	87.3	358	12.7
Oakland	487	96.5	48	9.9	2,639	96.6	91	3.4
Pawtucket	737	94.4	96	13.0	4,608	95.8	193	4.2
Pittsburgh	490	91.6	68	13.9	2,615	94.4	147	5.6
Portland	485	91.1	63	13.0	2,738	93.0	191	7.0
San Antonio	428	93.2	100	23.4	1,761	95.1	87	4.9
Seattle	519	94.6	61	11.8	2,312	95.5	105	4.5
Stanford	521	97.1	54	10.4	3,316	96.8	105	3.2
Stony Brook	378	95.8	51	13.5	2,428	96.0	98	4.0
Torrance	197	88.8	27	13.7	1,484	91.4	127	8.6
Tucson	466	88.2	85	18.2	2,926	89.3	313	10.7
UC Davis	503	91.3	64	12.7	2,706	92.5	204	7.5
Worcester	473	96.6	52	11.0	3,021	92.4	230	7.6
All FCs	19,241	92.7	2,793	14.5	109,825	93.7	6,948	6.3

1 - Excludes absolutely no contact and deceased participants

Table 9.6
CCC Data Entry Volume

10-1-08 to 9-30-09

Form	Forms					Sheets Scanned	Forms with Comments	
	Total	Key-Entered		Scanned				
	#	#	%	#	%	#	#	%
33 – Medical History Update	103,062	233	0.2	102,829	99.8	205,658	19,689	19.1
120 – Initial Notice of Death	419	419	100.0	0	0	0	0	0.0
134 – Addendum to Medical History Update	6	0	0.0	6	100	6	0	0.0
150 – Hormone Use Update	17,198	37	0.2	17,161	99.8	68,644	68	0.4
151 – Activities of Daily Living	103,248	229	0.2	103,019	99.8	103,019	1,046	1.0
Totals	223,933	918	0.4	223,015	99.6	377,327	20,803	9.3

Table 9.7
Status of Adjudication

Data as of 10/16/09

Committees	Total # Cases in WHIX	Cases at FCs Not Yet Forwarded to CCC				Cases at CCC								
						Referred From (included in total # of cases in WHIX			Total Cases (exc QA)	QA			Total QA	Total Cases
		< 14 Days	14-29 Days	≥ 30 Days	Total (not fwd to CCC)	Rec'd from FCs	Form 125 Review	Other Committee		Adj QA[1]	Pull Lists/ CDE [2]	Misc QA		
Extension														
Primary Cancers	4,176	30	26	6	62	3,892	151	71	4,114		498	668	1166	5,280
Other Cancers[3]	10,512	19	18	12	49	10,459		4	10,463		241	87	328	10,791
CVD (plus PE, DVT)	7,738	46	30	16	92	6,590	881	175	7,646	755	2025		2780	10,426
Fatal Events	5,179	63	38	43	144	5,014	13	8	5,035	199	8		207	5,242
Stroke	4,079	27	18	10	55	3,393	517	114	4,024	224	859		1083	5,107
Fracture	2,141	24	9	3	36	2,017	67	21	2,105	119			119	2,224
Misc (non committee specific)											323		323	323
Extension Total	**33,825**	**209**	**139**	**90**	**438**	**31,365**	**1,629**	**393**	**33,387**	**1,297**	**3,954**	**755**	**6006**	**39,393**
Form 125-Hospital	31,681	219	142	48	409	31,272			31,272					31,272
Pre-Extension Other Cancers														
Other Cancers	8,568			6	6	7,207		1,355	8,562		745		745	9,307
Total	8,568			6	6	7,207		1,355	8,562		745		745	9,307

1 - Adj QA = All Cases assigned as an adjudicator QA case (open & closed).

2 - Pull List/CDE(Custom Data Extracts) see r:\reports\outcomes\status of adj qa added: tab 'pull lists data'.

3 - "Other Cancers" listed under Extension include Pre-Extension Other Cancers.

Table 9.8
CCC Adjudication Workload

Data as of 10/16/09

	# Cases at CCC			CCC Action Required					
	Total	**Closed**	**Remaining**	**To Forward to Adjudicator**	**Wait for Return from Adjudicator**	**Data Enter and Close**	**Total**	**Total QA[1] To Do**	**Pull List/CDE To Do**
Extension									
Primary Cancers	5,280	4,687	593	104	3	79	186		409
Other Cancers[3]	10,791	6,237	4,554	**	**	**	**		134
CVD (plus PE, DVT)	10,426	9,053	1,373	88	99	58	245	68	1,061
Fatal Events	5,242	4,963	279	185	40	41	266	12	1
Stroke	5,107	3,913	1,194	215	77	35	327	24	843
Fracture	2,224	2,149	75	37	24	9	70	5	
Misc (non committee specific)	323	171	152						152
Extension Total	**39,393**	**31,173**	**8,220**	**629**	**243**	**222**	**1,094**	**109**	**2,600**
Form 125-Hospital	31,272	27,558	3,714	3,237	451	26	3,714		

Total Number of Cases to Data Enter & Close: **914**

Breakdown of Above Cases:

Cases Ready for Data Entry:

Adjudicator Forms: 234

Form 125 (Hosp): 181

Forms Requiring Adj Review: 63

Pending Full Committee Review: 16

Pending Queries: 172

Table 10.1
CT Outcomes Cases with Remaining Blood Sample by Estimated Volume (in ml)
After Accounting for Approved Core, BAA, and Ancillary Studies

					Volume of Designated Blood Components (ml)** as of 10-22-09																	
	Outcome	Total	No	Blood	0*		>0 - <.5		.5 - <1		1 - <1.5		1.5 - <2		2 - <2.5		2.5 - <3		3 - <3.5		3.5 - <4		4+	
Visit	As of 8/09	Ppts	Draw*	Type	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%
Base-	Breast Cancer	3735	10	Serum	14	0%	2	0%	8	0%	37	1%	20	1%	148	4%	95	3%	717	19%	143	4%	2551	68%
line				Citrate	23	1%	4	0%	2	0%	44	1%	14	0%	237	6%	9	0%	3310	89%			92	2%
				EDTA	50	1%			1	0%	13	0%	14	0%	260	7%	1	0%	3306	89%			90	2%
	Breast Cancer	3027	8	Serum	11	0%	2	0%	7	0%	34	1%	18	1%	133	4%	88	3%	632	21%	81	3%	2021	67%
	Invasive			Citrate	18	1%	2	0%	1	0%	40	1%	12	0%	191	6%	7	0%	2676	88%			80	3%
				EDTA	40	1%			1	0%	9	0%	9	0%	214	7%	1	0%	2675	88%			78	3%
	Breast Cancer,	753	2	Serum	3	0%			1	0%	3	0%	2	0%	16	2%	8	1%	92	12%	62	8%	566	75%
	Non-Invasive			Citrate	5	1%	2	0%	1	0%	5	1%	2	0%	49	7%	2	0%	672	89%			15	2%
				EDTA	11	1%					4	1%	5	1%	49	7%			669	89%			15	2%
	CHD	3028	11	Serum	19	1%	23	1%	24	1%	115	4%	108	4%	193	6%	54	2%	401	13%	250	8%	1841	61%
				Citrate	27	1%	21	1%	15	0%	193	6%	65	2%	321	11%	4	0%	2294	76%	1	0%	87	3%
				EDTA	45	1%	8	0%	20	1%	63	2%	185	6%	322	11%	2	0%	2298	76%	2	0%	83	3%
	Clinical MI	2326	10	Serum	17	1%	15	1%	20	1%	93	4%	90	4%	141	6%	41	2%	299	13%	189	8%	1421	61%
				Citrate	20	1%	17	1%	14	1%	152	7%	51	2%	245	11%	4	0%	1754	75%			69	3%
				EDTA	37	2%	8	0%	14	1%	51	2%	143	6%	246	11%	2	0%	1757	76%	1	0%	67	3%
	Colorectal	967	2	Serum	3	0%	1	0%	3	0%	16	2%	18	2%	65	7%	46	5%	344	36%	45	5%	426	44%
	Cancer			Citrate	9	1%	4	0%	1	0%	19	2%	2	0%	74	8%	1	0%	842	87%			15	2%
				EDTA	17	2%			2	0%	6	1%	4	0%	85	9%			838	87%			15	2%
	DVT/PE	840	2	Serum	3	0%	7	1%	4	0%	15	2%	21	2%	77	9%	53	6%	267	32%	108	13%	285	34%
				Citrate	10	1%	24	3%	6	1%	163	19%	42	5%	65	8%	2	0%	500	60%	1	0%	27	3%
				EDTA	11	1%	3	0%	3	0%	30	4%	12	1%	252	30%	2	0%	498	59%			29	3%
	Endometrial	502	2	Serum	5	1%	1	0%			4	1%	4	1%	10	2%	3	1%	46	9%	15	3%	414	82%
	Cancer			Citrate	5	1%					11	2%	3	1%	26	5%			446	89%			11	2%
				EDTA	6	1%					3	1%	5	1%	34	7%	1	0%	443	88%			10	2%
	Hip Fracture	1365	2	Serum	7	1%	2	0%	5	0%	28	2%	18	1%	73	5%	34	2%	240	18%	114	8%	844	62%
				Citrate	12	1%	6	0%	1	0%	45	3%	19	1%	83	6%	6	0%	1164	85%			29	2%
				EDTA	16	1%	1	0%	2	0%	12	1%	15	1%	121	9%	2	0%	1168	86%			28	2%
	Ovarian Cancer	322	1	Serum	2	1%			1	0%	6	2%	2	1%	6	2%	11	3%	35	11%	88	27%	171	53%
				Citrate	4	1%			1	0%	7	2%	2	1%	20	6%			281	87%			7	2%
				EDTA	2	1%					5	2%	4	1%	25	8%			279	87%			7	2%
	Stroke	2232	8	Serum	14	1%	10	0%	13	1%	55	2%	44	2%	253	11%	60	3%	337	15%	67	3%	1379	62%
				Citrate	27	1%	21	1%	11	0%	239	11%	60	3%	299	13%	43	2%	1481	66%			51	2%
				EDTA	35	2%	1	0%	2	0%	41	2%	28	1%	390	17%	4	0%	1681	75%			50	2%

*Participants with no draw included in 0 volume column
**Includes sample reserved for BAA (2 ml serum, 1 ml citrate, and 1 ml EDTA) and future WHI use (1 ml each serum, citrate, and EDTA)
Represents conservative estimate of 1 ml in each vial collected, with 4 serum, 3 citrate, and 3 EDTA vials collected at baseline for CT/OS, at AV1 for CT, and at AV3 for OS.

Table 10.1 (continued)
CT Outcomes Cases with Remaining Blood Sample by Estimated Volume (in ml)
After Accounting for Approved Core, BAA, and Ancillary Studies

					Volume of Designated Blood Components (ml)** as of 10-22-09																	
	Outcome	Total	No	Blood	0*		>0 - <.5		.5 - <1		1 - <1.5		1.5 - <2		2 - <2.5		2.5 - <3		3 - <3.5		3.5 - <4		4+	
Visit	As of 8/09	Ppts	Draw*	Type	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%
AV1	Breast Cancer	3534	188	Serum	191	5%	1	0%	2	0%	28	1%	7	0%	98	3%	73	2%	516	15%	396	11%	2222	63%
				Citrate	199	6%	1	0%	3	0%	38	1%	2	0%	231	7%	4	0%	3054	86%			5	0%
				EDTA	230	7%	1	0%			16	0%	11	0%	242	7%			3034	86%			5	0%
	Breast Cancer Invasive	2869	162	Serum	165	6%	1	0%	2	0%	24	1%	7	0%	88	3%	70	2%	464	16%	361	13%	1687	59%
				Citrate	171	6%	1	0%	1	0%	33	1%	1	0%	182	6%	4	0%	2473	86%			5	0%
				EDTA	196	7%					13	0%	9	0%	195	7%			2455	86%			5	0%
	Breast Cancer, Non-Invasive	710	26	Serum	26	4%					5	1%			10	1%	3	0%	56	8%	41	6%	569	80%
				Citrate	28	4%			2	0%	6	1%	1	0%	50	7%			623	88%			1	0%
				EDTA	35	5%	1	0%			3	0%	2	0%	48	7%			621	87%			1	0%
	CHD	2813	214	Serum	217	8%	2	0%	2	0%	23	1%	4	0%	64	2%	62	2%	359	13%	78	3%	2003	71%
				Citrate	241	9%	12	0%	8	0%	120	4%	53	2%	271	10%	6	0%	2104	75%			2	0%
				EDTA	255	9%	4	0%	13	0%	49	2%	101	4%	283	10%			2111	75%			2	0%
	Clinical MI	2145	150	Serum	152	7%	2	0%	2	0%	20	1%	4	0%	48	2%	47	2%	276	13%	55	3%	1540	72%
				Citrate	176	8%	9	0%	6	0%	96	4%	42	2%	204	10%	4	0%	1610	75%			2	0%
				EDTA	185	9%	4	0%	8	0%	41	2%	80	4%	214	10%			1616	75%			2	0%
	Colorectal Cancer	888	58	Serum	58	7%	1	0%			11	1%	4	0%	9	1%	11	1%	79	9%	73	8%	642	72%
				Citrate	61	7%	3	0%	1	0%	14	2%	3	0%	66	7%	1	0%	738	83%			1	0%
				EDTA	68	8%			1	0%	5	1%	4	0%	68	8%	1	0%	740	83%			1	0%
	DVT/PE	750	46	Serum	46	6%					2	0%	1	0%	16	2%	21	3%	119	16%	64	9%	481	64%
				Citrate	56	7%	14	2%	6	1%	94	13%	26	3%	71	9%	3	0%	480	64%			1	0%
				EDTA	55	7%	2	0%	2	0%	24	3%	7	1%	171	23%			489	65%			1	0%
	Endometrial Cancer	462	21	Serum	21	5%					2	0%	2	0%	10	2%	3	1%	36	8%	18	4%	370	80%
				Citrate	26	6%					9	2%	1	0%	24	5%			403	87%				
				EDTA	26	6%					1	0%	3	1%	31	7%			403	87%				
	Hip Fracture	1315	66	Serum	67	5%	1	0%	1	0%	10	1%	5	0%	28	2%	28	2%	128	10%	115	9%	932	71%
				Citrate	79	6%	3	0%	1	0%	40	3%	10	1%	81	6%	5	0%	1098	83%				
				EDTA	87	7%			1	0%	16	1%	7	1%	102	8%			1104	84%				
	Ovarian Cancer	302	18	Serum	18	6%					3	1%			1	0%	7	2%	30	10%	201	67%	42	14%
				Citrate	19	6%	1	0%			3	1%	3	1%	24	8%			252	83%				
				EDTA	21	7%					1	0%	2	1%	28	9%			250	83%				
	Stroke	2089	127	Serum	132	6%	3	0%			20	1%	8	0%	36	2%	69	3%	280	13%	111	5%	1430	68%
				Citrate	145	7%	11	1%	7	0%	169	8%	45	2%	309	15%	35	2%	1367	65%			2	0%
				EDTA	161	8%					36	2%	18	1%	298	14%			1575	75%			2	0%

*Participants with no draw included in 0 volume column
**Includes sample reserved for BAA (2 ml serum, 1 ml citrate, and 1 ml EDTA) and future WHI use (1 ml each serum, citrate, and EDTA)
Represents conservative estimate of 1 ml in each vial collected, with 4 serum, 3 citrate, and 3 EDTA vials collected at baseline for CT/OS, at AV1 for CT, and at AV3 for OS.

Table 10.2
OS Outcomes Cases with Remaining Blood Sample by Estimated Volume (in ml)
After Accounting for Approved Core, BAA, and Ancillary Studies

					Volume of Designated Blood Components (ml)** as of 10-22-09																			
	Outcome	Total	No	Blood	0*		>0 - <.5		.5 - <1		1 - <1.5		1.5 - <2		2 - <2.5		2.5 - <3		3 - <3.5		3.5 - <4		4+	
Visit	As of 8/09	Ppts	Draw*	Type	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%
Base-	Breast Cancer	5368	7	Serum	15	0%	3	0%	6	0%	37	1%	27	1%	215	4%	294	5%	620	12%	660	12%	3491	65%
line				Citrate	55	1%	5	0%	6	0%	55	1%	60	1%	413	8%	872	16%	3801	71%			101	2%
				EDTA	103	2%	5	0%	10	0%	90	2%	142	3%	541	10%	749	14%	3629	68%			99	2%
	Breast Cancer	4469	6	Serum	13	0%	3	0%	5	0%	31	1%	23	1%	201	4%	279	6%	572	13%	590	13%	2752	62%
	Invasive			Citrate	48	1%	5	0%	5	0%	46	1%	55	1%	368	8%	776	17%	3076	69%			90	2%
				EDTA	88	2%	5	0%	9	0%	79	2%	118	3%	454	10%	702	16%	2926	65%			88	2%
	Breast Cancer,	947	1	Serum	2	0%			2	0%	6	1%	5	1%	15	2%	18	2%	54	6%	73	8%	772	82%
	Non-Invasive			Citrate	8	1%			1	0%	9	1%	5	1%	49	5%	106	11%	758	80%			11	1%
				EDTA	16	2%			1	0%	12	1%	25	3%	92	10%	50	5%	740	78%			11	1%
	CHD	3552	2	Serum	11	0%	9	0%	20	1%	74	2%	46	1%	303	9%	80	2%	328	9%	545	15%	2136	60%
				Citrate	53	1%	30	1%	37	1%	204	6%	151	4%	678	19%	468	13%	1838	52%	2	0%	91	3%
				EDTA	85	2%	25	1%	59	2%	208	6%	252	7%	858	24%	555	16%	1419	40%	2	0%	89	3%
	Clinical MI	2738	1	Serum	8	0%	8	0%	15	1%	54	2%	39	1%	242	9%	63	2%	268	10%	466	17%	1575	58%
				Citrate	41	1%	25	1%	36	1%	158	6%	132	5%	535	20%	347	13%	1394	51%	2	0%	68	2%
				EDTA	67	2%	22	1%	51	2%	170	6%	200	7%	691	25%	426	16%	1041	38%	2	0%	68	2%
	Colorectal	1200	2	Serum	3	0%	2	0%	7	1%	17	1%	26	2%	138	12%	75	6%	303	25%	236	20%	393	33%
	Cancer			Citrate	14	1%	4	0%	5	0%	22	2%	31	3%	207	17%	338	28%	543	45%			36	3%
				EDTA	33	3%	7	1%	11	1%	107	9%	119	10%	585	49%	167	14%	138	12%			33	3%
	DVT/PE	98	0	Serum									2	2%	6	6%	1	1%	6	6%	10	10%	73	74%
				Citrate									3	3%	10	10%	4	4%	80	82%			1	1%
				EDTA	3	3%					7	7%	2	2%	15	15%	12	12%	58	59%			1	1%
	Endometrial	734	1	Serum	3	0%	1	0%	1	0%	9	1%	5	1%	47	6%	49	7%	98	13%	164	22%	357	49%
	Cancer			Citrate	9	1%					10	1%	12	2%	81	11%	179	24%	427	58%			16	2%
				EDTA	19	3%			4	1%	21	3%	19	3%	77	10%	49	7%	529	72%			16	2%
	Hip Fracture	1868	3	Serum	6	0%	12	1%	26	1%	71	4%	86	5%	201	11%	135	7%	273	15%	170	9%	888	48%
				Citrate	19	1%	2	0%	1	0%	21	1%	33	2%	174	9%	114	6%	1473	79%			31	2%
				EDTA	41	2%	4	0%	6	0%	40	2%	88	5%	244	13%	166	9%	1248	67%			31	2%
	Ovarian	480	0	Serum					1	0%	3	1%	4	1%	11	2%	13	3%	119	25%	182	38%	147	31%
	Cancer			Citrate	4	1%			1	0%	3	1%	3	1%	26	5%	21	4%	412	86%			10	2%
				EDTA	6	1%			1	0%	8	2%	13	3%	52	11%	78	16%	312	65%			10	2%
	Stroke	2865	1	Serum	3	0%	6	0%	11	0%	33	1%	39	1%	121	4%	60	2%	364	13%	551	19%	1677	59%
				Citrate	28	1%	15	1%	18	1%	183	6%	316	11%	577	20%	108	4%	1549	54%			71	2%
				EDTA	47	2%	38	1%	96	3%	384	13%	658	23%	775	27%	223	8%	574	20%	3	0%	67	2%

*Participants with no draw included in 0 volume column
**Includes sample reserved for BAA (2 ml serum, 1 ml citrate, and 1 ml EDTA) and future WHI use (1 ml each serum, citrate, and EDTA)
Represents conservative estimate of 1 ml in each vial collected, with 4 serum, 3 citrate, and 3 EDTA vials collected at baseline for CT/OS, at AV1 for CT, and at AV3 for OS.

Table 10.2 (continued)
OS Outcomes Cases with Remaining Blood Sample by Estimated Volume (in ml)
After Accounting for Approved Core, BAA, and Ancillary Studies

					Volume of Designated Blood Components (ml)** as of 10-22-09																	
					0*		>0 - <.5		.5 - <1		1 - <1.5		1.5 - <2		2 - <2.5		2.5 - <3		3 - <3.5		3.5 - <4		4+	
Visit	Outcome As of 8-09	Total Ppts	No Draw	Blood Type	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%
AV3	Breast Cancer	3762	477	Serum	490	13%					11	0%			22	1%	1	0%	55	1%	74	2%	3113	83%
				Citrate	538	14%					18	0%			41	1%			3188	85%			1	0%
				EDTA	587	16%	1	0%			22	1%	5	0%	162	4%	325	9%	2702	72%			2	0%
	Breast Cancer Invasive	3128	408	Serum	421	13%					11	0%			22	1%	1	0%	46	1%	63	2%	2568	82%
				Citrate	461	15%					15	0%			35	1%			2638	84%			1	0%
				EDTA	497	16%	1	0%			20	1%	5	0%	143	5%	319	10%	2176	70%			2	0%
	Breast Cancer, Non-Invasive	676	74	Serum	74	11%					1	0%							10	1%	11	2%	580	86%
				Citrate	82	12%					4	1%			6	1%			586	87%				
				EDTA	95	14%					2	0%	1	0%	21	3%	7	1%	559	83%				
	CHD	2791	519	Serum	525	19%					5	0%	1	0%	16	1%	13	0%	82	3%	91	3%	2060	74%
				Citrate	550	20%					7	0%			93	3%			2146	77%			1	0%
				EDTA	581	21%	1	0%			59	2%	13	0%	518	19%	112	4%	1520	54%			1	0%
	Clinical MI	2097	329	Serum	334	16%					3	0%	1	0%	12	1%	11	1%	61	3%	70	3%	1607	77%
				Citrate	353	17%					5	0%			75	4%			1670	80%				
				EDTA	377	18%	1	0%			50	2%	8	0%	425	20%	88	4%	1162	55%				
	Colorectal Cancer	868	142	Serum	146	17%	1	0%	1	0%	3	0%	2	0%	5	1%	3	0%	44	5%	222	26%	441	51%
				Citrate	150	17%					2	0%			13	1%			705	81%				
				EDTA	159	18%					8	1%	4	0%	55	6%	72	8%	573	66%				
	DVT/PE	74	16	Serum	17	23%					2	3%							2	3%	2	3%	52	70%
				Citrate	20	27%													54	73%				
				EDTA	21	28%									3	4%	1	1%	50	68%				
	Endometrial Cancer	521	77	Serum	79	15%									5	1%			13	2%	14	3%	411	79%
				Citrate	83	16%					3	1%			8	2%			429	82%				
				EDTA	89	17%					2	0%	1	0%	14	3%	11	2%	409	79%				
	Hip Fracture	1574	250	Serum	257	16%					1	0%			8	1%			24	2%	22	1%	1263	80%
				Citrate	270	17%					6	0%			13	1%			1284	82%			1	0%
				EDTA	284	18%	1	0%			8	1%	1	0%	59	4%	19	1%	1203	76%			1	0%
	Ovarian Cancer	344	68	Serum	69	20%									2	1%			19	6%	56	16%	198	58%
				Citrate	72	21%					2	1%			2	1%			269	78%				
				EDTA	74	22%					2	1%	2	1%	12	3%	55	16%	201	58%				
	Stroke	2269	400	Serum	406	18%					5	0%			20	1%	2	0%	45	2%	27	1%	1765	78%
				Citrate	428	19%					13	1%			40	2%			1794	79%				
				EDTA	462	20%					18	1%	2	0%	100	4%	29	1%	1669	74%				

*Participants with no draw included in 0 volume column
**Includes sample reserved for BAA (2 ml serum, 1 ml citrate, and 1 ml EDTA) and future WHI use (1 ml each serum, citrate, and EDTA)
Represents conservative estimate of 1 ml in each vial collected, with 4 serum, 3 citrate, and 3 EDTA vials collected at baseline for CT/OS, at AV1 for CT, and at AV3 for OS.

Table 10.3
CT and OS Outcomes Cases with DNA* Available
Data as of 9/30/09

		No DNA Available[1]		< 25 ug Extracted, no Buffy Coat Available for Extraction[2]		< 25 ug Extracted, with Buffy Coat Available for Extraction[3]		> 25 ug Extracted[4]	
Outcome As of 8/09	Ppts	#	%	#	%	#	%	#	%
CT									
Breast Cancer	3735	44	1.2%	16	0.4%	1221	32.7%	2454	65.7%
Breast Cancer Invasive	3027	33	1.1%	13	0.4%	696	23%	2285	75.5%
Breast Cancer, Non Invasive	753	11	1.5%	3	0.4%	542	72%	197	26.2%
CHD	3028	40	1.3%	38	1.3%	593	19.6%	2357	77.8%
Clinical MI	2326	30	1.3%	28	1.2%	436	18.7%	1832	78.8%
Colorectal Cancer	967	50	5.2%	7	0.7%	606	62.7%	304	31.4%
DVT/PE	840	9	1.1%	11	1.3%	118	14%	702	83.6%
Endometrial Cancer	502	9	1.8%	1	0.2%	331	65.9%	161	32.1%
Hip Fracture	1365	37	2.7%	42	3.1%	250	18.3%	1036	75.9%
Ovarian Cancer	322	3	0.9%	2	0.6%	219	68%	98	30.4%
Stroke	2232	31	1.4%	59	2.6%	294	13.2%	1848	82.8%
OS									
Breast Cancer	5368	54	1%	12	0.2%	1386	25.8%	3916	73%
Breast Cancer Invasive	4469	51	1.1%	11	0.2%	830	18.6%	3577	80%
Breast Cancer, Non Invasive	947	4	0.4%	2	0.2%	571	60.3%	370	39.1%
CHD	3552	49	1.4%	20	0.6%	279	7.9%	3204	90.2%
Clinical MI	2738	33	1.2%	13	0.5%	215	7.9%	2477	90.5%
Colorectal Cancer	1200	18	1.5%	8	0.7%	142	11.8%	1032	86%
DVT/PE	98	1	1%	0	0%	48	49%	49	50%
Endometrial Cancer	734	7	1%	1	0.1%	287	39.1%	439	59.8%
Hip Fracture	1868	20	1.1%	9	0.5%	297	15.9%	1542	82.5%
Ovarian Cancer	480	7	1.5%	1	0.2%	316	65.8%	156	32.5%
Stroke	2865	43	1.5%	15	0.5%	232	8.1%	2575	89.9%

*DNA measured by OD ratio or Pico Green
[1] < 25 ug DNA in inventory, either in daughter or parent aliquots, and no buffy coat available
[2] < 25 ug DNA in inventory, either in daughter or parent aliquots, and no buffy coat available
[3] < 25 ug DNA in inventory, either in daughter or parent aliquots, and 1 or more buffy coats not yet extracted
[4] 25+ ug DNA in inventory, either in daughter or parent aliquots, regardless of number of buffy coats not yet extracted

Table 10.4
Number of Funded Core, BAA, and Ancillary Studies
Using Blood Sample
by Outcome[1] and Specimen Type

	Serum/Plasma Only	Both Serum/Plasma and DNA	DNA Only	GWAS[2]	RBCs[3]	Total[4]
Cancer						
Bladder Cancer			1	1		1
Breast Cancer	9	1	5			15
Colon Cancer	1					1
Colorectal Cancer	5	4	4	1	1	13
Endometrial Cancer	2		1			3
Kidney Cancer			1	1		1
Lung Cancer	1	1	1			3
Lymphoma, Non Hodgkins		1				1
Melanoma			1			1
Multiple Myeloma		1				1
Stomach Cancer		1		1		1
Pancreatic Cancer	1	2	1	1	1	4
Ovarian Cancer	3					3
Cardiovascular						
CHD	11	1	4	1	1	16
Hypertension		1				1
Stroke	8	2	4	1	1	14
VTE	2	1	2	1		5
Fracture						
Elbow, Lower Humerus	1					1
Hip Fracture	4	2	2	1		8
Spine	2					2
Overall Fracture	1					1
Other						
Eye Disease	1					1
Frailty-disability		1				1
Sarcopenia		1				1
Type 2 Diabetes		1	2	1		3
Blacks/Hispanics			1	1		1

[1] Several studies include more than one outcome
[2] GWAS counted in number of DNA studies
[3] Study includes RBC
[4] Sum of Serum/Plasma, Both Serum/Plasma and DNA, and DNA only

Table 11.1
Approved and Proposed Core Studies[1]

Ref #	Title	Status	Study Pop	Blood	Analytes/Data	Used in Approved Publications
W1	CT core analytes on 6% Subsample; quarterly core analytes on QC pools A and B	Complete	Ppts: CT Controls:3800 *B, Y1, Y3, Y6 on 6% Blood Subsample	Y	Citrate 1.05 ml: FVII Ag; FVIIC; fibrinogen EDTA 1.05 ml: HDL-C; HDL-2; HDL-3; LDL-C; Lp(a); cholesterol; triglyceride Serum 1.05 ml: alpha-carotene; alpha-tocopherol; beta-carotene; beta-cryptoxanthine; gamma-tocopherol; glucose; insulin; lutein and zeaxanthin; lycopene; retinol	204, 210, 222, 240, 273, 345, 347, 350, 447, 448, 449, 520, 521, 524, 866
W2	OS-measurement precision study (OS-MPS)	Complete	Ppts: OS Controls:800 *B, 3 month	Y	Citrate 1.05 ml: FVII Ag; FVIIC; fibrinogen EDTA 1.05 ml: HDL-C; HDL-2; HDL-3; LDL-C; Lp(a); cholesterol; triglyceride Serum 1.05 ml: alpha-carotene; alpha-tocopherol; beta-carotene; beta-cryptoxanthine; gamma-tocopherol; glucose; insulin; lutein and zeaxanthin; lycopene; retinol	524, 442
W4	National validation and quality control assurance of vitamin D absorption from CaD tablets for WHI	Complete	Ppts: CaD Controls:448 *Y3	Y	Serum 1.05 ml: 25-OH Vitamin D_3	
W5	Correlates of endogenous sex hormone concentrations in WHI	Complete	Ppts: DM Controls:300 *150 DM Intervention + 150 DM controls at B and Y1	Y	Serum 3.05 ml: albumin; androstenedione; bioavailable estradiol; DHEA; DHEAS; dihydrotestosterone; estradiol; estrone; estrone sulfate; progesterone; prolactin; SHBG; testosterone	20, 280
W6	HT CVD Biomarkers: study of CHD, Stroke and VTE - Phase I	Complete	Ppts: HT CHD:402 Stroke:272 VTE:223 Controls:877 *B, Y1	Y	Citrate 1.05 ml: ATIII; CRP; D-dimers; FIX conc; FVIII activity; fibrinogen; PAI-1 Ag; PAP; protein C; protein S free; protein S total; prothrombin Ag; F1+2; TAFI; vWF DNA 3 ug: FXIII val34leu; FV Leiden; FV-HR2; MTHF reductase polymorphism; PAI-1; PT19911; PT20210; ESR1 Exon 1 +30; ESR1 IVS1 -1415; ESR1 IVS1 -1505; ESR1 IVS1 -354; ESR1 IVS1 -401; ESR beta - 1730 A/G; GP1ba M145T; integrin alpha 2 - 807 C/T; platelet glycoprotein IIIa - P1(A1), (A2)	204, 210, 222, 273, 345, 347, 350, 380, 429, 445, 462, 526, 589, 854, 866, 972

Table 11.1 (continued)
Approved and Proposed Core Studies[1]

Ref #	Title	Status	Study Pop	Blood	Analytes/Data	Used in Approved Publications
W6 (Con't)	CVD Biomarkers - Phase I	Complete	Ppts: HT CHD:402 Stroke:272 VTE:223 Controls:877 *B, Y1	Y	EDTA 1.3 ml: HDL-C; HDL size; large HDL; medium HDL; small HDL; HDL particles (total); LDL-C; LDL size; large LDL; medium LDL; small LDL (total); LDL particles (total); very small LDL; VLDL size; large VLDL/chylomicrons; medium VLDL;small VLDL; VLDL particles (total); VLDL trig; trig; Lp(a); E-selectin; HDL-C; HDL-2; HDL-3; homocysteine; IL-6; LDL-C; cholesterol; triglyceride Serum 0.05 ml: MMP9	
W7	Genome-wide scan on breast cancer, CHD, and stroke	Analysis	Ppts: OS/CT Breast Cancer:2145 CHD:2119 Stroke:2215 Controls:6479	Y	DNA 2 ug: GWAS – Phase I on pools of 125 samples; Phase II using about 3% SNPs (~6000) from Stage I; Phase III – validation of about 100 from Stage II in HT	
W8	Nutritional biomarkers study (NBS)	Complete	Ppts: DM	Y	NBS 24 hr urine: vol; nitrogen g/day; nitrogen g/L; sodium; potassium NBS spot urine 4 ml: % fat; DE-SU3; DE-SU4; DE-SU5; DE-SU6; EE3/5; EE4/6; fat-free mass; fluid; H2CONST; internal check DSRatio; LOT; Nd; No; O18-SU3; O18-SU4; O18-SU5; O18-SU6; O18CONST; RCO2-3/5; RCO2-4/6; TEE-CONRQ RQ control group (38.1/44.7/17.2 % E from F/C/P); TEE-INTVRQ intervention (29.8/52.7/17.5 % E from F/C/P); TEE-USRQ RQ assumed general US (34/47/18 %E F/C/P); total body water; r-H2O Serum 0.2 ml: alpha-carotene, alpha-tocopherol, beta-carotene, folate, gamma-tocopherol, cholesterol	464, 624, 646, 708, 831, 941, 945
W9	Biological markers of the effect of HT on risk of fractures in the Women's Health Initiative Clinical Trial	Funded	Ppts: HT Fracture - Hip:750 Controls:750 *Fill in with other non spine other fractures to make 750	Y	Serum .65ml: Estradiol (E2); Estradiol, bioavail; Estradiol, free; SHBG Serum .25ml: CTx; PINP	433

Table 11.1 (continued)
Approved and Proposed Core Studies[1]

Ref #	Title	Status	Study Pop	Blood	Analytes/Data	Used in Approved Publications
W10	Biological markers of the effect of HT on risk of breast cancer in the Women's Health Initiative Clinical Trial	Funded	HT Cases: n=758 Controls: n=758	Y	Serum 0.95 ml: Total, bioavailable, and free estradiol, estrone sulfate, estrone, SHBG at Baseline and Year 1; progesterone and total, bioavailable, and free testosterone at Baseline only	
W11	CVD biomarkers - Phase II: strokes after Feb 2001	Funded	Ppts: HT Stroke:316 Controls:316 *108 new E+P cases up to July 2002, 174 E alone cases up to March 2005 (316 total as of 4-8-05); B, Y1	Y	Citrate 0.9 ml: free TFPI; TFPI activity; total TFPI; APC-ETP DNA 1 ug: ESR1 Exon 1 +30; ESR1 IVS1 -1415; ESR1 IVS1 -1505; ESR1 IVS1 -354; ESR1 IVS1 -401; estrogen receptor beta - 1730 A/G; GP1ba M145T; integrin alpha 2 - 807 C/T; platelet glycoprotein IIIa - P1(A1), (A2) Serum 0.25 ml: glucose; insulin	435, 462
W14	CVD biomarkers - Phase I: additional assays	Analysis	Ppts: HT CHD:390 Stroke:270 VTE:220 Controls:880 *B, Y1	Y	Citrate .95ml: Citrate .35ml: TFPI activity; TFPI, free; TFPI, total Citrate .65ml: APC-ETP Serum .25ml: Glucose; Insulin;	866, 972
W15	CaD Vitamin D levels in CaD participants with colorectal cancer or fractures	Complete	Ppts: CaD Colorectal Cancer:334 Fracture - Hip:360 Fracture - Elbow, Lower humerous:853 Fracture - Spine Only:283 Controls:1830 *Y1; B only if Y1 not available	Y	Serum 0.2 ml: 25-OH-Vitamin D_3	450, 451, 581, 861, 876, 878, 910
W18	HT hormone pretest	Analysis	Ppts: HT Controls:240 *120 active + 120 placebo; B, Y1	Y	Serum 0.95 ml: total, free, and bioavailable estradiol, estrone, SHBG on both E-Alone and E+P samples; progesterone and total, bioavailable, and free testosterone on E+P only samples.	795
W19	WHI HT proteomic pilot Study	Analysis	Ppts: HT Controls:200 *100 active, 100 control; B, AV1	Y	Serum 0.55 ml: proteomics	843, 921

Table 11.1 (continued)
Approved and Proposed Core Studies[1]

Ref #	Title	Status	Study Pop	Blood	Analytes/Data	Used in Approved Publications
W20	WHI-EDRN pilot study for the identification of circulating biomarkers for colon cancer in pre-clinical specimens	Analysis	Ppts: OS Colorectal Cancer:100 Controls:120 *Colon cancer cases 6-18 mo after Year 3Controls: 120	Y	EDTA 0.55 ml: proteomics	
W22	Vitamin D in 6% blood subsample of CaD	Seeking approval	Ppts: CaD	Y	Serum 0.2 ml: 25-OH Vitamin D_3	843
W24	CaD Vitamin D and breast cancer	Analysis	Ppts: CaD Breast Cancer:1081 Controls:1081 *Use controls from W15 when possible	Y	Serum 0.2 ml: 25-OH Vitamin D_3	470, 861, 876, 878, 910
W25	WHI coronary artery calcification study in E-Alone (WHI-CACS)	Complete	Ppts: HT *1150 E-Alone ppts aged 50-59	N	Coronary artery calcification	503, 506, 570, 591, 806, 816, 912, 955
W26	Food grouping in WHI by FHCRC Nutrition Shared Resource group	Funded	Ppts: DM	N	4DFR food group codes	
W27	Nutrition and physical activity assessment study (AS218) lab work	Funded	Ppts: OS *450 ppts	Y	NPAAS 24 hr urine: vol; nitrogen g/day, nitrogen g/L NPAAS spot urine 4 ml: % fat; DE-SU3; DE-SU4; DE-SU5; DE-SU6; EE3/5; EE4/6; fat-free mass; Fluid; H2CONST; internal check DSRatio; LOT; Nd; No; O18-SU3; O18-SU4; O18-SU5; O18-SU6; O18CONST; RCO2-3/5; RCO2-4/6; TEE-CONRQ RQ control group (38.1/44.7/17.2 % E from F/C/P); TEE-INTVRQ intervention (29.8/52.7/17.5 %E from F/C/P); TEE-USRQ RQ assumed general US (34/47/18 % E F/C/P); total body water; r-H2O Serum 0.2 ml: alpha-carotene, alpha-tocopherol, beta-carotene, folate, gamma-tocopherol, cholesterol	
W28	Medicare claims data pilot	Complete	Ppts: OS/CT	N	Medicare claims data for 2 years on all WHI participants aged 65+.	

Table 11.1 (continued)
Approved and Proposed Core Studies[1]

Ref #	Title	Status	Study Pop	Blood	Analytes/Data	Used in Approved Publications
W30	Dietary assessment study	Complete	Ppts: DM *160 ppts for 4DFR analyses, repeat 24 hr recalls, and repeat FFQs	N	4DFR nutrient analyses; repeat 24 hr recalls; repeat FFQs	35
W31	4DFR and ovarian cancer	Complete	Ppts: DM Ovarian Cancer:160 *For DM Other Cancer paper	N	4DFR analyses for DM other cancer paper	469
W33	4DFR and DM breast cancer	Complete	Ppts: DM Breast Cancer:1800 *For DM Breast Cancer paper	N	4DFR analyses for DM breast cancer paper	448
W34	Extension of WHI stroke genome-wide association study (W7)	Funded	Ppts: OS/CT Stroke:2096 Controls:2096	Y	DNA 1 ug: 5,400 SNP; gene sequencing of selected genes	
W35	Full CMS data on all CT/OS participants	Funded	Ppts: OS/CT	N	CMS Medicare health data	
W37	EDRN WHI Phase 2: identification of circulating colon cancer biomarkers in pre-clinical and clinical specimens	Seeking Approval	Ppts: OS/CT Colon cancer:100 Controls:100 *Cases within 2 years of blood draw, either baseline, AV1 (CT), or AV3 (OS)	Y	EDTA .55ml: ANG; APP; ARMET; C8G; CATHB; CATHD; CFH; CST6; CULLIN; DJ1; F5; HP; HPR; IGFBP-2; KNG1; LOC442043; LRG1; MAPRE1; PDIA3; PKM2; PPBP; RAB; RANBP1; SPARC; TF; TNC	
W39	27-hydroxycholesterol inhibits cardiovascular effects of estrogen	Funded	Ppts: HT CHD:359 Controls:820 *CHD cases from W6-HT CVD Biomarkers	Y	Serum 0.55 ul: 27-OH-cholesterol	
W40	Validation of E-alone proteins in W19-HT proteomics	Funded	Ppts: HT Controls:100 *100 E-Alone ppts in active treatment arm	Y	Serum .55 ml: AHSG; CLL16; CP; FIX; F10; IGF-1; IGFBP-1; IGFBP-2; IGFBP-3; IGFBP-4; IGFBP-6; KNG1; MMP-2; Protein Z; SHBG; VTN; Vit D Binding	
W41	Medications inventory on WHI Extension participants	Funded	Ppts: OS/CT	N	Current medications and current supplements	
W42	SEER code WHI and ES non-primary cancers	Funded	Ppts: OS/CT	N	SEER coding of non-primary cancers	

Table 11.1 (continued)
Approved and Proposed Core Studies[1]

Ref #	Title	Status	Study Pop	Blood	Analytes/Data	Used in Approved Publications
W43	Gene sequencing of selected genes in breast cancer and stroke SNP studies (W7 and W34)	Funded	Ppts: HT E+P Breast Cancer:120 Controls:0 *60 active treatment. 60 placebo	Y	DNA 0 ug (use previously sent samples): gene sequencing	
W44	Biological validation of E+P effects on the serum proteome and comparison of E+P and E-Alone effects (see W18 and W40)	Funded	Ppts: HT Controls:50 *50 E+P ppts at baseline,AV1	Y	Serum 0.55 ml E+P and 0 ml E-Alone: AGTASE; Apo D; Apo F; B2M; CCL18; CSF1; LCN2; LGALS3BP; MCAM; RNASE4; THBS1; TNC; XLKD1 E+P only: CP, F10, IGF-1, IGFBP-1; IGFBP-2; IGFBP-4	921
W45	Proteomic Colon Cancer Study	Funded	Ppts: OS Colon cancer 100 Controls 100	Y	Citrate .15ml: ADAMTS13; APP; CEA; CXCL7/NAP2; ENO1; IGFBP-2; LGALS3BP; LRG1; LTF; MAPRE1; MMP-2; NID1; PPIA; SPARC	
W46	HT Proteomics: CHD, stroke and breast cancer	Seeking Approval	Ppts: HT CHD:100	Y	Serum .14ml	
W47	Breast Tumor Tissue Pilot	Approved	Ppts: DM	N	N/A	
W48	Estradiols in DM	Seeking Approval	Ppts: DM	Y		
W49	Assessing Recurrent Breast Cancer	Seeking Approval	Ppts: OS/CT	N		
W50	Biomarkers in Minorities	Seeking Approval	Ppts: OS/CT	Y		
W51	Transfer of AS62-WHISE blood samples to WHI repository	Funded	Ppts: OS/CT	N		
W52	SHARe data clean-up	Funded	Ppts: OS/CT	N		
W53	HT CHD Proteomics Coronary Heart Disease Pathogenesis and Postmenopausal Hormones	Approved	Ppts: HT	Y		
W54	CVD Biomarkers 2010-2015	Seeking Approval	Ppts: OS/CT	Y	Under discussion	
W55	Biomarkers for M13	Seeking Approval	Ppts: OS/CT	Y	Under discussion	

Table 11.1 (continued)
Approved and Proposed Core Studies[1]

Ref #	Title	Status	Study Pop	Blood	Analytes/Data	Used in Approved Publications
W56	Telomere Length Validity	Seeking Approval	Ppts: OS/CT Cases and Controls: 120	Y	DNA: Telomere Length Assays	
M3[2]	NCI Cancer Genetic Markers of Susceptibility (CGEMS) Initiative: Replication Phase	Analysis	Ppts: OS/CT Breast Cancer: 2956 Controls: 2956 Cauasians only	Y	NCI Genotype: DNA 4ug: SNPs 30K	874, 906, 907, 908,
M4[2]	Whole genome scan for pancreatic cancer risk in the pancreatic cancer cohort consortium (PANSCAN)	Analysis	Ppts: OS/CT Pancreatic Cancer: 283 Controls: 283	Y	NCI Genotype: DNA 4ug: GWAS	875, 930, 931, 932, 933, 934, 936, 1075
M5[2]	SHARe (SNP Health Association Resource) GWAS	Funded	Ppts: OS/CT Controls: 12,500 Blacks and Hispanics	Y	Affymetrix: DNA 2ug: GWAS	
M6[2]	PAGE: Population Architecture of Genes and Environment (formally Epidemiologic investigation of putative causal genetic variants: The Women's Health Initiative)	Funded	Ppts: OS/CT Controls: 80,000	Y	TGen: DNA 2ug: SNPs 96	
M13[2]	GWAS of Hormone Treatment and CVD and Metabolic Outcomes in the WHI	Funded	Ppts: OS/CT CHD:670 VTE: 392 Stroke: 457 Diabetes: 1404 Controls: 3821	Y	DNA 2ug: GWAS	
M15[2]	Beyond GWAS: Study of Type 2 Diabetes Genes in Multiethnic Populations.	Approved	Ppts: OS/CT Controls: 5350	Y	DNA 1ug: Fine Mapping	
M21[2]	WHI SHARe-CARe minority cohort post-GWAS	Approved	Ppts: OS/CT CHD: 8515	Y	Citrate: .5mL: Fibrinogen, D-dimer Serum: 1 mL: Creatinine, Glucose, GGTP, TC, HDL, TG, Insulin, ICAM, E-selectin, VitD, Lp-PLA2 EDTA: .45 mL: Apo A1, ApoB, Cystatin C, CRP, Lipoprotein Subfractions DNA: 2ug: GWAS Affymetrix RBCs: 100ul: HbA1c	
M22[2]	HT GWAS	Seeking Approval	Ppts: HT	Y		

Table 11.1 (continued)
Approved and Proposed Core Studies[1]

Ref #	Title	Status	Study Pop	Blood	Analytes/Data	Used in Approved Publications
M24[2]	Large-scale DNA Sequencing and Molecular Profiling of Well-phenotyped NHLBI Cohorts	Funded	Ppts: OS/CT	Y	DNA 2ug: large-scale genetic sequencing	

[1] Core studies are conducted using internal WHI Funds included in the Clinical Coordinating Center budget. Studies are developed and monitored by a study-wide Core Resources Working Group. NHLBI conducts additional peer review of proposed uses beyond those specified in the study protocol (certain subsamples) and pilot projects.
[2] Core initiative studies that are not funded through WHI funds (they are externally funded)

Table 11.2
Broad Agency Announcement Activities

BAA	Title	PI	Institution	Used in Approved Publications
1	Ancestry Association Analyses of WHI Traits	Dr. Michael Seldin	University of California, Davis	964
2	High-Dimensional Genotype in Relation to Breast Cancer and WHI Clinical Trial Interventions	Dr. Ross Prentice	Fred Hutchinson Cancer Research Center	846, 1045, 1055, 1070
3	Genome-wide Association Study to Identify Genetic Components of Hip Fracture	Dr. Rebecca Jackson	Ohio State University Research Foundation	
4	Proteomics and the Health Effects of Postmenopausal Hormone Therapy	Dr. Ross Prentice	Fred Hutchinson Cancer Research Center	843, 921
5	Identification and Validation of Circulating Biomarkers for the Early Detection of Breast Cancer in Pre-Clinical Specimens	Dr. Christopher Li	Fred Hutchinson Cancer Research Center	
6	Interaction Effects of Genes in the Inflammatory Pathway and Dietary, Supplement, and Medication Exposures on General Cancer Risk	Dr. Jianfeng Xu	Wake Forest University	1068, 1069
7	Endogenous Estradiol and the Effects of Estrogen Therapy on Major Outcomes of WHI	Dr. Steve Cummings	California Pacific Medical Center	
8	Predictive Value of Nutrient Biomarkers for CHD Death	Dr. Alice Lichtenstein	Tufts University	
9	Biochemical Antecedents of Fracture in Minority Women	Dr. Jane Cauley	University of Pittsburgh	841, 863, 945
10	Adipokines and Risk of Obesity-Related Diseases	Dr. Gloria Ho	Albert Einstein College of Medicine	893, 894, 922, 1025, 1029, 1061
11	Physical Activity, Obesity, Inflammation and CHD in a Multi-Ethnic Cohort of Women	Dr. I-Min Lee	Brigham and Women's Hospital	895
12	Hormone Therapy, Estrogen Metabolism and Risk of Breast Cancer or Hip Fracture in the WHI Hormone Trial	Dr. Lewis Kuller	University of Pittsburgh	916, 917
13	Markers of B-cell stimulation as potential predictors of Non-Hodgkins lymphoma	Dr. Anne DeRoos	Fred Hutchinson Cancer Research Center	

Table 11.2 (continued)
Broad Agency Announcement Activities

14	Inflammation and thrombosis gene pathways and cardiovascular disease	Dr. Alex Reiner	Fred Hutchinson Cancer Research Center	
15	Discovery and confirmation of cancer specific serum protein markers for ovarian cancer early detection	Dr. Martin McIntosh	Fred Hutchinson Cancer Research Center	
16	Identifying biomarkers for pancreatic cancer	Dr. Sunil Hingorani	Fred Hutchinson Cancer Research Center	
17	Proteomics based discovery of blood based biomarkers and risk factors for lung cancer among women smokers and never smokers	Dr. Sam Hanash	Fred Hutchinson Cancer Research Center	
18	Follow-up studies of genetically determined risk factors	Dr. Rebecca Jackson	Ohio State University	
19	Omega-3 fatty acid biomarkers and cognitive decline in WHIMS	Dr. William Harris	Sanford Research/University of South Dakota	1058
20	Evaluation of specific markers of rheumatoid arthritis, Inflammation, thrombogenesis and risk of cardiovascular disease and total mortality	Dr. Larry Mooreland	University of Pittsburgh	
21	Understanding the role of sex hormones in colorectal cancer	Dr. Marc Gunter	Albert Einstein College of Medicine	
22	Predictive modeling for CVD in a multiethnic cohort in women	Dr. Nancy Cook	Brigham and Women's Hospital and Harvard Medical School	

Table 11.3
Summary of Ancillary Studies

Data as of Sept. 30, 2009

Current Status	Number of Studies	Led by WHI Investigator	
		Yes	No
Dropped	134	46	88
Seeking approval	13	1	12
Approved	37	10	27
Funded	36	13	23
Data analysis in progress	21	10	11
Complete	56	26	30
Total	**297**	**106**	**191**

15/94 AS have CCC lead
16%

Table 11.4
All Ancillary Studies

AS #	Title	PIs	WHI Investigator	Status	Study Dates	Study Populations*	Blood Study	Ms #(s)
M8	NCI GWAS in bladder cancer	Anc: Chanock WHI: Anderson (Raitakari)	No	Funded	7/1/09-6/30/10	OS/CT Bladder Cancer:256 Controls: 256	Y	
M9	NCI GWAS in renal cell carcinoma (RCC): expansion of a primary scan	Anc: Chanock WHI: Kuller/ Anderson	No	Approved	10/1/08-10/31/10	OS/CT Kidney Cancer:300 Controls:300 *Non-Hispanic Caucasians	Y	
M11	NCI - The associations of pepsinogen I/II ratio, polymorphisms in alcohol metabolizing genes, and telomere length with gastric cancer risk	Anc: Dong WHI: Anderson	No	Approved	10/1/08-10/31/10	OS/CT Stomach Cancer:119 Controls:238	Y	
M12	NPAAS Sugar and Meat Biomarkers	WHI: Prentice	Yes	Approved		DM NPAAS ppts: 450	Y	
M14	Glioma GWAS	Anc: Rajaraman WHI: Thompson	No	Approved		OS/CT Brain Cancer: 1,973 Controls: 1,547	Y	
M16	Stroke GWAS	WHI: Smoller	Yes	Approved	9/30/09-9/29/11	OS/CT Stroke: 680 Controls: 680	Y	
M17	Urine BPA – FDA Study		No	Approved		OS/CT	Y	
M18	Breast Cancer Post GWAS	Anc: Hunter WHI: Prentice	No	Approved		OS/CT	Y	
M23	Genetic Susceptibility to Lung Cancer	Anc: Han WHI: Manson	No	Approved	7/1/10-6/30/14	OS Lung Cancer: 980 Controls: 980	Y	
M25	GWAS of Chronic Periodontitis	Anc: Wactawski-Wende	Yes	Approved		OS	Y	
288	Diet and activity methods study and evaluation of longitudinal (DAMSEL) effects in WHI women	Anc: Prentice WHI: Prentice	Yes	Approved	07/01/10-06/30/13	DM	N	
287	Metabolic syndrome, lifestyle factors and risk of periodontitis in older women	Anc: Lamonte WHI: Wactawski-Wende	No	Approved		OS	Y	
286	Objective measures and health benefits of physical activity in women	Anc: Buchner WHI: LaCroix	No	Approved	09/30/09-09/29/11	CT 10,000 ppts	N	
285	SNP-energy interaction and the risk of breast cancer	Anc: Vitolins WHI: Vitolins	Yes	Approved	07/01/10-06/30/13	OS/CT Breast Cancer:2700 Controls:1000	Y	

Table 11.4 (continued)
All Ancillary Studies

AS #	Title	PIs	WHI Investigator	Status	Study Dates	Study Populations*	Blood Study	Ms #(s)
284	Obesity-related pathways and risk of benign proliferative breast disease	Anc: Gunter WHI: Smoller	No	Approved		CT	Y	
283	Association between a LPA gene variant and CHD according to aspirin use in the WHI	Anc: Shiffman WHI: Kuller	No	Seeking Approval		OS/CT	Y	
282	Evaluation of serum markers for use in multi-stage ovarian cancer screening	Anc: Urban WHI: Anderson	No	Approved	07/01/09-06/30/11	OS/CT Ovarian Cancer:143 Controls:572	Y	
281	Epigenomics of obesity and nutrition in the WHI	Anc: Rajkovic WHI: Rajkovic	Yes	Approved	09/30/09-09/29/11	DM Obese: 60 Non-Obese: 30	Y	
280	Phenotyping estrogen effects on pericardial fat, coronary calcified plaque, hepatic steatosis, BMD and associated biomarkers in the WHI-CACS substudy	Anc: Carr WHI: Shumaker	No	Dropped		CT	Y	
279	Linking serotonin, estrogen, the musculoskeletal system and fractures in older women from the WHI	Anc: Chen WHI: Thomson	No	Seeking Approval		OS/CT	Y	
278	Hemostatic and inflammatory biomarkers as risk factors for hemorrhagic stroke	Anc: Greenland WHI: Van Horn	Yes	Approved	09/30/09-09/29/11	OS/CT Stroke:537 Controls:1074 *HT-495 (165 hemo.stroke/330 control) OS- 1116 (372 hemo. stroke/744 controls)	Y	
277	The role of adiponectin and its receptors in breast cancer risk in the WHI	Anc: Kaklamani WHI: Chlebowski	No	Approved	02/01/10-01/31/11	OS	Y	
276	Genetic variants of habitual physical activity	Anc: Nguyen WHI: LaCroix	No	Approved	04/01/10-03/31/14	OS Controls:6000 *8000 cases/controls Caucasians only (4000 highly active cases/4000 sedentary cases)	Y	
275	Urinary levels of melatonin and risk of breast cancer	Anc: Sturgeon WHI: Ockene	No	Approved	07/01/10-06/30/12	OS/CT	Y	
274	Cellular aging in postmenopausal women with depression	Anc: Simon WHI: Smoller	No	Approved	09/30/09-09/30/11	OS Controls:250 *250 cases with depression	Y	

Table 11.4 (continued)
All Ancillary Studies

AS #	Title	PIs	WHI Investigator	Status	Study Dates	Study Populations*	Blood Study	Ms #(s)
273	Evaluation of angiogenic factors as possible biological markers of breast cancer	Anc: Reeves WHI: Ockene	No	Seeking Approval		OS Breast Cancer:267 Controls:267	Y	
272	WHI Nutrition and Physical Activity Assessment Study (NPAAS) (Competitive Renewal)	Anc: Prentice WHI: Beresford	Yes	Approved	12/01/09-11/30/13	OS/CT	N	
271	Omega-3 and omega-6 fatty acids as a biomarker of hip fracture risk	Anc: Jackson WHI: Jackson	Yes	Funded	08/01/09-07/31/10	OS/CT Fracture - Hip:400 Controls:400 *half BMD, half non-BMD	Y	
270	Sodium intake and osteoporosis: Findings from the WHI.	Anc: Carbone WHI: Johnson	No	Approved	04/01/10-03/31/13	OS Fracture (general):1248 Controls:1248 *The number of samples for AV3 should be reduced by 15%.	Y	
269	An association study of mitochondrial DNA variation and breast cancer risk	Anc: Rohan WHI: Smoller	No	Approved	12/01/09-11/20/12	OS/CT Breast Cancer:5679 Controls:5679	Y	
268	Hepatic nuclear factor-4 alpha-a potential candidate for lower triglycerides in individuals of African ancestry	Anc: Mackey WHI: Kuller	No	Dropped		OS CHD:144 Controls:1172 *Same case/controls as AS189	Y	
267	Genetic variants of habitual physical activity	Anc: Nguyen WHI: LaCroix	No	Dropped		OS Controls:1000 *500 with physical activity	Y	
266	Serum levels of EGFR-signaling-network activators/inhibitor and risk of lung cancer	Anc: Ho WHI: Smoller	No	Approved	10/01/09-02/28/12	OS Cancer of Lung:973 Controls:1126	Y	
265	Urinary levels of endocrine disruptors (bisphenol A and phthalates) and risk of diabetes, CHD, and breast cancer in a case-cohort study	Anc: Ho WHI: Smoller	No	Seeking Approval		OS Breast Cancer:350 CHD:500 Type 2 Diabetes:490 Controls:1000	Y	
264	Genetic modification of PM-mediated arrhythmogenesis	Anc: Whitsel WHI: Heiss	No	Approved	12/01/09-11/30/12	CT Controls:3000 *5 geographical locations; ppts with ECG readings	Y	

Table 11.4 (continued)
All Ancillary Studies

AS #	Title	PIs	WHI Investigator	Status	Study Dates	Study Populations*	Blood Study	Ms #(s)
263	Gene-hormone therapy interaction and the risk of breast cancer	Anc: Sun WHI: Vitolins	No	Approved	07/01/10-06/30/13	OS/CT Breast Cancer - Invasive:2690 Controls:1800 *583 E+P invasive breast cancer, 307 E-alone Inv. Breast Cancer, 1800 OS Inv. Breast cancer, 1800 OS controls	Y	
262	Women's Health Initiative memory study of younger women (WHIMS-Y)	Anc: Shumaker WHI: Shumaker	Yes	Funded	10/01/08-06/30/11	HT 224 Ppts@9 clinics	N	
261	Genetic variants of serum lipid concentrations in different ethnic groups	Anc: Wang WHI: Smoller	No	Seeking Approval		OS/CT Controls:3800 *1500 Blacks, 1500 Whites, 800 Hispanics with lipid measurements	Y	
260	Anti-anticyclic citrulinated peptide (anti-CCP) antibody as a test for rheumatoid arthritis (RA)	Anc: Kuller WHI: Kuller	Yes	Dropped		OS Controls:95 *622 RA cases (245 in AS217)	Y	
259	Telomere length and breast cancer in women	Anc: Liu WHI: Nathan	Yes	Seeking Approval		OS Breast Cancer:2100 Controls:2100	Y	
258	Genetic variants in Wnt pathway and breast cancer risks	Anc: Agalliu WHI: Smoller	No	Approved	07/01/10-06/30/13	OS/CT Breast Cancer - Invasive:3933 Controls:3933 *OS invasive (3933)	Y	
257	Lifestyle factors reducing risk for age-related eye disease	Anc: Mares WHI: Sarto	No	Approved	04/01/10-05/31/13	OS Eye:361 Controls:1426	Y	
256	Long term effects of hormonal interventions on change in levels of inflammatory markers and adipokines	Anc: Rajpathak WHI: Smoller	No	Seeking Approval		CT Controls:1024 *From CT 6% blood subsample	Y	
255	Androgens and CHD in women with type 2 diabetes	Anc: Rajpathak WHI: Smoller	No	Seeking Approval		OS CHD:500 Controls:1000 *CHD cases with diabetes	Y	
254	Telomere and its biochemical and genetic regulators as predictors for clinical diabetes in women	Anc: Liu WHI: Nathan	Yes	Funded	06/01/09-05/31/11	OS Type 2 Diabetes:1800 Controls:2620	Y	

Table 11.4 (continued)
All Ancillary Studies

AS #	Title	PIs	WHI Investigator	Status	Study Dates	Study Populations*	Blood Study	Ms #(s)
253	Serum selenium and pancreatic cancer risk	Anc: Stolzenberg WHI: LaCroix	No	Seeking Approval		OS/CT Pancreatic Cancer:300 Controls:300	Y	
252	Environmental determinants of cognitive aging in WHIMS	Anc: Chen WHI: Heiss	No	Approved	07/01/08-06/30/13	HT	N	
251	Acute cardiovascular events and air pollution	Anc: Whitsel WHI: Heiss	No	Approved	07/01/08-06/30/11	OS/CT	N	
250	Genetic contributions to cognitive decline in normal and pathological aging in older post-menopausal women and modification by hormone therapy	Anc: Driscoll WHI: Shumaker	No	Funded	03/01/09-12/31/09	HT Controls:7479 *All 7479 WHIMS ppts	Y	
249	Epidemiology of alcohol metabolism genes, alcohol and Women's Health outcomes	Anc: Freiberg WHI: Kuller	No	Approved	05/01/09-04/30/14	OS/CT Breast Cancer:4500 MI:1900 Stroke:1800 Controls:10942 *CVD: 1117; Alcohol related cancer: 3390	Y	
248	Hormone therapy, changes in subpopulations of triglyceride-rich lipoproteins and HDL, and development of CHD in women.	Anc: Lamon-Fava WHI: Wasserthei l-Smoller	No	Seeking Approval		OS/CT CHD:444 Controls:444	Y	
247	Genetic factors associated with the risk of Parkinson Disease in the multiethnic cohort of the WHI	Anc: Saunders-Pullman WHI: Wasserthei l-Smoller	No	Seeking Approval		OS/CT Death - other cause:1376 Controls:450	Y	
246	Prospective study of hormones, autoantibodies and biomarkers and risk of systemic lupus erythematosus in women	Anc: Costenbader WHI: Manson	No	Seeking Approval		OS/CT Death - other cause:547 Controls:1641	Y	
245	Ghrelin, adiposity-derived hormones, and colorectal cancer	Anc: Lin WHI: Manson	No	Seeking Approval		OS Colorectal Cancer:700 Controls:700	Y	
244	Women's Health Initiative memory study epidemiology of cognitive health (WHIMS-ECOH)	Anc: Shumaker WHI: Vitolins	Yes	Approved	10/01/07-12/31/10	HT	N	

Table 11.4 (continued)
All Ancillary Studies

AS #	Title	PIs	WHI Investigator	Status	Study Dates	Study Populations*	Blood Study	Ms #(s)
243	Validation of direct measures of physical activity: an ancillary study to the Women's Health Initiative (WHI) nutrition and physical activity assessment study (NPAAS; AS218)	Anc: Sternfeld WHI: Caan	No	Analysis	04/15/07-12/31/08	OS	N	
242	DNA repair, telomere length and cutaneous malignant melanoma risk	Anc: Han WHI: Manson	No	Funded	05/01/08-04/30/10	OS Melanoma - Skin:259 Controls:259 *Malignant melanoma: 264	Y	
241	Dietary relationships to inflammatory bowel disease (IBD) in older women	Anc: Tamboli WHI: Wallace	No	Dropped		OS	N	
240	Microalbuminuria and cardiovascular risk in the WHI	Anc: Hsia WHI: Hsia	Yes	Dropped		OS/CT CHD:5500	Y	
239	Biomarkers related to energy balance and renal cell cancer	Anc: Cho WHI: Manson	No	Dropped		OS/CT Renal Cancer:182 Controls:546	Y	
238	Genetic and biochemical predictors of type 2 DM in women	Anc: Liu WHI: Nathan	Yes	Approved	12/01/09-11/30/12	OS Type 2 Diabetes:2150 Controls:3200	Y	
237	The hypothalamic-pituitary-adrenal (HPA) axis and postmenopausal breast cancer risk	Anc: Dorgan WHI: Lasser	No	Approved	12/01/09-11/30/13	OS Breast Cancer:4738 Controls:4738 *Caucasian only	Y	
236	Choline/betaine habitual intake and chronic disease endpoints	Anc: Siega-Riz WHI: Heiss	No	Funded	10/01/07-09/01/08	OS/CT	N	
235	Pilot study to explore assoc between task performance on fMRI w/ cog functioning and vascular, genetic & inflam. risk factors in WHISCA ppt characterized by differing body weight & waist-hip ratios	Anc: Kerwin WHI: Kotchen	No	Funded	11/01/06-06/30/09	CT	N	
234	Adipokines, inflammation and energy balance in postmenopausal women	Anc: Neuhouser WHI: Prentice	Yes	Dropped		DM	N	
233	WHIMS (AS39) extension	Anc: Shumaker WHI: Shumaker	Yes	Analysis	12/13/03-06/30/08	HT 3074 Ppts@32 clinics	N	
232	Carotenoids and incidence and progression of age-related eye disease in women	Anc: Mares-Perlman WHI: Sarto	No	Dropped		OS Eye:650 Controls:1250	Y	

Table 11.4 (continued)
All Ancillary Studies

AS #	Title	PIs	WHI Investigator	Status	Study Dates	Study Populations*	Blood Study	Ms #(s)
231	Relationship between circulating nutrient biomarkers and death from coronary heart disease or myocardial infarct	Anc: Lichtenstein WHI: Van Horn	No	Dropped		OS CHD:1200 Controls:1200	Y	
230	Markers of inflammation and renal function and the risk of coronary heart disease and mortality in women with diabetes	Anc: Rajpathak WHI: Smoller	No	Dropped		OS CHD:764 Controls:1736 *764 CHD+500 death cases (382+250 baseline diabetes)	Y	
229	Genome wide, case-control analysis of SNP associations with cardiovascular disease in african american women	Anc: Carlson WHI: LaCroix	No	Dropped		OS CHD:1825 Controls:1825	Y	
228	Obesity, diet, physical activity and Medicare costs	Anc: Yan WHI: Van Horn	No	Dropped		OS/CT	N	
227	Risk factors and biomarkers for Parkinson's disease	Anc: Ascherio WHI: Manson	No	Approved	07/01/09-06/30/14	OS/CT Controls:1191 *OS and HT Parkinson's disease: 397 cases + 794 controls for DNA; 308 cases + 616 controls for serum	Y	
226	Ambient air pollution and sleep disturbance in postmenopausal women	Anc: Chen WHI: Heiss	No	Approved	09/01/07-08/31/12	OS/CT	N	844
225	Potential gene-environment interaction on the association between chronic air pollution exposure and incident MI in the WHI OS	Anc: Sullivan WHI: Beresford	No	Dropped		OS	N	
224	Genome-wide association study for nonsynonymous SNPs in colon cancer	Anc: Peters WHI: Prentice	No	Funded	07/02/07-06/30/13	OS/CT Colon cancer:1930 Controls:1930 *Stage I: 700/700 OS Caucasian; Stage II: 330/330 OS non-Caucasians; Stage III: 900/900 CT. Shares controls and genotyping data with BA03 where possible.	Y	962
223	Women's Health Initiative cancer survivor cohort: biological, psychosocial, and behavioral predictors of survival: pilot study	Anc: Paskett WHI: Jackson	Yes	Funded	10/01/05-09/30/10	OS/CT	N	

Table 11.4 (continued)
All Ancillary Studies

AS #	Title	PIs	WHI Investigator	Status	Study Dates	Study Populations*	Blood Study	Ms #(s)
222	Developmental research of air pollution as a cause of common cancers	Anc: DeRoos WHI: LaCroix	No	Dropped		OS/CT	N	
221	Dietary modification, calcium/vitamin D supplementation, and change in breast density	Anc: Rohan WHI: Smoller	No	Dropped		ppts in DM & CaD	N	
220	Neighborhoods, women, and coronary heart disease: a prospective study	Anc: Bird WHI: Margolis	No	Funded	07/01/07-04/30/10	OS/CT	N	703, 704, 705, 726, 824, 854
219	Diet and eye health in the WHI: end of trial study: pilot study	Anc: Mares WHI: Sarto	No	Complete	01/01/06-12/31/06	DM 400 Ppts@Madison	N	577
218	WHI nutrition and physical activity assessment study (NPAAS)	Anc: Prentice WHI: Prentice	Yes	Funded	07/12/06-06/30/10	OS	N	
217	Validation of the self-report of rheumatoid arthritis and systemic lupus erythematosus: The Women's Health Initiative	Anc: Wallitt WHI: Howard	No	Complete	07/01/04-06/01/06	CT	N	635
216	Decision-making about cancer screening among older women	Anc: Messina WHI: Lane	No	Analysis	07/01/06-06/30/09	OS/CT 1300 Ppts@Stonybrook	N	
215	UGTs, NSAIDs, and breast cancer risk in the WHI observational study	Anc: Lampe WHI: Prentice	No	Dropped		OS Breast Cancer:3398 Controls:3398	Y	
214	Prospective cohort collaborative in pancreatic cancer epidemiology and pathogenesis (AS146 extension)	Anc: Fuchs WHI: Manson	No	Funded	09/01/07-06/30/12	OS Pancreatic Cancer:118 Controls:234	Y	
213	Assays for early detection of cancer	Anc: Hendrix WHI: Hendrix	Yes	Dropped		OS Ovarian Cancer:200 Controls:200	Y	
212	Biochemical antecedents of fracture in minority women (funded as BA09)	Anc: Cauley WHI: Kuller	Yes	Dropped		OS Fracture (general):1320 Controls:1320	Y	
211	Homocysteine levels, B vitamins and bone health in women	Anc: LeBoff WHI: Manson	No	Dropped		OS Fracture (general):2500 Controls:2500	Y	
210	The effect of a low fat diet on lipid profiles and adipokines in post-menopausal women: potential modulation by select genetic variants	Anc: Thomson WHI: Bassford	No	Dropped		DM	Y	

Table 11.4 (continued)
All Ancillary Studies

AS #	Title	PIs	WHI Investigator	Status	Study Dates	Study Populations*	Blood Study	Ms #(s)
209	Red blood cell omega-3 and trans fatty levels and the risk of coronary heart disease death	Anc: Robinson WHI: Wallace	No	Dropped		OS CHD:800 Controls:800	Y	
208	Pro and anti-inflammatory cytokines and colorectal cancer	Anc: Ho WHI: Smoller	No	Funded	04/25/08-03/31/11	OS Colorectal Cancer:500 Controls:900 *same cases/controls as AS129	Y	
207	IGF and multiple myeloma	Anc: Colditz WHI: Manson	No	Funded	08/01/07-05/31/11	OS/CT Multiple Myeloma:197 Controls:394 *EDTA: 639 (213 cases/ 426 controls)	Y	
206	Selenium, genetic variation in selenoenzymes and colorectal cancer	Anc: Peters WHI: Prentice	No	Funded	07/01/06-06/30/09	OS Colorectal Cancer:805 Controls:805 *Same cases/controls as AS195; controls include 100 Y3 samples	Y	814, 815, 828, 1026
204	Genetic susceptibility of chronic kidney disease	Anc: Vupputuri WHI: Heiss	No	Dropped		OS Kidney Disease:2278 Controls:6834	Y	
203	Infection of helicobacter pylori, other helicobacter species and the risk of pancreatic cancer among postmenopausal women	Anc: Ye WHI: Margolis	No	Dropped		OS/CT Pancreatic Cancer:310 Controls:620	Y	
202	Insulin/IGF and risk of benign breast disease (BBD): a cohort study	Anc: Rohan WHI: Smoller	No	Dropped		CT Benign Breast Disease:1000 Controls:1700	Y	
201	Effect of hormone therapy on angiotensin II and microalbuminuria among postmenopausal women	Anc: Agarwal WHI: Bonds	No	Dropped		HT Microalbuminuria:820 Controls:820 *120 samples for blood measurements	Y	
200	Women's Health Initiative cancer survivor cohort: biological, psychosocial, and behavioral predictors of survival	Anc: Paskett WHI: Jackson	Yes o	Dropped		OS	Y	

Table 11.4 (continued)
All Ancillary Studies

AS #	Title	PIs	WHI Investigator	Status	Study Dates	Study Populations*	Blood Study	Ms #(s)
199	Genetic factors of muscle loss (added to AS191)	Anc: Chen WHI: Bassford	No	Funded		OS Sarcopenia:800 Controls:2000 *Combined with AS191	Y	
198	Women's thoughts and feelings about participating in a clinical trial	Anc: Furniss WHI: Lasser	Yes	Dropped		HT	N	
197	Validity of self-reported diabetes mellitus in the Women's Health Initiative	Anc: Margolis WHI: Margolis	Yes	Analysis	07/01/07-08/31/09	CT 738 Ppts@4 clinics	N	
196	Heart failure evaluation in post-menopausal women: the Women's Health Initiative study	Anc: Klein WHI: Van Horn	No	Funded	09/30/07-08/31/10	HT	N	364, 935
195	Candidate pathways in colorectal carcinogenesis: one-carbon metabolism and inflammation	Anc: Ulrich WHI: Prentice	No	Funded	05/01/08-01/31/13	OS Colorectal Cancer:988 Controls:988 *Same cases/controls as AS206 where possible	Y	
194	Genetic epidemiology of hip fracture in WHI & SOF	Anc: Zmuda WHI: Kuller	No	Dropped		OS Fracture - Hip:700 Controls:1400	Y	
193	Immune dysregulation in the pathogenesis of non Hodgkin's lymphoma	Anc: DeRoos WHI: LaCroix	No	Dropped		OS Lymphoma, Non Hodgkins:500 Controls:1000	Y	
192	Estrogen and progesterone-related genes and colorectal cancer risk	Anc: Zhang WHI: Manson	No	Funded	09/01/06-08/31/10	OS Colorectal Cancer:644 Controls:1288 *Requests 10% blind duplicates (96 pairs)	Y	
191	Biomarkers and genetic factors related to sarcopenia in older women (includes AS199)	Anc: Chen WHI: Bassford	No	Funded	09/15/07-06/30/12	OS Sarcopenia:2800 *2800 for DNA, subset of 1400 for EDTA	Y	
190	Insulin resistance and vitamin D	Anc: Hsia WHI: Hsia	Yes	Dropped		CaD Insulin Resistance	Y	
189	Biochemical and anthropometric heterogeneity among morbid obese women in the Women's Health Initiative observational study	Anc: Mackey WHI: Kuller	No	Funded	05/01/06-04/30/10	OS CHD:144 Controls:1172	Y	698, 699

Table 11.4 (continued)
All Ancillary Studies

AS #	Title	PIs	WHI Investigator	Status	Study Dates	Study Populations*	Blood Study	Ms #(s)
188	Inflammation and the risk of hormonally-linked cancer	Anc: Modugno WHI: Kuller	No	Dropped		OS Breast Cancer:500 Endometrial Cancer:500 Ovarian Cancer:350 Controls:1250 *Maximize case/control overlap with AS129. Extra 750 breast cancer cases for DNA analyses	Y	
187	Serum fatty acids and incidence of ischemic stroke in women	Anc: He WHI: Van Horn	No	Funded	04/01/08-03/31/10	OS Stroke:971 Controls:971 *shares cases and controls with AS126	Y	944
186	Plasma fatty acids and risk of non-Hodgkin's lymphoma in the Women's Health Initiative observational study: a nested case-control study	Anc: Chiu WHI: Van Horn	No	Dropped		OS Lymphoma, Non Hodgkins:290 Controls:870	Y	
185	An assessment of symptoms and symptom self-management for women abruptly stopping hormone replacement study pills (extension of AS160)	Anc: Ritenbaugh WHI: Ritenbaugh	Yes	Dropped		HT E alone	N	
184	Measures for changes in skeletal muscle mass	Anc: Chen WHI: Bassford	No	Dropped		OS/CT	N	
183	Effects of hormone therapy on subclinical neurological pathology: WHIMS-MRI	Anc: Shumaker WHI: Shumaker	Yes	Analysis	07/01/04-06/30/08	HT E+P	N	542, 625, 626, 680, 683, 696, 727, 794, 883, 909, 937, 979, 1047
182	Genetic and epigenetic markers of lung cancer risk in post-menopausal women	Anc: Schlecht WHI: Smoller	No	Dropped		OS Cancer of Lung:720 Controls:1440	Y	
181	Estradiol, cytokines, and bone turnover: effects on hip fracture	Anc: Cauley WHI: Kuller	Yes	Funded	07/01/05-06/30/10	OS Fracture - Hip:400 Controls:400 *same as AS90	Y	634, 681, 714, 861, 878, 910

Table 11.4 (continued)
All Ancillary Studies

AS #	Title	PIs	WHI Investigator	Status	Study Dates	Study Populations*	Blood Study	Ms #(s)
180	Macrovascular complications of diabetes in postmenopausal women	Anc: Li WHI: Johnson	No	Dropped		OS Type 2 Diabetes:3164	Y	
179	Frailty in WHI: drugs, inflammatory and genetic markers	Anc: LaCroix WHI: LaCroix	Yes	Funded	09/15/05-07/31/10	OS Frailty-disability:900 Controls:900	Y	301, 302, 303, 662
178	Mammographic density and invasive breast cancer	Anc: Pisano WHI: Heiss	No	Analysis	03/12/04-08/31/08	CT 793 Ppts@34 clinics Breast Cancer	N	
177	Relative risk differences between FFQs and food records	Anc: Subar WHI: Patterson	No	Complete	09/30/03-09/30/04	DM	N	
176	Long term breast and colorectal cancer survivors in the OS	Anc: Rahmani WHI: Smoller	No	Dropped		OS	N	
175	Physical function determinants in minority women	Anc: Nicholas WHI: Bassford	No	Funded	12/01/03-12/01/10	OS	N	
174	Proinflammatory markers and colorectal cancer	Anc: Ho WHI: Smoller	No	Dropped		OS Colorectal Cancer:500 Controls:900	Y	
173	Relationship of biomarkers and genetic markers to risk of congestive heart failure	Anc: Chae WHI: Manson	No	Dropped		OS CHF:656 Controls:1312	Y	
172	Estrogen receptor polymorphisms and cardiovascular effects of HRT	Anc: Herrington WHI: Burke	No	Dropped		CT	N	
171	Analysis of heart rate variability from ultra-short records: the WHI study	Anc: Michael WHI: Ritenbaugh	Yes	Complete	01/01/03-06/01/03	CT	N	
170	WHI nutrition and diabetes study (WHINDS)	Anc: Margolis WHI: Margolis	Yes	Dropped		DM	N	
169	Risk factors for hemorrhagic stroke among postmenopausal women	Anc: Kaplan WHI: Smoller	No	Dropped		OS Stroke:357 Controls:757	Y	
168	Plasma inflammatory markers and colorectal cancer	Anc: Ho WHI: Smoller	No	Dropped		OS	Y	
167	Sex hormones, risk factors, and risk of ER+ and ER- breast cancer	Anc: Cummings WHI:	Yes	Analysis	01/01/05-05/30/08	OS Breast Cancer:311 Controls:592	Y	622
166	Estrogen replacement therapy and autoantibodies	Anc: Mackay WHI: Smoller	No	Dropped		OS	Y	

Table 11.4 (continued)
All Ancillary Studies

AS #	Title	PIs	WHI Investigator	Status	Study Dates	Study Populations*	Blood Study	Ms #(s)
165	Subclinical thyroid dysfunction and risk of myocardial infarction and stroke	Anc: Hartmann WHI: Heiss	No	Analysis	09/01/04-07/31/08	OS CHD:800 Stroke:591 Controls:3136	Y	402, 403
164	The IGF system and coronary heart disease	Anc: Kaplan WHI: Smoller	No	Dropped		OS CHD:350 Controls:350	Y	
163	Hormone use following the WHI E+P trial termination: a pilot study	Anc: Hays WHI: Hays	Yes	Complete	01/01/03-12/01/04	HT E+P	N	
162	Interactive telephone strategy to maintain diet change	Anc: Beresford WHI: Beresford	Yes	Dropped		CT	N	
161	Bone mass response to termination of estrogen + progestin	Anc: Cauley WHI: Kuller	Yes	Funded	07/10/02-10/01/02	HT E+P	N	
160	An assessment of symptoms and symptom self-management for women abruptly stopping hormone replacement study pills	Anc: Valanis WHI: Ritenbaugh	Yes	Complete	07/01/02-08/17/02	HT E+P	N	
159	The insulin-like growth factor (IGF) system and coronary heart disease	Anc: Kaplan WHI: Smoller	No	Dropped		OS	Y	
158	Potential mediators of the association of depression with CVD	Anc: Wylie-Rosett WHI: Smoller	Yes	Dropped		OS	Y	
157	Prediction of CHD among postmenopausal women using NMR spectroscopy lipoproteins	Anc: Kuller WHI: Kuller	Yes	Dropped		OS	Y	
156	The effect of domestic violence on health care costs and utilization	Anc: Mouton WHI: Schenken	Yes	Dropped		OS	N	
155	Carotenoids, transforming growth factors, and breast cancer risk	Anc: Rohan WHI: Smoller	No	Dropped		OS Breast Cancer:3500 Controls:3500	Y	
154	Serum and DNA precursors of colon cancer	Anc: Garland WHI: Langer	Yes	Dropped		OS Colon cancer:400 Controls:400	Y	

Table 11.4 (continued)
All Ancillary Studies

AS #	Title	PIs	WHI Investigator	Status	Study Dates	Study Populations*	Blood Study	Ms #(s)
153	Longitudinal changes in hip geometry and skeletal muscle	Anc: Chen WHI: Bassford	Yes	Funded	08/15/03- 06/30/10	OS 47 Ppts@Tucson Fracture - Hip	N	340, 456, 487, 489, 547, 566, 569, 633, 658, 687, 690, 691, 712, 888, 964
152	Growth factor genes and female breast, colorectal, and endometrial cancers	Anc: Ho WHI: Smoller	No	Analysis	08/01/03- 07/31/08	OS Breast Cancer:900 Colorectal Cancer:500 Endometrial Cancer:300 Controls:900 *Same as AS129	Y	559, 689, 776, 789, 790, 791
151	Behavioral management of urinary incontinence in African-American women	Anc: Ruff WHI: Howard	No	Dropped		OS	N	
150	Effect of airborne particulate matter and other air pollutants on the incidence of cardiovascular events in the Women's Health Initiative observational study	Anc: Kaufman WHI: Anderson	No	Analysis	05/01/02- 05/31/06	OS/CT CHD:	N	363, 725
149	Gene-environment interactions and human breast cancer risk	Anc: Hu WHI: Paskett	No	Dropped		OS Breast Cancer:800 Controls:800	Y	
148	Relationship between monoclonal hemopoiesis and other molecular abnormalities and the development of leukemia in older women	Anc: Preisler WHI: Black	No	Dropped		OS Leukemia:59 Controls:177	Y	
147	Gene-gene and gene-environment interactions and breast cancer risk	Anc: Eng WHI: Jackson	No	Dropped		OS	Y	
146	A prospective study of pancreatic cancer pathogenesis	Anc: Fuchs WHI: Manson	No	Complete	03/01/03- 12/31/04	OS Pancreatic Cancer:104 Controls:312	Y	482, 483, 484, 576
145	Pancreatic cancer	Anc: Whitcomb WHI: Kuller	No	Dropped		OS	Y	

Table 11.4 (continued)
All Ancillary Studies

AS #	Title	PIs	WHI Investigator	Status	Study Dates	Study Populations*	Blood Study	Ms #(s)
144	Interactions of polymorphisms in selected genes of thrombogenic & thrombolytic systems with hormone replacement therapy as risk factors for atherothrombotic events in postmenopausal women	Anc: Liu WHI:	No	Dropped		OS	Y	163
143	Treatment of elevated cholesterol among US postmenopausal women	Anc: Kaplan WHI: Smoller	No	Dropped		OS	Y	
142	Thrombosis-related genes in population subgroups narrowly defined by race, ethnicity, and place of birth	Anc: Kaplan WHI: Smoller	No	Dropped		OS	Y	
141	Periodontal disease and subclinical cardiovascular disease in post-menopausal women	Anc: Dorn WHI: Trevisan	No	Complete	06/01/01- 03/16/05	OS	N	
140	Air pollution and electrocardiographic abnormalities (Environmental Epidemiology of Arrhythmogenesis in WHI)	Anc: Whitsel WHI: Heiss	No	Funded	09/01/03- 05/31/10	CT	N	388, 389, 415, 430, 528, 529, 608, 609, 710, 850, 854
139	Follow-up of healthy breast cancer survivors in the WHI observational study	Anc: Paskett WHI: Burke	Yes	Complete	02/01/02- 01/31/03	OS	N	
138	The study of tamoxifen, raloxifene, and cognition (Co-STAR)	Anc: Shumaker WHI: Shumaker	Yes	Dropped		HT	N	
137	Postmenopause CHD risk: platelet genes and hormone therapy	Anc: Bray WHI: Hays	Yes	Analysis	09/27/03- 08/31/07	OS CHD:1060 Controls:2120	Y	593
136	The natural history of female pelvic organ prolapse	Anc: Handa WHI: Robbins	No	Dropped		HT	N	
135	Natural history of pelvic organ prolapse in WHI women	Anc: Nygaard WHI: Wallace	No	Complete	02/01/02- 06/30/07	HT	N	317, 323, 331, 495, 592
134	Serum estrogen hormone metabolites, hormone replacement therapy and the risk of breast cancer	Anc: Modugno WHI: Kuller	No	Complete	07/01/02- 05/31/04	OS Breast Cancer:200 Controls:200	Y	209
133	Biochemical and genetic predictors of incident hypertension in white and black women	Anc: Sesso WHI: Manson	No	Funded	08/01/04- 07/31/10	OS Hypertension:800 Controls:800	Y	654, 655

Table 11.4 (continued)
All Ancillary Studies

AS #	Title	PIs	WHI Investigator	Status	Study Dates	Study Populations*	Blood Study	Ms #(s)
132	A prospective study of genetic and biochemical predictors of type 2 diabetes mellitus	Anc: Liu WHI: Manson	No	Funded	08/01/02-07/31/10	OS Type 2 Diabetes:1800 Controls:2500	Y	369, 376, 486, 550, 554, 555, 572, 573, 582, 594, 660, 664, 668, 688, 709, 719, 1050
131	Sex steroid hormones, inflammatory cytokines and the risk of rheumatoid arthritis: a nested case control study	Anc: Shadick WHI: Manson	No	Dropped		OS	Y	
130	Randomized controlled trial of fat reduction, calcium/Vitamin D supplementation, hormone replacement therapy, and risk of proliferative forms of benign breast disease	Anc: Rohan WHI: Smoller	No	Analysis	07/01/01-07/31/08	CT 3901 Ppts@49 clinics Benign Breast Disease Controls	N	508, 509, 544, 584, 585, 586, 587
129	Association of diabetes and insulin-like growth factor-I (IGF-I) with risks of colorectal, breast, and endometrial cancer	Anc: Strickler WHI: Smoller	No	Funded	01/15/02-4/30/11	OS Breast Cancer:900 Colorectal Cancer:500 Endometrial Cancer:300 Controls:900 *same as AS152	Y	459, 460, 461, 959, 1061
128	Mismatch repair gene associated malignancies in women	Anc: Weber WHI: Smoller	No	Dropped		OS Colorectal Cancer:1025 Endometrial Cancer:710 Ovarian Cancer:405 Controls:1000 *sharing ovarian cases with AS97	Y	
127	CHD risk perception study	Anc: Barnhart WHI: Smoller	No	Analysis	05/15/02-04/30/07	OS	N	659
126	Stroke risk factors and molecular markers in postmenopausal women	Anc: Smoller WHI: Smoller	Yes	Analysis	08/01/03-07/31/06	OS Stroke:972 Controls:972	Y	601, 602, 603, 604, 672, 679, 829, 869, 872, 1061

Table 11.4 (continued)
All Ancillary Studies

AS #	Title	PIs	WHI Investigator	Status	Study Dates	Study Populations*	Blood Study	Ms #(s)
125	Osteoporosis in caribbean hispanic women	Anc: Cohen WHI: Smoller	No	Dropped		OS/CT	N	
124	Sociocultural influences on motivation for and maintenance of health-related dietary change among women	Anc: Namie WHI: Langer	No	Complete	06/01/00-12/01/00	DM	N	
123	Genetic and ethnic determinants of nicotine addiction in postmenopausal women	Anc: David WHI: Assaf	No	Dropped		OS/CT	N	
122	Feasibility study of computerized tailored dietary feedback	Anc: Glanz WHI: Curb	No	Complete	03/10/00-09/01/00	DM	N	
121	Hyperinsulinemia and ovarian cancer	Anc: Modugno WHI: Kuller	No	Complete	09/01/02-08/31/04	OS Ovarian Cancer:225 Controls:225 *originally a subset of AS97	Y	
120	Epidemiology of cervical and lumbar stenosis	Anc: Vogt WHI: Kuller	No	Dropped		OS	N	
119	The longevity consortium	Anc: Langer WHI: Langer	Yes	Dropped		OS/CT	N	
118	Accuracy of food portion estimation among postmenopausal women	Anc: Coy WHI: Hubble	No	Complete	12/01/99-04/01/00	DM	N	312
117	Risk factors for dry eye syndrome in postmenopausal women	Anc: Nichols WHI: Jackson	No	Analysis	02/01/01-04/30/12	OS 217 Ppts@Columbus	N	
116	National validation and quality assurance of vitamin D absorption from CaD tablets	Anc: Garland WHI: Langer	Yes	Dropped		CaD	N	
115	Diabetes in postmenopausal women	Anc: Howard WHI: Howard	Yes	Dropped		OS/CT Type 2 Diabetes	N	
114	Effects of hormone replacement therapy on cardiac function and ischemia	Anc: Haan WHI: Robbins	Yes	Dropped		HT	N	
113	Some aspects of mediterranean diet in relation to risk of chronic diseases among postmenopausal women	Anc: Hakim WHI: Bassford	No	Complete	08/01/99-07/31/02	OS	N	
112	Motivators and barriers to exercise in older women	Anc: Haan WHI:	Yes	Dropped		OS	N	
111	Glycemic index/glycemic load and blood lipids in the WHI	Anc: Shikany WHI: Lewis	Yes	Complete	07/01/03-06/30/05	OS/CT	N	172, 385, 463, 574

Table 11.4 (continued)
All Ancillary Studies

AS #	Title	PIs	WHI Investigator	Status	Study Dates	Study Populations*	Blood Study	Ms #(s)
110	Sex steroid hormones and risk of coronary heart disease: a nested case control study	Anc: Rexrode WHI: Manson	No	Complete	09/01/00-07/31/05	OS CHD:385 Controls:385 *79 matched cases-controls and 92 cases (but not controls) overlap with AS83.	Y	159, 266, 305
109	Proteomics initiative	Anc: Hsia WHI: Hsia	Yes	Dropped		HT CHD:100 Controls:100	Y	
108	Gene-environment effects and colorectal cancer	Anc: Lin WHI: Chlebowski	No	Complete	04/01/03-07/31/07	OS Colorectal Cancer:50 Controls:150	Y	507
107	Hashimoto's thyroiditis in postmenopausal women	Anc: Zakarija WHI: O'Sullivan	No	Dropped		OS Controls:2900	Y	
106	Gene-diet interactions in human breast cancer risk	Anc: Hu WHI: Paskett	No	Dropped		OS/CT	N	
105	Carotenoids in age-related eye disease study (also see M1)	Anc: Mares-Perlman WHI: Sarto	No	Analysis	06/01/00-08/31/10	OS 2007 Ppts@4 clinics Eye:1000 Controls:1000	Y	307, 308, 371, 444, 452, 835, 903, 904, 915, 950
104	Tamoxifen prevention: Is it acceptable to women at risk?	Anc: Melnikow WHI: Robbins	No	Complete	07/01/99-06/30/02	OS	N	
103	Effects of hormone replacement therapy on cognitive aging: Women's Health Initiative study of cognitive aging (WHISCA)	Anc: Shumaker WHI: Shumaker	Yes	Funded	04/01/99-06/30/10	HT 2266 Ppts@15 clinics	N	216, 237, 325, 579, 598, 695, 899, 914, 980, 1038
102	Quality of life improvements and willingness to pay: an investigation of selective estrogen receptor modulators	Anc: Fouad WHI: Oberman	Yes	Complete	09/01/98-10/01/98	OS	N	
101	Women's Health oral history project	Anc: Allen WHI: Allen	Yes	Dropped			N	
100	Genetic, biochemical and behavioral determinants of obesity	Anc: Hays WHI: Hays	Yes	Funded	01/01/99-04/30/04	OS 797 Ppts@3 clinics	N	

Table 11.4 (continued)
All Ancillary Studies

AS #	Title	PIs	WHI Investigator	Status	Study Dates	Study Populations*	Blood Study	Ms #(s)
99	Genetics of non-insulin dependent diabetes (GENNID)	Anc: Chlebowski WHI: Chlebowski	Yes	Complete	12/01/98-03/31/00	OS/CT	N	
98	Bone mineral density as a predictor for periodontitis	Anc: Wactawski-Wende WHI: Trevisan	Yes	Funded	04/01/02-03/30/07	OS 969 Ppts@Buffalo	N	271, 326, 527, 632, 652, 813, 928
97	Modeling serum markers for cost-effective ovarian cancer screening	Anc: Anderson WHI: Anderson	Yes	Analysis	09/30/01-06/30/09	OS Ovarian Cancer:280 Controls:558	Y	381
96	Longitudinal insulin sensitivity and postmenopausal HRT	Anc: Cottrell WHI:	No	Dropped		OS/CT	N	
95	Work organization, psychological distress, and health among minority older women	Anc: Rodriguez WHI: Curb	Yes	Complete	12/01/97-12/01/97	OS	N	
94	The effect of lowfat dietary modification on markers of bone turnover and bone mineral density	Anc: Jackson WHI: Jackson	Yes	Dropped		OS/CT	N	
93	The epidemiology of venous disease	Anc: Criqui WHI: Langer	Yes	Complete	03/11/98-06/30/99	OS	N	
92	Fasting glucose in baseline plasma from all CT participants	Anc: Howard WHI: Howard	Yes	Dropped		CT	N	
91	Alterations in calcium and calcitropic hormone levels in 4 ethnic groups in response to CaD supplementation: possible effect modulation by VDR phenotype	Anc: Lester WHI:	No	Dropped		CT	N	
90	WHI sex hormone and genetic risk factors for hip fracture	Anc: Cummings WHI:	Yes	Analysis	04/01/03-03/31/07	OS Fracture - Hip:400 Controls:400 *same as AS181	Y	479, 480, 481, 543, 563
89	Effect of HRT on plasma homocysteine concentration	Anc: Manson WHI: Manson	Yes	Dropped		HT	N	
88	Cholesterol distribution in lipoprotein particles in WHI DM intervention participants consuming a low-fat dietary pattern compared to comparison participants consuming their usual fat intake	Anc: Tinker WHI: Grimm	Yes	Dropped		DM	N	

Table 11.4 (continued)
All Ancillary Studies

AS #	Title	PIs	WHI Investigator	Status	Study Dates	Study Populations*	Blood Study	Ms #(s)
87	The effect of dietary change on blood flavonoid and F2-isoprostane levels	Anc: Simon WHI: Hendrix	No	Dropped		DM	N	
86	A pilot study to determine the sensitivity of form 39 to impaired executive control function (ECF) as measured by the CLOX: an executive clock-drawing task	Anc: Polk WHI: Schenken	No	Complete		HT	N	
85	Brain imaging with fluorometatyrosine in post-menopausal women on or off hormonal replacement therapy - implications for schizophrenia	Anc: Nordahl WHI:	No	Dropped			N	
84	Estrogen, vitamin E and cognitive change in women	Anc: Dunn WHI: Van Horn	Yes	Funded	09/01/01-02/28/10	OS/CT 546 Ppts@2 clinics	N	421, 600, 616, 621, 940
83	Thrombotic, inflammatory and genetic markers for coronary heart disease in postmenopausal women: a WHI umbrella study	Anc: Ridker WHI: Manson	No	Complete	09/01/99-08/31/03	OS CHD:650 Controls:650	Y	127, 128, 129
82	Extension of bone mineral density assessment in WHI Native American women	Anc: Chen WHI: Ritenbaugh	Yes	Complete	07/01/97-06/30/01	OS	N	
81	Androgeneic hair growth in postmenopausal women	Anc: Freeman WHI: Smoller	No	Dropped		OS	N	
80	Combine effect of HRT and heritable prothrombotic mutations on the risk of deep venous thrombosis (DVT) and pulmonary embolus (PE)	Anc: Psaty WHI:	Yes	Dropped		HT	N	
79	How a low fat diet is related to adiposity and body fat distribution: cross-sectional and longitudinal evaluation	Anc: Wylie-Rosett WHI: Smoller	Yes	Dropped		OS/CT	N	
78	Community strategy to retain women enrolled in research	Anc: Fouad WHI: Oberman	Yes	Complete	07/01/97-09/30/97	CT	N	
77	HRT decision project	Anc: Kerner WHI: Langer	No	Dropped		OS/CT	N	
76	Tailored messages to enhance adherence of older women to dietary programs for breast cancer control	Anc: Chlebowski WHI: Chlebowski	Yes	Complete	09/01/97-08/13/98	DM	N	
75	Adherence to dietary modification in the WHI	Anc: Rosal WHI: Ockene	Yes	Analysis	09/01/97-08/30/02	DM	N	126, 267

Table 11.4 (continued)
All Ancillary Studies

AS #	Title	PIs	WHI Investigator	Status	Study Dates	Study Populations*	Blood Study	Ms #(s)
74	The effectiveness of individual versus group behavioral strategies to increase participants adherence	Anc: Wodarski WHI: Trevisan	No	Complete	07/01/97-09/30/97	DM	N	
73	Psychosocial and cultural determinants of NIDDM in Latinas	Anc: Ritenbaugh WHI: Langer	Yes	Complete	05/01/97-04/30/98	OS	N	
72	Ethnicity, body composition, bone density and breast cancer	Anc: Chen WHI: Ritenbaugh	Yes	Dropped		OS	N	
71	Assessing stages of change in postmenopausal women enrolled in the dietary modification arm of the WHI	Anc: Brewer WHI: Applegate	No	Dropped		DM	N	
70	The prevalence and prognostic importance of myocardial ischemia during daily life, and its relationship to migraine status: WHI	Anc: Sheps WHI: Heiss	Yes	Complete	09/01/97-08/31/00	OS	N	171, 183, 716
69	Birth place and CVD risk in women	Anc: Wylie-Rosett WHI: Smoller	Yes	Dropped		OS/CT	N	
68	Coronary artery calcification detected with ultrafast CT as an indication of CAD in OS participants	Anc: Hsia WHI: Hsia	Yes	Complete	01/01/97-12/31/05	OS 735 Ppts@2 clinics	N	
67	Prevalence and natural history of autoimmune thyroid disease in postmenopausal women	Anc: Zakarija WHI: O'Sullivan	No	Dropped		OS	N	
66	Quantitative, patient-specific serially comparable (QPS) mammography	Anc: Morrisett WHI: Foreyt	No	Dropped		OS/CT	N	
65	Benign breast disease	Anc: Rohan WHI:	No	Complete	07/01/98-08/30/00	DM 101 Ppts@12 clinics	N	
64	Examine mammography sensitivity in WHI women	Anc: Foreyt WHI: Foreyt	Yes	Dropped		CT	N	
63	Development and evaluation of eating style index	Anc: Haines WHI: Heiss	No	Complete	10/01/96-06/30/99	OS	N	
62	Prevention of age-related maculopathy in the WHI HRT CT: WHI-SE	Anc: Haan WHI: Robbins	Yes	Analysis	01/01/99-01/01/07	HT 4430 Ppts@21 clinics	N	250, 251, 253, 476, 819
61	Longitudinal assessment of memory functioning in the WHI clinical trial	Anc: Ober WHI: Robbins	No	Analysis	09/01/96-08/31/09	HT	N	
60	Fat intake in husbands of WHI dietary arm participants	Anc: Shikany WHI: Oberman	Yes	Complete	12/01/96-12/01/96	DM	N	

Table 11.4 (continued)
All Ancillary Studies

AS #	Title	PIs	WHI Investigator	Status	Study Dates	Study Populations*	Blood Study	Ms #(s)
59	Prevalence and natural history of autoimmune thyroid disease (AITD) in postmenopausal women	Anc: Zakarija WHI: Greenland	No	Dropped		OS/CT	N	
58	Enrollment of hispanic women in prevention trials	Anc: Trapido WHI: Baum	No	Dropped		OS/CT	N	
57	Hispanic women's advocacy and retention strategies	Anc: Ritenbaugh WHI: Ritenbaugh	Yes	Complete	09/01/96-08/31/98	OS	N	
56	Behavioral and psychosocial predictors of dietary change in postmenopausal women	Anc: Pleuss WHI: Burke	No	Complete	09/01/96-08/31/98	DM	N	
55	Predictors of participation among latinos in clinical trials	Anc: Talavera WHI:	Yes	Dropped		OS/CT	N	
54	Women and minority recruitment / retention: a community-based intervention	Anc: Fouad WHI: Oberman	Yes	Dropped		DM	N	
53	A prospective study of diet and hormones in the development of prostate cancer	Anc: Kabat WHI: Smoller	No	Dropped		OS/CT	N	
52	Genetic polymorphisms in the hormonal etiology of breast cancer	Anc: McTiernan WHI:	Yes	Dropped		OS Breast Cancer	N	
51	Cross-sectional and longitudinal evaluation of bone quality	Anc: LeBlanc WHI: Foreyt	No	Dropped		OS/CT	N	
50	Nutrition practice guidelines for maintaining low-fat dietary change in post menopausal women	Anc: Burrows WHI: Grimm	Yes	Complete	10/01/96-09/30/97	DM	N	
49	Applying creative self-monitoring in the WHI	Anc: Rahmani WHI: Rahmani	Yes	Dropped		DM	N	
48	Prostate cancer survey of spouses of WHI screened women	Anc: Smoller WHI: Smoller	Yes	Complete	02/01/96-06/30/96	OS/CT	N	
47	Effect of diet intervention on motivation to make other health-related changes	Anc: WHI: Langer	Yes	Complete	05/01/96-04/30/97	DM	N	
46	Prostate and colorectal cancer in WHI dietary arm husbands	Anc: Oberman WHI: Oberman	Yes	Dropped		DM	N	
45	Response set biases in dietary self-report in the WHI DM	Anc: Herbert WHI:	Yes	Dropped		DM	N	
44	Estrogen and vaginal pH	Anc: Schaeffer WHI: Greenland	No	Dropped		HT	N	
43	Decrease of bone mass in older women	Anc: Goodman WHI: Judd	No	Dropped		CT	N	

Table 11.4 (continued)
All Ancillary Studies

AS #	Title	PIs	WHI Investigator	Status	Study Dates	Study Populations*	Blood Study	Ms #(s)
42	Impact of insurance status on health outcomes and health services utilization in the WHI	Anc: Hsia WHI: Miller	Yes	Dropped		OS	N	
41	Metabolism of lipoprotein and HRT	Anc: Morrisett WHI: Foreyt	No	Dropped		OS	N	
40	Ethnic and age differences in use of mammography	Anc: Smoller WHI: Smoller	Yes	Complete		OS	N	
39	The effects of HRT on the development and progression of dementia (WHIMS)	Anc: Shumaker WHI: Shumaker	Yes	Complete	06/01/96- 05/31/05	HT 7528 Ppts@48 clinics	N	60, 138, 173, 225, 226, 274, 276, 332, 336, 360, 370, 390, 397, 399, 427, 546, 558, 595, 597, 612, 639, 665, 670, 683, 727, 750, 881, 883, 938
38	Hemostatic/thrombotic and genetic markers for coronary disease in postmenopausal women	Anc: Ridker WHI: Manson	No	Dropped		OS	Y	
37	Lipid markers of atherosclerotic disease in post menopausal women	Anc: Manson WHI: Manson	Yes	Dropped		OS	Y	
36	HRT and changes in mammographic density	Anc: Hulka WHI: Heiss	Yes	Complete	01/31/98- 12/31/02	HT 857 Ppts@19 clinics Breast Cancer	N	285, 358, 694
35	Risk factors for fatigue in women ages 50 to 75	Anc: Hartz WHI: Kotchen	No	Dropped		CT	N	
34	Ethnic differences in hip bone geometry by DXA and QCT	Anc: Nelson WHI: Hendrix	No	Complete	12/01/96- 12/31/02	HT 311 Ppts@Detroit	N	
33	The association of HRT with abdominal and total body fat in postmenopausal women	Anc: Mayo WHI: Oberman	No	Complete	07/31/95- 03/31/96	OS	N	
32	Recruitment techniques in getting minority women to participate in breast cancer clinical trials	Anc: Boe WHI: Langer	No	Dropped		OS/CT	N	

Table 11.4 (continued)
All Ancillary Studies

AS #	Title	PIs	WHI Investigator	Status	Study Dates	Study Populations*	Blood Study	Ms #(s)
31	Eye care use	Anc: Kleinstein WHI: Oberman	No	Complete		OS	N	
30	The role of endocrine factors in the etiology of lung cancer in women	Anc: Kabat WHI: Smoller	No	Dropped		OS	N	
29	HRT and cardiovascular biomarkers related to oxidation status and platelet function	Anc: Gaziano WHI: Manson	No	Dropped		HT	N	
28	Perspectives on aging	Anc: Smoller WHI: Smoller	Yes	Dropped		OS/CT	N	
27	Vitamin D, calcium, and breast cancer	Anc: Hulka WHI: Sheps	Yes	Dropped		OS/CT	Y	
26	HRT and knee/hip osteoarthritis	Anc: Cerhan WHI: Wallace	No	Dropped		HT	N	
25	Ankle-arm blood pressure index measurement	Anc: Masaki WHI: Curb	No	Complete	02/01/96- 01/01/98	OS	N	
24	Cross-ethnic comparisons of skeletal health of postmenopausal women in San Diego county	Anc: Schneider WHI: Langer	No	Complete	01/03/95- 01/02/97	OS	N	
23	Non-steroidal anti-inflammatory drugs and cancers of the breast and colon	Anc: Harris WHI: Jackson	No	Dropped		OS/CT	N	
22	Vascular compliance as a predictor of cardiovascular disease in postmenopausal women	Anc: Robinson WHI: Grimm	No	Dropped		CT	N	
21	Effect of DM, HRT and CaD admin on progression of coronary atherosclerosis assessed by EBCT	Anc: Detrano WHI: Chlebowski	No	Dropped		CT	N	
20	Coronary screening of postmenopausal women using EBCT	Anc: Detrano WHI: Chlebowski	No	Dropped		OS	N	
19	Coagulation proteins, anticardiolipin antibodies and stroke in women	Anc: Orencia WHI: Greenland	No	Dropped		OS/CT	N	
18	WHT:FSMP DM follow-up	Anc: Grizzle WHI:	No	Dropped		DM	N	
17	Domestic violence in older women	Anc: Mouton WHI: Lasser	Yes	Complete	10/25/94- 10/24/96	OS	N	
16	Lower extremity atherosclerotic disease	Anc: McDermott WHI: Greenland	No	Dropped		OS	N	

Table 11.4 (continued)
All Ancillary Studies

AS #	Title	PIs	WHI Investigator	Status	Study Dates	Study Populations*	Blood Study	Ms #(s)
15	The relationship between osteopenia and periodontitis	Anc: Wactawski-Wende WHI: Trevisan	Yes	Complete	09/16/96-09/15/01	OS 1468 Ppts@Buffalo	N	553
14	High density lipoprotein metabolism	Anc: Going WHI: Moon	No	Complete	07/01/94-06/30/96	OS	N	
13	Prevalence and correlates of lumbar spinal stenosis	Anc: Vogt WHI: Kuller	No	Complete		CT	N	
12	Empowerment/nutritional counseling	Anc: Mouton WHI: Lasser	Yes	Dropped		DM	N	
11	Validation and exploration of sleep and mood predictors	Anc: Kripke WHI: Langer	Yes	Complete	08/01/95-07/31/99	OS	N	43, 749
10	Urinary estrogen metabolites and breast cancer risk	Anc: Meilahn WHI: Kuller	No	Dropped		DM	N	
9	Oral bone loss	Anc: Jeffcoat WHI: Lewis	No	Complete	05/29/95-11/30/04	OS 450 Ppts@Birmingham	N	72
8	Partner's health study	Anc: Langer WHI: Langer	Yes	Dropped			N	
7	Effect of HRT on cardiovascular morbidity and mortality in postmenopausal women with a low ankle/arm BPI	Anc: Kuller WHI: Kuller	Yes	Dropped		HT	N	
6	Incidence and impact of arthritis in older women	Anc: Hughes WHI: Greenland	No	Dropped		OS/CT	N	
5	Explanations for the development of fat distaste	Anc: Green WHI: Bowen	No	Complete	04/01/95-09/30/96	DM	N	
4	Dietary modification and prostate cancer in WHI husbands	Anc: Shikany WHI: Oberman	Yes	Dropped		DM	N	
3	PLCO offer to WHI-partners (PLCO-Partners)	Anc: Weissfeld WHI: Kuller	No	Dropped		OS/CT	N	
2	Prostate, lung, colorectal, and ovarian cancer screening trial (PLCO-OS)	Anc: Weissfeld WHI: Kuller	No	Dropped		OS/CT	N	
1	Arterial disease artherosclerosis prevention trial (ADAPT)	Anc: Crouse WHI: Burke	No	Dropped		DM	N	

*Number of Field Centers includes number of satellite sites.

Table 11.5
Recruitment to Ancillary Studies Requiring Separate Consents by Field Centers
Data as of August 14, 2009

	9	15	34	36	39	62	65	68	84	98	100	103	105
	Oral Bone Loss	The Relationship Between Osteopenia and Periodontitis	Ethnic Differences in Hip Bone Geometry by DXA and QCT	HRT and Changes in Mammographic Density	The Effects of HRT on the Development and Progression of Dementia (WHIMS)	Prevention of Age-Related Maculopathy in the WHI HRT CT: WHI-SE	Benign Breast Disease	Coronary Artery Calcification Detected with Ultrafast CT as an Indication of CAD in OS	Estrogen, Vitamin E and Cognitive Change in Women	Bone Mineral Density as a Predictor for Periodontitis	Genetic, Biochemical and Behav Determinants of Obesity	Effects of HRT on Cognitive Aging: WHI Studyof Cognitive Aging(WHISCA)	Carotenoids in Age-Related Eye Disease Study
Total	**450**	**1468**	**311**	**857**	**7528**	**4430**	**101**	**735**	**546**	**969**	**797**	**2266**	**2007**

Table 11.5 (continued)
Recruitment to Ancillary Studies Requiring Separate Consents by Field Centers
Data as of August 14, 2009

	117	130	153	178	197	216	218	219	233	W25	262	W30	Total
	Risk Factors for Dry Eye Syndrome in Postmenopausal Women	Randomized Controlled Trial of Fat Reduction, Calcium/ Vitamin D Supplementation, HRT, and Risk of Proliferative Forms of Benign Breast Disease	Longitudinal Changes in Hip Geometry and Skeletal Muscle	Mammographic Density and Invasive Breast Cancer	Validity of self-reported diabetes mellitus in the WHI	Decision-making About Cancer Screening Among Older Women	WHI Nutrition and Physical Activity Assessment Study (NPAAS)	Diet and Eye Health in the WHI: End of Trial Study	WHIMS Extension	WHI Coronary Artery Calcification Study in E-Alone	Memory Study of Younger Women (WHIMS-Y)	Dietary Assessment Study	
Total	**217**	**3901**	**47**	**793**	**738**	**1300**	**450**	**400**	**3074**	**1141**	**1**	**134**	**34661**

Table 11.6
Participant Enrollment in WHI Ancillary Studies
Requiring Separate Consents

Data as of August 14, 2009

CT+OS			
	Ppts	**%**	
CT+OS	161808		
Not Enrolled in Ancillary Studies	137393	84.91	
Enrolled in Ancillary Studies	24415	15.09	
Number of Studies	**Ppts**	**%**	**Enrollments**
1	17494	10.81	17494
2	4484	2.77	8968
3	1808	1.12	5424
4	559	0.35	2236
5	68	0.04	340
6	2	0.00	12
Total	**24415**	**15.09**	**34474**

Extension			
	Ppts	**%**	
Consented to Extension	115406		
Not Enrolled in Ancillary Studies	95199	82.49	
Enrolled in Ancillary Studies	20207	17.51	
Number of Studies	**Ppts**	**%**	**Enrollments**
1	13995	12.13	13995
2	3889	3.37	7778
3	1702	1.47	5106
4	552	0.48	2208
5	67	0.06	335
6	2	0.00	12
Total	**20207**	**17.51**	**29434**

Table 11.7
Funded BAA and Ancillary Studies PI List

Investigator		WHI	PI for	Sponsoring WHI PI for	Supporting CCC PI for
Last Name	First Name	Investigator	Study #	Study #	Study #
Anderson	Garnet	Yes	97	97, 150	97, 121, 129, 140, 150, BA6, BA11, BA15, BA21, M8
Barnhart	Janice	No	127		
Bassford	Tamsen	Yes		113, 153, 175, 191, 199	
Bird	Cloe	No	220		
Bowen	Deborah	Yes		5	39
Bray	Paul	Yes	137		
Burke	Greg	Yes		56, 139	
Burrows	Beth	Yes	50		
Caan	Bette	Yes		243	
Cauley	Jane	Yes	161, 181, BA9		
Chanock	Stephen	No	M3, M4, M8		
Chen	Zhao	No	82, 153, 191, 199		
Chlebowski	Rowan	Yes	76, 99	76, 99, 108	
Cochrane	Barbara	Yes			110, 133, 134, 146, 167, 192, 196, 214, 242, 250, 262
Colditz	Graham	No	207		
Cook	Nancy	No	BA22		
Coy	Christine	No	118		
Criqui	Michael	Former	93		
Cummings	Steve	Yes	90, 167, BA7		
Curb	David	Yes		25, 95, 122	
DeRoos	Anneclaire	No	BA13		
Dorn	Joan	No	141		
Driscoll	Ira	No	250		
Dunn	Julie	Yes	84		
Fouad	Mona	Yes	78, 102		
Fuchs	Charles	No	146, 214		
Glanz	Karen	No	122		
Going	Scott	No	14		
Green	Pamela	No	5		
Grimm	Richard	Yes		50	
Gunter	Marc	No	BA21		
Haan	Mary	Yes	62		
Haines	Pam	No	63		
Hakim	Iman	No	113		
Han	Jiali	No	242		
Hanash	Sam	No	BA17		
Harris	William S.	No	BA19		
Hartmann	Katherine	No	165		
Hays	Jennifer	Yes	100, 163	100, 137, 163	
He	Ka	No	187		

Table 11.7 (continued)
Funded BAA, and Ancillary Studies PI List

Investigator		WHI	PI for	Sponsoring WHI PI for	Supporting CCC PI for
Last Name	First Name	Investigator	Study #	Study #	Study #
Heiss	Gerardo	Yes		34, 36, 63, 70, 140, 165, 178,	
Hendrix	Susan	Yes		236	
Hingorani	Sunil	No	BA16		
Ho	Gloria	No	152, 208, BA10		
Howard	Barbara	Yes		217	
Hsia	Judith	Yes	68	68	
Hubble	Allan	Yes		118	
Hulka	Barbara	Yes	36		
Hunt	Julie	Yes			220, 223
Jackson	Rebecca	Yes	271, BA3, BA18	117, 223, 271, BA3	
Jeffcoat	Marjorie	No	9		
Kaufman	Joel	Yes	150		
Kerwin	Diana	No	235		
Klein	Liviu	No	196		
Kleinstein	Robert	No	31		
Kooperberg	Charles	Yes	M6	M6	90, 126, BA10, BA12, BA18, BA19, BA20
Kotchen	Jane	Yes		235	
Kripke	Daniel	No	11		
Kuller	Lew	Yes	BA12	13, 121, 134, 161, 181, 189	
LaCroix	Andrea	Yes	179	179, M4	79, 83, 137, 153, 165, 181, 191, 199, BA3, BA7, BA9, BA13, BA14, BA22, M2
Lane	Dorothy	Yes		216	
Langer	Robert	Yes		11, 24, 47, 73, 93, 124	
Lasser	Norm	Yes		17	
Lee	I-Minn	No	BA11		
Lewis	Beth	Yes		9, 111	
Li	Rongling	No	BA5		
Lichtenstein	Alice	No	BA8		
Lin	Henry	No	108		
Liu	Simin	Yes	132, 254		
Lund	Bernedine	Yes			206, 224
Mackey	Rachel	No	189		
Manson	JoAnn	Yes		83, 110,132, 133, 146, 192, 207, 214, 242, BA11	
Mares	Julie	Yes	105, 219		
Margolis	Karen	Yes	197	197, 220	
Masaki	Kamal	Former	25		
Mayo	Charlotte	No	33		
McIntosh	Martin	No	BA15		
McTiernan	Anne	Yes			36, 178
Melnikow	Joy	No	104		
Messina	Catherine	Yes	216		

Table 11.7 (continued)
Funded BAA, and Ancillary Studies PI List

Investigator		WHI	PI for	Sponsoring WHI PI for	Supporting CCC PI for
Last Name	First Name	Investigator	Study #	Study #	Study #
Michael	Yvonne	Yes	171		
Modugno	Francesmary	No	121, 134		
Moon	Tom	Former		14	
Moreland	Larry W.	No	BA20		
Mouton	Charles	Yes	17		
Namie	Joylin	No	124		
Nathan	Lauren	Yes		254	
Nelson	Dorothy	No	34		
Neuhouser	Marian	Yes			130, 195, 207, 236, BA8
Nicholas	J. Skye	No	175		
Nichols	Kelley	No	117		
Nygaard	Ingrid	No	135		
Ober	Beth	No	61		
Oberman	Albert	Former		31, 33, 60, 78, 102	
Ockene	Judith	Yes		75	
Paskett	Electra	Yes	139, 223		
Patterson	Ruth	Former		177	65, 108
Peters	Ulrike	No	206, 224		
Pisano	Etta	No	178		
Pleuss	Joan	No	56		
Polk	M.J.	No	86		
Prentice	Ross	Yes	218, BA2, BA4	195, 206, 218, 224, M3	84, BA1, BA2, BA4, BA5, BA16, BA17
Rajkovic	Aleksandar	Yes		M8	
Reiner	Alexander	No	BA14, M13		
Rexrode	Kathryn	No	110		
Ridker	Paul	No	83		
Ritenbaugh	Cheryl	Formero	57, 73	57, 82, 160, 171	
Robbins	John	Yes		61, 62, 104, BA1	
Rodriguez	Beatriz	Yes	95		
Rohan	Tom	No	65, 130		
Rosal	Milagros	No	75		
Sarto	Gloria	Yes		105, 219, M1	
Schenken	Robert	Former		86	
Schneider	Diane	No	24		
Seldin	Michael	No	BA1		
Sesso	Howard	No	133		
Sheps	David	Former	70		
Shikany	James	Yes	60, 111		
Shumaker	Sally	Yes	39, 103, 183, 233, 262	39, 103, 183, 233, 250, 262	
Siega-Riz	Anna Maria	No	236		
Smoller	Sylvia	Yes	40, 48, 126	40, 48, 126, 127, 129, 130, 152, 208, BA10	
Sternfeld	Barbara	No	243		
Strickler	Howard	No	129		

Table 11.7 (continued)
Funded BAA, and Ancillary Studies PI List

Investigator		WHI	PI for	Sponsoring WHI PI for	Supporting CCC PI for
Last Name	First Name	Investigator	Study #	Study #	Study #
Subar	Amy	No	177		
Tinker	Lesley	Yes			105, 111, 132, 152, 154, 187, 189, 208, 218, 219, 271, M1
Trevisan	Maurizio	Former		15, 74, 98, 141	
Ulrich	Cornelia	No	195		
Valanis	Barbara	Former	160		
Van Horn	Linda	Yes		84, 187, 196	
Vogt	Molly	No	13		
Wactawski-Wende	Jean	Yes	15, 98		
Wallace	Robert	Yes		135	
Wallitt	Brian	No	217		
Whitsel	Eric	No	140		
Wodarski	Lois	No	74		
Xu	Jianfeng	No	BA6		
Zhang	Shumin	No	192		

Table 12.1
WHI Manuscript Stages

Stage #	Definition	Number
12	Published	420
11	In press / accepted by journal	11
10	Submitted to journal	32
9	Final manuscript approved by P&P Committee	50
8	Final manuscript submitted to P&P Committee	8
7	Draft manuscript	32
6	Analysis completed	16
5	Analysis in progress	45
4	Analysis proposed	8
3	Manuscript proposal and writing group approved	165
2*	Approved/Writing group nominations open	44

*Stage 2 papers not included in Table 12.2

Table 12.2
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
1	Informed consent in the Women's Health Initiative Clinical Trial and Observational Study	**McTiernan,** Rossouw, Manson, Franzi, Taylor, Carleton, Johnson, Nevitt	12	Gen	J Womens Health. 1995;4(5):519-29	
4	The Women's Health Initiative: Overview of the nutrition components	**Tinker,** Burrows, Henry, Patterson, VanHorn, Rupp	12	Gen	In: Krummel DA, Kris-Etherton PM, eds. Nutrition and women's health. Gaithersburg, MD: Aspen Publishers,1996:510-42	
5	Women's Health Initiative: Why now? What is it? What's new?	**Matthews,** Shumaker, Bowen, Langer, Hunt, Kaplan, Klesges, Ritenbaugh	12	Gen	Am Psychol. 1997 Feb;52(2):101-16	
6	Low-fat diet practices of older women: Prevalence and implications for dietary assessment	**Patterson,** Kristal, Coates, Tylavsky, Ritenbaugh, VanHorn, Caggiula, Snetselaar	12	Gen	J Am Diet Assoc. 1996 Jul;96(7):670-9	
7	The evolution of the Women's Health Initiative: Perspectives from the NIH	**Rossouw,** Finnegan, Harlan, Pinn, Clifford, McGowan	12	Gen	J Am Med Womens Assoc. 1995 Mar-Apr;50(2):50-5	
8	Design of the Women's Health Initiative clinical trial and observational study	**The Women's Health Initiative Study Group**	12	Gen	Control Clin Trials. 1998 Feb;19(1):61-109	
9	Approaches to monitoring the results of long-term disease prevention trials: Examples from the Women's Health Initiative	**Freedman,** Anderson, Kipnis, Prentice, Wang, Rossouw, Wittes, DeMets	12	CT	Control Clin Trials. 1996;Dec 17(6):509-525	
11	The role of randomized controlled trials in assessing the benefits and risks of long-term hormone replacement therapy: Example of the Women's Health Initiative	**Prentice,** Rossouw, Johnson, Freedman, McTiernan	12	CT	Menopause. 1996;3(2):71-76	
12	Is insurance a more important determinant of healthcare access than perceived health? Evidence from the Women's Health Initiative	**Hsia,** Kemper, Sofaer, Bowen, Kiefe, Zapka, Mason, Lillington, Limacher	12	Gen	J Womens Health Gend Based Med. 2000 Oct;9(8):881-9	
13	Depression and cardiovascular sequelae in postmenopausal women. The Women's Health Initiative (WHI)	**Wassertheil-Smoller,** Shumaker, Ockene, Talavera, Greenland, Cochrane, Robbins, Aragaki, Dunbar	12	Gen	Arch Intern Med. 2004 Feb 9;164(3):289-98	

See Table 12.1 for Stage # key.

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
16	Differences between estimated caloric requirements and self-reported caloric intake in the Women's Health Initiative	**Hebert,** Patterson, Gorfine, Ebbeling, St. Jeor, Chlebowski	12	Gen	Ann Epidemiol. 2003 Oct;13(9):629-37	
17	Sexual orientation and health: Comparisons in the Women's Health Initiative sample	**Valanis,** Bowen, Bassford, Whitlock, Charney, Carter	12	CT	Arch Fam Med. 2000 Sep-Oct;9(9):843-53	
19	Ethnic, socioeconomic, and lifestyle correlates of obesity in U.S. women: The Women's Health Initiative	**Manson,** Lewis, Kotchen, Allen, Johnson, Stefanick, Foreyt, Klesges, Tinker, Noonan, Perri, Hall	12	Gen	Clin J Womens Health. 2001;Dec 1(5):225-34	
20	Relation of demographic factors, menstrual history, reproduction and medication use to sex hormones in postmenopausal women	**McTiernan,** Wu, Barnabei, Chen, Hendrix, Modugno, Rohan, Stanczyk, Wang	12	CT	Breast Cancer Res Treat. 2008 Mar;108(2):217-231. Epub 2007 May 22	W5
21	Hypertension and its treatment in postmenopausal women: Baseline data from the Women's Health Initiative	**Wassertheil-Smoller,** Anderson, Psaty, Black, Manson, Wong, Francis, Grimm, Kotchen, Langer, Lasser	12	OS	Hypertension. 2000 Nov;36(5):780-9	
22	Pelvic organ prolapse in the Women's Health Initiative: Gravity and gravidity	**Hendrix,** Clark, Nygaard, Aragaki, Barnabei, McTiernan	12	CT	Am J Obstet Gynecol. 2002 Jun;186(6):1160-6	
24	Estimation of the correlation between nutrient intake measures under restricted sampling	**Wang,** Anderson, Prentice	12	Gen	Biometrics. 1999 Sep;55(3):711-7	
25	Estrogen and progestin use and the QT interval in postmenopausal women	**Kadish,** Greenland, Limacher, Frishman, Daugherty, Schwartz	12	CT	Ann Noninvasive Electrocardiol. 2004 Oct;9(4):366-74	
26	Special populations recruitment for the Women's Health Initiative: Successes and limitations	**Fouad,** Corbie-Smith, Curb, Howard, Mouton, Simon, Talavera, Thompson, Wang, White, Young	12	Gen	Control Clin Trials. 2004 Aug;25(4):335-52	
27	The effects of insurance coverage and ethnicity on mammography utilization in a postmenopausal population	**Bush,** Langer	12	Gen	West J Med. 1998 Apr;168(4):236-40	
35	Measurement characteristics of the Women's Health Initiative food frequency questionnaire	**Patterson,** Kristal, Tinker, Carter, Bolton, Agurs-Collins	12	Gen	Ann Epidemiol. 1999 Apr;9(3):178-87	W30

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
40	The associations between health and domestic violence in older women: Results of a pilot study	**Mouton,** Rovi, Furniss, Lasser	12	OS	J Womens Health Gend Based Med. 1999 Nov;8(9):1173-9	
41	Cross-sectional correlates of fasting hyperinsulinaemia in post-menopausal women of different ethnic origin	**Pradhan,** Manson, Hendrix, Johnson, Wagenknecht, Haan, Weidner, LaCroix, Cook	12	Gen	Diabet Med. 2006 Jan;23(1):77-85	
43	Sleep complaints of postmenopausal women	**Kripke,** Brunner, Freeman, Hendrix, Jackson, Masaki, Carter	12	CT	Clin J Womens Health. 2001;1(5):244-52	AS11
51	Relationship of social support and social burden to repeated breast cancer screening in the Women's Health Initiative	**Messina,** Lane, Glanz, West, Taylor, Frishman, Powell	12	Gen	Health Psychol. 2004 Nov;23(6):582-94	
55	Factor structure and measurement invariance of the Women's Health Initiative Insomnia Rating Scale	**Levine,** Kaplan, Kripke, Bowen, Naughton, Shumaker	12	Gen	Psychol Assess. 2003 Jun;15(2):123-36	
59	Risk factors for kidney stones in postmenopausal women in the southern United States	**Hall,** Pettinger, Oberman, Watts, Johnson, Paskett, Limacher, Hays	12	Gen	Am J Med Sci. 2001 Jul;322(1):12-8	
60	The Women's Health Initiative Memory Study (WHIMS): A trial of the effect of estrogen therapy in preventing and slowing the progression of dementia [WHIMS]	**Shumaker,** Reboussin, Espeland, Rapp, McBee, Dailey, Bowen, Terrell, Jones	12	WHIMS	Control Clin Trials. 1998 Dec;19(6):604-21	AS39
62	Self-reported urogential symptoms in postmenopausal women: Women's Health Initiative	**Pastore,** Carter, Hulka, Wells	12	Gen	Maturitas. 2004 Dec 10;49(4):292-303	
63	The importance of health insurance as a determinant of cancer screening: Evidence from the Women's Health Initiative	**Hsia,** Kemper, Kiefe, Zapka, Sofaer, Pettinger, Bowen, Limacher, Lillington, Mason	12	OS	Prev Med. 2000 Sep;31(3):261-70	
66	Walking compared with vigorous exercise for the prevention of cardiovascular events in women	**Manson,** Greenland, LaCroix, Stefanick, Mouton, Oberman, Perri, Sheps, Pettinger, Siscovick	12	OS	N Engl J Med. 2002 Sep 5;347(10):716-25	
67	Yogurt consumption is associated with healthy behavior in postmenopausal women	**Mossavar-Rahmani,** Garland, Caan, Hebert, Wodarski, Vitolins, Himes, Parker	12	OS	Clin J Womens Health. 2002;2(3):128-134	
69	Correlates of serum lypocene in older women	**Casso,** White, Patterson, Agurs-Collins, Kooperberg, Haines	12	CT	Nutr Cancer. 2000;36:163-69	

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
70	Correlates of serum alpha- and gamma-tocopherol in the Women's Health Initiative	**White,** Kristal, Shikany, Wilson, Chen, Mares-Perlman, Masaki, Caan	12	CT	Ann Epidemiol. 2001 Feb;11(2):136-44	
71	The Women's Health Initiative: Goals, rationale, and current status	**Liu**	12	Gen	Menopausal Medicine. 1998;6(2):1-4	
72	Postmenopausal bone loss and its relationship to oral bone loss	**Jeffcoat,** Lewis, Reddy, Wang, Redford	12	Gen	Periodontol. 2000; June23(1):94-102	AS9
74	Breast cancer survivors' health-related quality of life: Racial differences and comparisons with noncancer controls	**Paskett,** Alfano, Davidson, Andersen, Naughton, Sherman, McDonald, Hays	12	OS	Cancer. 2008 Dec 1;113(11):3222-30. Epub 2008 Oct 30	
76	Differences in eating pattern labels between maintainers and nonmaintainers in the Women's Health Initiative	**Hopkins,** Burrows, Bowen, Tinker	12	CT	J Nutr Educ. 2001 Sep-Oct;33(5):278-83	
78	Lack of a relation between vitamin and mineral antioxidants and bone mineral density: Results from the Women's Health Initiative	**Wolf,** Cauley, Pettinger, Jackson, LaCroix, LeBoff, Lewis, Nevitt, Simon, Stone, Wactawski-Wende	12	Gen	Am J Clin Nutr. 2005 Sep;82(3):581-8	
80	Insulin resistance and weight gain in postmenopausal women of diverse ethnic groups	**Howard,** Adams-Campbell, Allen, Black, Pasaro, Rodabough, Rodriguez, Safford, Stevens, Wagenknecht	12	Gen	Int J Obes Relat Metab Disord. 2004 Aug;28(8):1039-47	
83	Recreational physical activity and the risk of breast cancer in postmenopausal women: The Women's Health Initiative Cohort Study	**McTiernan,** Kooperberg, White, Wilcox, Coates, Adams-Campbell, Woods, Ockene	12	Gen	JAMA. 2003 Sep 10;290(10):1331-6	
84	Research staff turnover and participant adherence in the Women's Health Initiative	**Jackson,** Berman, Huber, Snetselaar, Granek, Boe, Milas, Spivak, Chlebowski	12	CT	Control Clin Trials. 2003 Aug;24(4):422-35	
85	The Women's Health Initiative: Rationale, design and progress report	**Johnson,** Anderson, Barad, Stefanick	12	CT	J Br Menopause Soc. 1999;5:155-9	
86	The effects of physical and emotional status on adherence to a low-fat dietary pattern in the Women's Health Initiative	**Tinker,** Perri, Patterson, Bowen, McIntosh, Parker, Sevick, Wodarski	12	CT	J Am Diet Assoc. 2002 Jun;102(6):789-800, 888	
88	Estimating normal hemogram values for postmenopausal women	**Assaf,** Carleton, Miller, Coccio	12	Gen	Clin J Womens Health. 2000;1(1):23-28	

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
91	Compliance with National Cholesterol Education Program dietary and lifestyle guidelines among older women with self-reported hypercholesterolemia. The Women's Health Initiative	**Hsia,** Rodabough, Rosal, Cochrane, Howard, Snetselaar, Frishman, Stefanick	12	OS	Am J Med. 2002 Oct 1;113(5):384-92	
92	Comparison of self-report, hospital discharge codes, and adjudication of cardiovascular events in the Women's Health Initiative	**Heckbert,** Kooperberg, Safford, Psaty, Hsia, McTiernan, Gaziano, Frishman, Curb	12	Gen	Am J Epidemiol. 2004 Dec 15;160(12):1152-8	
93	Fat intake in husbands of participants in the dietary modification component of the Women's Health Initiative	**Shikany**	12	Gen	Nutr Res. 2002;22:577-586	
95	The effects of widowhood on physical and mental health, health behaviors, and health outcomes: The Women's Health Initiative	**Wilcox,** Evenson, Aragaki, Wassertheil-Smoller, Mouton, Loevinger	12	OS	Health Psychol. 2003 Sep;22(5):513-22	
98	Antioxidant supplement use in Women's Health Initiative participants	**Shikany,** Patterson, Agurs-Collins, Anderson	12	Gen	Prev Med. 2003 Mar;36(3):379-87	
99	Risk factor clustering in the insulin resistance syndrome and its relationship to cardiovascular disease in postmenopausal white, black, hispanic, and Asian/Pacific Islander women	**Howard,** Criqui, Curb, Rodabough, Safford, Santoro, Wilson, Wylie-Rosette	12	OS	Metabolism. 2003 Mar;52(3):362-71	
100	Frequency and predictive value of a mammographic recommendation for short-interval follow-up	**Yasmeen,** Romano, Pettinger, Chlebowski, Robbins, Lane, Hendrix	12	Gen	J Natl Cancer Inst. 2003 Mar 19;95(6):429-36	
102	Association between cardiovascular outcomes and antihypertensive drug treatment in older women	Wassertheil-Smoller, Psaty, Greenland, Oberman, Kotchen, Mouton, Black, Aragaki, Trevisan	12	OS	JAMA. 2004 Dec 15;292(23):2849-59	
103	The Women's Health Initiative: Recruitment complete--looking back and looking forward	**Rossouw,** Hurd	12	CT	J Womens Health. 1999 Jan-Feb;8(1):3-5	
104	Promoting adherence and retention to clinical trials in special populations: A Women's Health Initiative workshop	**Wilcox,** Shumaker, Bowen, Naughton, Rosal, Ludlam, Dugan, Hunt, Stevens	12	Gen	Control Clin Trials. 2001 Jun;22(3):279-89	
105	Retention of under-served women in clinical trials: A focus group study	**Johnson,** Williams, Nagy, Fouad	12	CT	Ethn Dis. 2003 Spring;13(2):268-78	

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
107	Vigorous leisure activity through women's adult life: The Women's Health Initiative Observational Cohort Study	**Evenson,** Wilcox, Pettinger, Brunner, King, McTiernan	12	OS	Am J Epidemiol. 2002 Nov 15;156(10):945-53	
108	Cross-sectional geometry, bone strength, and bone mass in the proximal femur in black and white postmenopausal women	**Nelson,** Barondess, Hendrix, Beck	12	CT	J Bone Miner Res. 2000 Oct;15(10):1992-7	
111	Effects of fat content on fat hedonics: Cognition or taste?	**Bowen,** Green, Vizenor, Vu, Kreuter, Rolls	12	OS	Physiol Behav. 2003 Feb;78(2):247-53	
112	Results of an adjunct dietary intervention program in the Women's Health Initiative	**Bowen,** Ehret, Pedersen, Snetselaar, Johnson, Tinker, Hollinger, Lichty, Bland, Sivertsen, Ocken, Staats, Beedoe	12	OS	J Am Diet Assoc. 2002 Nov;102(11):1631-7	
113	Prior oral contraception and postmenopausal fracture: A Women's Health Initiative observational cohort study	**Barad,** Kooperberg, Wactawski-Wende, Liu, Hendrix, Watts	12	Gen	Fertil Steril. 2005 Aug;84(2):374-83	
115	Prevalence and 3-year incidence of abuse among postmenopausal women	**Mouton,** Rodabough, Rovi, Hunt, Talamantes, Brzyski, Burge	12	OS	Am J Public Health. 2004 Apr;94(4):605-12	
120	Obesity, body size, and risk of postmenopausal breast cancer: the Women's Health Initiative (United States)	**Morimoto,** White, Chen, Chlebowski, Hays, Kuller, Lopez, Manson, Margolis, Muti, Stefanick, McTiernan	12	OS	Cancer Causes Control. 2002 Oct;13(8):741-51	
122	Statin use, clinical fracture, and bone density in postmenopausal women: Results from the Women's Health Initiative Observational Study	**LaCroix,** Cauley, Pettinger, Hsia, Bauer, McGowan, Chen, Lewis, McNeeley, Pasaro, Jackson	12	OS	Ann Intern Med. 2003 Jul 15;139(2):97-104	
126	Influences on older women's adherence to a low-fat diet in the Women's Health Initiative	**Kearney,** Rosal, Ockene, Churchill	12	CT	Psychosom Med. 2002 May-Jun;64(3):450-7	AS75
128	Inflammatory biomarkers, hormone replacement therapy, and incident coronary heart disease: Prospective analysis from the Women's Health Initiative observational study	**Pradhan,** Manson, Rossouw, Siscovick, Mouton, Rifai, Wallace, Jackson, Pettinger, Ridker	12	OS	JAMA. 2002 Aug 28;288(8):980-7	AS83
129	Tissue plasminogen activator antigen and D-dimer as markers for atherothrombotic risk among healthy postmenopausal women	**Pradhan,** LaCroix, Langer, Trevisan, Lewis, Hsia, Oberman, Kotchen, Ridker	12	OS	Circulation. 2004 Jul 20;110(3):292-300. Epub 2004 Jul 6	AS83

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
130	Baseline associations between post and inflammatory, haemostatic, and lipid biomarkers of coronary heart disease. The Women's Health Initiative Observational Study	**Langer,** Pradhan, Lewis, Manson, Rossouw, Hendrix, LaCroix, Ridker	12	OS	Thromb Haemost. 2005 Jun;93(6):1108-16	
132	Association of nonmelanoma skin cancer with second malignancy	**Rosenberg,** Greenland, Khandekar, Loar, Ascensao, Lopez	12	Gen	Cancer. 2004 Jan 1;100(1):130-8	
134	Additional self-monitoring tools in the dietary modification component of the Women's Health Initiative	**Mossavar-Rahmani,** Henry, Rodabough, Bragg, Brewer, Freed, Kinzel, Pedersen, Soule, Vosburg	12	CT	J Am Diet Assoc. 2004 Jan;104(1):76-85	
135	Radiographic measurements, bone mineral density, and the Singh Index in the proximal femur of white and black postmenopausal women	**Barondess,** Singh, Hendrix, Nelson	12	Gen	Dis Mon. 2002 Oct;48(10):637-46	
137	Recruitment of hispanic women to the Women's Health Initiative: The case of Embajadoras in Arizona	**Larkey,** Staten, Ritenbaugh, Hall, Buller, Bassford, Altimari	12	Gen	Control Clin Trials. 2002 Jun;23(3):289-98	
138	Baseline experience with Modified Mini Mental State Exam: The Women's Health Initiative Memory Study (WHIMS) [WHIMS]	**Rapp,** Espeland, Hogan, Jones, Dugan, The WHIMS Investigators	12	WHIMS	Aging Ment Health. 2003 May;7(3):217-23	AS39
139	Cholesteryl ester transfer protein and lecithin:cholesterol acyltransferase activities in hispanic and anglo postmenopausal women: Associations with total and regional body fat	**Greaves,** Going, Fernandez, Milliken, Lohman, Bassford, McNamara	12	OS	Metabolism. 2003 Mar;52(3):282-9	
140	Usefulness of prior hysterectomy as an independent predictor of Framingham risk score (The Women's Health Initiative)	**Hsia,** Barad, Margolis, Rodabough, McGovern, Limacher, Oberman, Wassertheil-Smoller, Women's Health Initiative Research Group	12	Gen	Am J Cardiol. 2003 Aug 1;92(3):264-9	
142	Coronary artery calcification in black women and white women	**Khurana,** Rosenbaum, Howard, Adams-Campbell, Detrano, Klouj, Hsia	12	OS	Am Heart J. 2003 Apr;145(4):724-9	

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
144	Risk of cardiovascular disease by hysterectomy status, with and without oophorectomy: The Women's Health Initiative Observational Study	**Howard,** Kuller, Langer, Manson, Allen, Assaf, Cochrane, Larson, Lasser, Rainford, VanHorn, Stefanick, Trevisan	12	OS	Circulation. 2005 Mar 29;111(12):1462-70. Epub 2005 Mar 21	
145	Breast cancer and nonsteroidal anti-inflammatory drugs: Prospective results from the Women's Health Initiative	**Harris,** Chlebowski, Jackson, Frid, Ascensao, Anderson, Loar, Rodabough, White, McTiernan	12	OS	Cancer Res. 2003 Sep 15;63(18):6096-101	
148	Incidence of cervical cytological abnormalities with aging in the Women's Health Initiative: A randomized controlled trial	**Yasmeen,** Romano, Pettinger, Johnson, Hubbell, Lane, Hendrix	12	CT	Obstet Gynecol. 2006 Aug;108(2):410-9	
149	A community-based study of postmenopausal white women with back and leg pain: Health status and limitations in physical activity	**Vogt,** Lauerman, Chirumbole, Kuller	12	OS	J Gerontol A Biol Sci Med Sci. 2002 Aug;57(8):M544-50	
155	Changes in food sources of dietary fat in response to an intensive low-fat dietary intervention: Early results from the Women's Health Initiative	**Patterson,** Kristal, Rodabough, Caan, Lillington, Mossavar-Rahmani, Simon, Snetselaar, VanHorn	12	CT	J Am Diet Assoc. 2003 Apr;103(4):454-60	
163	Ethnicity and breast cancer: Factors influencing differences in incidence and outcome	**Chlebowski,** Chen, Anderson, Rohan, Aragaki, Lane, Dolan, Paskett, McTiernan, Hubbell, Adams-Campbell, Prentice	12	OS	J Natl Cancer Inst. 2005 Mar 16;97(6):439-48	AS144
164	Leukocyte count as a predictor of cardiovascular events and mortality in postmenopausal women: The Women's Health Initiative Observational Study	**Margolis,** Manson, Greenland, Rodabough, Bray, Safford, Grimm, Howard, Assaf, Prentice, Women's Health Initiative Research Group	12	OS	Arch Intern Med. 2005 Mar 14;165(5):500-8	
166	Habitual tea consumption and risk of osteoporosis: A prospective study in the Women's Health Initiative observational cohort	**Chen,** Pettinger, Ritenbaugh, LaCroix, Robbins, Caan, Barad, Hakim	12	OS	Am J Epidemiol. 2003 Oct 15;158(8):772-81	
169	Reliability and validity of the Women's Health Initiative Insomnia Rating Scale	**Levine,** Kripke, Kaplan, Lewis, Naughton, Bowen, Shumaker	12	Gen	Psychol Assess. 2003 Jun;15(2):137-48	

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
171	Prevalence and correlates of panic attacks in postmenopausal women: Results from an ancillary study to the Women's Health Initiative	**Smoller,** Pollack, Wassertheil-Smoller, Barton, Hendrix, Jackson, Dicken, Oberman, Sheps, Women's Health Initiative Investigators	12	Gen	Arch Intern Med. 2003 Sep 22;163(17):2041-50	AS70
173	A prospective study of the effect of hypertension and baseline blood pressure on cognitive decline and dementia in postmenopausal women: The Women's Health Initiative Memory Study [WHIMS]	**Johnson,** Margolis, Espeland, Colenda, Fillit, Manson, Masaki, Mouton, Prineas, Robinson, Wassertheil-Smoller, for the WHIMS and WHI Investigators	12	WHIMS	J Am Geriatr Soc. 2008 Aug;56(8):1449-58. Epub 2008 Jul 15	AS39
174	Statin use and breast cancer: Prospective results from the Women's Health Initiative	**Cauley,** McTiernan, Rodabough, LaCroix, Bauer, Margolis, Paskett, Vitolins, Furberg, Chlebowski, Women's Health Initiative Research Group	12	OS	J Natl Cancer Inst. 2006 May 17;98(10):700-7	
176	Predicting risk of breast cancer in postmenopausal women by hormone receptor status	**Chlebowski,** Anderson, Lane, Aragaki, Rohan, Yasmeen, Sarto, Rosenberg, Hubbell, Women's Health Initiative Investigators	12	Gen	J Natl Cancer Inst. 2007 Nov 21;99(22):1695-705. Epub 2007 Nov 13	
177	Validity of self-report for fractures among a multiethnic cohort of postmenopausal women: Results from the Women's Health Initiative observational study and clinical trials	**Chen,** Kooperberg, Pettinger, Bassford, Cauley, LaCroix, Lewis, Kipersztok, Borne, Jackson	12	Gen	Menopause. 2004 May-Jun;11(3):264-74	
179	Progression and remission of pelvic organ prolapse: A longitudinal study of menopausal women	**Handa,** Garret, Hendrix, Gold, Robbins	12	CT	Am J Obstet Gynecol. 2004 Jan;190(1):27-32	
181	Alcohol and folate intake and breast cancer risk in the WHI Observational Study	**Duffy,** Assaf, Cyr, Burkholder, Coccio, Rohan, McTiernan, Paskett, Lane, Chetty	12	OS	Breast Cancer Res Treat. 2009 Aug;116(3):551-62. Epub 2008 Sep 11.	
183	Panic attacks, daily life ischemia, and chest pain in postmenopausal women	**Smoller,** Pollack, Wassertheil-Smoller, Brunner, Curb, Torner, Oberman, Hendrix, Hsia, Sheps	12	Gen	Psychosom Med. 2006 Nov-Dec;68(6):824-32. Epub 2006 Nov 13	AS70

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
186	Physical activity and diabetes risk in postmenopausal women	**Hsia,** Wu, Allen, Oberman, Lawson, Torrens, Safford, Limacher, Howard, Women's Health Initiative Research Group	12	Gen	Am J Prev Med. 2005 Jan;28(1):19-25	
187	Postmenopausal hormone therapy and cardiovascular disease	**Rossouw**	12	OS	In: Yusuf S, ed. Evidence based cardiology. 2nd ed. London: BMJ Books,2002:244-58	
188	Electrocardiographic abnormalities that predict coronary heart disease events and mortality in postmenopausal women: The Women's Health Initiative	**Rautaharju,** Kooperberg, Larson, LaCroix	12	CT	Circulation. 2006 Jan 31;113(4):473-80	
189	Dietary adherence in the Women's Health Initiative Dietary Modification Trial	**The Women's Health Initiative Study Group**	12	CT	J Am Diet Assoc. 2004 Apr;104(4):654-8	
190	Prevalence and determinants of electrocardiographic left ventricular hypertrophy among a multiethnic population of postmenopausal women (The Women's Health Initiative)	**Oberman,** Prineas, Larson, LaCroix, Lasser	12	CT	Am J Cardiol. 2006 Feb 15;97(4):512-9. Epub 2006 Jan 4	
192	Bone mineral density of American Indian and Alaska Native women compared with non-Hispanic white women: Results from the Women's Health Initiative Study	**Wampler,** Chen, Jacobsen, Henderson, Howard, Rossouw	12	Gen	Menopause. 2005 Sep-Oct;12(5):536-44. Epub 2005 Sep 1	
195	Predictors of adherence in the Women's Health Initiative Calcium and Vitamin D Trial	**Brunner,** Dunbar-Jacob, LeBoff, Granek, Bowen, Snetselaar, Shumaker, Ockene, Rosal, Wactawski-Wende, Cauley, Cochrane, Tinker, Jackson, Wang	12	CT	Behav Med. 2009 Winter;34(4):145-55	
196	Predictors of dietary change and maintenance in the Women's Health Initiative Dietary Modification Trial	**Tinker,** Rosal, Young, Perri, Patterson, VanHorn, Assaf, Bowen, Ockene, Hays, Wu	12	CT	J Am Diet Assoc. 2007 Jul;107(7):1155-65	
197	Predictors of angina pectoris versus myocardial infarction from the Women's Health Initiative Observational Study	**Hsia,** Aragaki, Bloch, LaCroix, Wallace, Women's Health Initiative Investigators	12	OS	Am J Cardiol. 2004 Mar 15;93(6):673-8	

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Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
198	The Women's Health Initiative: Aspects of the management and coordination	**Cochrane,** Lund, Anderson, Prentice	12	Gen	In: Hawkins JW, Haggerty LA, eds. Diversity in health care research: strategies for multisite, multidisciplinary, and multi-ethnic projects. New York: Springer,2003:181-207	
200	Expression and ambivalence over expression of negative emotion: Psychometric analysis in the Women's Health Initiative	**Michael,** Perrin, Bowen, Cochrane, Wisdom, Brzyski, Ritenbaugh	12	Gen	J Women Aging. 2005;17(1-2):5-18	
201	Normal standards for QT and QT subintervals derived from a large ethnically diverse population of women aged 50 to 79 years (the Women's Health Initiative [WHI])	**Rautaharju,** Prineas, Kadish, Larson, Hsia, Lund	12	Gen	Am J Cardiol. 2006 Mar 1;97(5):730-7. Epub 2006 Jan 11	
202	Depressive symptoms and heart rate variability in postmenopausal women	**Kim,** McGorray, Bartholomew, Marsh, Dicken, Wassertheil-Smoller, Curb, Oberman, Barton, McMahon, Hsia, Gardin, Wong, Barton	12	Gen	Arch Intern Med. 2005 Jun 13;165(11):1239-44	
203	Influence of estrogen plus progestin on breast cancer and mammography in healthy postmenopausal women: The Women's Health Initiative Randomized Trial	**Chlebowski,** Hendrix, Langer, Stefanick, Gass, Lane, Rodabough, Gilligan, Cyr, Thomson, Khandekar, Petrovich, McTiernan, Women's Health Initiative Investigators	12	CT	JAMA. 2003 Jun 25;289(24):3243-53	
204	Effect of estrogen plus progestin on stroke in postmenopausal women: the Women's Health Initiative: A randomized trial	**Wassertheil-Smoller,** Hendrix, Limacher, Heiss, Kooperberg, Baird, Kotchen, Curb, Black, Rossouw, Aragaki, Safford, Stein, Laowattana, Mysiw	12	CT	JAMA. 2003 May 28;289(20):2673-84	W1, W6
206	Fracture risk among breast cancer survivors: Results from the Women's Health Initiative Observational Study	**Chen,** Maricic, Bassford, Pettinger, Ritenbaugh, Lopez, Barad, Gass, LeBoff	12	Gen	Arch Intern Med. 2005 Mar 14;165(5):552-8	

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Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
208	Effects of estrogen plus progestin on risk of fracture and bone mineral density: The Women's Health Initiative randomized trial	**Cauley,** Robbins, Chen, Cummings, Jackson, LaCroix, LeBoff, Lewis, McGowan, Neuner, Pettinger, Stefanick, Wactawski-Wende, Watts, Women's Health Initiative Investigators	12	CT	JAMA. 2003 Oct 1;290(13):1729-38	
209	Obesity, hormone therapy, estrogen metabolism and risk of postmenopausal breast cancer	**Modugno,** Kip, Cochrane, Kuller, Klug, Rohan, Chlebowski, Lasser, Stefanick	12	OS	Int J Cancer. 2006 Mar 1;118(5):1292-301	AS134
210	Estrogen plus progestin and the risk of coronary heart disease	**Manson,** Hsia, Johnson, Rossouw, Assaf, Lasser, Trevisan, Black, Heckbert, Detrano, Strickland, Wong, Crouse, Stein, Cushman	12	CT	N Engl J Med. 2003 Aug 7;349(6):523-34	W1, W6
211	Effects of estrogen plus progestin on health-related quality of life	**Hays,** Ockene, Brunner, Kotchen, Manson, Patterson, Aragaki, Shumaker, Brzyski, LaCroix, Granek, Valanis, Women's Health Initiative Investigators	12	CT	N Engl J Med. 2003 May 8;348(19):1839-54. Epub 2003 Mar 17	
212	Effect of oestrogen plus progestin on the incidence of diabetes in postmenopausal women: Results from the Women's Health Initiative Hormone Trial	**Margolis,** Bonds, Rodabough, Tinker, Phillips, Allen, Bassford, Burke, Torrens, Howard, Women's Health Initiative Investigators	12	CT	Diabetologia. 2004 Jul;47(7):1175-87. Epub 2004 Jul 14	
215	Influence of stressors on breast cancer incidence in the Women's Health Initiative	**Michael,** Carlson, Chlebowski, Aickin, Weihs, Ockene, Bowen, Ritenbaugh	12	OS	Health Psychol. 2009 Mar;28(2):137-146	
216	Effects of combination estrogen plus progestin hormone treatment on cognition and affect [WHISCA]	**Resnick,** Maki, Rapp, Espeland, Brunner, Coker, Granek, Hogan, Ockene, Shumaker, Women's Health Initiative Study of Cognitive Aging Investigators	12	CT	J Clin Endocrinol Metab. 2006 May;91(5):1802-10. Epub 2006 Mar 7	AS103
220	The Women's Health Initiative: Implications for practice	**Furniss**	12	CT	Adv Nurse Pract. 2002 Nov;10(11):53-5	

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Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
221	Effects of estrogen plus progestin on gynecologic cancers and associated diagnostic procedures: The Women's Health Initiative randomized trial	**Anderson,** Judd, Kaunitz, Barad, Beresford, Pettinger, Liu, McNeeley, Lopez, Women's Health Initiative Investigators	12	CT	JAMA. 2003 Oct 1;290(13):1739-48	
222	Estrogen plus progestin and risk of venous thrombosis	**Cushman,** Kuller, Prentice, Rodabough, Psaty, Stafford, Sidney, Rosendaal, Women's Health Initiative Investigators	12	CT	JAMA. 2004 Oct 6;292(13):1573-80	W1, W6
224	Estimation of dependence between paired correlated failure times in the presence of covariate measurement error	**Gorfine,** Hsu, Prentice	12	OS	J R Stat Soc [Ser B]. 2003;65(3):633-61	
225	Estrogen plus progestin and the incidence of dementia and mild cognitive impairment in postmenopausal women: the Women's Health Initiative Memory Study: A randomized controlled trial [WHIMS]	**Shumaker,** Legault, Rapp, Thal, Wallace, Ockene, Hendrix, Jones, Assaf, Jackson, Kotchen, Wassertheil-Smoller, Wactawski-Wende, The WHIMS Investigators	12	CT	JAMA. 2003 May 28;289(20):2651-62	AS39
226	Effect of estrogen plus progestin on global cognitive function in postmenopausal women: the Women's Health Initiative Memory Study: A randomized controlled trial [WHIMS]	**Rapp,** Espeland, Shumaker, Henderson, Brunner, Manson, Gass, Stefanick, Lane, Hays, Johnson, Coker, Dailey, Bowen, The WHIMS Investigators	12	CT	JAMA. 2003 May 28;289(20):2663-72	AS39
229	Menopausal symptoms and treatment-related effects of estrogen and progestin in the Women's Health Initiative	**Barnabei,** Cochrane, Aragaki, Nygaard, Williams, McGovern, Young, Wells, O'Sullivan, Chen, Schenken, Johnson, Women's Health Initiative Investigators	12	CT	Obstet Gynecol. 2005 May;105(5 Pt 1):1063-73	
230	Use of electric blankets and association with prevalence of endometrial cancer	**Abel,** Hendrix, McNeeley, O'Leary, Mossavar-Rahmani, Johnson, Kruger	12	OS	Eur J Cancer Prev. 2007 Jun;16(3):243-50	
232	Women's Health Initiative: Statistical aspects and selected early results	**Prentice,** Anderson	12	Gen	In: Armitage P, Colton T, eds. Encyclopedia of biostatistics. 2nd ed. Wiley,2005	

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Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
233	Estrogen plus progestin and colorectal cancer in postmenopausal women	**Chlebowski,** Wactawski-Wende, Ritenbaugh, Hubbell, Ascensao, Rodabough, Rosenberg, Taylor, Harris, Chen, Adams-Campbell, White, Women's Health Initiative Investigators	12	CT	N Engl J Med. 2004 Mar 4;350(10):991-1004	
234	Postmenopausal hormone therapy and body composition: A substudy of the estrogen plus progestin trial of the Women's Health Initiative	**Chen,** Bassford, Green, Cauley, Jackson, LaCroix, LeBoff, Stefanick, Margolis	12	CT	Am J Clin Nutr. 2005 Sep;82(3):651-6	
235	Hormone replacement therapy and risk of cardiovascular disease: Implications of the results of the Women's Health Initiative	**Kuller**	12	CT	Arterioscler Thromb Vasc Biol. 2003 Jan 1;23(1):11-6	
237	The Women's Health Initiative Study of Cognitive Aging (WHISCA): A randomized clinical trial of the effects of hormone therapy on age-associated cognitive decline [WHISCA]	**Resnick,** Coker, Maki, Rapp, Espeland, Shumaker	12	CT	Clin Trials. 2004;1(5):440-50	AS103
240	Risks and benefits of estrogen plus progestin in healthy postmenopausal women: Principal results From the Women's Health Initiative randomized controlled trial	**Rossouw,** Anderson, Prentice, LaCroix, Kooperberg, Stefanick, Jackson, Beresford, Howard, Johnson, Kotchen, Ockene, The Writing Group for the Women's Health Initiative Investigators	12	CT	JAMA. 2002 Jul 17;288(3):321-33	W1
242	Estrogen deficiency symptom management in breast cancer survivors in the changing context of menopausal hormone therapy	**Chlebowski,** Kim, Col	12	CT	Semin Oncol. 2003 Dec;30(6):776-88	
243	Combined postmenopausal hormone therapy and cardiovascular disease: Toward resolving the discrepancy between observational studies and the Women's Health Initiative clinical trial	**Prentice,** Langer, Stefanick, Howard, Pettinger, Anderson, Barad, Curb, Kotchen, Kuller, Limacher, Wactawski-Wende, Women's Health Initiative Investigators	12	CT	Am J Epidemiol. 2005 Sep 1;162(5):404-14. Epub 2005 Jul 20	

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Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
246	WHI response to Goodman, Goldzieher and Ayala's critique of the Women's Health Initiative report on the risks and benefits of estrogen plus progestin	**Hendrix,** Prentice	12	CT	Menopausal Medicine. 2003;11:1-4	
248	Progression of coronary calcification in healthy postmenopausal women	**Hsia,** Klouj, Prasad, Burt, Adams-Campbell, Howard	12	OS	BMC Cardiovasc Disord. 2004 Dec 1;4:21	
249	Effects of estrogen with and without progestin on urinary incontinence	**Hendrix,** Cochrane, Nygaard, Handa, Barnabei, Iglesia, Aragaki, Naughton, Wallace, McNeeley	12	CT	JAMA. 2005 Feb 23;293(8):935-48	
250	Hormone therapy and age-related macular degeneration: The Women's Health Initiative Sight Exam Study [WHISE]	**Haan,** Klein, Klein, Deng, Blythe, Seddon, Musch, Kuller, Hyman, Wallace	12	CT	Arch Ophthalmol. 2006 Jul;124(7):988-92	AS62
253	Cardiovascular disease, its risk factors and treatment, and age-related macular degeneration: Women's Health Initiative Sight Exam ancillary study [WHISE]	**Klein,** Deng, Klein, Hyman, Seddon, Frank, Wallace, Hendrix, Kuppermann, Langer, Kuller, Brunner, Johnson, Thomas, Haan	12	CT	Am J Ophthalmol. 2007 Mar;143(3):473-83. Epub 2007 Jan 10	AS62
265	Comparing SF-36 scores across three groups of women with different health profiles	**Yost,** Haan, Levine, Gold	12	Gen	Qual Life Res. 2005 Jun;14(5):1251-61	
271	Factors associated with treatment initiation after osteoporosis screening	**Brennan,** Wactawski-Wende, Crespo, Dmochowski	12	CT	Am J Epidemiol. 2004 Sep 1;160(5):475-83	AS98
272	Effect of estrogen therapy on gallbladder disease	**Cirillo,** Wallace, Rodabough, Greenland, LaCroix, Limacher, Larson	12	CT	JAMA. 2005 Jan 19;293(3):330-9	
273	Effects of conjugated equine estrogen in postmenopausal women with hysterectomy. The Women's Health Initiative randomized controlled trial	**Anderson,** Limacher, Assaf, Bassford, Beresford, Black, Bonds, Brunner, Brzyski, Caan, Chlebowski, Curb, Gass, Hays, et al	12	CT	JAMA. 2004 Apr 14;291(14):1701-12	W1, W6
274	Association between reported alcohol intake and cognition: Results from the Women's Health Initiative Memory Study [WHIMS]	**Espeland,** Gu, Masaki, Langer, Coker, Stefanick, Ockene, Rapp	12	CT	Am J Epidemiol. 2005 Feb 1;161(3):228-38	AS39

Table 12.2 (continued)
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Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
277	Estrogen plus progestin and the risk of peripheral arterial disease: The Women's Health Initiative	**Hsia,** Criqui, Rodabough, Langer, Resnick, Phillips, Allison, Bonds, Masaki, Caralis, Kotchen, Women's Health Initiative Investigators	12	CT	Circulation. 2004 Feb 10;109(5):620-6	
279	Symptom experience after discontinuing use of estrogen plus progestin	**Ockene,** Barad, Cochrane, Larson, Gass, Wassertheil-Smoller, Manson, Barnabei, Lane, Brzyski, Rosal, Wylie-Rosette, Hays	12	CT	JAMA. 2005 Jul 13;294(2):183-93	
280	Relation of BMI and physical activity to sex hormones in postmenopausal women	**McTiernan,** Wu, Chen, Chlebowski, Mossavar-Rahmani, Modugno, Perri, Stanczyk, VanHorn, Wang, Women's Health Initiative Investigators	12	CT	Obesity (Silver Spring). 2006 Sep;14(9):1662-77	W5
282	Improving dietary self-monitoring and adherence with hand-held computers: A pilot study	**Glanz,** Murphy, Moylan, Evensen, Curb	12	CT	Am J Health Promot. 2006 Jan-Feb;20(3):165-70	
285	Estrogen-plus-progestin use and mammographic density in postmenopausal women: Women's Health Initiative randomized trial	**McTiernan,** Martin, Peck, Aragaki, Chlebowski, Pisano, Wang, Brunner, Johnson, Manson, Lewis, Kotchen, Hulka, Women's Health Initiative Mammogram Density Study Investigators	12	CT	J Natl Cancer Inst. 2005 Sep 21;97(18):1366-76	AS36
287	Prior hormone therapy and breast cancer risk in the Women's Health Initiative randomized trial of estrogen plus progestin	**Anderson,** Chlebowski, Rossouw, Rodabough, McTiernan, Margolis, Aggerwal, Curb, Hendrix, Hubbell, Khandekar, Lane, Lasser, Lopez, Potter	12	CT	Maturitas. 2006 Sep 20;55(2):103-15. Epub 2006 Jul 11	
288	Insulin, physical activity, and caloric intake in postmenopausal women: Breast cancer implications	**Chlebowski,** Pettinger, Stefanick, Howard, Mossavar-Rahmani, McTiernan	12	Gen	J Clin Oncol. 2004 Nov 15;22(22):4507-13	
289	Cutaneous melanoma in postmenopausal women following nonmelanoma skin carcinoma: The Women's Health Initiative Observational Study	**Rosenberg,** Khandekar, Greenland, Rodabough, McTiernan	12	OS	Cancer. 2006 Feb 1;106(3):654-63	

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
292	Menopausal hormone therapy informed consent	**Hendrix**	12	Gen	Am J Obstet Gynecol. 2003 Oct;189(4 Suppl):S31-2; discussion S32-6	
294	Weighted estimators for proportional hazards regression with missing covariates	**Qi,** Wang, Prentice	12	OS	J Am Stat Assoc. 2005;100:1250-1263	
298	The association between aspirin use and the incidence of colorectal cancer in women	**Allison,** Garland, Chlebowski, Criqui, Langer, Wu, Roy, McTiernan, Kuller, Women's Health Initiative Investigators	12	OS	Am J Epidemiol. 2006 Sep 15;164(6):567-75. Epub 2006 Jul 17	
301	Angiotensin-converting enzyme inhibitor use and incident frailty in women aged 65 and older: prospective findings from the Women's Health Initiative Observational Study	**Gray,** LaCroix, Aragaki, McDermott, Cochrane, Kooperberg, Murray, Rodriguez, Black, Woods	12	Gen	J Am Geriatr Soc. 2009 Feb;57(2):297-303	AS179
302	Frailty: Emergence and consequences in women aged 65 and older in the Women's Health Initiative Observational Study	**Woods,** LaCroix, Gray, Aragaki, Cochrane, Brunner, Masaki, Murray, Newman	12	Gen	J Am Geriatr Soc. 2005 Aug;53(8):1321-30	AS179
303	Statin use and incident frailty in women aged 65 years or older: Prospective findings from the Women's Health Initiative Observational Study	**LaCroix,** Gray, Aragaki, Cochrane, Newman, Kooperberg, Black, Curb, Greenland, Woods	12	Gen	J Gerontol A Biol Sci Med Sci. 2008 Apr;63(4):369-75	AS179
307	Predictors of optical density of lutein and zeaxanthin in retinas of older women in the Carotenoids in Age-Related Eye Disease Study, an ancillary study of the Women's Health Initiative [CAREDS]	**Mares-Perlman,** LaRowe, Snodderly, Moeller, Gruber, Klein, Wooten, Johnson, Chappel, CAREDS Macular Pigment Study Group and Investigators	12	OS	Am J Clin Nutr. 2006 Nov;84(5):1107-22	AS105
314	Aspirin use, dose, and clinical outcomes in postmenopausal women with stable cardiovascular disease: The Women's Health Initiative Observational Study	**Berger,** Brown, Burke, Oberman, Kostis, Langer, Wong, Wassertheil-Smoller	12	OS	Circ Cardiovasc Qual Outcomes 2009 2: 78-87.	
316	Daily coffee consumption and prevalence of nonmelanoma skin cancer in Caucasian women	**Abel,** Hendrix, McNeeley, Johnson, Rosenberg, Mossavar-Rahmani, Vitolins, Kruger	12	OS	Eur J Cancer Prev. 2007 Oct;16(5):446-452	
317	Pelvic organ prolapse in older women: Prevalence and risk factors	**Nygaard,** Bradley, Brandt, Women's Health Initiative	12	CT	Obstet Gynecol. 2004 Sep;104(3):489-97	AS135

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
318	Depressive symptoms, bone loss, and fractures in postmenopausal women	**Spangler,** Scholes, Brunner, Robbins, Reed, Newton, Melville, LaCroix	12	OS	J Gen Intern Med. 2008 May;23(5):567-74. Epub 2008 Feb 20	
319	The relationship between religion and cardiovascular outcomes and all-cause mortality in the Women's Health Initiative Observational Study	**Schnall,** Wassertheil-Smoller, Swencionis, Zemon, Tinker, O'Sullivan, VanHorn, Goodwin	12	OS	Psychol Health. 2008 Nov 17. [Epub ahead of print]	
322	Postmenopausal hormone therapy and risk of cardiovascular disease by age and years since menopause	**Rossouw,** Prentice, Manson, Wu, Barad, Barnabei, Ko, LaCroix, Margolis, Stefanick	12	CT	JAMA. 2007 Apr 4;297(13):1465-77	
323	Vaginal wall descensus and pelvic floor symptoms in older women	**Bradley,** Nygaard	12	OS	Obstet Gynecol. 2005 Oct;106(4):759-66	AS135
324	Mortality and cardiac and vascular outcomes in extremely obese women	**McTigue,** Larson, Valoski, Burke, Kotchen, Lewis, Stefanick, VanHorn, Kuller	12	OS	JAMA. 2006 Jul 5;296(1):79-86	
325	Association between alcohol intake and domain-specific cognitive function in older women [WHISCA]	**Espeland,** Coker, Wallace, Rapp, Resnick, Limacher, Powell, Messina, Women's Health Initiative Study of Cognitive Aging	12	CT	Neuroepidemiology. 2006;27(1):1-12. Epub 2006 May 24	AS103
326	The association between osteoporosis and alveolar crestal height in postmenopausal women	**Wactawski-Wende,** Hausmann, Hovey, Trevisan, Grossi, Genco	12	CT	J Periodontol. 2005 Nov;76(11 Suppl):2116-24	AS98
327	Low-fat dietary pattern and weight change over 7 years: The Women's Health Initiative Dietary Modification Trial	**Howard,** Manson, Stefanick, Beresford, Frank, Jones, Rodabough, Snetselaar, Thomson, Tinker, Vitolins, Prentice	12	CT	JAMA. 2006 Jan 4;295(1):39-49	
328	Prospective study of leukocyte count as a predictor of incident breast, colorectal, endometrial, and lung cancer and mortality in postmenopausal women	**Margolis,** Rodabough, Thomson, Lopez, McTiernan, for the Women's Health Initiative Research Group	12	OS	Arch Intern Med. 2007 Sep 24;167(17):1837-44	
330	Effects of estrogen with and without progestin and obesity on symptomatic gastroesophageal reflux	**Zheng,** Margolis, Liu, Tinker, Ye, Women's Health Initiative Investigators	12	CT	Gastroenterology. 2008 Jul;135(1):72-81. Epub 2008 Mar 25	

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Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
331	Pelvic floor symptoms and lifestyle factors in older women	**Bradley,** Kennedy, Nygaard	12	CT	J Womens Health (Larchmt). 2005 Mar;14(2):128-36	AS135
332	Conjugated equine estrogens and global cognitive function in postmenopausal women: Women's Health Initiative Memory Study [WHIMS]	**Espeland,** Rapp, Shumaker, Brunner, Manson, Sherwin, Hsia, Margolis, Hogan, Wallace, Dailey, Freeman, Hays	12	WHIMS	JAMA. 2004 Jun 23;291(24):2959-68	AS39
336	Conjugated equine estrogens and incidence of probable dementia and mild cognitive impairment in postmenopausal women: Women's Health Initiative Memory Study [WHIMS]	**Shumaker,** Legault, Kuller, Rapp, Thal, Lane, Fillit, Stefanick, Hendrix, Lewis, Masaki, Coker	12	WHIMS	JAMA. 2004 Jun 23;291(24):2947-58	AS39
337	Estrogen plus progestin therapy and breast cancer in recently postmenopausal women	**Prentice,** Chlebowski, Stefanick, Manson, Pettinger, Hendrix, Kooperberg, Kuller, Lane, McTiernan, O'Sullivan, Rossouw, Anderson	12	Gen	Am J Epidemiol. 2008 May 15;167(10):1207-16. Epub 2008 Mar 27	
339	Validity of diabetes self-reports in the Women's Health Initiative: comparison with medication inventories and fasting glucose measurements	**Margolis,** Qi, Brzyski, Bonds, Howard, Kempainen, Liu, Robinson, Safford, Tinker, Phillips	12	Gen	Clin Trials. 2008;5(3):240-7	
340	Hormone therapy improves femur geometry among ethnically diverse postmenopausal participants in the Women's Health Initiative Hormone Intervention Trials	**Chen,** Beck, Cauley, Lewis, LaCroix, Bassford, Wu, Sherrill, Going	12	CT	J Bone Miner Res. 2008 Dec;23(12):1935-45. Epub 2008 Jul 29	AS153
341	Race/ethnicity, socioeconomic status, and lifetime morbidity burden in the Women's Health Initiative: A cross-sectional analysis	**Gold,** Michael, Whitlock, Hubbell, Mason, Rodriguez, Safford, Sarto	12	Gen	J Womens Health (Larchmt). 2006 Dec;15(10):1161-73	
342	Body mass index is not a good predictor of bone density: Results from WHI, CHS, and EPIDOS	**Robbins,** Schott, Azari, Kronmal	12	OS	J Clin Densitom. 2006 Jul-Sep;9(3):329-34	

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
343	Effects of conjugated equine estrogens on breast cancer and mammography screening in postmenopausal women with hysterectomy	**Stefanick,** Anderson, Margolis, Hendrix, Rodabough, Paskett, Lane, Hubbell, Assaf, Sarto, Schenken, Yasmeen, Lessin, Chlebowski, Women's Health Initiative Investigators	12	CT	JAMA. 2006 Apr 12;295(14):1647-57	
344	Elderly women diagnosed with nonspecific chest pain may be at increased cardiovascular risk	**Robinson,** Wallace, Limacher, Sato, Cochrane, Wassertheil-Smoller, Ockene, Blanchette, Ko	12	Gen	J Womens Health (Larchmt). 2006 Dec;15(10):1151-60	
345	Conjugated equine estrogens and coronary heart disease: The Women's Health Initiative	**Hsia,** Langer, Manson, Kuller, Johnson, Hendrix, Pettinger, Heckbert, Greep, Crawford, Eaton, Kostis, Caralis, Prentice, Women's Health Initiative Investigators	12	CT	Arch Intern Med. 2006 Feb 13;166(3):357-65	W1, W6
346	Estrogen plus progestin and breast cancer detection by means of mammography and breast biopsy	**Chlebowski,** Anderson, Pettinger, Lane, Langer, Gilligan, Walsh, Chen, McTiernan	12	CT	Arch Intern Med. 2008 Feb 25;168(4):370-377	
347	Effects of conjugated equine estrogen on stroke in the Women's Health Initiative	**Hendrix,** Wassertheil-Smoller, Johnson, Howard, Kooperberg, Rossouw, Trevisan, Aragaki, Baird, Bray, Buring, Criqui, Herrington, Lynch, Rapp	12	CT	Circulation. 2006 May 23;113(20):2425-34. Epub 2006 May 15	W1, W6
348	Effects of conjugated equine estrogen on health-related quality of life in postmenopausal women with hysterectomy: Results from the Women's Health Initiative randomized clinical trial	**Brunner,** Gass, Aragaki, Hays, Granek, Woods, Mason, Brzyski, Ockene, Assaf, LaCroix, Matthews, Wallace, Women's Health Initiative Investigators	12	CT	Arch Intern Med. 2005 Sep 26;165(17):1976-86	
350	Venous thrombosis and conjugated equine estrogen in women without a uterus	**Curb,** Prentice, Bray, Langer, VanHorn, Barnabei, Bloch, Cyr, Gass, Lepine, Rodabough, Sidney, Uwaifo, Rosendaal	12	CT	Arch Intern Med. 2006 Apr 10;166(7):772-80	W1, W6

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Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
352	Body size, weight cycling, and risk of renal cell carcinoma among postmenopausal women: The Women's Health Initiative (United States)	**Luo,** Margolis, Adami, Lopez, Lessin, Ye, Women's Health Initiative Investigators	12	Gen	Am J Epidemiol. 2007 Oct 1;166(7):752-9. Epub 2007 Jul 5	
353	Conjugated equine estrogens and colorectal cancer incidence and survival: The Women's Health Initiative Randomized Clinical Trial	**Ritenbaugh,** Stanford, Ascensao, Chlebowski, Frank, Garland, Lane, Mason, McNeeley, Shikany, Stefanick, Taylor, Wu	12	CT	Cancer Epidemiol Biomarkers Prev. 2008 Oct;17(10):2609-2618. Epub 2008 Sep 30	
354	Effects of conjugated equine estrogen on risk of fractures and BMD in postmenopausal women with hysterectomy: Results from the Women's Health Initiative randomized trial	**Jackson,** Wactawski-Wende, LaCroix, Pettinger, Yood, Watts, Robbins, Lewis, Beresford, Ko, Naughton, Satterfield, Bassford, Women's Health Initiative Investigators	12	CT	J Bone Miner Res. 2006 Jun;21(6):817-28	
357	The effect of conjugated equine oestrogen on diabetes incidence: The Women's Health Initiative randomised trial	**Bonds,** Lasser, Qi, Brzyski, Caan, Heiss, Limacher, Liu, Mason, Oberman, O'Sullivan, Phillips, Prineas, Tinker	12	CT	Diabetologia. 2006 Mar;49(3):459-68. Epub 2006 Jan 27	
359	Risk of fracture in women with type 2 diabetes: The Women's Health Initiative Observational Study	**Bonds,** Larson, Schwartz, Strotmeyer, Robbins, Rodriguez, Johnson, Margolis	12	OS	J Clin Endocrinol Metab. 2006 Sep;91(9):3404-10. Epub 2006 Jun 27	
361	Effect of hormone therapy on risk of hip and knee joint replacement in the Women's Health Initiative	**Cirillo,** Wallace, Wu, Yood	12	CT	Arthritis Rheum. 2006 Oct;54(10):3194-204	
362	Effects of postmenopausal hormone therapy on rheumatoid arthritis: The Women's Health Initiative randomized controlled trials	**Walitt,** Pettinger, Weinstein, Katz, Torner, Wasko, Howard, Women's Health Initiative Investigators	12	CT	Arthritis Rheum. 2008 Mar 15;59(3):302-10. Epub 2008 Feb 28	
363	Long-term exposure to air pollution and incidence of cardiovascular events in women	**Miller,** Siscovick, Sheppard, Shepherd, Sullivan, Anderson, Kaufman	12	CT	N Engl J Med. 2007 Feb 1;356(5):447-58	AS150
367	The Women's Health Initiative: A potential resource for future studies of autoimmune diseases	**Howard**	12	Gen	Autoimmunity. 2004 Jun;37(4):265-8	

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Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
368	Postmenopausal hormone therapy in relation to cardiovascular disease and cognition	**Prentice**	12	CT	Proceedings of the Forty Seventh Study Group of the Royal College of Obstetricians and Gynecologists. 2004	
369	A prospective study of inflammatory cytokines and diabetes mellitus in a multiethnic cohort of postmenopausal women	**Liu,** Tinker, Song, Rifai, Bonds, Cook, Heiss, Howard, Hotamisligil, Hu, Kuller, Manson	12	OS	Arch Intern Med. 2007 Aug 13-27;167(15):1676-85	AS132
370	Benchmarks for designing two-stage studies using modified mini-mental state examinations: Experience from the Women's Health Initiative Memory Study [WHIMS]	**Espeland,** Rapp, Robertson, Granek, Murphy, Albert, Bassford	12	CT	Clin Trials. 2006;3(2):99-106	AS39
371	Associations between intermediate age-related macular degeneration and lutein and zeaxanthin in the Carotenoids in Age-related Eye Disease Study (CAREDS): Ancillary study of the Women's Health Initiative [CAREDS]	**Moeller,** Parekh, Tinker, Ritenbaugh, Blodi, Wallace, Mares-Perlman	12	OS	Arch Ophthalmol. 2006 Aug;124(8):1151-62	AS105
372	Factors associated with 5-year risk of hip fracture in postmenopausal women	**Robbins,** Aragaki, Kooperberg, Watts, Wactawski-Wende, Jackson, LeBoff, Lewis, Chen, Stefanick, Cauley	12	OS	JAMA. 2007 Nov 28;298(20):2389-98	
373	Conjugated equine estrogens and peripheral arterial disease risk: The Women's Health Initiative	**Hsia,** Criqui, Herrington, Manson, Wu, Heckbert, Allison, McDermott, Robinson, Masaki, Women's Health Initiative Research Group	12	CT	Am Heart J. 2006 Jul;152(1):170-6	
376	Circulating levels of endothelial adhesion molecules and risk of diabetes in an ethnically diverse cohort of women	**Song,** Manson, Tinker, Rifai, Cook, Hu, Hotamisligil, Ridker, Rodriguez, Margolis, Oberman, Liu	12	OS	Diabetes. 2007 Jul;56(7):1898-904. Epub 2007 Mar 27	AS132
378	Expression and ambivalence over expression of negative emotion: Cross-sectional associations with psychosocial factors and health-related quality of life in postmenopausal women	**Michael,** Wisdom, Perrin, Bowen, Cochrane, Brzyski, Ritenbaugh	12	Gen	J Women Aging. 2006;18(2):25-40	

Table 12.2 (continued)
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Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
385	Development of a glycemic index database for food frequency questionnaires used in epidemiologic studies	**Neuhouser,** Tinker, Thomson, Caan, VanHorn, Snetselaar, Parker, Patterson, Robinson, Beresford, Shikany	12	CT	J Nutr. 2006 Jun;136(6):1604-9	AS111
386	The role of antioxidants and vitamin A in ovarian cancer: Results from the Women's Health Initiative	**Thomson,** Neuhouser, Shikany, Caan, Monk, Mossavar-Rahmani, Sarto, Parker, Modugno, Anderson	12	Gen	Nutr Cancer. 2008;60(6):710-9	
387	Major and minor ECG abnormalities in asymptomatic women and risk of cardiovascular events and mortality	**Denes,** Larson, Lloyd-Jones, Prineas, Greenland	12	CT	JAMA. 2007 Mar 7;297(9):978-85	
388	Accuracy of commercial geocoding: Assessment and implications	**Whitsel,** Quibrera, Smith, Catellier, Liao, Henley, Heiss	12	CT	Epidemiol Perspect Innov. 2006 Jul 20;3:8	AS140
394	Association between cigarette smoking and colorectal cancer in the Women's Health Initiative	**Paskett,** Reeves, Rohan, Allison, Williams, Messina, Whitlock, Sato, Hunt	12	Gen	J Natl Cancer Inst. 2007 Nov 21;99(22):1729-35. Epub 2007 Nov 13	
398	Osteoporosis and rate of bone loss among postmenopausal survivors of breast cancer	**Chen,** Maricic, Pettinger, Ritenbaugh, Lopez, Barad, Gass, LeBoff, Bassford	12	OS	Cancer. 2005 Oct 1;104(7):1520-30	
401	Are depressive symptoms associated with cancer screening and cancer stage at diagnosis among postmenopausal women? The Women's Health Initiative Observational Cohort	**Aggarwal,** Freund, Sato, Adams-Campbell, Lopez, Lessin, Ockene, Wallace, Williams, Bonds	12	OS	J Womens Health (Larchmt). 2008 Oct;17(8):1353-61. Epub 2008 Sep 14	
404	Fracture risk increases after diagnosis of breast or other cancers in postmenopausal women: Results from the Women's Health Initiative	**Chen,** Maricic, Aragaki, Mouton, Arendell, Lopez, Bassford, Chlebowski	12	Gen	Osteoporos Int. 2009 Apr;20(4):527-36. Epub 2008 Sep 3.	
409	Clinical risk factors for fractures in multi-ethnic women: The Women's Health Initiative	**Cauley,** Wu, Wampler, Barnhart, Allison, Chen, Jackson, Robbins	12	OS	J Bone Miner Res. 2007 Nov;22(11):1816-26	
414	Prehypertension and cardiovascular disease risk in the Women's Health Initiative	**Hsia,** Margolis, Eaton, Wenger, Allison, Wu, LaCroix, Black, Women's Health Initiative Investigators	12	CT	Circulation. 2007 Feb 20;115(7):855-60	
415	GIS approaches for the estimation of residential-level ambient PM concentrations	**Liao,** Peuquet, Duan, Whitsel, Dou, Smith, Lin, Chen, Heiss	12	CT	Environ Health Perspect. 2006 Sep;114(9):1374-80	AS140

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Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
416	Influence of estrogen plus testosterone supplementation on breast cancer	**Ness,** Albano, McTiernan, Cauley	12	OS	Arch Intern Med. 2009 Jan 12;169(1):41-6	
417	Impact of cyclooxygenase inhibitors in the Women's Health Initiative Hormone Trials: Secondary analysis of a randomized trial	**Hsia,** Manson, Kuller, Pettinger, Choe, Langer, Limacher, Oberman, Ockene, O'Sullivan, Robinson	12	CT	PLoS Clin Trials. 2006 Sep 29;1(5):e26	
418	Linear measurement error models with restricted sampling	**Gorfine,** Lipshtat, Freedman, Prentice	12	CT	Biometrics. 2007 Mar;63(1):137-42	
421	Serum alpha-tocopherol, concurrent and past vitamin E intake, and mild cognitive impairment	**Dunn,** Weintraub, Stoddard, Banks	12	Gen	Neurology. 2007 Feb 27;68(9):670-6	AS84
423	Combined analysis of Women's Health Initiative observational and clinical trial data on postmenopausal hormone treatment and cardiovascular disease	**Prentice,** Langer, Stefanick, Howard, Pettinger, Anderson, Barad, Curb, Kotchen, Kuller, Limacher, Wactawski-Wende, Women's Health Initiative Investigators	12	Gen	Am J Epidemiol. 2006 Apr 1;163(7):589-99. Epub 2006 Feb 16	
426	Incident invasive breast cancer, geographic location of residence, and reported average time spent outside	**Millen,** Pettinger, Freudenheim, Langer, Rosenberg, Mossavar-Rahmani, Duffy, Lane, McTiernan, Kuller, Lopez, Wactawski-Wende	12	OS	Cancer Epidemiol Biomarkers Prev. 2009 Feb;18(2):495-507. Epub 2009 Feb 3	
428	Association of pelvic organ prolapse and fractures in postmenopausal women: Analysis of baseline data from the Women's Health Initiative Estrogen plus Progestin Trial	**Pal,** Hailpern, Santoro, Freeman, Barad, Kipersztok, Barnabei, Wassertheil-Smoller	12	Gen	Menopause. 2008 Jan-Feb;15(1):59-66; 2007 Aug 9 [Epub ahead of print]	
429	Can biomarkers identify women at increased stroke risk? The Women's Health Initiative Hormone Trials	**Kooperberg,** Cushman, Hsia, Robinson, Aragaki, Lynch, Baird, Johnson, Kuller, Beresford, Rodriguez	12	Gen	PLoS Clin Trials. 2007 Jun 15;2(6):e28	W6
430	Sleep duration and risk of ischemic stroke in postmenopausal women	**Chen,** Brunner, Ren, Wassertheil-Smoller, Larson, Levine, Allison, Naughton, Stefanick	12	Gen	Stroke. 2008 Dec;39(12):3185-92. Epub 2008 Jul 17	AS140

Table 12.2 (continued)
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Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
433	Baseline serum estradiol and fracture reduction during treatment with hormone therapy: The Women's Health Initiative randomized trial	**Cauley,** LaCroix, Robbins, Larson, Wallace, Wactawski-Wende, Chen, Bauer, Cummings, Jackson	12	CT	Osteoporos Int. 2009 May 13. [Epub ahead of print]	W9
438	Walking speed and risk of incident ischemic stroke among postmenopausal women	**McGinn,** Kaplan, Verghese, Rosenbaum, Psaty, Baird, Lynch, Wolf, Kooperberg, Larson, Wassertheil-Smoller	12	Gen	Stroke. 2008 Apr;39(4):1233-9. Epub 2008 Feb 21	
440	Monitoring and reporting of the Women's Health Initiative randomized hormone therapy trials	**Anderson,** Kooperberg, Gellar, Rossouw, Pettinger, Prentice	12	CT	Clin Trials. 2007;4(3):207-17	
441	Calcium plus vitamin D supplementation and the risk of postmenopausal weight gain	**Caan,** Neuhouser, Aragaki, Lewis, Jackson, LeBoff, Margolis, Powell, Uwaifo, Whitlock, Wylie-Rosette, LaCroix	12	CT	Arch Intern Med. 2007 May 14;167(9):893-902	
442	Test-retest reliability of the Women's Health Initiative Physical Activity Questionnaire	**Meyer,** Evenson, Morimoto, Siscovick, White	12	OS	Med Sci Sports Exerc. 2009 Mar;41(3):530-8. Epub 2009 Feb 6.	W2
444	Associations between age-related nuclear cataract and lutein and zeaxanthin in the diet and serum in the Carotenoids in the Age-Related Eye Disease Study, an Ancillary Study of the Women's Health Initiative [CAREDS]	**Moeller,** Voland, Tinker, Blodi, Klein, Gehrs, Johnson, Snodderly, Wallace, Chappell, Parekh, Ritenbaugh, Mares	12	OS	Arch Ophthalmol. 2008 Mar;126(3):354-364	AS105
445	Usefulness of baseline lipids and C-reactive protein in women receiving menopausal hormone therapy as predictors of treatment-related coronary events	**Bray,** Larson, LaCroix, Manson, Limacher, Rossouw, Lasser, Lawson, Stefanick, Langer, Margolis	12	Gen	Am J Cardiol. 2008 Jun 1;101(11):1599-1605. Epub 2008 Apr 2	W6
447	Low-fat dietary pattern and risk of cardiovascular disease: The Women's Health Initiative Randomized Controlled Dietary Modification Trial	**Howard,** VanHorn, Hsia, Manson, Stefanick, Wassertheil-Smoller, Kuller, LaCroix, Langer, Lasser, Lewis, Limacher, Margolis, Mysiw, et al	12	CT	JAMA. 2006 Feb 8;295(6):655-66	W1

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Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
448	Low-fat dietary pattern and risk of invasive breast cancer: The Women's Health Initiative Randomized Controlled Dietary Modification Trial	**Prentice,** Caan, Chlebowski, Patterson, Kuller, Ockene, Margolis, Limacher, Manson, Parker, Paskett, Phillips, Robbins, Rossouw, et al	12	CT	JAMA. 2006 Feb 8;295(6):629-42	W1, W33
449	Low-fat dietary pattern and risk of colorectal cancer: The Women's Health Initiative Randomized Controlled Dietary Modification Trial.	**Beresford,** Johnson, Ritenbaugh, Lasser, Snetselaar, Black, Anderson, Assaf, Bassford, Bowen, Brunner, Brzyski, Caan, Chlebowski, et al	12	CT	JAMA. 2006 Feb 8;295(6):643-54	W1
450	Calcium plus vitamin D supplementation and the risk for fractures	**Jackson,** LaCroix, Gass, Wallace, Robbins, Lewis, Bassford, Beresford, Black, Blanchette, Bonds, Brunner, Brzyski, Caan, et al	12	CT	N Engl J Med. 2006 Feb 16;354(7):669-83	W15
451	Calcium plus vitamin D supplementation and the risk of colorectal cancer	**Wactawski-Wende,** Kotchen, Anderson, Assaf, Brunner, O'Sullivan, Margolis, Ockene, Phillips, Pottern, Prentice, Robbins, Rohan, Sarto, et al	12	CT	N Engl J Med. 2006 Feb 16;354(7):684-96	W15
452	Macular pigment density and age-related maculopathy in the Carotenoids in Age-Related Eye Disease Study. An ancillary study of the Women's Health Initiative [CAREDS]	**LaRowe,** Mares-Perlman, Snodderly, Klein, Wooten, Chappell, CAREDS Macular Pigment Study Group	12	CT	Ophthalmology. 2008 May;115(5):876-883.e1. Epub 2007 Sep 14	AS105
456	Dual-energy X-ray absorptiometry is a valid tool for assessing skeletal muscle mass in older women	**Chen,** Wang, Lohman, Heymsfield, Outwater, Nicholas, Bassford, LaCroix, Sherrill, Punyanitya, Wu, Going	12	Gen	J Nutr. 2007 Dec;137(12):2775-80	AS153
459	A prospective evaluation of insulin and insulin-like growth factor-I as risk factors for endometrial cancer	**Gunter,** Hoover, Yu, Wassertheil-Smoller, Manson, Li, Harris, Rohan, Xue, Ho, Einstein, Kaplan, Burk, Wylie-Rosette, Pollak	12	OS	Cancer Epidemiol Biomarkers Prev. 2008 Apr;17(4):921-9	AS129

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
460	Insulin, insulin-like growth factor-I, endogenous estradiol, and risk of colorectal cancer in postmenopausal women	**Gunter,** Hoover, Yu, Wassertheil-Smoller, Rohan, Manson, Howard, Wylie-Rosette, Anderson, Ho, Kaplan, Li, Xue, Harris, Burk	12	OS	Cancer Res. 2008 Jan 1;68(1):329-37	AS129
461	Insulin, insulin-like growth factor-I, and risk of breast cancer in postmenopausal women	**Gunter,** Hoover, Yu, Wassertheil-Smoller, Rohan, Manson, Li, Ho, Xue, Anderson, Kaplan, Harris, Howard, Wylie-Rosette, Burk	12	OS	J Natl Cancer Inst. 2009 Jan 7;101(1):48-60. Epub 2008 Dec 30	AS129
464	Use of recovery biomarkers to calibrate nutrient consumption self-reports in the Women's Health Initiative [NBS]	**Neuhouser,** Tinker, Shaw, Schoeller, Bingham, VanHorn, Beresford, Caan, Thomson, Satterfield, Kuller, Heiss, Smit, Sarto, Ockene	12	CT	Am J Epidemiol. 2008 May 15;167(10):1247-59. Epub 2008 Mar 15	W8
467	Low-fat, increased fruit, vegetable, and grain dietary pattern, fractures, and bone mineral density: the Women's Health Initiative Dietary Modification Trial	**McTiernan,** Wactawski-Wende, Wu, Rodabough, Watts, Tylavsky, Freeman, Hendrix, Jackson	12	CT	Am J Clin Nutr. 2009 Jun;89(6):1864-76. Epub 2009 Apr 29.	
468	Effect of calcium and vitamin D supplementation on blood pressure: The Women's Health Initiative Randomized Trial	**Margolis,** Ray, VanHorn, Manson, Allison, Black, Beresford, Connelly, Curb, Grimm, Kotchen, Kuller, Wassertheil-Smoller, Thomson, Torner	12	CT	Hypertension. 2008 Nov;52(5):847-55. Epub 2008 Sep 29	
469	Low-fat dietary pattern and cancer incidence in the Women's Health Initiative Dietary Modification Randomized Controlled Trial	**Prentice,** Thomson, Caan, Hubbell, Anderson, Beresford, Pettinger, Lane, Lessin, Yasmeen, Singh, Khandekar, Shikany, Satterfield, Chlebowski	12	CT	J Natl Cancer Inst. 2007 Oct 17;99(20):1534-43. Epub 2007 Oct 9	W31
471	Calcium/vitamin D supplementation and cardiovascular events	**Hsia,** Heiss, Ren, Allison, Dolan, Greenland, Heckbert, Johnson, Manson, Sidney, Trevisan, Women's Health Initiative Investigators	12	CT	Circulation. 2007 Feb 20;115(7):846-54	

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
472	Calcium plus Vitamin D supplementation and mortality in postmenopausal women: The Women's Health Initiative Calcium-Vitamin D Randomized Controlled Trial	**LaCroix,** Kotchen, Anderson, Brzyski, Cauley, Cummings, Gass, Johnson, Ko, Larson, Manson, Stefanick, Wactawski-Wende	12	CT	J Gerontol A Biol Sci Med Sci. 2009 May;64(5):559-67. Epub 2009 Feb 16.	
475	Calcium, vitamin D supplementation, and physical function in the Women's Health Initiative	**Brunner,** Cochrane, Jackson, Larson, Lewis, Limacher, Rosal, Shumaker, Wallace, Women's Health Initiative Investigators	12	CT	J Am Diet Assoc. 2008 Sep;108(9):1472-9	
479	Homocysteine levels and risk of hip fracture in postmenopausal women	**LeBoff,** Narweker, LaCroix, Wu, Jackson, Lee, Bauer, Cauley, Kooperberg, Lewis, Thomas, Cummings	12	OS	J Clin Endocrinol Metab. 2009 Apr;94(4):1207-13. Epub 2009 Jan 27.	AS90
481	Associations of serum sex hormone-binding globulin and sex hormone concentrations with hip fracture risk in postmenopausal women	**Lee,** LaCroix, Wu, Cauley, Jackson, Kooperberg, LeBoff, Robbins, Lewis, Bauer, Cummings	12	OS	J Clin Endocrinol Metab. 2008 May;93(5):1796-803. Epub 2008 Mar 11	AS90
482	Plasma folate, vitamin B6, vitamin B12, and homocysteine and pancreatic cancer risk in four large cohorts	**Schernhammer,** Wolpin, Rifai, Cochrane, Manson, Ma, Giovannucci, Thomson, Stampfer, Fuchs	12	OS	Cancer Res. 2007 Jun 1;67(11):5553-60	AS146
483	Prediagnostic plasma C-peptide and pancreatic cancer risk in men and women	**Michaud,** Wolpin, Giovannucci, Liu, Cochrane, Manson, Pollak, Ma, Fuchs	12	OS	Cancer Epidemiol Biomarkers Prev. 2007 Oct;16(10):2101-9. Epub 2007 Sep 28	AS146
484	Circulating insulin-like growth factor axis and the risk of pancreatic cancer in four prospective cohorts	**Wolpin,** Michaud, Giovannucci, Schernhammer, Stampfer, Manson, Cochrane, Rohan, Ma, Pollak, Fuchs	12	OS	Br J Cancer. 2007 Jul 2;97(1):98-104. Epub 2007 May 29	AS146
486	Insulin sensitivity and insulin secretion determined by homeostasis model assessment and risk of diabetes in a multiethnic cohort of women: The Women's Health Initiative Observational Study	**Song,** Manson, Tinker, Howard, Kuller, Nathan, Rifai, Liu	12	OS	Diabetes Care. 2007 Jul;30(7):1747-52. Epub 2007 Apr 27	AS132
489	Does obesity really make the femur stronger? Bone Mineral Density, geometry and fracture incidence in the Women's Health Initiative - Observational Study	**Beck,** Petit, Wu, LeBoff, Cauley, Chen	12	OS	J Bone Miner Res. 2009 Aug;24(8):1369-79.	AS153

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
492	Cardiovascular risk in women with non-specific chest pain (from the Women's Health Initiative Hormone Trials)	**Robinson,** Wallace, Limacher, Ren, Cochrane, Wassertheil-Smoller, Ockene, Blanchette, Ko	12	CT	Am J Cardiol. 2008 Sep 15;102(6):693-9. Epub 2008 Jul 2	
493	Panic attacks and risk of Incident cardiovascular events among postmenopausal women in the Women's Health Initiative observational study	**Smoller,** Pollack, Wassertheil-Smoller, Jackson, Oberman, Wong, Sheps	12	OS	Arch Gen Psychiatry. 2007 Oct;64(10):1153-60	
495	Natural history of pelvic organ prolapse in postmenopausal women	**Bradley,** Zimmerman, Qi, Nygaard	12	CT	Obstet Gynecol. 2007 Apr;109(4):848-54	AS135
496	Hip bone density predicts breast cancer risk independently of Gail score: Results from the Women's Health Initiative	**Chen,** Arendell, Aickin, Cauley, Lewis, Chlebowski	12	Gen	Cancer. 2008 Sep 1;113(5):907-15. Epub 2008 Jul 29	
501	Health risks and benefits 3 years after stopping randomized treatment with estrogen and progestin	**Heiss,** Wallace, Anderson, Aragaki, Beresford, Brzyski, Chlebowski, Gass, LaCroix, Manson, Prentice, Rossouw, Stefanick, Women's Health Initiative Investigators	12	CT	JAMA. 2008 Mar 5;299(9):1036-45	
503	Oophorectomy, hormone therapy, and subclinical coronary artery disease in women with hysterectomy: the Women's Health Initiative coronary artery calcium study [WHI-CACS]	**Allison,** Manson, Langer, Carr, Rossouw, Pettinger, Phillips, Cochrane, Eaton, Greenland, Hendrix, Hsia, Hunt, Jackson, Johnson	12	CT	Menopause. 2008 Jul-Aug;15(4 Pt 1):639-47. Epub 2008 May 2	W25
504	A comparison of two dietary instruments for evaluating the fat-breast cancer relationship	**Freedman,** Potischman, Kipnis, Midthune, Schatzkin, Thompson, Troiano, Prentice, Patterson, Carroll, Subar	12	CT	Int J Epidemiol. 2006 Aug;35(4):1011-21. Epub 2006 May 3	
506	Estrogen therapy and coronary-artery calcification [WHI-CACS]	**Manson,** Allison, Rossouw, Carr, Langer, Hsia, Kuller, Cochrane, Hunt, Ludlam, Pettinger, Gass, Margolis, Nathan, et al	12	CT	N Engl J Med. 2007 Jun 21;356(25):2591-602	W25
508	Alcohol and folate consumption and risk of benign proliferative epithelial disorders of the breast [Benign breast disease study]	**Cui,** Page, Chlebowski, Beresford, Hendrix, Lane, Rohan	12	CT	Int J Cancer. 2007 Sep 15;121(6):1346-51	AS130

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
509	Cigarette smoking and risk of benign proliferative epithelial disorders of the breast in the Women's Health Initiative [Benign breast disease study]	**Cui,** Page, Chlebowski, Hsia, Hubbell, Johnson, Rohan	12	CT	Cancer Causes Control. 2007 May;18(4):431-8. Epub 2007 Feb 24	AS130
514	Selected antioxidants and risk of hormone receptor-defined invasive breast cancers among postmenopausal women in the Women's Health Initiative Observational Study	**Cui,** Shikany, Liu, Yasmeen, Rohan	12	OS	Am J Clin Nutr. 2008 Apr;87(4):1009-18	
518	Baseline monograph - foreword	**Rossouw,** Anderson, Oberman	12	Gen	Ann Epidemiol. 2003 Oct;13:S1-S4	
519	Implementation of the Women's Health Initiative study design	**Anderson,** Manson, Wallace, Lund, Hall, Davis, Shumaker, Wang, Stein, Prentice	12	Gen	Ann Epidemiol. 2003 Oct;13(9 Suppl):S5-17	
520	The Women's Health Initiative recruitment methods and results	**Hays,** Hunt, Hubbell, Anderson, Limacher, Allen, Rossouw	12	OS	Ann Epidemiol. 2003 Oct;13(9 Suppl):S18-77	W1
521	The Women's Health Initiative postmenopausal hormone trials: Overview and baseline characteristics of participants	**Stefanick,** Cochrane, Hsia, Barad, Liu, Johnson	12	Gen	Ann Epidemiol. 2003 Oct;13(9 Suppl):S78-86	W1
522	The Women's Health Initiative Dietary Modification trial: Overview and baseline characteristics of participants	**Ritenbaugh,** Patterson, Chlebowski, Caan, Tinker, Howard, Ockene	12	Gen	Ann Epidemiol. 2003 Oct;13(9 Suppl):S87-97	
523	The Women's Health Initiative calcium-vitamin D trial: Overview and baseline characteristics of participants	**Jackson,** LaCroix, Cauley, McGowan	12	Gen	Ann Epidemiol. 2003 Oct;13(9 Suppl):S98-106	
524	The Women's Health Initiative Observational Study: Baseline characteristics of participants and reliability of baseline measures	**Langer,** White, Lewis, Kotchen, Hendrix, Trevisan	12	OS	Ann Epidemiol. 2003 Oct;13(9 Suppl):S107-21	W1, W2
525	Outcomes ascertainment and adjudication methods in the Women's Health Initiative	**Curb,** McTiernan, Heckbert, Kooperberg, Stanford, Nevitt, Johnson, Proulx-Burns, Pastore, Criqui, Daugherty, WHI Morbidity and Mortality Committee	12	Gen	Ann Epidemiol. 2003 Oct;13(9 Suppl):S122-8	

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
526	Inflammatory, lipid, thrombotic, and genetic markers of coronary heart disease risk in the Women's Health Initiative trials of hormone therapy	**Rossouw,** Cushman, Greenland, Lloyd-Jones, Bray, Kooperberg, Pettinger, Robinson, Hendrix, Hsia	12	CT	Arch Intern Med. 2008 Nov 10;168(20):2245-53	W6
527	Predictors of change in calcium intake in postmenopausal women after osteoporosis screening	**McLeod,** McCann, Horvath, Wactawski-Wende	12	OS	J Nutr. 2007 Aug;137(8):1968-73	AS98
529	Ambient fine particulate matter exposure and myocardial ischemia in the Environmental Epidemiology of Arrhythmogenesis in the Women's Health Initiative (EEAWHI)	**Zhang,** Whitsel, Quibrera, Smith, Liao, Anderson, Prineas	12	CT	Environ Health Perspect. 2009 May;117(5):751-6. Epub 2009 Jan 23.	AS140
535	Lipoprotein particle concentrations may explain the absence of coronary protection in the Women's Health Initiative Hormone Trials	**Hsia,** Otvos, Rossouw, Wu, Wassertheil-Smoller, Hendrix, Robinson, Lund, Kuller, for the Women's Health Initiative Research Group	12	CT	Arterioscler Thromb Vasc Biol. 2008 Sep;28(9):1666-71. Epub 2008 Jul 3	
536	Sexual satisfaction and cardiovascular disease: The Women's Health Initiative	**McCall-Hosenfeld,** Freund, Legault, Jaramillo, Cochrane, Manson, Wenger, Eaton, McNeeley, Rodriguez, Bonds	12	OS	Am J Med. 2008 Apr;121(4):295-301	
538	Electrocardiographic predictors of incident congestive heart failure and all-cause mortality in postmenopausal women: The Women's Health Initiative	**Rautaharju,** Kooperberg, Larson, LaCroix	12	CT	Circulation. 2006 Jan 31;113(4):481-9	
541	Low-fat dietary pattern and risk of treated diabetes mellitus in postmenopausal women: the Women's Health Initiative randomized controlled dietary modification trial	**Tinker,** Bonds, Margolis, Manson, Howard, Larson, Perri, Beresford, Robinson, Rodriguez, Safford, Wenger, Stevens, Parker	12	CT	Arch Intern Med. 2008 Jul 28;168(14):1500-11	
542	Enrollment in a brain magnetic resonance study: Results from the Women's Health Initiative Memory Study Magnetic Resonance Imaging Study (WHIMS-MRI) [WHIMS-MRI]	**Jaramillo,** Felton, Andrews, Desiderio, Hallam, Jackson, Coker, Robinson, Ockene, Espeland, Women's Health Initiative Memory Study Research Group	12	WHIMS	Acad Radiol. 2007 May;14(5):603-12	AS183

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
544	Menstrual and reproductive history, postmenopausal hormone use, and risk of benign proliferative epithelial disorders of the breast: A cohort study [Benign breast disease study]	**Cui,** Page, Lane, Rohan	12	CT	Breast Cancer Res Treat. 2009 Mar;114(1):113-20. Epub 2008 Mar 22	AS130
549	Semiparametric estimation exploiting covariate independence in two-phase randomized trials	**Dai,** LeBlanc, Kooperberg	12	Gen	Biometrics. 2009 Mar;65(1):178-87. Epub 2008 May 13.	
550	Common genetic variation in calpain-10 gene (CAPN10) and diabetes risk in a multi-ethnic cohort of American postmenopausal women	**Song,** You, Hsu, Sul, Wang, Tinker, Eaton, Liu	12	OS	Hum Mol Genet. 2007 Dec 1;16(23):2960-71. Epub 2007 Sep 12	AS132
554	Genetic variants in the UCP2-UCP3 gene cluster and risk of diabetes in the Women's Health Initiative Observational Study	**Hsu,** Niu, Song, Tinker, Kuller, Liu	12	OS	Diabetes. 2008 Apr;57(4):1101-7. Epub 2008 Jan 25	AS132
560	Loop diuretic use and fracture in postmenopausal women: Findings from the Women's Health Initiative	**Carbone,** Johnson, Bush, Robbins, Larson, Thomas, LaCroix	12	CT	Arch Intern Med. 2009 Jan 26;169(2):132-40	
563	Cystatin-C, renal function, and incidence of hip fracture in postmenopausal women	**LaCroix,** Lee, Wu, Cauley, Shlipak, Ott, Robbins, Curb, LeBoff, Bauer, Jackson, Kooperberg, Cummings	12	OS	J Am Geriatr Soc. 2008 Aug;56(8):1434-41. Epub 2008 Jul 24	AS90
565	Self-reported osteoarthritis, ethnicity, body mass index, and other associated risk factors in postmenopausal women: Results from the Women's Health Initiative	**Wright,** Kershner Riggs, Lisse, Chen	12	Gen	J Am Geriatr Soc. 2008 Sep;56(9):1736-43. Epub 2008 Jul 17	
569	Hip structural geometry and incidence of hip fracture in postmenopausal women: What does it add to conventional bone mineral density?	**LaCroix,** Beck, Cauley, Lewis, Bassford, Jackson, Wu, Chen	12	CT	Osteoporos Int. 2009 Sep 15. [Epub ahead of print]	AS153
576	Circulating insulin-like growth factor binding protein-1 and the risk of pancreatic cancer	**Wolpin,** Michaud, Giovannucci, Schernhammer, Stampfer, Manson, Cochrane, Rohan, Ma, Pollak, Fuchs	12	OS	Cancer Res. 2007 Aug 15;67(16):7923-8	AS146

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Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
577	Women's Health Initiative Diet Intervention did not increase macular pigment optical density in an Ancillary Study of a subsample of the Women's Health Initiative	**Moeller,** Voland, Sarto, Gobel, Streicher, Mares-Perlman	12	CT	J Nutr. 2009 Sep;139(9):1692-9. Epub 2009 Jul 8.	AS219
583	Multivitamin use and risk of cancer and cardiovascular disease in the Women's Health Initiative cohorts	**Neuhouser,** Wassertheil-Smoller, Thomson, Aragaki, Anderson, Manson, Patterson, Rohan, VanHorn, Shikany, Thomas, LaCroix, Prentice	12	CT	Arch Intern Med. 2009 Feb 9;169(3):294-304	
584	A randomized controlled trial of calcium plus vitamin D supplementation and risk of benign proliferative breast disease [Benign breast disease study]	**Rohan,** Negassa, Chlebowski, Ceria-Ulep, Cochrane, Lane, Ginsberg, Wassertheil-Smoller, Page	12	CT	Breast Cancer Res Treat. 2009 Jul;116(2):339-50. Epub 2008 Oct 14.	AS130
585	Low-fat dietary pattern and risk of benign proliferative breast disease: A randomized, controlled dietary modification trial [Benign breast disease study]	**Rohan,** Negassa, Caan, Chlebowski, Curb, Ginsberg, Lane, Neuhouser, Shikany, Wassertheil-Smoller, Page	12	CT	Cancer Prev Res (Phila Pa). 2008 Sep;1(4):275-84. Epub 2008 Jul 9	AS130
586	Conjugated equine estrogen and risk of benign proliferative breast disease: A randomized controlled trial [Benign breast disease study]	**Rohan,** Negassa, Chlebowski, Habel-Oakland, McTiernan, Ginsberg, Wassertheil-Smoller, Page	12	CT	J Natl Cancer Inst. 2008 Apr 16;100(8):563-71. Epub 2008 Apr 8	AS130
587	Estrogen plus progestin and risk of benign proliferative breast disease [Benign breast disease study]	**Rohan,** Negassa, Chlebowski, Lasser, McTiernan, Schenken, Wassertheil-Smoller, Page	12	CT	Cancer Epidemiol Biomarkers Prev. 2008 Sep;17(9):2337-43. Epub 2008 Aug 25	AS130
590	Duration of lactation and risk factors for maternal cardiovascular disease	**Schwarz,** Ray, Stuebe, Allison, Ness, Freiberg, Cauley	12	Gen	Obstet Gynecol. 2009 May;113(5):974-982.	
591	Association between different measures of blood pressure and coronary artery calcium in postmenopausal women [WHI-CACS]	**Allison,** Manson, Langer, Aragaki, Wassertheil-Smoller, Lewis, Thomas, Lawson, Cochrane, Hsia, Hunt, Robinson	12	CT	Hypertension. 2008 Nov;52(5):833-40. Epub 2008 Sep 15	W25
592	Vaginal descent and pelvic floor symptoms in postmenopausal women: A longitudinal study	**Bradley,** Zimmerman, Wang, Nygaard	12	CT	Obstet Gynecol. 2008 May;111(5):1148-53	AS135

Table 12.2 (continued)
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Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
594	Association between dietary fiber and markers of systemic inflammation in the Women's Health Initiative Observational Study	**Ma,** Hebert, Li, Bertone-Johnson, Olendzki, Pagoto, Tinker, Rosal, Ockene, Ockene, Griffith, Liu	12	OS	Nutrition. 2008 Oct;24(10):941-9. Epub 2008 Jun 18	AS132
602	Inflammation and hemostasis biomarkers for predicting stroke in postmenopausal women: the Women's Health Initiative Observational Study	**Kaplan,** McGinn, Baird, Hendrix, Kooperberg, Lynch, Rosenbaum, Johnson, Strickler, Wassertheil-Smoller	12	OS	J Stroke Cerebrovasc Dis. 2008 Nov-Dec;17(6):344-55	AS126
603	Lipoprotein-associated phospholipase A2, hormone use, and the risk of ischemic stroke in postmenopausal women	**Wassertheil-Smoller,** Kooperberg, McGinn, Kaplan, Hsia, Hendrix, Manson, Berger, Kuller, Allison, Baird	12	OS	Hypertension. 2008 Apr;51(4):1115-22. Epub 2008 Feb 7	AS126
609	Ambient particulate air pollution and ectopy: The environmental epidemiology of arrhythmogenesis in Women's Health Initiative Study, 1999-2004	**Liao,** Whitsel, Duan, Lin, Quibrera, Smith, Peuquet, Prineas, Zhang, Anderson	12	CT	J Toxicol Environ Health A. 2009;72(1):30-8	AS140
613	Obesity and risk of pancreatic cancer among postmenopausal women: the Women's Health Initiative (United States)	**Luo,** Margolis, Adami, LaCroix, Ye, Women's Health Initiative Investigators	12	Gen	Br J Cancer. 2008 Aug 5;99(3):527-31. Epub 2008 Jul 15	
614	Incidence of fractures compared to cardiovascular disease and breast cancer: The Women's Health Initiative Observational Study	**Cauley,** Wampler, Barnhart, Wu, Allison, Chen, Hendrix, Robbins, Jackson	12	OS	Osteoporos Int. 2008 Dec;19(12):1717-23. Epub 2008 Jul 16	
618	Dietary carbohydrate, glycemic index, and glycemic load in relation to colorectal cancer risk in the Women's Health Initiative	**Kabat,** Shikany, Beresford, Caan, Neuhouser, Tinker, Rohan	12	CT	Cancer Causes Control. 2008 Dec;19(10):1291-8. Epub 2008 Jul 10	
620	Calcium plus vitamin D supplementation and the risk of incident diabetes in the Women's Health Initiative	**DeBoer,** Tinker, Connelly, Curb, Howard, Kestenbaum, Larson, Manson, Margolis, Siscovick, Weiss, Women's Health Initiative Investigators	12	CT	Diabetes Care. 2008 Apr;31(4):701-7. Epub 2008 Jan 30	
624	Biomarker-calibrated energy and protein consumption and increased cancer risk among postmenopausal women [NBS]	**Prentice,** Shaw, Bingham, Beresford, Caan, Neuhouser, Patterson, Stefanick, Satterfield, Thomas, Snetselaar, Thomson, Tinker	12	Gen	Am J Epidemiol. 2009 Apr 15;169(8):977-89. Epub 2009 Mar 3.	W8

Table 12.2 (continued)
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Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
625	Postmenopausal hormone therapy and subclinical cerebrovascular disease: The WHIMS-MRI Study [WHIMS-MRI]	**Coker,** Hogan, Bryan, Kuller, Margolis, Betterman, Wallace, Lao, Freeman, Stefanick, Shumaker	12	WHIMS	Neurology. 2009 Jan 13;72(2):125-34	AS183
626	Postmenopausal hormone therapy and regional brain volumes: The WHIMS-MRI Study [WHIMS-MRI]	**Resnick,** Espeland, Jaramillo, Hirsch, Stefanick, Murray, Ockene, Davatzikos	12	WHIMS	Neurology. 2009 Jan 13;72(2):135-42	AS183
628	Benefits and risks of postmenopausal hormone therapy when it is initiated soon after menopause	**Prentice,** Manson, Langer, Anderson, Pettinger, Jackson, Johnson, Kuller, Lane, Wactawski-Wende, Brzyski, Allison, Ockene, Sarto, Rossouw	12	Gen	Am J Epidemiol. 2009 Jul 1;170(1):12-23. Epub 2009 May 25.	
630	Colorectal cancer in relation to postmenopausal estrogen and estrogen plus progestin in the Women's Health Initiative Clinical Trial and Observational Study	**Prentice,** Pettinger, Beresford, Wactawski-Wende, Hubbell, Stefanick, Chlebowski	12	Gen	Cancer Epidemiol Biomarkers Prev. 2009 May;18(5):1531-7.	
631	Body mass index and waist circumference in relation to lung cancer risk in the Women's Health Initiative	**Kabat,** Kim, Hunt, Chlebowski, Rohan	12	Gen	Am J Epidemiol. 2008 Jul 15;168(2):158-69. Epub 2008 May 15	
632	Clinical attachment loss, systemic bone density, and subgingival calculus in postmenopausal women	**Brennan,** Genco, Hovey, Trevisan, Wactawski-Wende	12	OS	J Periodontol. 2007 Nov;78(11):2104-11	AS98
633	Vitamin A and retinol intakes and the risk of fractures among participants of the Women's Health Initiative Observational Study	**Caire-Juvera,** Ritenbaugh, Wactawski-Wende, Snetselaar, Chen	12	OS	Am J Clin Nutr. 2009 Jan;89(1):323-30. Epub 2008 Dec 3	AS153
634	Serum 25-hydroxyvitamin D concentrations and risk for hip fractures	**Cauley,** LaCroix, Wu, Horwitz, Danielson, Bauer, Lee, Jackson, Robbins, Stanczyk, LeBoff, Wactawski-Wende, Sarto, Ockene, Cummings	12	OS	Ann Intern Med. 2008 Aug 19;149(4):242-50	AS181
635	Validation of self-report of rheumatoid arthritis and systemic lupus erythematosus: The Women's Health Initiative	**Walitt,** Constantinescu, Katz, Weinstein, Wang, Hernandez, Hsia, Howard	12	OS	J Rheumatol. 2008 May;35(5):811-8. Epub 2008 Apr 1	AS217

Table 12.2 (continued)
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Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
636	Effect of weight change on natural history of pelvic organ prolapse	**Kudish,** Iglesia, Sokol, Cochrane, Richter, Larson, Hendrix, Howard	12	CT	Obstet Gynecol. 2009 Jan;113(1):81-88	
641	Resting heart rate as a low tech predictor of coronary events in women: prospective cohort study	**Hsia,** Larson, Ockene, Sarto, Allison, Hendrix, Robinson, LaCroix, Manson, Women's Health Initiative Research Group	12	Gen	BMJ. 2009 Feb 3;338:b219. doi: 10.1136/bmj.b219	
645	Abdominal aortic aneurysm events in the Women's Health Initiative: cohort study	**Lederle,** Larson, Margolis, Allison, Freiberg, Cochrane, Graettinger, Curb	12	Gen	BMJ. 2008 Oct 14;337:a1724	
651	Alcohol consumption, hypertension, and total mortality among women	**Freiberg,** Chang, Kraemer, Robinson, Adams-Campbell, Kuller	12	OS	Am J Hypertens. 2009 Sep 3. [Epub ahead of print]	
652	Osteoporosis and oral infection: Independent risk factors for oral bone loss	**Brennan-Calanan,** Genco, Wilding, Hovey, Trevisan, Wactawski-Wende	12	OS	J Dent Res. 2008 Apr;87(4):323-7	AS98
657	Correlates of sexual satisfaction among sexually active postmenopausal women in the Women's Health Initiative-Observational Study	**McCall-Hosenfeld,** Jaramillo, Legault, Freund, Cochrane, Manson, Wenger, Eaton, Rodriguez, McNeeley, Bonds	12	OS	J Gen Intern Med. 2008 Dec;23(12):2000-9. Epub 2008 Oct 7	
660	Relation of genetic variation in the gene coding for c-reactive protein with its plasma protein levels: Findings from the Women's Health Initiative observational cohort	**Lee,** You, Song, Hsu, Manson, Nathan, Tinker, Liu	12	OS	Clin Chem. 2009 Feb;55(2):351-60. Epub 2008 Dec 18.	AS132
662	Inflammation and thrombosis biomarkers and incident frailty in postmenopausal women	**Reiner,** Aragaki, Gray, Wactawski-Wende, Cauley, Cochrane, Kooperberg, Woods, LaCroix	12	OS	Am J Med. 2009 Aug 12. [Epub ahead of print]	AS179
664	FTO polymorphisms are associated with obesity but not diabetes risk in postmenopausal women	**Song,** You, Hsu, Howard, Langer, Manson, Nathan, Niu, Tinker, Liu	12	OS	Obesity (Silver Spring). 2008 Nov;16(11):2472-80. Epub 2008 Sep 11	AS132
673	Mortality risk associated with physical and verbal abuse in women aged 50 to 79	**Baker,** LaCroix, Wu, Cochrane, Wallace, Woods	12	Gen	J Am Geriatr Soc. 2009 Aug 13. [Epub ahead of print]	

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
676	Vasomotor symptoms, adoption of a low-fat dietary pattern, and risk of invasive breast cancer: A secondary analysis of the Women's Health Initiative Randomized Controlled Dietary Modification Trial	**Caan,** Aragaki, Thomson, Stefanick, Chlebowski, Hubbell, Tinker, Vitolins, Rajkovic, Bueche, Ockene	12	CT	J Clin Oncol. 2009 August 17. [Epub ahead of print]	
677	Calcium plus vitamin D supplementation and the risk of breast cancer	**Chlebowski,** Johnson, Kooperberg, Pettinger, Wactawski-Wende, Rohan, Lane, O'Sullivan, Yasmeen, Hiatt, Shikany, Vitolins, Khandekar, Hubbell, Rossouw	12	CT	J Natl Cancer Inst. 2008 Nov 19;100(22):1581-1591. Epub 2008 Nov 11	
689	A partial least-square approach for modeling gene-gene and gene-environment interactions when multiple markers are genotyped	**Wang,** Ho, Ye, Strickler, Elston	12	OS	Genet Epidemiol. 2008 Jul 9;33(1):6-15.	AS152
697	Optimism, cynical hostility, and incident coronary heart disease and mortality in the Women's Health Initiative	**Tindle,** Chang, Kuller, Manson, Robinson, Rosal, Siegle, Matthews	12	Gen	Circulation. 2009 Aug 25;120(8):656-62. Epub 2009 Aug 10.	
700	Women's Health Initiative dietary modification randomized controlled trial	**Mossavar-Rahmani,** Tinker	12	CT	In: D'Agostino RB et al, eds. Wiley encyclopedia of clinical trials. New York: Wiley-Interscience, 2008	
701	Statistical issues arising in the Women's Health Initiative	**Prentice,** Pettinger, Anderson	12	Gen	Biometrics. 2005 Dec;61(4):899-911; discussion 911-41	
715	Projecting individualized absolute invasive breast cancer risk in African American women	**Gail,** Costantino, Pee, Bondy, Newman, Selvan, Anderson, Malone, Marchbanks, McCaskill-Stevens, Norman, Simon, Spirtas, Ursin, Bernstein	12	Gen	J Natl Cancer Inst. 2007 Dec 5;99(23):1782-92. Epub 2007 Nov 27	
723	Breast cancer after use of estrogen plus progestin in postmenopausal women	**Chlebowski,** Kuller, Prentice, Stefanick, Manson, Gass, Aragaki, Ockene, Lane, Sarto, Rajkovic, Schenken, Hendrix, Ravdin, Rohan	12	CT	N Engl J Med. 2009 Feb 5;360(6):573-87	

Table 12.2 (continued)
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Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
731	Postmenopausal hormone therapy for disease prevention: Have we learned any lessons from the past?	**Rossouw**	12	Gen	Clin Pharmacol Ther. 2008 Jan;83(1):14-6	
732	The Women's Health Initiative: Be part of the answer!	**Tinker**	12	Gen	J Am Diet Assoc. 1995 Dec;95(12):1375	
733	The Women's Health Initiative Clinical Trial and Observational Study: History and overview	**Assaf,** Carleton	12	Gen	R I Med. 1994 Dec;77(12):424-7	
734	Barriers to black women's participation in cancer clinical trials	**Mouton,** Harris, Rovi, Solorzano, Johnson	12	Gen	J Natl Med Assoc. 1997 Nov;89(11):721-7.	
735	Evaluation of a simplified vitamin supplement inventory developed for the Women's Health Initiative	**Patterson,** Levy, Tinker, Kristal	12	Gen	Public Health Nutr. 1999 Sep;2(3):273-6	
736	Meeting the challenges of recruiting and retaining participants in clinical trials	**Vozenilek**	12	CT	J Am Diet Assoc. 1999 Oct;99(10):1190, 1192	
737	Commentary on the Women's Health Initiative	**McGowan,** Pottern	12	Gen	Maturitas. 2000 Feb 15;34(2):109-12	
738	Individually randomized intervention trials for disease prevention and control	**Anderson,** Prentice	12	CT	Stat Methods Med Res. 1999 Dec;8(4):287-309	
739	Effect of postmenopausal hormone therapy on cardiovascular risk	**Rossouw**	12	CT	J Hypertens Suppl. 2002 May;20(2):S62-5	
740	Hormone replacement therapy: Applying the results of the Women's Health Initiative	**Johnson**	12	CT	Cleve Clin J Med. 2002 Sep;69(9):682, 685	
741	Participant characteristics associated with errors in self-reported energy intake from the Women's Health Initiative food-frequency questionnaire	**Horner,** Patterson, Neuhouser, Lampe, Beresford, Prentice	12	Gen	Am J Clin Nutr. 2002 Oct;76(4):766-73	
742	Risks, fears and choices: Unexpected lessons from the Women's Health Initiative	**Jeffcoat**	12	Gen	J Am Dent Assoc. 2002 Oct;133(10):1314, 1316, 1318	
743	The Women's Health Initiative estrogen plus progestin trial: The study and how it changes our practice	**Hendrix**	12	CT	J Am Osteopath Assoc. 2003 Feb;103(2 Suppl 2):S3-5	
744	Treatment of menopause: Recommendations for hormonal and non-hormonal therapy	**Johnson**	12	Gen	J Okla State Med Assoc. 2003 Mar;96(3):140-2	

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
745	Hormone therapy: Evolving concepts	**Hendrix**	12	CT	Curr Opin Rheumatol. 2003 Jul;15(4):464-8	
746	Impact of WHI conclusions and ACOG guidelines on clinical practice	**Gass**	12	Gen	Int J Fertil Womens Med. 2003 May-Jun;48(3):106-10; discussion 137-8	
747	HT and breast cancer risk	**Geller,** Chlebowski	12	Gen	Fertil Steril. 2003 Oct;80 Suppl 4:5-9; quiz 54-5	
748	Estrogen with and without progestin: Benefits and risks of short-term use	**LaCroix**	12	Gen	Am J Med. 2005 Dec 19;118 Suppl 12B:79-87	
749	Ethnicity, sleep, mood, and illumination in postmenopausal women	**Kripke,** Jean-Louis, Elliott, Klauber, Rex, Tuunainen, Langer	12	CT	BMC Psychiatry. 2004 Apr 7;4:8	AS11
750	Women's cognitive health: Postmenopausal dementia and the Women's Health Initiative Memory Study [WHIMS]	**Klein,** Rapp	12	CT	Womens Health Issues. 2004 May-Jun;14(3):71-4	AS39
751	Concerns about published data from the estrogen-progestin (HT) arm of the WHI	**Gass,** Anderson, Barad	12	CT	Am J Obstet Gynecol. 2005 Jan;192(1):333; author reply 334	
752	Validation of the Women's Health Initiative Insomnia Rating Scale in a multicenter controlled clinical trial	**Levine,** Dailey, Rockhill, Tipping, Naughton, Shumaker	12	CT	Psychosom Med. 2005 Jan-Feb;67(1):98-104	
753	Menopausal hormone therapy: Currently no evidence for cardiac protection	**Wenger**	12	Gen	Pediatr Blood Cancer. 2005 Jun 15;44(7):625-9	
754	Postmenopausal hormone therapy: Critical reappraisal and a unified hypothesis	**Phillips,** Langer	12	CT	Fertil Steril. 2005 Mar;83(3):558-66	
755	Reanalysis of the Women's Health Initiative oral contraceptive data reveals no evidence of delayed cardiovascular benefit	**Stefanick,** Prentice, Anderson, Gass, Manson, Hendrix, Vista-Deck, McNeeley, Women's Health Initiative Steering Committee	12	Gen	Fertil Steril. 2005 Apr;83(4):853-4	
756	Abnormal mammographic findings with short-interval follow-up recommendation	**Chlebowski,** Khalkhali	12	Gen	Clin Breast Cancer. 2005 Aug;6(3):235-9	
757	Estrogens and progestins: Background and history, trends in use, and guidelines and regimens approved by the US Food and Drug Administration	**Stefanick**	12	Gen	Am J Med. 2005 Dec 19;118 Suppl 12B:64-73	

Table 12.2 (continued)
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Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
758	Aspects of the design and analysis of high-dimensional SNP studies for disease risk estimation	**Prentice,** Qi	12	Gen	Biostatistics. 2006 Jul;7(3):339-54. Epub 2006 Jan 27	
759	Observational studies and clinical trials of menopausal hormone therapy: Can they both be right?	**Allison,** Manson	12	Gen	Menopause. 2006 Jan-Feb;13(1):1-3	
760	Postmenopausal hormone therapy: New questions and the case for new clinical trials	**Manson,** Bassuk, Harman, Brinton, Cedars, Lobo, Merriam, Miller, Naftolin, Santoro	12	Gen	Menopause. 2006 Jan-Feb;13(1):139-47	
761	Re: "combined postmenopausal hormone therapy and cardiovascular disease: toward resolving the discrepancy between observational studies and the Women's Health Initiative clinical trial"	**Willett,** Manson, Grodstein, Stampfer, Colditz	12	Gen	Am J Epidemiol. 2006 Jun 1;163(11):1067-8; author reply 1068-9. Epub 2006 Apr 26	
762	Is estrogen for you?	**Manson,** Bassuk	12	Gen	Newsweek. 2006 Apr 24;147(17):72-3	
763	The Women's Health Initiative	**Nabel**	12	Gen	Science. 2006 Sep 22;313(5794):1703	
764	Hot flashes and hormones	**Manson,** Bassuk	12	Gen	Newsweek. 2007 Jan 15;149(3):56-7	
765	Implications of recent clinical trials of postmenopausal hormone therapy for management of cardiovascular disease	**Rossouw**	12	CT	Ann N Y Acad Sci. 2006 Nov;1089:444-53	
766	Prevalence, clinical significance, and management of peripheral arterial disease in women: Is there a role for postmenopausal hormone therapy?	**Mazhari,** Hsia	12	Gen	Vasc Health Risk Manag. 2005;1(2):111-7	
767	Dietary fat and cardiovascular disease: Putting the Women's Health Initiative in perspective	**Howard**	12	Gen	Nutr Metab Cardiovasc Dis. 2007 Mar;17(3):171-4. Epub 2007 Feb 21	
768	The decrease in breast-cancer incidence in 2003 in the United States	**Ravdin,** Cronin, Howlader, Berg, Chlebowski, Feuer, Edwards, Berry	12	Gen	N Engl J Med. 2007 Apr 19;356(16):1670-4	

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
769	How the Women's Health Initiative (WHI) influenced physicians' practice and attitudes	**Bush,** Bonomi, Nekhlyudov, Ludlam, Reed, Connelly, Grothaus, LaCroix, Newton	12	Gen	J Gen Intern Med. 2007 Sep;22(9):1311-6. Epub 2007 Jul 18	
770	Invited commentary: Hormone therapy and risk of coronary heart disease - why renew the focus on the early years of menopause?	**Manson,** Bassuk	12	Gen	Am J Epidemiol. 2007 Sep 1;166(5):511-7. Epub 2007 Jul 23	
771	The Women's Health Initiative and hormone therapy, 5 years later	**Johnson**	12	Gen	Cleve Clin J Med. 2007 Oct;74(10):755-6	
772	Observational studies, clinical trials, and the Women's Health Initiative	**Prentice**	12	Gen	Lifetime Data Anal. 2007 Dec;13(4):449-62. Epub 2007 Oct 18	
773	Do diet, folic acid, and vitamins matter? What did we learn from the Women's Health Initiative, the Women's Health Study, the Women's Antioxidant and Folic Acid Cardiovascular Study, and other clinical trials?	**Wenger**	12	Gen	Cardiol Rev. 2007 Nov-Dec;15(6):288-90	
774	BMI and headache among women: Results from 11 epidemiologic datasets	**Keith,** Wang, Fontaine, Cowan, Allison	12	Gen	Obesity (Silver Spring). 2008 Feb;16(2):377-83	
775	Risks and benefits of therapy with menopausal hormones versus selective estrogen-receptor modulators in peri- and postmenopausal women at increased breast cancer risk	**Col,** Chlebowski	12	CT	Menopause. 2008 Jul-Aug;15(4 Suppl):804-9	
777	Coronary heart disease and stroke with aromatase inhibitor, tamoxifen and menopausal hormone therapy use	**Chlebowski,** Anderson, Geller, Col	12	CT	Clin Breast Cancer. 2006;6(suppl 2):S58-64	
778	Menopausal hormone therapy and breast cancer: Where we are after the WHI	**Chlebowski**	12	Gen	ASBD Advisor. 2003;2:7-10	
779	The Women's Health Initiative: Implications for clinicians	**VanHorn,** Manson	12	Gen	Cleve Clin J Med. 2008 May;75(5):385-90	

Table 12.2 (continued)
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Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
780	Risks and benefits of estrogen plus progestin in healthy postmenopausal women: The Women's Health Initiative	**Manson,** Bassuk	12	Gen	In: Braunwald E et al, eds. Harrison's principles of internal medicine online: Clinical trial update. McGraw-Hill,2002	
781	Clinical practice. Postmenopausal hormone-replacement therapy	**Manson,** Martin	12	Gen	N Engl J Med. 2001 Jul 5;345(1):34-40	
782	Understanding the divergent data on postmenopausal hormone therapy	**Grodstein,** Clarkson, Manson	12	Gen	N Engl J Med. 2003 Feb 13;348(7):645-50	
783	Postmenopausal hormone therapy. A reversal of fortune	**Michels,** Manson	12	Gen	Circulation. 2003 Apr 15;107(14):1830-3	
784	The menopause transition and postmenopausal hormone therapy	**Manson,** Bassuk	12	Gen	In: Kasper DL et al, eds. Harrison's principles of internal medicine. 16th ed. New York: McGraw-Hill,2004:2209-13	
785	Is age at initiation of hormone therapy a key determinant of coronary heart disease outcomes?	**Allison,** Manson	12	Gen	Johns Hopkins Adv Stud in Med. 2006;6(7):329-30	
786	Postmenopausal hormone therapy: Observational studies to clinical trials	**Bassuk,** Manson	12	Gen	In: Liu JH, Gass MLS, eds. Management of the perimenopause (Practical pathways in obstetrics and gynecology). New York: McGraw Hill,2006:377-408	
787	Menopausal hormone therapy and the risk of coronary heart disease. Does the relation vary by age or time since menopause? The investigator's perspective	**Manson,** Bassuk	12	Gen	The Monitor. 2007 Oct:17-22	
788	Hormone replacement therapy	**Allison,** Manson	12	Gen	In: Encyclopedia of Epidemiology. Thousand Oaks, CA: Sage Publications,2007:503-10	

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Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
794	Brain volumes, cognitive impairment, and conjugated equine estrogens [WHIMS-MRI]	**Espeland,** Tindle, Bushnell, Jaramillo, Kuller, Margolis, Mysiw, Maldjian, Melman, Resnick, for the Women's Health Initiative Memory Study	12	CT	J Gerontol A Biol Sci Med Sci. 2009 Sep 3. [Epub ahead of print].	AS183
799	Women's Ischemic Syndrome Evaluation: current status and future research directions: Report of the National Heart, Lung and Blood Institute workshop: October 2-4, 2002 : Section 4: lessons from hormone replacement trials	**Waters,** Gordon, Rossouw, Cannon, Collins, Herrington, Hsia, Langer, Mosca, Ouyang, Sopko, Stefanick	12	Gen	Circulation. 2004 Feb 17;109(6):e53-5	
800	The rise and fall of menopausal hormone therapy	**Barrett-Connor,** Grady, Stefanick	12	Gen	Annu Rev Public Health. 2005;26:115-40	
801	Estrogen therapy: Prevention and treatment of osteoporosis	**McGowan,** Stefanick	12	Gen	In: Marcus R et al, eds. Osteoporosis. 3rd ed. San Diego, CA: Elsevier Academic Press,2008:1687-704	
802	Reply: Reanalysis of the data--science at its best and always informative	**Barad,** Stefanick, Manson, Gass, Anderson	12	CT	Fertil Steril. 2006 June;85(6): author reply e14. Epub 2006 May 4	
803	Risk-benefit profiles of raloxifene for women	**Stefanick**	12	CT	N Engl J Med. 2006 Jul 13;355(2):190-2	
807	Repeated measures of serum glucose and insulin in relation to postmenopausal breast cancer	**Kabat,** Kim, Caan, Chlebowski, Gunter, Ho, Rodriguez, Shikany, Strickler, Vitolins, Rohan	12	CT	Int J Cancer. 2009 Jun 2. [Epub ahead of print]	
808	Longitudinal study of serum carotenoid, retinol, and tocopherol concentrations in relation to breast cancer risk among postmenopausal women	**Kabat,** Kim, Adams-Campbell, Caan, Chlebowski, Neuhouser, Shikany, Rohan	12	CT	Am J Clin Nutr. 2009 Jul;90(1):162-9. Epub 2009 May 27.	
810	The Women's Health Initiative: Lessons learned	**Prentice,** Anderson	12	Gen	Annu Rev Public Health. 2008;29:131-50	
813	Bacterial species in subgingival plaque and oral bone loss in postmenopausal women	**Brennan,** Genco, Wilding, Hovey, Trevisan, Wactawski-Wende	12	OS	J Periodontol. 2007 Jun;78(6):1051-61	AS98

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Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
825	Conjugated equine estrogens and breast cancer risk in the Women's Health Initiative clinical trial and observational study	**Prentice,** Chlebowski, Stefanick, Manson, Langer, Pettinger, Hendrix, Hubbell, Kooperberg, Kuller, Lane, McTiernan, O'Sullivan, Rossouw, Anderson	12	Gen	Am J Epidemiol. 2008 Jun 15;167(12):1407-15. Epub 2008 Apr 29	
826	The role of hormone therapy and calcium plus vitamin D for reduction of bone loss and risk for fractures: Lessons learned from the Women's Health Initiative	**Jackson,** Shidham	12	Gen	Curr Osteoporos Rep. 2007 Dec;5(4):153-9	
837	Women's Health Iinitiative studies of postmenopausal breast cancer	**Prentice**	12	Gen	Adv Exp Med Biol. 2008;617:151-60	
843	Application of serum proteomics to the Women's Health Initiative conjugated equine estrogens trial reveals a multitude of effects relevant to clinical findings	**Katayama,** Paczesny, Prentice, Aragaki, Faca, Pitteri, Zhang, Wang, Silva, Kennedy, Rossouw, Jackson, Hsia, Chlebowski, Manson	12	OS	Genome Med. 2009 Apr 29;1(4):47.	W19
845	Colorectal cancer in women after stopping postmenopausal hormone therapy-reply	**Chlebowski**	12	CT	JAMA. 2008; 299(23):2744-5	
848	Oestrogen plus progestin and lung cancer in postmenopausal women (Women's Health Initiative trial): a post-hoc analysis of a randomised controlled trial	**Chlebowski,** Schwartz, Wakelee, Anderson, Stefanick, Manson, Rodabough, Chien, Wactawski-Wende, Gass, Kotchen, Johnson, O'Sullivan, Ockene, Chen	12	CT	Lancet. 2009 Sep 20. [Epub ahead of print]	
850	Heart rate variability, ambient particulate matter air pollution, and glucose homeostasis: The Environmental Epidemiology of Arrhythmogenesis in the Women's Health Initiative	**Whitsel,** Quibrera, Christ, Liao, Anderson, Prineas, Heiss	12	CT	Am J Epidemiol. 2009 Mar 15;169(6):693-703. Epub 2009 Feb 10.	AS140
865	Menopausal hormone therapy in BRCA1 mutation carriers: Uncertainty and caution	**Chlebowski,** Prentice	12	Gen	J Natl Cancer Inst. 2008 Oct 1;100(19):1341-3. Epub 2008 Sep 23	
871	Data analysis methods and the reliability of analytic epidemiologic research	**Prentice**	12	Gen	Epidemiology. 2008 Nov;19(6):785-8; discussion 789-93.	

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Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
874	A multistage genome-wide association study in breast cancer identifies two new risk alleles at 1p11.2 and 14q24.1 (RAD51L1)	**Thomas,** Jacobs, Kraft, Yeager, Wacholder, Cox, Hankinson, Hutchinson, Wang, Yu, Chatterjee, Garcia-Closas, Gonzalez-Bosquet, Prokunina-Olsson, Orr	12	Gen	Nat Genet. 2009 May;41(5):579-84. Epub 2009 Mar 29.	M3
875	Cigarette smoking and pancreatic cancer: A pooled analysis from the Pancreatic Cancer Cohort Consortium (PanScan)	**Lynch,** Vrieling, Lubin, Kraft, Mendelsohn, Hartge, Canzian, Steplowski, Arslan, Gross, Helzlsouer, Jacobs, LaCroix, Petersen, Zheng	12	Gen	Am J Epidemiol. 2009 Aug 15;170(4):403-13. Epub 2009 Jun 26.	M4
879	Epidemiology of fracture risk in the Women's Health Initiative	**Jackson,** Donepudi, Mysiw	12	Gen	Curr Osteoporos Rep. 2008 Dec;6(4):155-61	
882	A longitudinal study of the metabolic syndrome and risk of postmenopausal breast cancer	**Kabat,** Kim, Chlebowski, Khandekar, Ko, McTiernan, Neuhouser, Parker, Shikany, Stefanick, Thomson, Rohan	12	CT	Cancer Epidemiol Biomarkers Prev. 2009 Jul;18(7):2046-53. Epub 2009 Jun 30.	
907	Newly discovered breast cancer susceptibility loci on 3p24 and 17q23.2	**Ahmed,** Thomas, Ghoussaini, Healey, Humphreys, Platte, Morrison, Maranian, Pooley, Luben, Eccles, Evans, Fletcher, Johnson, Silva	12	Gen	Nat Genet. 2009 May;41(5):585-90. Epub 2009 Mar 29.	M3
929	Reassessing benefits and risks of hormone therapy	**Gass,** Bassuk, Manson	12	CT	Am J Lifestyle Med. 2009 Jan;3(1):29-43	
936	Genome-wide association study identifies variants in the ABO locus associated with susceptibility to pancreatic cancer	**Amundadottir,** Kraft, Stolzenberg-Solomon, Fuchs, Petersen, Arslan, Bueno-de-Mesquita, Gross, Helzlsouer, Jacobs, LaCroix, Zheng, Albanes, Bamlet, Berg	12	Gen	Nat Genet. 2009 Aug 2. [Epub ahead of print]	M4
971	Statistical aspects of the use of biomarkers in nutritional epidemiology research	**Prentice,** Huang, Tinker, Beresford, Lampe, Neuhouser	12	OS	Statistics in Biosciences. 2009 Apr 29. [Epub ahead of print]	
1071	WHI hormone trials: A window to the future, a view from the past	**Stefanick**	12		Sexualty, Reproduction and Menopause. 2009 August.	

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Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
308	Association between dietary fats and age-related macular degeneration (AMD) in the Carotenoids in Age-Related Eye Disease Study (CAREDS), an ancillary study of the Women's Health Initiative [CAREDS]	**Parekh,** Voland, Moeller, Blodi, Ritenbaugh, Chappel, Wallace, Mares	11	OS	In press, Arch Ophthalmol	AS105
358	Conjugated equine estrogen influence on mammographic density in postmenopausal women: The Women's Health Initiative Randomized Trial	**McTiernan,** Martin, Peck, Aragaki, Pisano, Wang, Chlebowski, Heiss, Wallace, Johnson, Vitolins, Manson	11	CT	In press, J Clin Oncol	AS36
375	Intentional weight loss as a possible risk factor for B-cell lymphomas	**DeRoos,** Ulrich, Ray, Mossavar-Rahmani, Rosenberg, Caan, Thomson, McTiernan, LaCroix	11	OS	In press, Cancer Causes Control	
551	Antidepressant use and risk of incident cardiovascular morbidity and mortality among post-menopausal women in the Women's Health Initiative Study	**Smoller,** Allison, Cochrane, Curb, Perlis, Robinson, Rosal, Wang, Wenger, Wassertheil-Smoller	11	OS	In press, Arch Int Med	
567	New-onset breast tenderness after initiation of estrogen plus progestin hormone therapy and future breast cancer risk: The Women's Health Initiative Estrogen Plus Progestin Trial	**Crandall,** Aragaki, Chlebowski, McTiernan, Anderson, Hendrix, Cochrane, Langer, Kuller, Cauley	11	CT	In press, Arch Intern Med	
579	Relative effects of Tamoxifen, Raloxifene, and conjugated equine estrogens on cognition: Results from the Women's Health Initiative Memory Study (WHIMS) and the Cognition in the Study of Tamoxifen and Raloxifene (CoSTAR) Clinical Trials [WHISCA]	**Espeland,** Shumaker, Limacher, Rapp, Bevers, Barad, Coker, Jaramillo, Stefanick, Lane, Maki, Resnick	11	WHIMS	In press, J Womens Health	AS103
598	Effects of conjugated equine estrogens on cognition and affect in postmenopausal women with prior hysterectomy [WHISCA]	**Resnick,** Espeland, An, Maki, Coker, Jackson, Stefanick, Wallace, Rapp	11	CT	In press, J Clin Endocrinol Metab.	AS103

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Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
727	Women's Health Initiative Memory Study (WHIMS) Program: Emerging findings [WHIMS]	**Espeland,** Shumaker, Hogan, Resnick, Henderson, Hogervorst	11	CT	In press, chapter in Hormones, cognition and dementia: State of the art and emergent therapeutic strategies; Cambridge University Press	AS39, AS183
873	Understanding the effects of menopausal hormone therapy: Using the Women's Health Initiative randomized trials and observational study to improve inference	**Anderson,** Prentice	11	Gen	In press, article in APA book	
883	Postmenopausal hormone therapy and cognitive outcomes: the Women's Health Initiative Memory Study [WHIMS; WHIMS-MRI]	**Coker,** Dailey, Espeland, Hogan, Jaramillo, Legault, Rapp, Resnick, Shumaker	11	CT	In press, J Steroid Biochem Mol Biol	AS39, AS183
153	Hostility in relation to incident diabetes and increase in metabolic syndrome characteristics in postmenopausal women	**Wylie-Rosette,** Aragaki, Cochrane, Perri, Rosal, Rapp	10	CT	Submitted, Diabetes Metab Syndr	
154	The role of dietary proteins in the disposition to fractures: A prospective analysis of postmenopausal women from the Women's Health Initiative observational study	**Barzel,** Aragaki, Ritenbaugh, LeBoff, Wylie-Rosette	10	OS	Submitted, J Nutr	
172	The association of glycemic load with cardiovascular disease risk factors in the Women's Health Initiative observational study	**Shikany,** Tinker, Neuhouser, Ma, Patterson, Phillips, Liu, Redden	10	Gen	Submitted, J Nutr	AS111
218	Psychosocial effects of physical and verbal abuse among postmenopausal women	**Mouton,** Rodabough, Rovi, Brzyski, Katerndahl	10	OS	Submitted, Ann Fam Med.	
312	Accuracy of food portion estimation among postmenopausal women	**Coy,** Frank, Lee, Meyskens	10	CT	Submitted, Am J Clin Nutr	AS118
356	The cross-sectional relationship between body weight, obesity and cognitive function in postmenopausal women enrolled in the Women's Health Initiative (WHI)	**Kerwin,** Zhang, Kotchen, Espeland, VanHorn, McTigue, Robinson, Powell, Kooperberg, Coker, Hoffman	10	CT	Submitted, JAMA	

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Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
389	Hierarchical models for the effect of spatial interpolation error on the inferred relationship between ambient particulate matter exposure and cardiovascular health	**Crooks,** Whitsel, Catellier, Liao, Quibrera, Smith	10	CT	Submitted, Biostatistics	AS140
390	Identifying risk factors for cognitive change in the Women's Health Initiative Memory Study: A neural networks approach [WHIMS]	**Bandelow,** Espeland, Coker, Henderson, Hogervorst, Resnick, Wallace	10	WHIMS	Submitted, Cambridge University Press	AS39
399	Subtypes of mild cognitive impairment in the Women's Health Initiative Memory Study [WHIMS]	**Rapp,** Legault, Absher, Brunner, Henderson, Jones, Masaki, Thal	10	WHIMS	Submitted to Alzheimer Dis Assoc Disord.	AS39
453	Relationship between degree of obesity and quality of life and functioning in women of diverse racial-ethnic backgrounds	**McTigue,** Adams-Campbell, Bost, Hays, Kuller, Lynch, Manson, Sarto, Tinker, Vitolins	10	Gen	Submitted, J Womens Health	
470	Calcium plus vitamin D and exogenous estrogen influence on joint symptoms	**Chlebowski,** Johnson, Wactawski-Wende, Cummings, Kooperberg, Hubbell, Hiatt, Vitolins, Lane, Yasmeen, Shikany, Khandekar, O'Sullivan, Rohan	10	CT	Submitted, J Clin Oncol	W24
473	Self-reported urinary tract stone occurrence in the Women's Health Initiative Calcium-Vitamin D Trial	**Wallace,** Wactawski-Wende, O'Sullivan, Wu, Cochrane, Gass, Masaki, Nelson, Whitlock	10	CT	Submitted, Arch Intern Med.	
507	Hematopoietic prostaglandin D synthase variant (Val187Ile) in African Americans: enzyme characterization, urine PGD2 metabolites, and case-control analyses of colorectal neoplasia in four studies	**Tippen,** Levine, Materi, Park, Song, Keku, Dai, Huang, Zhou, Frankl, Hardy, Patterson, Chlebowski, Henderson, Kolonel	10	OS	Submitted, J Biol Chem	AS108
534	Menopausal symptom experience before and after stopping estrogen therapy in The Women's Health Initiative Randomized Placebo-Controlled Trial	**Brunner,** Aragaki, Barnabei, Gass, Hendrix, Lane, Ockene, Yasmeen, Woods, Stefanick	10	CT	Submitted, Menopause	
558	The relationship between cognitive function and physical performance in older women: Results from the Women's Health Initiative Memory Study [WHIMS]	**Atkinson,** Rapp, Williamson, Lovato, Absher, Gass, Henderson, Johnson, Kostis, Mouton, Ockene, Stefanick, Lane, Espeland	10	WHIMS	Submitted, J Gerontol	AS39

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
562	Increased incidence of fractures associated with anemia in older multiethnic women	**Chen,** Thomson, Aickin, Nicholas, Van Wyck, Lewis, Cauley, Bassford	10	Gen	Submitted, Osteoporos Int	M2
570	Calcium/vitamin D supplementation and coronary artery calcification [WHI-CACS]	**Manson,** Allison, Carr, Langer, Cochrane, Hendrix, Hsia, Hunt, Lewis, Margolis, Robinson, Rodabough, Thomas	10	CT	Submitted, JAMA	W25
575	Hormone therapy and change in function in the Women's Health Initiative	**Michael,** Gold, Manson, Keast, Cochrane, Woods, Brzyski, McNeeley, Wallace	10	CT	Submitted, Arch Int Med	
619	Dietary fish intake and incident atrial fibrillation: Findings from the Women's Health Initiative	**Berry,** Passman, Prineas, VanHorn, Larson, Goldberger, Snetselaar, Tinker, Liu, Lloyd-Jones	10	CT	Submitted, Am J Cardiol	
647	Evaluation of the AHA Cardiovascular Disease Prevention Guidelines in the Women's Health Initiative	**Hsia,** Rodabough, Manson, Liu, Freiberg, Graettinger, Rosal, Cochrane, Lloyd-Jones, Robinson, Howard	10	Gen	Submitted, Circ CV Quality & Outcomes	
649	Effects of low-fat dairy products and yogurt on diabetes incidence in post-menopausal women	**Margolis,** DeBoer, Howard, Liu, Manson, Mossavar-Rahmani, Phillips, Safford, Shikany, Tinker, Wei	10	OS	Submitted, Diabetes Care.	
656	Multi-marker prediction of coronary heart disease risk: The Women's Health Initiative	**Kim,** Greenland, Rossouw, Manson, Cochrane, Lasser, Limacher, Lloyd-Jones, Margolis, Robinson	10	OS	Submitted, J Am Coll Cardiol.	
670	Sleep duration, cognitive function, and neurocognitive impairment in older women [WHIMS]	**Chen,** Espeland, Brunner, Lovato, Wallace, Phillips, Robinson, Kotchen, Johnson, Manson, Stefanick, Sarto, Mysiw	10	WHIMS	Submitted, JAMA	AS39

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
683	Education, neuropathology, and cognitive performance in older, postmenopausal women [WHIMS]	**Rapp,** Espeland, Manson, Resnick, Wassertheil-Smoller, Coker, Phillips, Stefanick, Sarto, Bryan, Women's Health Initiative Memory Study Research Group	10	WHIMS	Submitted, J Am Geriatrics As	AS39, AS183
718	Anticonvulsant use and osteoporosis in postmenopausal women: Findings from the Women's Health Initiative (WHI)	**Carbone,** Johnson, Robbins, Larson, Curb, Watson, Gass, LaCroix	10	Gen	Submitted, J Bone Min Res	
722	Oral bisphosphonate use and breast cancer incidence in postmenopausal women	**Chlebowski,** Chen, Cauley, Rodabough, McTiernan, Lane, Manson, Snetselaar, Yasmeen, O'Sullivan, Safford, Hendrix, Wallace	10	Gen	Submitted, N Engl J Med	
728	Estrogen alone and breast cancer detection by means of mammography and breast biopsy	**Chlebowski,** Anderson, Manson, Pettinger, Yasmeen, Lane, Langer, Hubbell, McTiernan, Hendrix, Schenken, Stefanick	10	CT	Submitted, Arch Intern Med	
793	Low doses of Vitamin D with Calcium reduce the risk of fractures: Patient level pooled analysis of 68,500 patients from seven major Vitamin D trials in the U.S. and Europe	**Abrahamsen,** Masud, Avenell, Anderson, Meyer, Cooper, Smith, LaCroix, Torgerson, Johansen, Jackson, Rejnmark, Wactawski-Wende, Brixen, Mosekilde	10	CT	Submitted, BMJ	
831	Association between protein intake and incident frailty in the Women's Health Initiative Observational Study [NBS]	**Beasley,** LaCroix, Neuhouser, Prentice, Huang, Tinker, Michael, Woods, Curb	10	OS	Submitted	W8, AS179
840	Migraine history and breast cancer risk among postmenopausal women	**Li,** Mathes, Bluhm, Caan, Cavanagh, Chlebowski, Michael, O'Sullivan, Prentice, Stefanick	10	OS	Submitted, J Clin Oncol	
888	Positive effects of physical exercise on the proximal femur are confounded by body size and more evident in geometry than BMD	**Beck,** Kohlmeier-Nisco, Petit, Wu, LeBoff, Cauley, Chen	10	OS	Submitted, J Bone Miner Res	AS153

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
921	Postmenopausal Estrogen and Progestin effects on the serum proteome	**Prentice,** Pitteri, Aragaki, Amon, Chen, McIntosh, Wang, Kooperberg, Rossouw, Jackson, Manson, Hsia, Liu, Martin, Hanash	10	CT	Submitted, Genome Med	W19, W44
127	Homocysteine and incident coronary heart disease: Prospective analysis from the Women's Health Initiative observational study	**Siscovick,** Manson, Trevisan, Wallace, Howard, Burke, Ridker	9	OS		AS83
377	Patterns of long-term medication utilization for the secondary prevention of coronary heart disease in older women: The Women's Health Initiative	**Robinson,** Wallace, Safford, Cochrane, Pettinger, Ko, O'Sullivan, Masaki, Petrovich	9	Gen		
392	Family history of myocardial infarction predicts incident coronary heart disease in postmenopausal women with diabetes: The Women's Health Initiative Observational Study	**Li,** Johnson, O'Sullivan, Robinson, Safford, Curb	9	OS		
432	The role of extreme obesity in heart disease and death in diverse older women	**McTigue,** Chang, Eaton, Garcia, Johnson, Lewis, Liu, Mackey, Robinson, Rosal, Snetselaar, Valoski, Kuller	9	Gen		
436	Health characteristics of postmenopausal women with breast implants many years ago	**Rubin,** Song, Shestak, Lane, Valoski, Chang, Kuller	9	Gen		
476	Associations between dietary fat intake and Age Related Macular Degeneration (ARM) for the Women's Health Initiative-Sight Exam (WHI-SE) Study participants [WHISE]	**Kannan,** Haan, Blythe, Moore, Hazzouri, Deng, Tong	9	CT		AS62
510	Alcohol consumption and the risk of coronary heart disease in women with diabetes: Results from the Women's Health Initiative observational study	**Rajpathak,** Freiberg, Wang, Wylie-Rosette, Wildman, Rohan, Robinson, Liu, Wassertheil-Smoller	9	OS		
532	Incidence of urinary incontinence in postmenopausal women with diabetes: The Women's Health Initiative Observational Study	**Bonds,** Hogan, Cochrane, Hendrix, Masaki, Sarto	9	OS		

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
553	Association of dopamine genotypes with physical activity and body habitus in post-menopausal women	**Leddy,** Hovey, Salis, Brennan, Epstein, Wactawski-Wende	9	OS		AS15
572	Relation of Genetic Variants in Fatty Acid Binding Protein-4 (FABP4)/ Adipocyte P2 (aP2) and clinical diabetes risk in the Women's Health Initiative Observational Study	**Chan,** Song, Hsu, You, Tinker, Liu	9	OS		AS132
582	The utility of circulating biomarkers of inflammation and endothelial dysfunction for risk prediction and stratification of clinical diabetes in postmenopausal women - The Women's Health Initiative Observational Study	**Chao,** Song, Cook, Manson, Eaton, Phillips, Rodriguez, Tinker, Liu	9	OS		AS132
600	Reading ability influences race-ethnic differences in cognitive testing: The Cognitive Change in Women ancillary study to the Women's Health Initiative	**Dunn,** Harty, Stoddard, Gavett, Weintraub	9	OS		AS84
639	Psychiatric disorders and cognitive dysfunction among older, postmenopausal women: Results from the Women's Health Initiative Memory Study [WHIMS]	**Colenda,** Rapp, Legault, Hogan, DeBon, Wallace, Hershey, Ockene, Whitmer, Phillips, Sarto	9	WHIMS		AS39
646	Biomarker-Calibrated Energy and Protein Consumption and Cardiovascular Disease Risk among Postmenopausal Women [NBS]	**Johnson,** Huang, Kuller, Tinker, VanHorn, Stefanick, Sarto, Ockene, Prentice	9	OS		W8
650	Proton pump inhibitor use, hip fracture and change in bone density in postmenopausal women: Results from the Women's Health Initiative	**Gray,** LaCroix, Larson, Cauley, Robbins, Manson, Chen	9	Gen		
658	Rheumatoid Arthritis is associated with less optimal hip structural geometry	**Wright,** Lisse, Beck, Sherrill, Mohler, Bassford, Cauley, LaCroix, Lewis, Chen	9	Gen		AS153
672	Body size phenotypes and inflammation in the Women's Health Initiative	**Wildman,** Kaplan, Manson, Rajkovic, Connelly, Mackey, Tinker, Curb, Eaton, Wassertheil-Smoller	9	OS		AS126

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
680	A uniform approach to modeling risk factors relationships for ischemic lesion prevalence and extent: The Women's Health Initiative Magnetic Resonance Imaging Study [WHIMS-MRI]	**Espeland,** Resnick, Tooze, An, Bryan, Coker, Robinson, Jaramillo	9	WHIMS		AS183
688	Relation of dietary magnesium intake to biomarkers of inflammation and endothelial dysfunction in an ethnically diverse cohort of postmenopausal women	**Chacko,** Song, Nathan, Tinker, DeBoer, Tylavsky, Wallace, Liu	9	OS		AS132
696	Relationship of HTN, blood pressure (BP) and BP control with magnetic resonance imaging (MRI) outcomes in the Women's Health Initiative Memory Study (WHIMS) MRI Study [WHIMS-MRI]	**Kuller,** Margolis, Jaramillo, Bryan, Kerwin, Limacher, Moonis, Wassertheil-Smoller, Williamson, Robinson	9	CT		AS183
704	A longitudinal analysis of the impact of neighborhood SES on coronary heart disease among women	**Bird,** Shih, Eibner, Griffin, Slaughter, Whitsel, Margolis, Escarce, Jewell, Mouton, Lurie	9	OS		AS220
716	Migraines, ST depression and risk for cardiac events: Results from the MIMS Study	**York,** Li, Hassan, Ephross, Brunner, Limacher, Wassertheil-Smoller, Sheps	9	OS		AS70
724	Low-fat dietary pattern and lipoprotein risk factors: The Women's Health Initiative Randomized Controlled Dietary Modification Trial	**Howard,** Curb, Eaton, Kooperberg, Ockene, Kostis, Rajkovic, Robinson, Rossouw, Sarto, Shikany, VanHorn	9	CT		
792	Electrocardiographic Q-ST wave abnormalities for the independent prediction of total mortality and Coronary Heart Disease death: Evaluation and comparison of the Minnesota Code and Novacode in the Women's Health Initiative	**Zhang,** Prineas, Eaton	9	CT		
795	The effects of postmenopausal hormone therapy on serum estrogen, progesterone and sex hormone binding globulin levels in healthy post-menopausal women	**Edlefsen,** Jackson, Anderson, Prentice, Rajkovic, Janssen, O'Sullivan	9	CT		W18

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
815	Genetic variation at chromosome 8q24 and risk of colon cancer	**Hutter,** Slattery, Duggan, Muehling, Curtin, Hsu, Beresford, Rajkovic, Sarto, Marshall, Hammad, Wallace, Makar, Prentice, Caan	9	OS		AS206
829	Lipid biomarkers and the risk of ischemic stroke in postmenopausal women	**Berger,** McGinn, Howard, Kuller, Manson, Otvos, Curb, Eaton, Kaplan, Lynch, Rosenbaum, Wassertheil-Smoller	9	OS		AS126
832	Effect of 5 year calcium plus vitamin D supplementation on change in circulating lipids	**Rajpathak,** Xue, Wassertheil-Smoller, VanHorn, Robinson, Liu, Allison, Martin, Ho, Rohan	9	CT		
833	Effect of long term low-fat dietary intervention on change in hemostatic factors	**Rajpathak,** Xue, Rohan, Wassertheil-Smoller, Snetselaar, VanHorn, Martin	9	CT		
846	Variation in the FGFR2 gene and the effects of postmenopausal hormone therapy on invasive breast cancer	**Prentice,** Huang, Hinds, Peters, Cox, Beilarz, Chlebowski, Rossouw, Caan, Ballinger	9	CT		BAA2
894	Hepatocyte growth factor (HGF) and the risk of ischemic stroke among postmenopausal women	**Rajpathak,** Wang, Wassertheil-Smoller, Kaplan, Strickler, McGinn, Wildman, Rosenbaum, Rohan, Scherer, Cushman, Ho	9	OS		BAA10
898	Coronary heart disease in postmenopausal users of estrogen plus progestin hormone therapy: does the increased risk ever disappear?	**Toh,** Hernandez-Diaz, Rossouw, Hernan	9	CT		
906	Newly discovered SNPs and prediction of breast cancer	**Prentice,** Chlebowski, Jackson, Kooperberg	9	OS		M3
915	Risk factors for nuclear cataract in postmenopausal women from the Carotenoids in Age-Related Eye Disease Study, an Ancillary Study of the Women's Health Initiative [CAREDS]	**Mares,** Voland, Adler, Tinker, Millen, Moeller, Blodi, Gehrs, Wallace, Chappell, Neuhouser, Sarto	9	OS		AS105
927	The Women's Health Initiative: Lessons for preventive nutrition	**Thomson,** Beresford, Ritenbaugh	9	CT		

Table 12.2 (continued)
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Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
928	Clinical and community risk models of incident tooth loss in postmenopausal women	**Bole,** Wactawski-Wende, Hovey, Genco, Hausmann	9	OS		AS98
930	Genome wide association study identifies susceptibility blood group ABO variants for pancreatic cancer	**LaCroix,** Anderson, Kooperberg, Rajkovic, Wactawski-Wende	9	Gen		M4
931	Alcohol intake and pancreatic cancer: A pooled analysis from the Pancreatic Cancer Cohort Consortium (PanScan)	**Michaud,** Vrieling, Jiao, Mendelsohn, Steplowski, Lynch, Wactawski-Wende, Arslan, Bueno-de-Mesquita, Fuchs, Buring, Gaziano, Gross, Helzlsouer, Jacobs	9	Gen		M4
932	Anthropometry, body mass index and pancreatic cancer: A pooled analysis from the Pancreatic Cancer Cohort Consortium (PanScan)	**Arslan,** Helzlsouer, Kooperberg, Shu, Steplowski, Bueno-de-Mesquita, Fuchs, Gross, Jacobs, LaCroix, Petersen, Stolzenberg-Solomon, Zheng, Albanes, Amundadottir	9	Gen		M4
933	Family history of cancer and risk of pancreatic cancer: a pooled analysis from the pancreatic cancer cohort consortium (PANSCAN)	**Jacobs,** Chanock, Fuchs, LaCroix, McWilliams, Steplowski, Stolzenberg-Solomon, Arslan, Bueno-de-Mesquita, Gross, Helzlsouer, Petersen, Zheng, Agalliu, Allen	9	Gen		M4
951	Alcohol consumption and risk of breast cancer by subtype among postmenopausal women enrolled in the Women's Health Initiative Observational Study	**Li,** Chlebowski, Freiberg, Johnson, Kuller, Lane, Lessin, O'Sullivan, Wactawski-Wende, Yasmeen, Prentice	9	OS		
962	Assessing gene-set enrichment in genome-wide association studies	**Chen,** Peters, Hutter, Potter, Prentice, Hsu	9	OS		AS224
965	Lifetime risks for fatal and non-fatal cardiovascular events in different race/ethnic groups: Cardiovascular Lifetime Risk Pooling Project	**Lloyd-Jones,** Berry, Thomas, Garside, Cai, VanHorn, Tracy, Dyer	9	OS		

Table 12.2 (continued)
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Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
251	Reproductive history and age-related maculopathy in the Women's Health Initiative Sight Exam Study [WHISE]	**Haan,** Wallace, Hendrix, Seddon, Klein, Klein, Musch, Langer, Brunner, Wactawski-Wende	7	CT		AS62
276	Social support and cognitive functioning in post-menopausal women [WHIMS]	**Messina,** Espeland, Jaramillo, Coker, Lane, Masaki, Phillips, Powell, Rosal, Shumaker	7	WHIMS		AS39
360	Body mass index, waist-hip ratio, and cognitive decline in postmenopausal women: Results from the WHIMS [WHIMS]	**Kerwin,** Jaramillo, Chlebowski, Coker, Hoffman, Espeland, Kotchen, Kuller, Nicklas, Rainford, Vitolins	7	WHIMS		AS39
374	Tamoxifen and coronary heart disease (CHD) risk	**Chlebowski,** Allison, Brzyski, Greep, Kooperberg, O'Sullivan, Robinson	7	Gen		
380	Coagulation factors, postmenopausal hormone replacement therapy and the risk of venous thrombosis: The Women's Health Initiative clinical trials of postmenopausal hormone therapy	**Cushman,** Rosendaal, Baird, Bray, Curb, Eaton, Heckbert, Howard, Phillips, Stafford	7	CT		W6
406	Effect of estrogen and estrogen plus progestin replacement therapy on the incidence of stroke in older women with atrial fibrillation	**Perez,** Robinson, Wallace, Black, Frishman, Oberman, Sarto, Williams, Wassertheil-Smoller	7	CT		
458	BMI and prognostic features of endometrial cancer	**Paskett,** Cunyun, Lane, McNeeley, Reeves	7	Gen		
466	Dietary modification, quality of life, and depression	**Assaf,** Beresford, Brunner, Bowen, Naughton, Petrovich, Granek, Whitlock, Phillips, Haines, DeCosimo, Robinson-O'Brien, Rosal, Wenger, Snetselaar	7	CT		
528	Ambient air pollution and ventricular repolarization: Environmental epidemiology of arrhythmogenesis in WHI,1999-2001	**Whitsel,** Anderson, Catellier, Chen, Crooks, Liao, Peuquet, Prineas, Quibrera, Smith	7	CT		AS140
543	Insulin-like growth hormone-1, risk factors, and risk for hip fracture in postmenopausal women	**Jackson,** Lee, Cummings	7	OS		AS90

Table 12.2 (continued)
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Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
546	Predictors of incident dementia in postmenopausal women enrolled in a trial of hormone therapy: The Women's Health Initiative Memory Study [WHIMS]	**Coker,** Legault, Colenda, Greep, Limacher, Murray, Rainford, Vitolins, Wallace	7	WHIMS		AS39
581	Correlations between serum vitamin D, total vitamin D Intake, and estimates of sunlight exposure in the Women's Health Initiative nested case-control studies	**Millen,** Jackson, LaCroix, LeBoff, Liu, Mares-Perlman, Melamed, Robbins, Tylavsky, Wactawski-Wende	7	CT		W15
595	Quality assurance and training in a low event long-term clinical trial [WHIMS]	**Dailey,** Felton, Summerville, Coker, Nance, Kidd	7	WHIMS		AS39
596	Family history of non-early-onset breast cancer and the incidence of breast cancer among women with breast-healthy lifestyles	**Gramling,** Assaf, Lash, Cabral, Eaton, Harrigan, Hunt, Rothman, Stefanick	7	OS		
597	Prevalence of anticholinergic drug use and impact on cognition and function in older women [WHIMS]	**Sink,** Espeland, Gass, Goff, Rapp, Sherwin, Thomas	7	WHIMS		AS39
605	Glycemic index, glycemic load, and risk of pancreatic cancer among postmenopausal women	**Cui,** Liu, Neuhouser, Rohan, Shikany, Simon, Nirmal, Abrams	7	Gen		
616	Subjective and informant-reported memory complaints and cognitive function in non-demented older women	**Gavett,** Dunn, Harty, Stoddard, Weintraub	7	OS		AS84
654	Plasma adiponectin, gene polymorphisms on the adiponectin gene, and risk of hypertension in White and Black women	**Sesso,** Manson, Wang, Brunner, Cochrane, Cook, Kwiatkowski, Liu, Miller	7	OS		AS133
667	Vasomotor symptoms and incident cardiovascular disease in postmenopausal women	**Szmuilowicz,** Manson, Seely, Howard, Rodriguez, Grobbee, Sarto, Rossouw, Ockene, Johnson, Margolis, Vitolins, Stefanick, O'Sullivan, Greep	7	OS		
685	Diet and the risk for clinical cardiovascular disease in the Women's Health Initiative Observational Study	**Belin,** VanHorn, Greenland, Lloyd-Jones, Tinker, Howard, Allison, Shikany, Martin	7	OS		

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
686	Fish, omega-3 fat, and trans fat intake and the risk for incident congestive heart failure in the Women's Health Initiative	**Belin,** VanHorn, Greenland, Lloyd-Jones, Tinker, Robinson, Oberman, Martin	7	OS		
694	Dietary vitamin D and calcium intake and mammographic density	**Bertone-Johnson,** Chlebowski, Manson, McTiernan, Pisano, Rexrode, Rohan, Sarto, Tamimi, Thomson, Wactawski-Wende, Peck, Martin	7	CT		AS36
822	Low-fat dietary pattern and risk of metabolic syndrome	**Neuhouser,** Thomson, Stefanick, Howard, Tinker, Rohan, Caan, VanHorn	7	CT		
849	Effect of a low-fat dietary pattern on glucose and insulin resistance in the Women's Health Initiative Dietary Modification Trial	**Margolis,** Shikany, Beresford, Brzyski, Jackson, Limacher, Liu, Phillips, Tinker	7	CT		
886	Cardiovascular disease, fractures, and cancer following bilateral oophorectomy versus ovarian conservation at the time of hysterectomy: The Women's Health Initiative Observational Study and Clinical Trial	**Jacoby,** Stefanick, Grady, Sarto, Wactawski-Wende, Manson, Robbins, Phillips, Martin, O'Sullivan, Allison, Kuppermann, Jackson	7	Gen		
889	The effects of menopausal hormones on risk of atrial fibrillation: The WHI Randomized Hormone Trials	**Wang,** Perez, Stefanick, Wassertheil-Smoller, Curb, Robinson, Manson, Martin, Klein, Cochrane	7	CT		
938	Insomnia, snoring and sleepiness, and risk of cognitive impairments in older women [WHIMS]	**Chen,** Espeland	7	WHIMS		AS39
45	Socio-demographic determinants of folic acid intake	**Beresford,** Kritchevsky, Vitolins, Wodarski	6	Gen		
266	Correlation of endogenous sex steroid hormones with fasting glucose and insulin levels, HOMA indices, and incident diabetes mellitus in postmenopausal women	**Weinstein,** Rexrode, Ridker, Manson, Kuller, Hankinson, Cochrane	6	OS		AS110

Table 12.2 (continued)
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Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
304	The effect of E+P discontinuation on risk for fracture: The WHI	**Jackson,** Watts, Lewis, Chen, Neuner, Cauley, Mouton, Robbins, Greep, LaCroix, Stefanick, Caralis, O'Sullivan	6	Gen		
305	Serum sex hormone levels and risk of hypertension in postmenopausal women	**Joffe,** Rexrode, Cochrane, Allison, Kotchen, O'Sullivan, Safford	6	OS		AS110
395	Hormone therapy, lean mass, falling and fracture risk among postmenopausal women: Results from the Women's Health Initiative hormone trials	**Bea,** Bassford, Cauley, Jackson, LaCroix, Lewis, Chen	6	CT		
420	Postmenopausal hormone use and the risk of nephrolithiasis: Results from the Women's Health Initiative	**Maalouf,** Welch, Robbins, Cochrane, Moe, Sakhaee	6	CT		
547	CaD and hip geometry	**Chen,** Jackson	6	Gen		AS153
608	Ambient air pollution, atrioventricular / ventricular conduction and their abnormalities: The environmental epidemiology of arrhythmogenesis in WHI, 1999-2003	**Liao,** Anderson, Duan, Lin, Peuquet, Prineas, Quibrera, Smith, Whitsel	6	CT		AS140
621	Factors associated with 3-year change in cognitive function in older women	**Dunn,** Gavett, Harty, Stoddard, Weintraub	6	OS		AS84
710	Insomnia and risk of cardiovascular diseases in postmenopausal women	**Chen,** Wassertheil-Smoller, Allison, Kotchen, Mellman, Sarto, Stefanick, Brunner, Naughton, Levine, Ren	6	Gen		AS140
717	Dietary omega 3 fatty acids, the omega 6/omega 3 ratio, bone mineral density and fractures in the Women's Health Initiative	**Jackson,** Orchard, Frank, Snetselaar, Lee, Wactawski-Wende, Neuhouser, Robinson, Cauley, Tylavsky	6	Gen		
720	Association between non-melanoma skin cancer and subsequent hematolymphoid malignancy by WHO diagnostic subtype, implications for subclinical immunosuppression and relationship to disease-specific and all-cause mortality	**Edlefsen,** DeRoos, LaCroix, Cherian, Rosenberg, Kotchen	6	Gen		

Table 12.2 (continued)
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Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
811	The effect of calcium plus vitamin D on risk for invasive cancer: Results of the Women's Health Initiative calcium plus vitamin D randomized clinical trial	**Brunner,** Wactawski-Wende, Millen, LaCroix, Cochrane, Caan, Wallace, Lane, Jacobs, Sarto, Margolis, Vitolins, Gass, Chlebowski	6	CT		
858	Comparison of prevalence and risk factors for pelvic organ prolapse by race	**Kudish,** Howard, Iglesia, Gass, Rodgers, Gutman, Iglesia, Sokol, Abu-Sitta, O'Sullivan	6	CT		
890	Risk factors for atrial fibrillation in postmenopausal women: The Women's Health Initiative Observational Study	**Perez,** Wang, Stefanick, Wassertheil-Smoller, Soliman, Manson, Martin, Klein, Limacher, Rodriguez, Prineas, Connelly	6	OS		
924	Does the benefit of medication adherence relate more to a drug effect or the behavior itself? Quantifying the effect of adherence behavior using data from the placebo arms of the WHI	**Curtis,** LaCroix, Delzell, Safford, Chlebowski, Judd	6	CT		
90	Passive smoke exposure in childhood and adulthood and prevalent coronary heart disease in women enrolled in the WHI	**Frishman,** Wagenknecht, Wong, Ockene	5	OS		
141	The association of food and nutrient intake with the incidence of stroke in the WHI observational study	**Beresford,** Shikany, St. Jeor, Torrens, Mossavar-Rahmani, Heiss, Patterson, VanHorn	5	Gen		
180	Alcohol use and the risk of endometrial cancer in the Women's Health Initiative observational study	**Assaf,** Beresford, Ockene, Chen, Cyr, Coccio, Moulton, Duffy, Burkholder	5	OS		
182	The effect of moderate alcohol consumption on the incidence of ovarian cancer	**Assaf,** Coccio, Anderson, Caan, Kaunitz, DeSantis, Duffy, Burkholder	5	OS		
297	Racial/ethnic differences in menopausal symptoms in minority vs. White women in the observational study cohort of WHI at baseline	**Potter,** Cochrane, Brzyski, Schenken, Murphy, O'Sullivan, Mossavar-Rahmani, Kempainen	5	OS		
381	Estimating ovarian cancer risk	**Anderson,** Chlebowski, Johnson, Kaunitz, Sato, Monk	5	Gen		AS97

Table 12.2 (continued)
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Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
384	Frailty in WHI clinical trials participants: Comparison of self-report and physical performance measures	**Woods,** LaCroix, Brunner, Cochrane, O'Sullivan, Wallace	5	CT		
410	Associations of psychosocial stress to cancer stage and grade among postmenopausal women diagnosed with breast, colorectal, and endometrial cancer: findings in the Women's Health Initiative observational study	**Moshesh,** Eaton, Hunt, Paskett, Woods, Yasmeen, Franks, Robbins	5	OS		
422	The occurrence of postmenopausal breast cancer following nonmelanoma skin cancer - A prospective observational study from the Women's Health Initiative	**Rosenberg,** Greenland, Khandekar, McTiernan, Rodabough, Sharma	5	OS		
427	Statin use and cognition in postmenopausal women: The Women's Health Initiative Memory Study [WHIMS]	**Legault,** Fillit, Hsia, Limacher, Manson, Ockene, Robinson, Sherwin, Sink	5	CT		AS39
462	Estrogen receptor polymorphisms and cardiovascular effects of hormone therapy	**Rossouw,** Bray, Hsia, Lewis, Schenken, Bonds, Hendrix, Kooperberg, Papanicolaou	5	CT		W6, W11
463	Glycemic load and risk of coronary heart disease in the Women's Health Initiative observational study	**Shikany,** Tinker, Liu, Allison, Hsia, Ma, Neuhouser, Uwaifo, VanHorn	5	OS		AS111
478	Correlates of medication utilization for the secondary prevention of coronary heart disease in older women	**Robinson,** Wallace, Cochrane, Johnson, Safford	5	CT		
480	Thyroid disease and risk for hip fracture in postmenopausal women	**Cummings,** Bauer, Cauley, Jackson, Kooperberg, LaCroix, LeBoff, Lee, Lewis, Thomas, Wu	5	OS		AS90
487	Body composition and physical function in a cohort of multiethnic older women: The WHI observational study and clinical trials	**Chen,** Bassford, Lohman, Nicholas, Wu, Wright, Wang, Going, LaCroix, Sherrill, Heymsfield	5	OS		AS153
494	The effect of lipid-lowering agents on the development of malignant melanoma: A prospective study from the Women's Health Initiative	**Rosenberg,** Levy, Greenland, McTiernan	5	Gen		

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
499	Prospective analysis of association between use of statins or other lipid lowering agents and colorectal cancer risk	**Rosenberg,** Roy, Khandekar, Cauley, Greenland, Lane, Ockene	5	Gen		
502	Menopausal hormone therapy and risk of ovarian cancer	**Anderson,** Barnabei, Brzyski, Chlebowski, Hendrix, Lane, Monk, Ockene, Rodriguez, Sarto	5	CT		
578	Depression and the risk of peripheral arterial disease: Results from the Women's Health Initiative observational study	**Cherr,** Wassertheil-Smoller, Trevisan, Wactawski-Wende, Allison, Johnson, Hsia, Hunt	5	OS		
611	Blood pressure response to dietary modification in postmenopausal women: Results from the Women's Health Initiative Clinical Trial	**VanHorn,** Margolis, Thomson, Kotchen, Allison, Beresford, Black, Cantey, Curb, Frank, Grimm, Kuller, O'Sullivan, Wassertheil-Smoller, Torner	5	CT		
623	Factors associated with life satisfaction and health in postmenopausal women	**Ceballos,** Beresford, Tinker, O'Sullivan, Brunner, Hunt, Manson	5	OS		
665	Ascertaining dementia related outcomes for deceased or proxy-dependent participants: An overview of WHIMS supplemental case ascertainment protocol (WHIMS-SCAP) [WHIMS]	**Jaramillo,** Rapp, Absher, Espeland, Jones	5	WHIMS		AS39
681	Bone turnover and the risk of hip fracture: The Women's Health Initiative	**Bauer,** Cauley, LeBoff, LaCroix, Robbins, Jackson, Greep	5	OS		AS181
702	Cost effectiveness of a dietary modification program and a low-fat diet in the prevention of breast cancer	**Bos,** Howard, Urban, Ennis, Beresford, Tinker, Waters, Bos, Chlebowski, Messina, Yasmeen	5	CT		
703	Street connectivity, urban sprawl and incident CHD in women	**Eibner,** Bird, Griffin, Margolis, Whitsel, Lurie, Allison, Hunt	5	Gen		AS220
706	Vasomotor symptoms and cardiovascular risk markers in postmenopausal women	**Szmuilowicz,** Seely, Manson, Vaidean, Rossouw, Vitolins, Stefanick, O'Sullivan, Greep	5	OS		

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
713	World Health Organization (WHO) absolute fracture risk score: How well does it predict fractures in minority women	**Cauley,** Robbins, LaCroix, Lewis, Wactawski-Wende, Masaki, Johnson, O'Sullivan, Jackson, Hendrix	5	Gen		
714	Inflammatory markers and the risk of hip fracture: The Women's Health Initiative	**Cauley,** Jackson, LaCroix, Lee, Robbins, Allison, Greep, Cummings, Wallace	5	OS		AS181
729	Do changes within specific nutrients or food groups within the WHI dietary intervention explain a reduction in breast cancer incidence?	**Patterson,** Thomson, Hubbell, Lane, Curb, Johnson, Kuller, VanHorn, Gass, Prentice, Chlebowski, Yasmeen, Beresford, Mossavar-Rahmani, Caan	5	CT		
730	Changes in dietary intake associated with the WHI dietary modification intervention and colorectal cancer incidence	**Vitolins,** Beresford, Caan, Shikany, Kotchen, Hunt, Parker, Adams-Campbell, Perri	5	CT		
806	The effect of treatment with conjugated equine estrogen on the presence and extent of subclinical atherosclerosis in the thoracic aorta of women 50 - 59 years of age at enrollment in the Women's Health Initiative [WHI-CACS]	**Carr,** Allison, Manson, Lewis, Curb, Johnson, Kuller, Martin, Trevisan, Woods, O'Sullivan, Langer, Wallace, Terry, Cochrane	5	CT		W25
834	Reproductive history, menopausal hormone use and lung cancer risk in the Women's Health Initiative Clinical Trial and Observational Study	**Schwartz,** Simon, Hubbell, Kooperberg, Chen, Wakelee, Wactawski-Wende, Manson, Abrams, Stefanick, O'Sullivan, Cote, Sokol, Chlebowski, Hendrix	5	Gen		
847	Evaluation of dietary fiber, whole grains, and dietary fat in relation to colorectal cancer using different dietary assessment methods: Food Frequency Questionnaire vs. 4-day food record	**Park,** Schatzkin, Prentice, Neuhouser, Tinker, Caan, Subar, Kipnis, Thompson	5	OS		

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
861	25(OH)Vitamin D levels and incident cardiovascular events in the WHI	**Manson,** Margolis, VanHorn, Rossouw, O'Sullivan, Martin, Eaton, Allison, Chlebowski, Robinson, Stefanick, Curb, Howard, Ockene, Shikany	5	Gen		W15, W24, AS181
870	Body image dissatisfaction in postmenopausal women	**Ginsberg,** Margolis, Hunt, Mossavar-Rahmani, Messina, Kudish, Kotchen, Adams-Campbell, Stefanick, Lynch, Manson, Gass, Gray	5	OS		
876	25(OH)Vitamin D levels and incident hypertension in the WHI	**Margolis,** Martin, Kerby, Manson, Liu, Allison, Curb, Kotchen, Wassertheil-Smoller	5	CT		W15, W24
878	25(OH)Vitamin D levels and all-cause mortality in the WHI	**Eaton,** Robinson, Martin, Kuller, Johnson, Curb, Allison, VanHorn, McTiernan, Liu, Manson, Ockene	5	Gen		W15, W24, AS181
885	Predictors of change in pain interference and functioning among postmenopausal women with persistent or recurrent pain conditions in the Women's Health Initiative Observational Cohort	**Brennan Braden,** Sullivan, LaCroix, Walitt, Martin	5	OS		
891	Self-rated health and medical outcomes in the Women's Health Initiative: The aging continuum, health, morbidity, mortality	**Brunner,** Hubbell, LaCroix, Lane, Stefanick, Safford, Woods, Watts, Beresford, Rapp	5	Gen		
905	Estrogen plus progestin and breast cancer mortality in postmenopausal women: The Women's Health Initiative Randomized Trial	**Chlebowski,** Prentice, Johnson, Wactawski-Wende, Rajkovic, Yasmeen, Lane, Gass, Kuller, Rohan, Ockene, Stefanick, Manson	5	CT		
910	25(OH)Vitamin D levels and incident type 2 diabetes in the WHI	**Robinson,** Manson, Phillips, Johnson, Howard, VanHorn, Liu, Curb, Watts, Allison, Song, Shikany, Stefanick	5	Gen		W15, W24, AS181

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
912	Coronary artery calcium and body morphology in postmenopausal women [WHI-CACS]	**Langer,** Manson, Allison, Cochrane, Hunt, Johnson, Phillips, Martin, Liu	5	CT		W25
923	Factors leading to involuntary weight loss in older women	**Yukawa,** LaCroix, VanHorn, Wassertheil-Smoller, Woods, Vitolins	5	CT		
943	Effects of body composition and metabolic syndrome on weight change over time in postmenopausal women	**Greco,** Stefanick, Eaton, Phillips, Vitolins, Allison, Michael, Sims	5	Gen		
1066	Estrogen alone and lung cancer in postmenopausal women	**Chlebowski,** Schwartz, Wakelee, Anderson, Stefanick, Manson, Rodabough, Chien, Wactawski-Wende, Gass, Kotchen, Johnson, O'Sullivan, Ockene, Chen	5	CT		
267	Adherence to dietary modification: A theoretical framework	**Rosal,** Ockene, Fletcher, Lasser, Tinker	4	CT		AS75
434	The effect of physical activity frequency, duration, and intensity on cardiovascular outcomes in WHI observational study	**Meyer,** Evenson, Heiss, Manson	4	OS		
446	Hormone exposure and risk of Parkinson's disease among women with natural menopause	**Saunders-Pullman,** Bressman, Chiu, Derby, Lipton, Santoro, Wassertheil-Smoller	4	OS		
491	Cause of death in women who die after hip fracture: WHI experience	**Robbins,** Pastore	4	OS		
513	Alcohol consumption and the risk of cardiovascular disease among black and white women: The effects of current and lifetime patterns of alcohol consumption among participants from the Women's Health Initiative	**Freiberg,** Adams-Campbell, Allison, Beresford, Curb, Hunt, Kraemer, Kuller, Safford, Trevisan, Robinson	4	OS		
593	Effect of genetic polymorphisms on coronary cardiac events among women in the Women's Health Initiative (WHI) study	**Bray,** Afshar-Kharghan, Hays, Hendrix, Herrington, Howard, Johnson, Kuller, LaCroix, Langer, Leal	4	OS		AS137

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
644	Association between reproductive history, adult weight stability and postmenopausal BMI and body composition	**Rosal,** Crawford, Bodenlos, Brzyski, Hardy, Hays, Hunt, Liu, Masaki, McNeeley, Moore-Simas, Phillips, Thomson, VanHorn	4	Gen		
920	Coffee and tea consumption in relation to risk of autoimmune rheumatic disease in the Women's Health Initiative (WHI)	**Collins,** Walitt, Parks, Howard, Hunt	4	OS		
364	Hormone replacement therapy and chronic heart failure incidence and outcomes in post-menopausal women	**Greenland,** Klein, Lloyd-Jones, LaCroix, Limacher, Robinson, Wong, Howard, Chae, Gulati, Sueta, Margolis, Kang, Ning	3	CT		AS196
397	Is there an association between baseline macronutrient intake and changes in cognition? Results from the Women's Health Initiative Memory Study [WHIMS]	**Vitolins,** Espeland, Thomson, Mossavar-Rahmani, Lovato, Wassertheil-Smoller, Wallace, Masaki, Shikany	3	WHIMS		AS39
402	Subclinical thyroid dysfunction and risk of MI	**Lorenz,** Hartmann, Heiss, LeGrys, Garrett, Cooper, Schectman, Manson, Jackson	3	OS		AS165
403	Sub-clinical thyroid dysfunction and risk of stroke	**Lorenz,** Hartmann, Heiss, LeGrys, Garrett, Cooper, Schectman	3	OS		AS165
412	Validation of WHO model for absolute risk of fracture	**Cauley,** Watts, Chen, Cummings, Jackson, LeBoff, McGowan, O'Sullivan, Robbins, Wactawski-Wende	3	Gen		
443	Statin use and lung cancer risk in non-smoking postmenopausal women	**Schlecht,** Wassertheil-Smoller, Johnson, Kamensky	3	OS		
457	Elevated blood pressure and kidney cancer	**Kuller,** Chang, Curb, Fried, Liu, Tevisan	3	OS		
485	Caffeine and risk of Parkinson's disease in women	**Saunders-Pullman,** Wassertheil-Smoller, Lipton, Santoro, Derby, Bressman, Chiu, Ravina	3	OS		

Table 12.2 (continued)
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Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
497	Extreme obesity and incident hypertension and diabetes: Racial and ethnic patterns in the WHI study	**McTigue,** Kuller, Valoski, Safford	3	Gen		
500	Results from the long term stability, standardization and quality control for the core analytes at the central laboratory for the WHI program	**Stein,** Chen, LaCroix, Lund, Rossouw, Miller	3	Gen		
505	Body image satisfaction in postmenopausal women	**Ginsberg,** Margolis, Gray, Tinker, Rosal, Manson, Sangi-Haghpeykar	3	OS		
530	One-carbon nutrients and risk of incident colorectal cancer in the Women's Health Initiative observational cohort	**Ulrich,** Beresford, Neuhouser, Lane, Shikany, Song, Zheng	3	OS		
540	Interaction between family history of cardiovascular disease and diabetes for the risk of coronary heart disease and stroke in postmenopausal women without diabetes at baseline: The WHI observational study	**Li,** Johnson, Curb, Robinson, Snetselaar, Allison, Safford, Liu	3	OS		
555	Genetic variation in the peroxisome proliferator-activated receptor y is associated with type 2 diabetes mellitus in the Women's Health Initiative observational study	**Song,** Manson, Tinker, Howard, Kuller, Nathan, Rifai, Liu	3	OS		AS132
557	Characteristics of the built environment in Seattle and weight change over time	**Littman,** Beresford	3	CT		
559	Tagging SNPs and haplotypes in 9 genes involved in insulin and IGF-I signaling and their associations with breast cancer risk	**Ho**	3	OS		AS152
564	Assessing the relationship between rheumatoid arthritis and fracture risk	**Wright,** Lisse, Chen, Eaton, Walitt	3	OS		
571	Cause of death in women who die after hip fracture: WHI	**Robbins,** Pastore, Masaki, Stefanick, Gass, Carbone, LaCroix	3	Gen		
573	Common genetic variation in the endothelial nitric oxide synthase (NOS3) gene and type 2 diabetes in an ethnically diverse cohort of women	**Liu,** Hsu, Papps, Tinker	3	OS		AS132

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
574	Dietary glycemic index/glycemic load and risk of breast cancer in the Women's Health Initiative observational study	**Shikany,** Chlebowski, Lane, Liu, Neuhouser, Rohan, Simon, Tinker	3	OS		AS111
599	Estrogen and progesterone and the risk of Parkinson's disease in the clincial trial	**Saunders-Pullman,** Lipton, Wassertheil-Smoller, Tanner, Derby, Santoro	3	CT		
601	Relationship between aspirin use, dose and inflammatory markers in postmenopausal women	**Berger,** Wassertheil-Smoller, Baird, Kaplan, Lynch, McGinn, Rosenbaum, Phillips, Wactawski-Wende, Johnson	3	OS		AS126
604	Metabolic syndrome and incident stroke	**McGinn,** Wassertheil-Smoller, Wolf, Allison, Baird, Berger, Hsia, Kaplan, Kooperberg, Kuller, Rexrode, Rosenbaum	3	OS		AS126
607	Race, psychosocial stress, and mammography: Prospective analysis in the Women's Health Initiative	**Michael,** Bowen, Carson, Chlebowski, Hubbell, Lane, Yasmeen	3	OS		
612	Impact of prehypertension on cognitive function [WHIMS]	**Robinson,** Espeland	3	WHIMS		AS39
622	Sex hormones, risk factors and risk of ER-positive and ER-negative breast cancers in postmenopausal women: Women's Health Initiative Observational Study	**Cummings,** Lee, Cauley, Rohan, Vitolins, Chlebowski, Manson, Lane, Sarto, Yasmeen, Hubbell, Cochrane, Hankinson, Crandall, Farhat	3	OS		AS167
627	Neighborhood environment and the risk of coronary heart disease in WHI participants	**Li,** Crawford, Ma, Ockene	3	Gen		
629	Dietary potassium intake and the risk of incident stroke and mortality	**Rajpathak,** Wassertheil-Smoller	3	OS		
642	Thiazolidinedione (TZD) use and fracture risk in postmenopausal women with diabetes	**Schwartz,** Bonds, Cummings, Liu, Margolis, Palermo, Phillips, Vittinghoff	3	Gen		
655	Plasma inflammatory markers and the risk of developing hypertension in white and black women	**Sesso,** Cochrane, Cook, Gaziano, Liu, Manson, Ridker, Rifai, Wang	3	OS		AS133

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
659	Coronary heart disease (CHD) risk perception and its relation to health behaviors in the Women's Health Initiative	**Barnhart,** Walker, Wassertheil-Smoller	3	OS		AS127
661	Racial differences in Vitamin D levels: Results from the WHI	**Melamed,** Cauley, Chlebowski, Jacobs, LaCroix, LeBoff, Liu, Millen, Robbins, Tylavsky, Wactawski-Wende, Wassertheil-Smoller, Wylie-Rosette	3	CT		
668	Dietary antioxidants, inflammation and diabetes mellitus in a multi-ethnic cohort of postmenopausal women	**Rodriguez,** Liu, Manson, Song, Nathan, Phillips, Mouton, Li, Shikany, Curb, Yasmeen, Bonds, Tinker, Rosal	3	OS		AS132
679	Physical activity, incident ischemic stroke and cardiovascular biomarkers	**McGinn,** Wassertheil-Smoller, Kaplan, Johnson, Phillips, Robinson, Lee, Beresford, Kooperberg, Stefanick	3	OS		AS126
682	Effect of migraine on stroke risk associated with hormone therapy in post-menopausal women in the Women's Health Initiative	**Schumacher,** Wassertheil-Smoller, Gass, Mysiw, Rossouw, O'Sullivan, Oberman, Manson	3	CT		
687	Associations between body composition and hip geometry in postmenopausal women in the Women's Health Initiative	**Going,** Chen	3	Gen		AS153
690	Hip geometric structure is weaker in anemic women: Results from the Women's Health Initiative Observational Study	**Wu,** Chen	3	OS		AS153
691	Changes in Hip Geometric Structures with Aging---Longitudinal Data Analysis from the Women's Health Initiative Observational Study	**Chen**	3	OS		AS153
692	Change in dietary intake in response to the DM Intervention is associated with change in physical activity among postmenopausal women in the Women's Health Initiative	**Russell,** Beresford, Bowen, Shikany, Snetselaar, Curb, Limacher, Parker	3	CT		

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
693	The association of dietary fructose intake in older women with the risk of obesity, type 2 diabetes mellitus, and cardiovascular disease	**Margolis,** Tinker, Shikany, Manson, Howard, Ritenbaugh, Wei, Johnson, Snetselaar, VanHorn, Rosal, Liu, Plodkowski, Kratz	3	OS		
695	Application of hidden Markov models to longitudinal measures of cognition collected by the Women's Health Initiative Study of Cognitive Aging [WHISCA]	**Ip,** Rapp, Zhang, Legault, Snow-Jones	3	CT		AS103
698	Distribution and correlates of adiponectin, leptin, ghrelin and lipoprotein subclasses among black and white postmenopausal women across a range of BMI	**Mackey,** Kuller, Evans, Tinker, Howard, Barinas-Mitchell, Robinson, Manson, McTigue, Phillips, Stefanick, Allison, Rosal, Beresford, Liu	3	OS		AS189
699	Metabolically healthy obese phenotype among black and white postmenopausal women: Definition and risk of incident CHD	**Mackey,** Kuller, Evans, Tinker, Kulick, Howard, Lewis, Wildman, Phillips, Liu, Curb, Stefanick, Barinas-Mitchell, McTigue, Manson	3	OS		AS189
705	Clustering of mortality in the Women's Health Initiative observational study and clinical trials	**Griffin,** Whitsel, Escarce, Eibner, Bird, Hunt	3	Gen		AS220
707	Animal fat intake and ovarian cancer incidence	**Freedman,** Prentice, Lessin, VanHorn, Rajkovic, O'Sullivan, Chlebowski, Manson, Thomson, Smith, Tinker, Lubin, Chetrit, Oberman	3	CT		
708	Comparison of methods used for correcting dietary data for underreporting [NBS]	**Schoeller,** Neuhouser, Bingham, Tylavsky, Tinker, Parker, Snetselaar, Vitolins, Beresford, Liu, LaRowe, Alvig	3	Gen		W8
709	Diet-gene interaction and the risk of diabetes in postmenopausal women	**Ma,** Ockene, Liu, Ockene, Olendzki, Pagoto, Li, Niu, Song, Eaton, Rajkovic, Phillips, Tinker, Plodkowski, Wallace	3	OS		AS132

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
712	Evidence that women with a history of fracture have reduced mechanosensitivity compared to those who have never fractured	**Beck,** Jackson, Going, Chen, LeBoff, Cauley, Wu, LaCroix, Khaled	3	OS		AS153
719	Depression and risk of type 2 diabetes in postmenopausal women	**Ma,** Pagoto, Schneider, Liu, Rodriguez, Ockene, Carnethon, Rosal, Safford, Culver, Sepavich, Tinker, Olendzki	3	OS		AS132
725	Air pollution components and cardiovascular disease in women	**Miller,** Vedal, Kaufman, Anderson, Siscovick, Sheppard, Larson, Eaton, Manson, Kuller	3	OS		AS150
726	The association between neighborhood retail food environment, obesity, blood pressure and Framingham Risk Score	**Fernandes,** Escarce, Ghosh-Datsidar, Margolis, Eibner, Bird, Whitsel, Li, Michael, Manson, Hunt	3	CT		AS220
776	Insulin-resistance associated TCF7L2 polymorphisms and risk of insulin-related cancers	**Ho,** Chen, Anderson, Chlebowski, Rajkovic	3	OS		AS152
789	Tagging SNPs and haplotypes in genes involved in insulin and IGF-I signaling and their associations with colorectal cancer risk	**Ho,** Adams-Campbell, Chlebowski, Peters	3	OS		AS152
790	Tagging SNPs and haplotypes in genes involved in insulin and IGF-I signaling and their associations with endometrial cancer risk	**Ho,** Chen, Rajkovic	3	OS		AS152
791	Polymorphisms of genes involved in insulin and IGF-I signaling and serum biomarkers in the IGF/insulin axis	**Ho,** Chen, Tinker	3	OS		AS152
804	Trajectories of physical activity in post-menopausal women: Influence of demographic characteristics, lifestyle behaviors and health status	**Nguyen,** LaCroix, Perry, Herting, Kohen, Tinker, Beresford, Adams-Campbell, Eaton	3	Gen		
805	B adrenergic inhibitors (ß Blockers) and risk for melanoma, multiple myeloma and nasopharyngeal cancer	**Glaser,** Jackson, Saltz, Lemeshow, Benson, Hofmeister, Yang, Rajkovic, Simon	3	Gen		

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
809	Physical activity and mortality in breast cancer survivors: Results from the Women's Health Initiative	**Irwin,** McTiernan, Chlebowski, Wactawski-Wende, Stefanick, Craft, Lane, Sternfeld, Thomson, Manson, Martin	3	Gen		
814	Variation in the selenoenzyme genes and risk of colorectal cancer	**Peters,** Hutter, Hsu, Prentice, Rajkovic, Marshall, Beresford, Caan, Potter, Duggan, Slattery, Ulrich, Foster, Diamond, Davis	3	OS		AS206
819	Genetic and epidemiologic factors associated with AMD among women in the WHI-SE study [WHISE]	**Seddon,** Haan, Peter, Wactawski-Wende, Johnson, Hyman	3	Gen		AS62
821	Farm history, residential, and work place insecticide exposures in relation to risk of autoimmune rheumatic disease in the Women's Health Initiative (WHI) cohorts	**Parks,** Walitt, Pettinger, Hunt, Walitt, DeRoos, Sarto, Howard	3	OS		
824	Economic and racial/ethnic segregation and incident CHD in women	**Shih,** Bird, Eibner, Escarce, Griffin, Lurie, Michael, Manson, Gold, Sarto, Allison, Masaki, Rosal, Safford	3	Gen		AS220
827	Is social support related to cardiovascular disease in the Women's Health Initiative observational study cohort?	**Freeborne,** Katz, Simmens	3	OS		
828	Serum selenium concentration and risk of colorectal cancer in postmenopausal women	**Peters,** Takata, Hsu, Prentice, Langer, Petrovich, Shikany, Diamond, Foster, Davis, King, Song, Duggan	3	OS		AS206
830	The association of consumption of whole grains and fiber with incident diabetes	**Parker,** Margolis, Tinker, Eaton, VanHorn, Rodriguez, Shikany, Liu, Wei	3	OS		
835	Determinants of serum 25-hydroxyvitamin D in the carotenoids in age-related eye disease study [CAREDS]	**Millen,** Mares, Sarto, Snetselaar	3	OS		AS105

Table 12.2 (continued)
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Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
836	Nutrient intake and anemia risk in the WHI Observational trial	**Thomson,** Chen, Aickin, Neuhouser, Snetselaar, Stefanick, Arendell	3	OS		M2
838	Biomarker-calibrated protein intake and bone health in the Women's Health Initiative Clinical Trial (WHI-CT) and Observational Study (WHI-OS)	**Beasley,** LaCroix, Neuhouser, Snetselaar, Tinker, Johnson, Eaton, Jackson, Bingham, Prentice, Huang	3	Gen		
841	Serum 25 hydroxyvitamin 25(OH)D and parathyroid hormone (PTH) and fracture risk in multi-ethnic women: The Women's Health Initiative	**Cauley,** Danielson, Boudreau, Jackson, Bauer, Ensrud	3	OS		BAA9
844	Environmental determinants of sleep disturbance in postmenopausal women	**Chen,** Levine, Cai, Kaufmann, Rudra, Rosal, Hunt, Brunner, Michael, O'Sullivan, Wassertheil-Smoller, Kravitz, Serre	3	CT		AS226
854	Ambient particulate matter air pollution and venous thromboembolism	**Shih,** Whitsel, Cushman, Liao, Eaton, Rudra, Margolis, Griffin, Bird, Eibner	3	CT		AS140, AS220, W6
857	Religion as a predictor of healthy lifestyle behaviors in WHI women	**Ockene,** Salmoirago-Blotcher, Crawford, Ockene, O'Sullivan, Rapp, Scheider, Granek, Schnall, Powell, Manson, Fitchett, Hunt	3	OS		
859	Assessing the predictive value of the driver risk score for colorectal cancer among women participating in the Women's Health Initiative	**Ling,** Kuller, Beresford, Freiberg, Lane	3	Gen		
860	The role of hormones in adenocarcinoma of the esophagus among postmenopausal women	**Bodelon,** Vaughan, Anderson, Rossing, Ochs-Balcom, Chlebowski	3	Gen		
862	Sub-clinical electrocardiographic findings and mortality in healthy women with a normal resting electrocardiogram: A random forest analysis	**Gorodeski,** Prineas, Lauer, Vitolins, Manson, Martin, Curb, Ishwaran, Blackstone, Zhang	3	CT		
863	Renal function and fracture risk in multi-ethnic women: The Women's Health Initiative	**Ensrud,** Cauley, Danielson, Boudreau, Jackson, Bauer, Canales, LaCroix	3	OS		BAA9

Table 12.2 (continued)
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Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
864	Does neighborhood walkability moderate the effects of intrapersonal characteristics on amount of walking in post-menopause women?	**Perry,** Berke, Beresford, Ockene, Manson, Nguyen, Moudon, LaCroix	3	Gen		
866	Low serum 25-hydroxyvitamin D levels in relation to biomarkers of type 2 diabetes, cardiovascular disease, and inflammation	**Chacko,** Liu, Eaton, McTiernan, Curb, Manson, Wylie-Rosette, Phillips, VanHorn, Martin, Plodkowski	3	CT		W1, W6, W14
868	Co-occurrence of anemia with other morbidities in the WHI cohort at baseline	**Chen,** Aickin, Thomson, Lewis, Cauley, Lessin, Eaton, Woods, Rodriguez	3	Gen		M2
869	HMW adiponectin and incident stroke	**Ogorodnikova,** Wassertheil-Smoller, Wildman, Rodriguez, Allison, Mancuso, Sowers, Baird, Rajpathak	3	OS		AS126
872	Stroke risk reclassification with lipoprotein-associated phospholipase a2 and c-reactive protein in the Women's Health Initiative	**Wassertheil-Smoller,** Wolf, McGinn, Kaplan, Hendrix, Allison, Xue, Eaton, Curb, Ko, Martin	3	OS		AS126
877	Diabetes, Metformin use and breast cancer	**Chlebowski,** McTiernan, Strickler, Wactawski-Wende, Manson, Phillips, Vitolins, Gunter, Wallace, Liu, Rohan, Euhus, Kaklamani	3	Gen		
880	Defining the relationship between obesity and disability in postmenopausal women	**Fowler-Brown,** LaCroix, Mouton, Kotchen, Blanchette, Stefanick, Dugan, Leveille, Wee	3	CT		
881	Change in cognitive function in cancer patients among WHIMS participants [WHIMS]	**Resnick,** Driscoll, Longo, Rapp, Jaramillo, Chlebowski, Masaki, Espeland, Stefanick, Lane	3	CT		AS39
884	Effects on dementia and cognitive functioning 3 years after stopping estrogen with and without progestin: the Women's Health Initiative Memory Study [WHIMS]	**Legault,** Shumaker, Curb, Manson, Johnson, Stefanick	3	CT		AS39

Table 12.2 (continued)
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Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
887	Racial and ethnic differences in the incidence and etiology of heart failure in the WHI	**Eaton,** Abdulbaki, Howard, Curb, Robinson, Manson, Margolis, Martin, Klein, Limacher, Allison, Liu, Ko	3	Gen		
892	Racial differences in the efficacy of estrogen for menopausal vasomotor symptom relief: Results from the WHI	**Lasser,** Goldsmith, Harrigan, Safford, Gass, Ko, Iglesia, Kim	3	CT		
893	Circulating levels of adipokines (leptin, adiponectin and resistin) and risk of incident stroke	**Rajpathak,** Wang, Wassertheil-Smoller, Ho, Curb, Mackey	3	OS		BAA10
895	Physical activity and inflammatory markers in a multi-ethnic cohort of women	**Lee,** Manson, Sesso, Mouton, Stefanick	3	OS		BAA11
896	Hemostatic and inflammatory markers as risk factors for hemorrhagic stroke	**Greenland,** Kim, Eaton, Curb, Manson, Martin, Allison, Li, Wassertheil-Smoller	3	CT		
899	Long term effects of exposure to conjugated equine estrogens therapies on domain-specific cognitive function: Results from the Women's Health Initiative Study of Cognitive Aging (WHISCA) Extension [WHISCA]	**Espeland,** Resnick, Hogan, Coker, Brunner, Granek, Legault, Rapp	3	CT		AS103
902	Reproductive life characteristics and risk of venous thromboembolism among postmenopausal women	**Canonico,** Scarabin, Carcaillon, Manson, O'Sullivan, Curb, Stefanick, Cochrane	3	CT		
903	Relationships between vitamin D status and age-related macular degeneration in the Carotenoids in Age-Related Eye Disease Study [CAREDS]	**Millen,** Mares	3	OS		AS105
904	Relationships between healthy diet patterns and age-related macular degeneration in the Carotenoids in Age-Related Eye Disease Study [CAREDS]	**Mares,** Sarto, Tinker	3	OS		AS105
908	C-GEMS paper	**Prentice,** Kooperberg, Wactawski-Wende, Caan	3	Gen		M3
909	Spatial distribution of ischemic lesions in WHIMS-MRI and effects of postmenopausal hormone therapy [WHIMS-MRI]	**Davatzikos,** Resnick, Bryan, Casanova, Espeland	3	CT		AS183

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
911	Impact of potential drug interactions on health outcomes in post menopausal women: Results from the Women's Health Initiative study	**Suda,** Johnson, Wan, Self, Phillips, O'Sullivan, Mouton	3	CT		
916	Hormone therapy, estrogen metabolism and risk of breast cancer in the WHI HT Trial	**Mackey,** Kuller, Modugno, Chlebowski, Manson, Curb, Cauley, Klug	3	CT		BAA12
917	Hormone therapy, estrogen metabolism and risk of hip fracture in the WHI HT Trial	**Mackey,** Kuller, Modugno, Curb, Cauley, Klug	3	CT		BAA12
919	Depressive symptoms and incidence of mild cognitive impairment and probable dementia in elderly women: The Women's Health Initiative Memory Study [WHIMS]	**Goveas,** Kotchen, Tarima, Wassertheil-Smoller, Woods	3	CT		AS39
922	Adipokines and risk of colorectal cancer in postmenopausal women	**Ho,** Chlebowski, Vitolins	3	OS		BAA10
925	Dietary intake and survival in women diagnosed with breast cancer: Results from the Women's Health Initiative	**Snetselaar,** Wallace, Tinker, Caan, Chlebowski, Lane, Lasser, Ockene, Prentice, VanHorn, Simon, Yasmeen, Vitolins, Thomson, Millen	3	Gen		
934	PanScan diabetes paper	**LaCroix,** Howard, Kooperberg, Phillips, Simon	3	Gen		M4
935	Association of socioeconomic status and incident heart failure in women	**Shah,** Lloyd-Jones, Klein, VanHorn, Phillips, Eaton, Martin, Rosal, Manson, Kang, Winkleby	3	CT		AS196
937	Psychological attitudes and neuroanatomy: the Women's Health Initiative Magnetic Resonance Imaging study [WHIMS-MRI]	**Tindle,** Resnick, Espeland, Kuller, Brunner	3	CT		AS183
939	Association between lactation history and breast cancer risk in WHI	**Stendall-Hollis,** Thompson, Thomson, O'Sullivan, Chlebowski, Yasmeen	3	Gen		
940	Trans- and saturated fatty acids and cognitive decline in elderly U.S. women	**Naqvi,** Harty, Weintraub, Dunn	3	Gen		AS84

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
941	Biomarker-calibrated energy and protein consumption in relation to diabetes risk [NBS]	**Tinker,** Sarto, Howard, Eaton, Margolis, Phillips, Neuhouser, Prentice, Mossavar-Rahmani, Huang, Beasley	3	Gen		W8
942	Physical activity and age-related changes in weight, BMI, and WHR of postmenopausal women: The Women's Health Initiative Study	**Sims,** Stefanick, Greco, Sarto, Johnson, Martin, LaMonte, Michael	3	CT		
944	Dietary fat and ischemic stroke	**Yaemsiri,** He, Sen, Tinker, Rosamond, Wassertheil-Smoller, Heiss	3	OS		AS187
945	Biomarker-calibrated protein intake and renal function in the Women's Health Initiative Observational Study	**Beasley,** LaCroix, Cauley, Ensrud, Jackson, Aragaki, Neuhouser, Tinker	3	OS		W8, BAA9
946	Dietary risk factors for nephrolithiasis in women	**Stoller,** Eisner, LaCroix, Wallace, Reiner, Shikany, Kahn, Jacobs, Wactawski-Wende, O'Sullivan, Jackson	3	Gen		
948	The relationship of hemoglobin levels to overall health, physical function, fatigue and quality of life in post-menopausal women	**Eaton,** Hochberg, Assaf, Cryer, LaCroix, Rodriguez, Manson, Lessin, Limacher, O'Sullivan, Woods, Connelly, Chen	3	Gen		
950	Combining self-reported intake and concentration biomarkers to investigate the association of lutein and zeaxanthin with age-related nuclear cataract in the Carotenoids in Age-Related Eye Disease Study [CAREDS]	**Freedman,** Tasevska, Potischman, Mares, Tinker, Schatzkin, Kipnis, Midthune	3	OS		AS105
952	Psychological attitudes and incidence of cancer	**Tindle,** Kuller, Matthews, Scheier, Ockene, Rosal, Messina, Manson, Thomson, Woods, Taylor, Hunt	3	Gen		
953	Combined impact of healthy lifestyle factors on mortality among post-menopausal women: a WHI Study	**Waring,** Eaton, Brunner, Parker, Manson, Ockene, VanHorn, Powell, Vitolins, Stefanick, Li, Mossavar-Rahmani	3	Gen		

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
955	Resting heart rate and coronary artery calcium	**Allison,** Hsia, Manson, Kuller, Trevisan, Phillips, Eaton	3	CT		W25
956	Psychological attitudes and important health outcomes in "healthy" vs. "unhealthy" populations	**Tindle,** Kuller, Matthews, Connelly, Brunner, Tinker, Wylie-Rosette, Rosal, Messina, Woods, White, Hunt	3	Gen		
957	Depression, Antidepressant Use, and Incident Frailty in the Women's Health Initiative Observational Study	**Lakey,** LaCroix, Gray, Borson, Williams, Calhoun, Goveas, Smoller, Ockene, Masaki, Coday, Rosal, Woods	3	OS		
958	Psychological attitudes and important health outcomes: is it more important to be optimistic, or to not be pessimistic?	**Tindle,** Kuller, Matthews, Tinker, Coday, Rosal, Messina, Manson, Woods, Hunt	3	Gen		
959	Evaluation of differences in the association of insulin/IGF axis components with breast cancer risk by estrogen receptor status in a case-cohort investigation: a formal analysis	**Cai,** Kang, Gunter, Strickler, Xue, Wassertheil-Smoller, Vitolins, Chlebowski	3	OS		AS129
961	Electrocardiographic p wave indices in healthy post-menopausal women: The Women's Health Initiative	**Gorodeski,** Magnani, Prineas, Lauer, Blackstone, Ishwaran, O'Sullivan, Soliman, Martin, Limacher, Curb, Cochrane	3	CT		
963	Ethnic and racial variation in colorectal cancer risk and protective factors in the Women's Health Initiative	**Simon,** Chlebowski, Pettijohn, Hubbell, O'Sullivan, Mouton, Lane, Thomson, Adams-Campbell, Abrams, Kato	3	Gen		
964	Percent African ancestry is significantly related to hip structural geometry	**Chen,** Seldin, Robbins, Qi, Beck, Lewis, Cauley, Wright	3	OS		AS153, BAA1
968	Calcium/ Vitamin D supplementation and the risk of peripheral artery disease: the Women's Health Initiative	**Berger,** Mohler, Wassertheil-Smoller, Manson, Allison, Connelly, Hiatt	3	CT		

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
972	Does metabolic syndrome modify CHD risk among postmenopausal women using oral estrogen plus progestin or estrogen-alone in the Women's Health Initiative Clinical Trials?	**Wild,** Manson, Martin, Phillips, Yasmeen, Trevisan, Stefanick, Curb	3	CT		W6, W14
973	Hormone exposure and risk of Parkinson's disease among women with surgical menopause	**Saunders-Pullman,** Derby, Santoro, Wassertheil-Smoller, Petrovich, Cochrane	3	OS		
974	Obesity, metabolic syndrome, insulin resistance, and risk of type 2 diabetes or cardiovascular disease in postmenopausal women	**Greco,** Stefanick, Howard, Phillips, Allison, Liu, Thomas, Rajpathak, Wildman, LaMonte	3	Gen		
975	Developing methods to determine health outcomes in the presence of competing risks for effectiveness research	**Weiss,** Segal, Varadhan, Wallace, Boyd, Wu, Lopez, Robinson, Eaton	3	Gen		
976	Prevalence and incidence of hypertension by socioeconomic status (SES) among African American and Latino women	**Zambrana,** Dinwiddie, Gaskin, Wassertheil-Smoller, Trevisan, Phillips, Pokras	3	Gen		
977	Hypertension treatment and control among African American and Latino women	**Dinwiddie,** Zambrana, Gaskin, Wassertheil-Smoller, Phillips, Eaton, Pokras	3	Gen		
978	The associations between hypertension status, access/use indicators and geographic location among African American and Latino women	**Gaskin,** Dinwiddie, Zambrana, Wassertheil-Smoller, Phillips, Li, Pokras	3	Gen		
979	Depression and cerebrovascular changes in post-menopausal women - The WHIMS-MRI Study [WHIMS-MRI]	**Goveas,** Kotchen, Tarima, Brunner, Ockene, Wassertheil-Smoller, Hogan, Espeland, Coker, Woods, Resnick, Dotson	3	WHIMS		AS183
980	Within-person cross-domain test variability and incident dementia: The Women's Health Initiative Study of Cognitive Aging: (WHISCA) [WHISCA]	**Espeland,** Rapp, Dagenbach, Jaramillo, Jennings, Resnick, Sink, Brunner	3	WHIMS		AS103
1000	Risk factors of invasive triple-negative breast cancer	**Li,** Phipps, Chlebowski, Prentice, Adams-Campbell, Kuller, Lane, McTiernan, Stefanick, Wactawski-Wende, Vitolins	3	OS		

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
1005	Development and evaluation of prediction rules for stroke in postmenopausal women	**Cai,** Lee-Jen, Smoller, Wassertheil-Smoller, Manson	3	OS		
1023	Vitamin D and depression in the WHI	**Johnson,** Manson, Spangler, Brunner, Ockene, Ockene, Wassertheil-Smoller, Michael, Liu, Millen, Bueche, Salmoirago-Blotcher	3	OS		
1025	Serum levels of hepatocyte growth factor and risk of endometrial cancer in postmenopausal women	**Wang,** Ho	3	OS		BAA10
1026	Genetic variation in chromosomal region 9p24 and colorectal cancer risk	**Kocarnik,** Peters, Potter, Prentice, Rajkovic, Sarto, Marshall, Hammad, Wallace, Beresford, Caan, Potter, Duggan, Slattery, Makar	3	OS		AS206
1027	Relationship of Hemoglobin levels and change in Hemoglobin levels to health utilities in post-menopausal women with chronic disease	**Eaton,** Harrow, Assaf, Sands, Manson, Chen, Roberts	3	Gen		
1028	Sleep characteristics and risk of mortality among older women: evidence from the Women's Health Initiative	**Tom,** LaCroix, Landis, Brunner, Ockene, Stefanick, Wactawski-Wende, Wassertheil-Smoller, Woods	3	Gen		
1029	Interaction between c-reactive protein and estrogen in risk of endometrial cancer: A prospective study in postmenopausal women	**Wang,** Ho	3	OS		BAA10
1030	Sarcopenia and falls and hip fractures	**Cawthon,** Chen, Thomson, Stefanick, Thomas	3	OS		
1032	Vitamin C supplementation and osteoporosis	**Womack,** Johnson, Carbone, Jackson, Snetselaar, O'Sullivan, Neuhouser	3	Gen		
1034	Physical activity as a moderator of sleep duration in postmenopausal women: The Women's Health Initiative Study	**Sims,** Stefanick, Thomson, Phillips, Isasi, Hale	3	OS		

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
1037	Active and passive smoking in relation to risk of ductal carcinoma in situ (DCIS) of the breast in the Women's Health Initiative	**Kabat,** Kim, Rohan, Wassertheil-Smoller, Ockene, Wactawski-Wende, Luo, Tindle, Kakani	3	Gen		
1038	The relation of folate intake and cognitive decline and dementia in the Women's Health Initiative Memory Study [WHIMS;WHISCA]	**Agnew-Blais,** Smoller, Wassertheil-Smoller, Snetselaar, Hogan, Coker, Mysiw	3	WHIMS		AS39, AS103
1041	Interaction between smoking and obesity and the risk of developing breast cancer among postmenopausal women	**Luo,** Margolis, Ockene, Stefanick, Simon, Tong, Horn	3	Gen		
1042	Relationships that cognitive function and changes in cognitive function have with incident cardiovascular disease: The Women's Health Initiative Memory Study (WHIMS) [WHIMS]	**Shumaker,** Espeland, Curb, Lasser, Limacher, Manson, Ockene, Stefanick, Wallace, Wassertheil-Smoller, Phillips, Lovato	3	WHIMS		AS39
1046	Predictors of consent to extended follow-up in randomized prevention trials	**Hunt,** McNabb, Anderson, Granek	3	Gen		
1047	Effects of conjugated equine estrogen therapy on region-specific brain volumes: The Women's Health Initiative Magnetic Resonance Imaging Study (WHIMS-MRI) [WHIMS-MRI]	**Casanova,** Resnick, Davatzikos, Espeland, Brunner, Johnson, Kuller, Mysiw, Goveas, Maldjian, Wagner	3	WHIMS		AS183
1048	Vitamin D and risk of atrial fibrillation in the WHI	**Soliman,** Vitolins, Case, Shalash, Prineas, Goff, Curb, Limacher, Manson, Snetselaar, Wassertheil-Smoller, Allison, Martin	3	CT		
1050	Common genetic variation in the ion channel transient receptor potential membrane melastatin 6 (TRPM6) in relation to type 2 diabetes, and systemic inflammation among postmenopausal women	**Chacko,** Liu, Song, Curb, Eaton	3	OS		AS132
1051	Vitamin D and depression in the WHI CaD Trial	**Johnson,** Manson, Spangler, Brunner, Ockene, Ockene, Wassertheil-Smoller, Michael, Liu, Millen, Bueche, Salmoirago-Blotcher, Powers	3	CT		

Table 12.2 (continued)
Manuscripts – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study#
1054	Pathway analysis with regularized hotelling's T2 statistics	**Chen,** Prentice, Wang	3	CT		
1061	A prospective evaluation of circulating adipokine levels and postmenopausal breast cancer risk	**Gunter,** Wassertheil-Smoller, Chlebowski, Manson, McTiernan, Snetselaar, Kakani	3	OS		BAA10, AS126, AS129
1067	Physical activity as a moderator of cardiovascular risk factors associated with sleep duration in postmenopausal women: The Women's Health Initiative Study	**Sims,** Stefanick, Ockene, Phillips, McGinn, Martin, Seguin, Hale	3	OS		
1068	Genetic variants in inflammatory genes influence the risk to multiple cancers	**Kim,** Vitolins, Xu, Chang, Kim, Li, Smith, Sun, Tooze, Turner, Zhang, Zheng, Zhu, Wallace	3	OS		BAA6
1069	Confirmation of cancer risk variants in African American women	**Kim,** Vitolins, Xu, Adams, Chang, Cheng, Kim, Li, Smith, Sun, Tooze, Turner, Zhang, Zheng, Zhu	3	OS		BAA6
1075	Panscan II	**Kooperberg,** LaCroix, Howard, Wactawski-Wende, Rajkovic	3	Gen		M4
1077	Alcohol consumption in relation to risk of ductal carcinoma in situ (DCIS) of the breast in the Women's Health Initiative	**Kabat,** Kim, Rohan, Wassertheil-Smoller, Chlebowski, Lane, Powell, Shikany, Stefanick, Wactawski-Wende, Freiberg, Rodgers, Kazlauskaite	3	Gen		
1079	Development and measurement properties of a positive aging phenotype	**Woods,** Cochrane, LaCroix, Beasley, Seguin, Lane, Manson, Tinker, Mouton, Espeland, Robinson, Brunner	3	Gen		
1080	Ethnic and racial variation in colorectal cancer survival in the Women's Health Initiative	**Simon,** Chlebowski, Pettijohn, Hubbell, O'Sullivan, Mouton, Lane, Thomson, Adams-Campbell, Abrams, Kato	3	Gen		
1084	Meta-analysis of APOE SNPs	**McKay,** Haan, Seddon, Peter	3	Gen		
1087	Application of novel statistical methods to evaluate markers for electing treatment	**Janes,** Pepe, Anderson	3	CT		

Appendix A

Women's Health Initiative Memory Suite of Studies (WHIMS)

October 2009

The data contained in this report are preliminary and may contain unvalidated findings. These data are not intended for public use. Public use of these data could create erroneous conclusions which, If acted upon, could threaten public health or safety.

Table of Contents

Introduction

This report has been prepared to support the Observational Study Monitoring Board in its review of the Women's Health Initiative Memory Program. The current major initiatives in this Program are the:

- Women's Health Initiative Memory Study (WHIMS) ECHO
- WHIMS Supplemental Case Ascertainment Protocol (SCAP)
- Women's Health Initiative Memory Study of Cerebral Magnetic Resonance Imaging (WHIMS-MRI)
- Women's Health Initiative Memory Study of Younger Women (WHIMS-Y)
- Women's Health Initiative Study of Cognitive Aging (WHISCA) Extension
- Validation study of Cognitive Assessment by Telephone (CAT)

These studies include cohorts of women, all of whom, except for CAT, were participants in the Women's Health Initiative Hormone Trials (WHI-HT), and intersecting subsets of WHI clinical sites. The WHIMS studies' Coordinating Centers are located in the Division of Public Health Sciences at Wake Forest University School of Medicine.

Materials are drawn from study databases and records in September, 2009 to provide an up-to-date accounting. Live study databases were accessed at time points spanning several weeks so that minor discrepancies may exist across exhibits.

We organized this report into sections to describe each of the initiatives listed above. The WHIMS ECHO is continuing surveillance of the original WHIMS cohort to identify incident cases of probable dementia (PD) and mild cognitive impairment (MCI). We describe the cohort and provide data on the post-trial incidence of study endpoints according to women's original treatment assignments. The SCAP is reaching out to proxies of deceased women to assess the participant's status at time of death. The WHISCA Extension is completing analyses of candidate genes from DNA samples in WHISCA participants. The WHIMS-MRI study is beginning its second phase. The CAT study was just completed and we report on comparisons between telephone and face-to-face cognitive assessments.

WHIMS Coordinating Center
September 28, 2009

Section 2.

Overview of Suite of Studies

The Women's Health Initiative Memory Study (WHIMS)

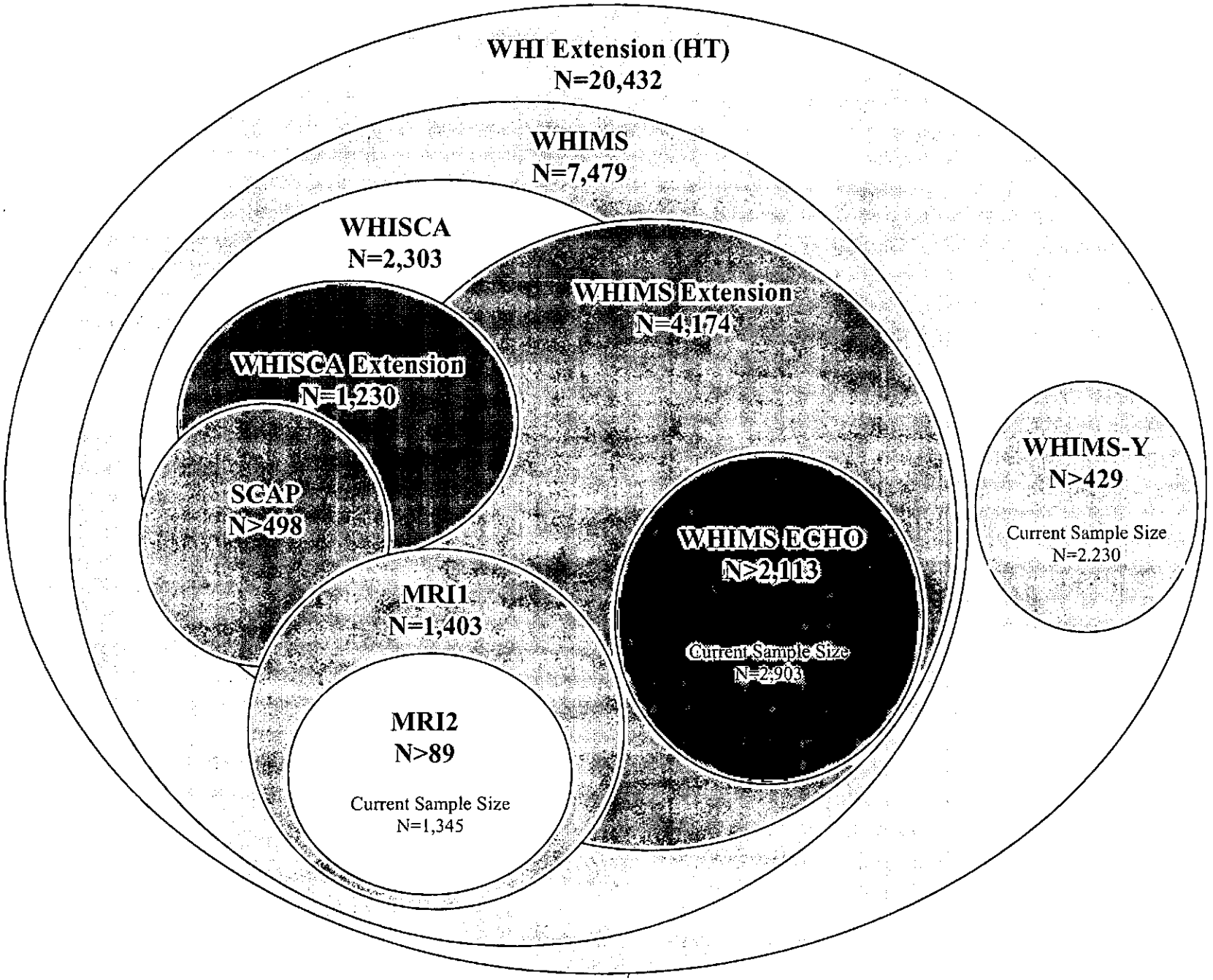
The Women's Health Initiative Memory Study (WHIMS) Extension

The Women's Health Initiative Study of Cognitive Aging (WHISCA)

The Women's Health Initiative Study of Cognitive Aging (WHISCA) Extension

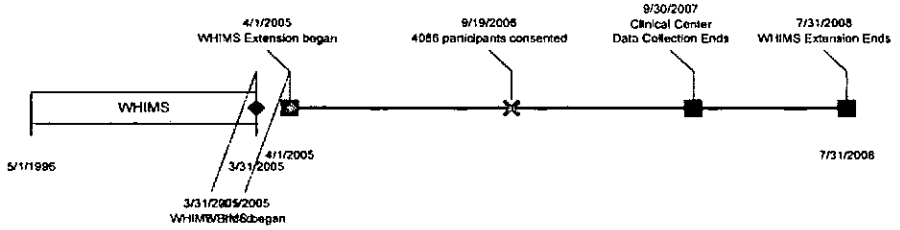
The Women's Health Initiative Memory Study of Cerebral Magnetic Resonance Imaging (WHIMS-MRI-1+2)

2.1 Relationships Among Study Cohorts

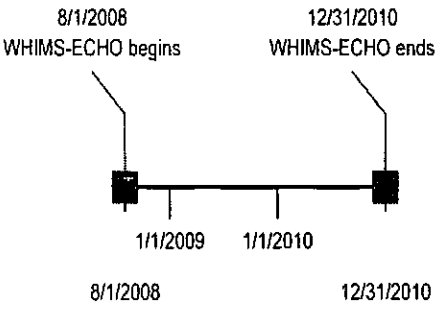


2.2 Timelines for the WHIMS, WHIMS Extension, WHIMS-ECHO, WHIMS-MRI, WHIMS-MRI2, WHISCA, WHISCA Extension, and WHIMS-Y Studies

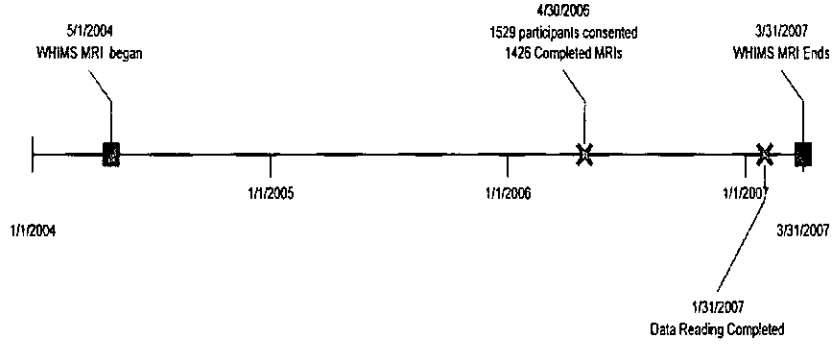
WHIMS Extension Timeline



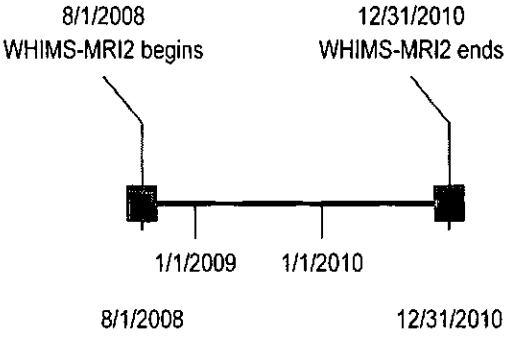
WHIMS-ECHO Timeline



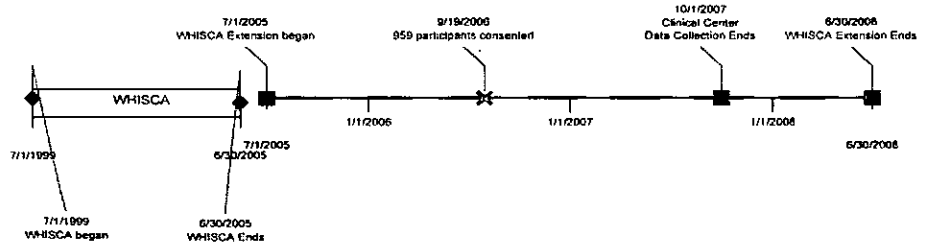
WHIMS MRI Timeline



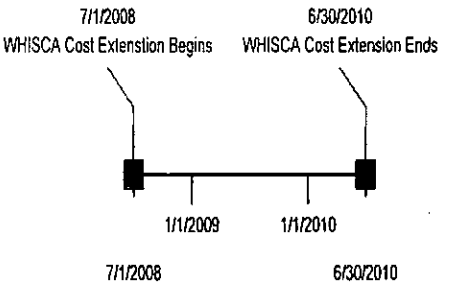
WHIMS MRI2 Timeline



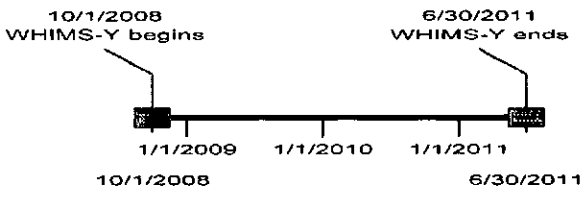
WHISCA Extension Timeline



WHISCA Cost Extension Timeline



WHIMS-Y Timeline



2.3 Studies Objectives

2.3.1 Women's Health Initiative Memory Study (WHIMS)

The Women's Health Initiative Memory study was an ancillary study designed to assess the effects of hormone therapy on the development and progression of symptoms associated with dementia in approximately 8,311 women, 65 years of age and older, participating in the Hormone Therapy (HT) trials of the Women's Health Initiative (WHI). The study was divided into four phases. In **Phase 1**, the participants completed a primary screening assessment of cognitive functioning (WHI Form 39) at baseline and annually thereafter for eight years. The screen consisted of the Modified Mini Mental State (3MS) Examination. Based on the participants' scores, approximately 20% (representing about 88% sensitivity on the 3MS) continued to Phase 2 of the study for the identification of dementia and/or MCI. **Phase 2** assessments were conducted by a certified technician and included: neuropsychological test battery and a brief neuropsychiatric assessment, and informant data on physical functioning. The battery took approximately two hours to complete and score. **Phase 3** consisted of a standardized interview with a clinician (e.g., neurologist, psychiatrist, or geriatrician). After reviewing data from Phase 2 and Phase 3, the clinician made a provisional diagnostic impression of either probable dementia (PD), minor cognitive impairment (MCI), or no dementia (ND). **Phase 4** of the ancillary study included all laboratory data collected on the women identified as having all-cause dementia in Phase 3. The tests were performed by local laboratories, and the results were reviewed by the clinician in order to make a differential diagnosis. It was anticipated that about 60% of these women would be diagnosed with Alzheimer's-related dementia with the remaining 40% falling into other dementia categories.

Once a woman was identified as having dementia, she continued to be followed with Phase 1 and Phase 2 testing throughout the study in order to assess symptom progression. All diagnosis and classification data were sent to an adjudication panel comprised of clinicians with expertise in dementia. It was hypothesized that the symptoms associated with dementia would be delayed in women who were on active hormone therapy, as opposed to placebo.

The overall objective of the ancillary study was to determine the incidence of dementia syndromes, through cognitive functioning screening, neuropsychiatric and neuropsychological evaluations, in approximately 7,479 women who were 65 years of age and older, and who were participating in the HT trials of the WHI. Annual assessments of cognitive function allowed for tracking the rate of progression of cognitive decline.

Another important aim of the ancillary study was to quantify the efficacy of HT separately in women who had and who had not had a hysterectomy. If approximately equal numbers of these women comprise the dementia study cohort, the study design afforded statistical powers of 77%, 65% and 52% to detect treatment effects of 45%, 40% and 35% in the two subgroups in separate comparisons. (These power projections do not incorporate adjustments for multiple comparisons, but do indicate the coverage properties of unadjusted confidence intervals.)

On July 9, 2002, the National Heart, Lung, Blood Institute (NHLBI) of the National Institutes of Health (NIH) stopped early Women's Health Initiative (WHI) combined estrogen and progesterone versus placebo HT trial due to an increased risk of breast cancer, heart attacks, strokes, and blood clots in the lungs and the legs in comparison to the women in the placebo

group. WHIMS continued collection of cognitive testing and clinical examination data from these participants.

The estrogen-alone (E-alone) WHI hormone trial was stopped early on February 29, 2004. Corresponding to an extension for WHI, a concomitant 4 year 7 month extension for safety monitoring in the WHIMS E-alone and the E+P trials (WHIMS Extension) was funded in March 2004 by the NHLBI.

Trial results from WHIMS E+P and E-Alone HT trials have been published. Findings suggest that E+P versus placebo increased women's risk for dementia and declines in global cognitive function. E-Alone versus placebo increased women's risk for dementia and MCI combined, and for declines in global cognitive functioning. Ongoing analyses are underway, with a number of papers emerging from trial and follow-up data. (See publications list at the end of the report.)

2.3.2 Women's Health Initiative Memory Study (WHIMS) Extension

The WHIMS Extension was sponsored by the NHLBI and was an ancillary study to the NHLBI sponsored Women's Health Initiative. The goal of the WHIMS Extension was to provide post-trial follow-up and surveillance of participants from the completed E+P and E-alone trials to determine whether an increased risk of dementia was sustained following study drug termination.

WHIMS Extension was designed to be conducted during the time period of the safety monitoring extension for the WHI hormone trials. There were no data available from other studies on how the cessation of E+P or E-alone therapy impacted critical cognitive-related outcomes. Given the data derived from the WHI E+P and E-alone trials, and the fact that millions of women decided to stop taking combination hormone therapy following the WHI and WHIMS publications regarding E+P, it was critical that we determine the implications of this decision for postmenopausal women's cognitive health. By continuing the careful ascertainment of PD, MCI, and global cognitive functioning, we increased the power in the surveillance component. This enabled us to provide more accurate estimates of cognitive risk associated with prior exposure to E+P or E-alone therapy, as well as more sophisticated and hypothesis-generating sub-analyses. The WHIMS Epidemiology of Cognitive Health Outcomes (WHIMS-ECHO) continues the follow-up of this cohort (see Section 3).

During the WHIMS Extension, the Modified Mini-Mental Status Exam (3MSE) was administered yearly (Phase 1) to the participants by a trained and certified WHIMS technician. Based on the 3MSE score and her education level, the participant could be referred for further neuropsychological testing and functional assessments (Phase 2) and a clinician's examination (Phase 3).

2.3.3 Women's Health Initiative Study of Cognitive Aging (WHISCA)

The Women's Health Initiative Study of Cognitive Aging (WHISCA) was two, parallel randomized, placebo controlled, clinical trials designed to assess the efficacy of postmenopausal hormone therapy (HT)- conjugated equine estrogen (CEE) 0.625mg/day with or without medroxyprogesterone acetate (MPA) 2.5mg/day compared with placebo on age related changes

on domain specific cognitive functions. WHISCA was an ancillary study to the WHI Memory Study and enrolled 2,303 women from 14 of the WHIMS clinical sites, aged 66 to 84 years, who did not meet the criteria for dementia at enrollment into WHISCA. Women with a prior history of hysterectomy were randomly assigned by the WHI to CEE-Alone and those with an intact uterus received CEE+ MPA for an average of three years before the first WHISCA cognitive assessment. WHISCA investigated the effects of hormone therapy on rates of change over time in memory, other aspects of cognition (language, attention, spatial ability), motor function, and mood.

2.3.4 Women's Health Initiative Study of Cognitive Aging (WHISCA) Extension Study

An Extension to WHISCA was funded on July 1, 2005 and provided follow-up cognitive testing off-study medication until October 2007. All of the original 14 WHISCA clinical sites participated in the Extension study. Annual cognitive testing was conducted with the same standardized neuropsychological (NP) battery used in the original WHISCA study. This NP battery was developed by the National Institute on Aging and designed to be sensitive to the effects of age and HT.

Additional goals addressed by the WHISCA Extension were:

- To determine the long-term effects of HT on changes in memory, other cognitive functions, and affect;
- To determine the effects of discontinuation of HT on changes in memory, other cognitive functions, and affect;
- To determine whether vascular disease and atrophy, measured by MRI, modify the effects of HT on cognitive change;
- To investigate predictors of the transitions between normal aging and mild cognitive impairment and mild cognitive impairment and dementia.

A cost extension began on July 1, 2008 using existing carry over funds and continued until June 30, 2009. The goals of the cost extension were:

- Collaborate with the NIA in order to complete scoring of a subset of the WHISCA data and to plan and conduct collaborative analyses.
- To analyze and disseminate findings from WHISCA data through a series of publications and presentation at selected national meetings.
- To offer a visiting scholar program to provide opportunities for investigators, including junior scientists, to conduct scholarly work during brief, intensive, onsite collaborations with WHISCA investigators at WFUHS (Drs. Sally Shumaker, Mark Espeland, Stephen Rapp, Laura Coker) and from the NIA in Baltimore (Drs. Susan Resnick and Alan Zonderman).
- To host a conference for WHISCA principal investigators from each clinical site. This conference will be held in conjunction with another conference to maximize participation.
- To support analyses for apoE status among women enrolled in WHISCA by acquiring extracted DNA for apoE genotyping for up 2,303 women enrolled in WHISCA.

An additional cost extension, using remaining carryover funds, was approved and began on July 1, 2009 and will continue until June 30, 2010.

These Extensions of WHISCA will allow the investigators to complete the planned work and to reach the ultimate study goal of providing critical information to clinicians and researchers on the effects of hormone therapy on cognition and aging in a healthy, older cohort of women.

The mean age at the end of the Extension was 79.9 years of age and the oldest participant was 93 years old. The rate of attrition was projected to be 10% per year over the life of the study. To date 1,844 participants were reported to be at full follow-up status, leaving 266 participants who were alive but not making clinic visits. There were192 participant deaths since the beginning of the study. Enrollment in the WHISCA Extension totaled 1,230 (89% of potential enrollment).

2.3.5 The WHIMS Cerebral Magnetic Resonance Imaging (WHIMS-MRI-1+2) sub-studies

WHIMS-MRI-1 was a cross-sectional substudy of 1,403 women who were enrolled in the WHIMS E+P and E-Alone studies. The 14 participating sites in the WHIMS-MRI-1 study were selected on the basis of interest, experience, and the availability of imaging resources, with preference given to sites who were also participating in the WHISCA trial. Thirteen of the 14 sites were also WHISCA sites. Based on the results of the WHIMS E+P and E-Alone HT trials, the primary goal was to assess the impact of hormone therapy on subclinical neuropathological changes (ischemic lesion volume and brain volume) to further our understanding of the processes by which hormone therapy may increase participants' risk for stroke and adverse cognitive findings.

WHIMS-MRI2 will collect a second scan on women who had been enrolled in WHIMS-MRI-1, an average of 3-5 years after their initial scan (see Section 7).

3.1 WHIMS ECHO Protocol Summary

The Women's Health Initiative Memory Study - Epidemiology of Cognitive Health Outcomes (WHIMS-ECHO) continues annual cognitive assessments in the WHIMS Extension cohort through December 31, 2010. This extended follow-up will increase the total cases of probable dementia and cognitive impairment, thereby enhancing the epidemiologic value of the program by providing statistical power necessary to:

- characterize how women transition among cognitive states,
- identify subtypes of cognitive deficit/impairment, and
- identify predictors related to cognitive health and decline.

To increase efficiency, lower participant burden, and reduce costs, centralized validated annual telephone assessments will be administered to all participants. If a woman scores below a predetermined cut-point on the TICSm, a standardized cognitive screening test, her friend or family member will also be interviewed using the Dementia Questionnaire (DQ). Together, all assessments will be used to adjudicate participants as ND, MCI and PD. The WHIMS-ECHO Coordinating Center (CoC) includes expert investigators and experienced cognitive interviewers from the WHIMS program. A national Steering Committee of WHIMS investigators and topic area experts guides the conduct of the study.

3.2 WHIMS ECHO Progress Report

Data collection for Year 1 began 09/11/2009. Currently, 13 cognitive interviewers are certified to administer the cognitive telephone assessment. There are a total of 3,700 women across 38 WHI Field Centers who are eligible to participate in WHIMS ECHO. To date, 2,887 (78%) women have agreed to CoC contact, 337 declined to release contact information and 442 women have not yet been contacted by the WHI field centers.

3.3 Enrollment: Overall

Enrollment rates for the WHIMS ECHO average 78% for eligible WHI Extension participants across all sites. Currently, there are 2,887 participants enrolled in the WHIMS ECHO. As of 09/10/2009, a total of 2,120 participants have completed YEAR 1 cognitive assessments (Table 3-1).

Table 3-1 WHIMS ECHO Enrollment Tracking of Call Attempts for Visit 1 2709 Participants Contacted Generated on 09/10/09

Call Outcome		
Attempts at call completion ended	**N**	**%**
Call Completed	**2120**	**78.26**
Declined	**96**	**3.54**
Phone Disconnected	**49**	**1.81**
Unable to locate	**7**	**0.26**
Left a message	**209**	**7.72**
Hearing Impaired	**18**	**0.66**
Discontinued	**14**	**0.52**
Deceased	**22**	**0.81**
Ongoing calls		
No Answer	**75**	**2.77**
Other	**2**	**0.07**
Scheduled	**38**	**1.40**
Re-Contact	**59**	**2.18**

3.4 Enrollment: By Clinical Site

The WHIMS ECHO Enrollment Report (Table 3-2) shows the total number of eligible participants at each field center, the total number of women who have agreed to WHIMS CoC contact, the number of women who refused CoC contact, and the number remaining to be contacted by the clinic for CoC contact permission.

Table 3-2 WHIMS ECHO Participants by Field Center Removing Deceased, Absolutely No Follow-up, Lost to Follow-up and WHIMS Extension Withdrawals Report Generated 09/10/09

		Agreed to CoC contact?		
Field Center	Total Eligible	Yes	No	Not yet contacted by Field Center
ALL Field Centers	3700	2887	371	442
11=Davenport	23	20	3	0
12=Birmingham	88	56	10	22
13=Greensboro	21	18	2	1
14=Boston	101	92	9	0
15=Buffalo	106	90	16	0
16=Chicago	3	3	0	0
19=Atlanta	62	56	4	2
20=Chicago-Evanston	10	6	4	0
21=Iowa City	19	17	2	0
23=Pawtucket	92	84	7	1
24=Memphis	39	34	5	0
25=Minneapolis	113	80	4	29
26=Newark	66	19	1	46
27=Phoenix	41	38	2	1

Table 3-2 WHIMS ECHO Participants by Field Center Removing Deceased, Absolutely No Follow-up, Lost to Follow-up and WHIMS Extension Withdrawals Report Generated 09/10/09				
		Agreed to CoC contact?		
Field Center	Total Eligible	Yes	No	Not yet contacted by Field Center
28=Pittsburgh	94	90	3	1
29=Tucson	49	43	5	1
30=Davis	108	69	9	30
42=Stanford	166	141	23	2
43=Milwaukee	125	98	17	10
44=George Wash.	106	78	0	28
45=Honolulu	53	40	13	0
46=Gainesville	90	53	3	34
47=Houston	56	53	3	0
48=Worcester	168	138	28	2
49=New York	148	111	36	1
50=Columbus	122	109	13	0
51=MedStar	101	88	13	0
53=Oakland	107	90	17	0
54=Jacksonville	54	40	0	14
55=Torrance	22	20	1	1
56=Madison	90	87	3	0
57=Stony Brook	126	117	9	0
58=Chapel Hill	134	124	6	4

Table 3-2 WHIMS ECHO Participants by Field Center Removing Deceased, Absolutely No Follow-up, Lost to Follow-up and WHIMS Extension Withdrawals Report Generated 09/10/09				
		Agreed to CoC contact?		
Field Center	Total Eligible	Yes	No	Not yet contacted by Field Center
59/60=Chicago-Rush	58	50	8	0
61=Cincinnati	111	94	17	0
62=Detroit	60	56	4	0
63=Irvine	77	0	0	77
65=Nevada	105	95	9	1
66=Portland	107	0	0	107
67=San Antonio	37	29	8	0
68=Los Angeles	85	50	12	23
69=Fall River	82	72	8	2
70=Pauline	17	15	2	0
71=Bowman Gray	12	10	0	2
72=New Brunswick	114	100	14	0
73=Des Moines	132	114	18	0

3.5 Call Completion Rates

As shown in Table 3-3, the majority (85%) of calls were completed during the first three attempts to reach the participant. An attempt has been made to contact 2,709 (93%) of the women who have agreed to be contacted by the CoC. Currently, interviewers make up to eight attempts to reach the participant unless the participant returns a "left message" call which could result in a ninth attempt.

Table 3-3 WHIMS ECHO Tracking of Completed Calls for Visit 1, 2709 Participants contacted Report generated on 09/10/09	
Attempt Which Call Was Completed	**N (%)**
1	626 (29.5%)
2	765 (36.1%)
3	415 (19.6%)
4	207 (9.77%)
5	61 (2.88%)
6	33 (1.56%)
7	9 (0.42%)
8	2 (0.09%)
9	1 (0.05%)

3.6 Characteristics of Enrollees

Table 3-4 Characteristics of Enrollees	
Characteristic	N (%)
WHI Treatment Assignment	
E-Alone Placebo	383 (18.16%)
E-Alone	382 (18.11%)
E+P	656 (31.10%)
E+P Placebo	688 (32.62%)
Age at WHI Enrollment	
64-69	1123 (53.25%)
70-74	732 (34.71%)
75-80	254 (12.04%)
Age as of September 11, 2008	
74-78	627 (29.73%)
79-83	980 (46.47%)
84-88	437 (20.72%)
89+	65 (3.08%)
Baseline WHIMS 3MS	
Below screening cutpoint	87 (4.18%)
Cutpoint to 95	440 (21.13%)
95-100	1555 (74.69%)
Race/Ethnicity	
American Indian/Alaskan native	6 (0.28%)
Asian/Pacific Islander	26 (1.23%)
Black/African American	130 (6.16%)
Hispanic/Latino	29 (1.38%)
White	1899 (90.04%)
Other	19 (0.90%)

3.7 WHIMS ECHO Test Scores

Table 3-5 WHIMS ECHO Cognitive Test Scores				
Cognitive test	Mean (SD)	Min	Median	Max
Telephone Interview of Cognitive Status (TICS-m)	33.86 (5.44)	8	34	49
East Boston Memory Test (EBMT)	9.12 (1.94)	0	9	12
Verbal Fluency – Animals (VF-A)	16.4 (5.05)	2	16	35
Oral Trial Making Test Part A – Errors	0.01 (0.12)	0	0	2
Oral Trial Making Test Part A –Correct	24.97 (0.51)	9	25	26
Oral Trial Making Test Part B – Errors	1.34 (1.78)	0	0	9
Oral Trial Making Test Part B –Correct	23.41 (4.22)	0	25	25
Digits Forward	7.76 (2.40)	0	7	14
Digits Backward	6.42 (2.56)	0	6	14
Geriatric Depression Scale (GDS)	1.75 (2.17)	0	1	13
TICS-m Word List Long Delay	2.59 (1.93)	0	2	10
East Boston Memory Test (EBMT) Recall	8.19 (2.84)	0	9	12

3.8 WHIMS ECHO Adjudication

The WHIMS-ECHO adjudication process provides quality assurance measures in determining the final study classification of ND, MCI or PD for study participants who score below the cut-point (≤30) on the Telephone Interview of Cognitive Status-modified (TICSm) and who complete the WHIMS-ECHO neurocognitive test battery. A supplemental telephone interview (DQ) is also administered to the proxies of those participants who score below the cut-point. The DQ is initially used to assign a pre-adjudication status of ND, MCI or PD to each participant assessed and is later used by the Adjudication Committee. The DQ assesses cognitive and behavioral changes specific to dementia observed by a knowledgeable person. By comparing DQ results with cognitive test scores, adjudicators are able to make classifications required by the study. In rare instances where the DQ is not available, cases will proceed through the adjudication process. Should they be unable to clinically classify a case due to the absence of the DQ data, adjudicators are permitted to designate the case as 'unable to classify'.

Pre-classification is used to control the number of cases sent to adjudication. It is based on an algorithm designed to maximize sensitivity and specificity by using responses on items from two sections of the DQ: (a) observed cognitive impairment and (b) impairment of daily functions by cognitive impairment. If a and b are present, the case is pre-classified as probable dementia; whereas if a is present but not b, then the case is pre-classified as MCI; and, if neither a nor b is present then the case is pre-classified as ND. Note that for those women for whom no DQ data are available, they automatically go forward to adjudication with all other data (listed below) provided to the adjudicators and PD or MCI cases derived from these are tracked separately in the analyses.

The adjudicators are an independent panel of experts in dementia who conduct a thorough review of the following for each participant who scores below the TICSm cut-point:

- WHIMS-ECHO cognitive battery (TICS-m, East Boston Memory Test, Digit Span Test, Oral Trail Making Test, Verbal Fluency-Animals, Geriatric Depression Scale-Short Form, WHI Insomnia Rating Scale);
- DQ;
- WHIMS History of Scores Report (this report provides data from all previous WHIMS visits).

Selection of participant files for adjudication is based on the pre-adjudication status. Adjudicators review the following:

- 100% of PD pre-classifications. This includes participants who return for yearly follow-up testing after receiving an adjudication classification of PD;
- 100% of MCI pre-classifications;
- Participants pre-classified as ND will not be adjudicated and will return the next year for testing.

From WHIMS ECHO currently, 294 women qualified for work-up towards adjudication based on (TICSm) scores below the study cut-points. 294 progressed to DQ (TICS score ≤30 and no

prior diagnosis of PD). Of these, 49 proceeded to and were not selected for further adjudication based on the algorithm. From 135 completed DQs, 86 progressed to adjudication. Adjudication has been completed on 25 (categorized as PD or MCI by the algorithm) and the remainder are in process (see Table 3-6).

These activities currently yielded the following classifications: PD (n=10), MCI (n=14) and ND (n=1) (Table 3-7).

Table 3-6 Dementia Questionnaire Administration in WHIMS ECHO

Protocols Eligible for Dementia Questionnaire (DQ)	294
DQ Completed and Ready for Adjudication	135 (46%)
DQ In Process (i.e. scheduled, needs call back, etc.)	128 (44%)
Proxy refused to complete DQ	31 (11%)

Table 3-7 Cases Eligible to be Reviewed by Adjudication Committee

Total Cases eligible to be reviewed by Adjudication Committee (DQ call completed, ECHO battery completed)		135
Adjudication in process		61 (45%)
Adjudication Completed		25 (19%)
	Completed Adjudicated Cases Final Classification	
	No Dementia	1
	Minor Cognitive Impairment	14
	Probable Dementia	10
Cases with final classification of No Dementia by computer algorithm (not reviewed by adjudication committee)		49 (36%)

Section 4.

Supplemental Case Ascertainment Protocol (SCAP)

4.1. SCAP Protocol Summary

In WHIMS, a determination of PD (the primary endpoint) is reached by decision of an adjudication committee. As the study has progressed, some participants have died and others have ceased full follow-up participation without a "determination" of cognitive status at the time of death or separation from the study. WHIMS investigators are concerned that among these participants are women who would have been classified as PD had they completed the scheduled assessments. In order to capture these possible cases, WHIMS, with the approval of WHI, implemented a supplemental telephone survey to be conducted by trained staff at the WHIMS Central Coordinating Center (CoC). Staff from each field center is responsible for contacting the WHIMS Extension participants' proxy/family member prior to the WHIMS CoC interview to obtain verbal consent and contact information. Staff from the WHIMS CoC is responsible for contacting the WHIMS ECHO and WHIMS-Y participants' proxy/family member prior to the WHIMS CoC interview to obtain verbal consent and contact information. Participants that were previously classified as PD or who had the WHI status of "absolutely no follow-up" prior to becoming eligible are excluded.

Survey Researchers at the WHIMS CoC have undergone specific training for administration of the Supplemental Case Ascertainment Protocol (SCAP). Upon receiving a completed Follow-Up Form, a trained Survey Researcher telephones the designated contact (either the proxy or the friend/family member listed on the form) and conducts the SCAP survey. The completed survey is then sent through data entry and adjudication.

The SCAP survey is a standardized, validated instrument used to reliably diagnose dementia and specifically, Alzheimer's disease in deceased persons (Ellis et al, 1998). It has demonstrated sensitivity and specificity. The SCAP survey consists of 48 items assessing memory and other cognitive functions, language, daily functioning, insight, and other medical and psychiatric difficulties. Education and demographic data are also collected. The SCAP survey is a semi-structured interview that can be administered by telephone to informants who are knowledgeable about the participant's medical history and ante-mortem functional status.

4.2 SCAP Progress Report

Currently, there are 890 SCAP-eligible participants. Seven-hundred-thirty-six of the SCAP-eligible WHI proxies or the WHIMS friend/family members have been contacted by the field center staff. Of those contacted, 496 have agreed to be contacted by the WHIMS CoC staff for administration of the SCAP. Two-hundred-forty have refused contact. Staff at the WHIMS CoC contacted 489 proxies or friend/family members, with 7 contacts not yet attempted. The protocol for the SCAP is for WHIMS CoC staff to attempt a maximum of 4 attempts to reach the proxy or friend/family member. One-hundred-sixty-five contacts have been made at the first attempt, 71 contacts at the second attempt, 45 contacts at the third attempt, and 208 contacts at the fourth attempt. Of the 489 contacts, 253 SCAP protocols have been completed. The completed SCAP protocols are at various stages of data entry and adjudication.

4.3 SCAP Field Center Report

Overall, the WHIMS field centers have 890 participants who have either the status of proxy (83) or deceased (807), who are SCAP-eligible. Of the 890 SCAP-eligible, 736 of the identified proxies or friend/family members have been contacted by the field center staff.

Of the 83 SCAP-eligible participants who have the status of "proxy" and are not deceased, the field centers have contacted 58 of these participants' proxies or friend/family members. Of these 58, 43 agreed to be contacted by the WHIMS CoC staff and 15 refused contact.

Of the 807 SCAP-eligible participants who have the status of "deceased", the field centers have contacted 678 of their identified proxies or friend/family members. Of the 678 contacted, 453 agreed to be contacted by the WHIMS CoC staff and 225 refused contact. Table 4-2 shows the current progress as outlined.

Table 4-2 SCAP Field Center Report

	Overall			Proxy					Deceased				
	Eligible	Contacted		Eligible	Contacted		Status		Eligible	Contacted		Status	
Field Center	N	N	%	N	N	%	Agrees	Refuses contact	N	N	%	Agrees	Refuses contact
ALL FCs	890	736	82.70%	83	58	69.88%	43	15	807	678	84.01%	453	225

4.4 SCAP Adjudication

With SCAP adjudication,

- Each participant will be classified as "ND", "MCI" or "PD" based on evaluation and scoring of the telephone administered DQ.
- Central adjudication will be completed as follows:
  - 100% of "PD" pre-classifications,
  - 100% of "MCI" pre-classifications
  - 10% of "ND" pre-classifications which are systematically sampled by selecting every 10th case for adjudication.

SCAP adjudication will follow the same process as that outlined for WHIMS participants who progress through the system. Adjudicators will be provided with results of the telephone administered DQ in addition to data from all previous WHIMS visits and WHIMS ECHO assessments.

These activities have yielded 217 cases of SCAP protocols for adjudication. Of those, 63 (29.03%) have been adjudicated and 5 (2.3%) are under review. There are 149 (68.66%) protocols that were not adjudicated (ND or MCI). (Table 4-3)

The overall classification of SCAP protocols (Adjudicated + Not Adjudicated) includes 212 cases. Of those, 158 (74.53%) were classified as ND, 15 (7.08%) were MCI and 39 (18.40%) were PD. (Table 4-4)

Table 4-3 SCAP Protocols		
	Subtotal	
	N	%
SCAP Phase 2 Protocols	217	
- - - - Adjudicated Protocols	63	29.03
- - - - Protocols Under Review by Adjudicators	5	2.30
- - - - Protocols Not Adjudicated (ND or MCI)	149	68.66

Table 4-4 Overall Classification of SCAP Protocols		
	Subtotal	
	N	%
Overall Classification of Protocols	212	
----ND	158	74.53
----MCI	15	7.08
----PD	39	18.40

Section 5.

Validation Study of Cognitive Assessment by Telephone (CAT)

5.1 Introduction

One important step in transitioning the Women's Health Initiative Memory Study (WHIMS) into the WHIMS Epidemiology of Cognitive Health Outcomes (WHIMS ECHO) is to re-validate the use of cognitive assessment instruments, previously used in face-to-face administration, for use by telephone with women of comparable demographic and health status to the WHIMS cohort.

The purpose of CAT is to determine the test-retest reliability and validity of a battery of cognitive tests for administration over the telephone. A subset of cognitive tests, some of which have been used for ***in person*** evaluations in ongoing studies, including WHIMS and the WHISCA, were evaluated for use over the telephone. Telephone administration was compared with face-to-face ***in person*** administration in older women who were comparable to many of the participants evaluated in these studies. Determination of reliability and validity of a cognitive test battery for telephone administration will increase feasibility, increase potential sample size and power, and reduce the cost of incorporating cognitive assessments in other future observational studies and clinical trials.

The study was designed to evaluate the feasibility and reliability of a cost-effective method for assessing cognitive functioning in large-scale, community-based studies such as WHIMS-ECHO. Telephone, as compared to face-to-face assessment is expected to lower participant burden, increase efficiency and reduce study costs, without affecting validity of the instruments or decreasing their reliability over time.

5.2 CAT Design

CAT was designed to compare the performance of telephone-based and traditional face-to-face cognitive assessment over time, using a 2x2 factorial design, in which women ages 65 and older were recruited and randomly assigned, with equal probability, to receive two administrations of a cognitive battery spaced six months apart in one of the four following orders (1^{st} administration/2^{nd} administration): telephone/telephone; telephone/face-to-face; face-to-face/telephone; or face-to-face/face-to-face. The cognitive battery was developed to assess key cognitive domains: verbal memory and learning (California Verbal Learning Test), language (Category and Letter Fluency), attention/concentration (Digit Span Forward), executive function /working memory (Digit Span Backward), global cognitive functioning (Telephone Interview for Cognitive Status -Modified), and perceived memory (7 questions from the Nurses' Health Study). In addition, The Women's Health Initiative Insomnia Rating Scale (WHIRS), the MOS Short Form, and the Geriatric Depression Scale –Short Form were also included.

5.3 CAT Recruitment and Methods

Potential participants were screened in a face-to-face interview for significant hearing deficits and for ability to complete the Modified Mini Mental State Exam (3MSE). Participants were excluded from the study if any of the following exclusion criteria was met:

- Significant hearing problems
- A previous clinical diagnosis of dementia

- A stroke within the past 6 months
- Inability to complete the 3MSE screening instrument
- Scoring >8 points below the cutoff of 80 points on the 3MSE.

In order to enhance applicability of the data derived from this study to a broad range of cognitive functioning levels, participants with a full range of 3MSE scores were recruited: Sixty-four (64) participants scoring higher than 95 (high normal range), 31 participants scoring between 88-95 (low normal range) and 15 participants scoring lower than 88, but not below 72 (milder cognitive impairment range). Those participants who were consented and randomized to receive face-to-face first proceeded directly to administration of the assessment battery. Those participants randomized to receive telephone first were instructed about a future telephone administration and released. Each participant was administered the neurocognitive test battery by a certified cognitive testing specialist, by telephone and/or interviewed face-to-face, depending upon randomization group. In six months, each participant was contacted a second time by telephone and/or interviewed face-to-face for a repeat cognitive assessment.

5.4 CAT Progress Report

The CAT study has completed recruitment, screening and test administration for baseline and six-month follow-up visits.

One-hundred-sixty-nine participants were screened and met the eligibility criteria for participation in the study. Of those screened, 119 agreed to participate and gave their written consent. Fifty participants refused consent citing various personal reasons. Of the 119 participants who gave their consent, nine participants' scores placed them in strata which had filled the recruitment quota. One-hundred-ten participants were randomized into the study and baseline data were collected on 105. (Of the 110 randomized participants, 19 did not complete follow-up for the following reasons: deceased (n=1), lost to follow-up (n=2), and personal reasons (n=16).) Exhibit 5.1 summarizes follow-up on the 105 women. Exhibit 5.2 summarizes baseline demographic characteristics, demonstrating good balance among arms. Baseline cognitive data appear in Exhibit 5.3.

Exhibit 5.1. Enrollment and Follow-up: Number (%) of Participants by Visit and Arm

Enrollment and Follow-up: Number (%) of Participants by Visit and Arm

	Face/ Face N=26	Face/ Telephone N=26	Telephone/ Face N=28	Telephone/ Telephone N=25	Total
Baseline	26 (100)	26 (100)	28 (100)	25 (100)	105 (100)
Six-months	22 (85)	24 (92)	23 (82)	22 (88)	91 (87)

Exhibit 5.2. Demographic Characteristics at Baseline by Arm

Demographic Characteristics at Baseline by Arm

Characteristic	Face/ Face N=26	Face/ Telephone N=26	Telephone/ Face N=28	Telephone/ Telephone N=25	P-value
Race/ethnicity, n (%)					0.28[a,b]
Native American	0 (0)	1 (4)	0 (0)	0 (0)	
African American	2 (8)	5 (19)	2 (7)	2 (8)	
White	24 (92)	20 (77)	26 (93)	23 (92)	
Age, years, n (%)					0.84
65-69	12 (46)	9 (35)	11 (39)	12 (48)	
70-74	8 (31)	12 (46)	9 (32)	9 (36)	
75+	6 (23)	5 (19)	8 (29)	4 (16)	
Age, years, mean (SD)	72.0 (6.1)	72.9 (5.5)	72.9 (6.1)	71.5 (5.6)	0.79
Educational level, n (%)					0.69[a]
High school grad or less	5 (19)	2 (8)	4 (14)	3 (12)	
Beyond high school	21 (81)	24 (92)	24 (86)	22 (88)	
3MSE, mean (SD)	93.9 (6.5)	93.5 (5.8)	94.6 (4.8)	93.6 (5.9)	0.90

[a] Based on Fisher's Exact Test.
[b] Collapsed to white and non-white categories.

Exhibit 5.3: Test Scores at Baseline, by Mode of Administration

		N	Mean	Std	Min	Max	P
3MSE	**Arm**						0.70
	Face	52	93.69	6.11	78	100	
	Telephone	53	94.13	5.28	74	100	
	Total	105	93.91	5.68	74	100	
Perceived Memory	**Arm**						0.98
	Face	52	2.31	1.60	0	6	
	Telephone	53	2.30	1.84	0	6	
	Total	105	2.31	1.71	0	6	
Verbal Fluency (FAS)	**Arm**						0.43
	Face	52	34.63	10.88	16	65	
	Telephone	53	32.91	11.28	14	73	
	Total	105	33.76	11.06	14	73	
Animal Fluency	**Arm**						0.14
	Face	52	18.88	5.02	10	39	
	Telephone	53	17.36	5.27	7	27	
	Total	105	18.11	5.18	7	39	
CVLT Total list A trials	**Arm**						0.72
	Face	52	27.13	5.24	10	36	
	Telephone	52	26.63	8.18	13	46	
	Total	104	26.88	6.84	10	46	
CVLT Total list B trial	**Arm**						0.51
	Face	52	6.38	2.20	2	13	
	Telephone	52	6.77	3.55	0	15	
	Total	104	6.58	2.94	0	15	
CVLT short-delay free recall	**Arm**						0.50
	Face	52	7.10	3.16	0	14	
	Telephone	52	7.56	3.72	1	14	
	Total	104	7.33	3.44	0	14	

		N	Mean	Std	Min	Max	P
CVLT long-delay free recall	**Arm**						0.81
	Face	52	7.71	3.20	0	14	
	Telephone	52	7.54	4.01	0	16	
	Total	104	7.63	3.61	0	16	
CVLT short-delay cued recall	**Arm**						0.82
	Face	52	9.58	2.48	2	14	
	Telephone	52	9.44	3.33	4	15	
	Total	104	9.51	2.92	2	15	
CVLT long-delay cued recall	**Arm**						0.43
	Face	52	8.83	3.15	0	14	
	Telephone	52	9.37	3.70	3	16	
	Total	104	9.10	3.43	0	16	
CVLT recognition	**Arm**						0.53
	Face	52	12.62	2.15	8	15	
	Telephone	52	12.90	2.48	8	16	
	Total	104	12.76	2.32	8	16	
TICS	**Arm**						0.71
	Face	51	28.98	1.91	23	31	
	Telephone	53	28.81	2.60	20	31	
	Total	104	28.89	2.28	20	31	
Digit Span Forward	**Arm**						0.88
	Face	52	7.90	2.39	4	13	
	Telephone	53	7.98	2.46	4	14	
	Total	105	7.94	2.42	4	14	
Digit Span Backward	**Arm**						0.45
	Face	52	6.48	2.07	4	13	
	Telephone	53	6.81	2.35	2	12	
	Total	105	6.65	2.21	2	13	

		N	Mean	Std	Min	Max	P
SF-12 Physical Component	**Arm**						0.25
	Face	52	47.84	8.68	20	62	
	Telephone	52	45.44	11.92	14	63	
	Total	104	46.64	10.45	14	63	
SF-12 Mental Component	**Arm**						0.70
	Face	52	53.89	8.19	30	66	
	Telephone	52	53.22	9.05	22	68	
	Total	104	53.56	8.60	22	68	
Insomnia Rating Scale	**Arm**						0.10
	Face	52	8.29	5.20	0	20	
	Telephone	53	6.75	4.22	0	16	
	Total	105	7.51	4.77	0	20	
Geriatric Depression Scale	**Arm**						0.39
	Face	52	1.29	1.40	0	7	
	Telephone	53	1.62	2.37	0	12	
	Total	105	1.46	1.95	0	12	

5.4 CAT Findings

Results of preliminary analyses of the CAT data are presented in Exhibits 5.4 and 5.5. These focus on the cognitive test data. Exhibit 5.4 presents estimates of the bias of telephone assessments relative to face-to-face assessments (i.e. telephone assessment minus face-to-face assessment). These are expressed in standard deviation units, to allow comparisons among different tests, and are developed from general linear models. For all but one test, the estimated relative biases do not reach statistical significance ($p>0.05$). For the assessment of category verbal fluency, however, there is some evidence that women scored lower on telephone administrations than face-to-face administrations.

Exhibit 5.5 examines the consistency of 6-month differences in test scores, depending on whether they were both administered via telephone versus face-to-face. The 6-month differences may reflect underlying changes in cognition, but they also likely reflect some measure of a training (learning) effect. For two tests there was some evidence of differences associated with mode of administration. The CVL free recall long delay increased more over 6-months among women who had telephone administrations than face-to-face administrations (nominal $p=0.03$). Category verbal fluency scores declined over 6 months when administered face-to-face, but tended to increase when administered by telephone (nominal $p=0.01$).

The conclusions from the CAT study are being developed by its writing groups. In general, it appears that for most measures of cognitive function, telephone and face-to-face administrations are comparable. For two tests, however, mode of administration may influence data.

Exhibit 5.4: Relative bias of telephone administration compared to face-to-face administration of cognitive function measures – in standard deviation units. Covariates are age, baseline 3MSE, and race.

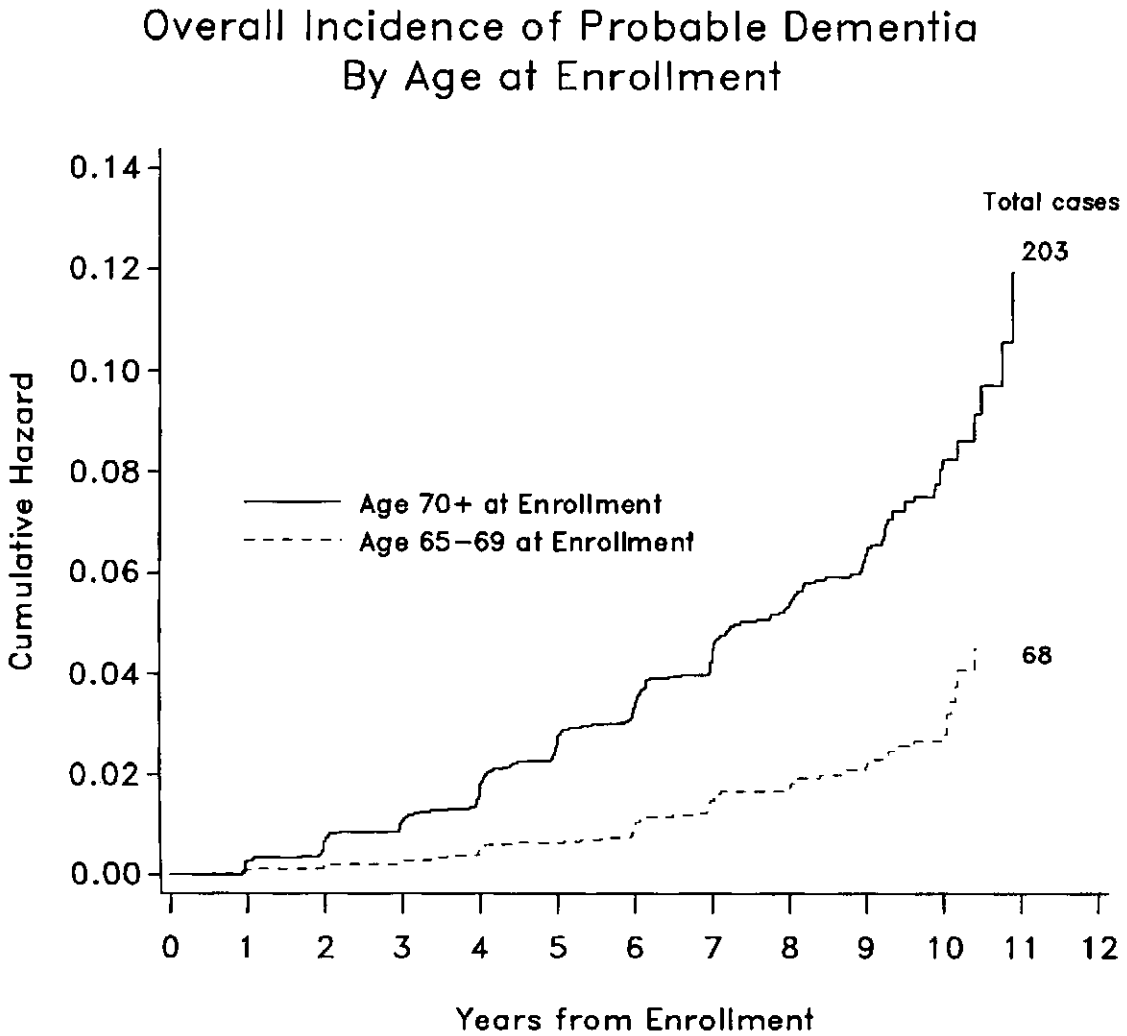
Cognitive Test	Mean Relative Bias of Telephone Versus Face-to-Face		p-value
	Mean	SE	
TICS	-0.07	0.15	0.64
CVLT			
Total A	-0.09	0.15	0.55
Total B	0.17	0.18	0.36
Free recall short delay	0.19	0.15	0.20
Free recall long delay	-0.13	0.14	0.33
Cued recall short delay	-0.06	0.15	0.19
Cued recall long delay	0.24	0.14	0.10
Recognition	0.13	0.18	0.47
Perceived memory	0.07	0.15	0.61
Verbal fluency			
Letter	-0.16	0.13	0.18
Category	-0.32	0.13	0.02
Digit Span			
Forward	0.02	0.16	0.91
Backward	0.17	0.16	0.31

Exhibit 5.5: Comparison of changes (6 months minus baseline) when both tests are administered by telephone compared to face-to-face administration – in standard deviation units. Covariates are age, baseline 3MSE, and race.

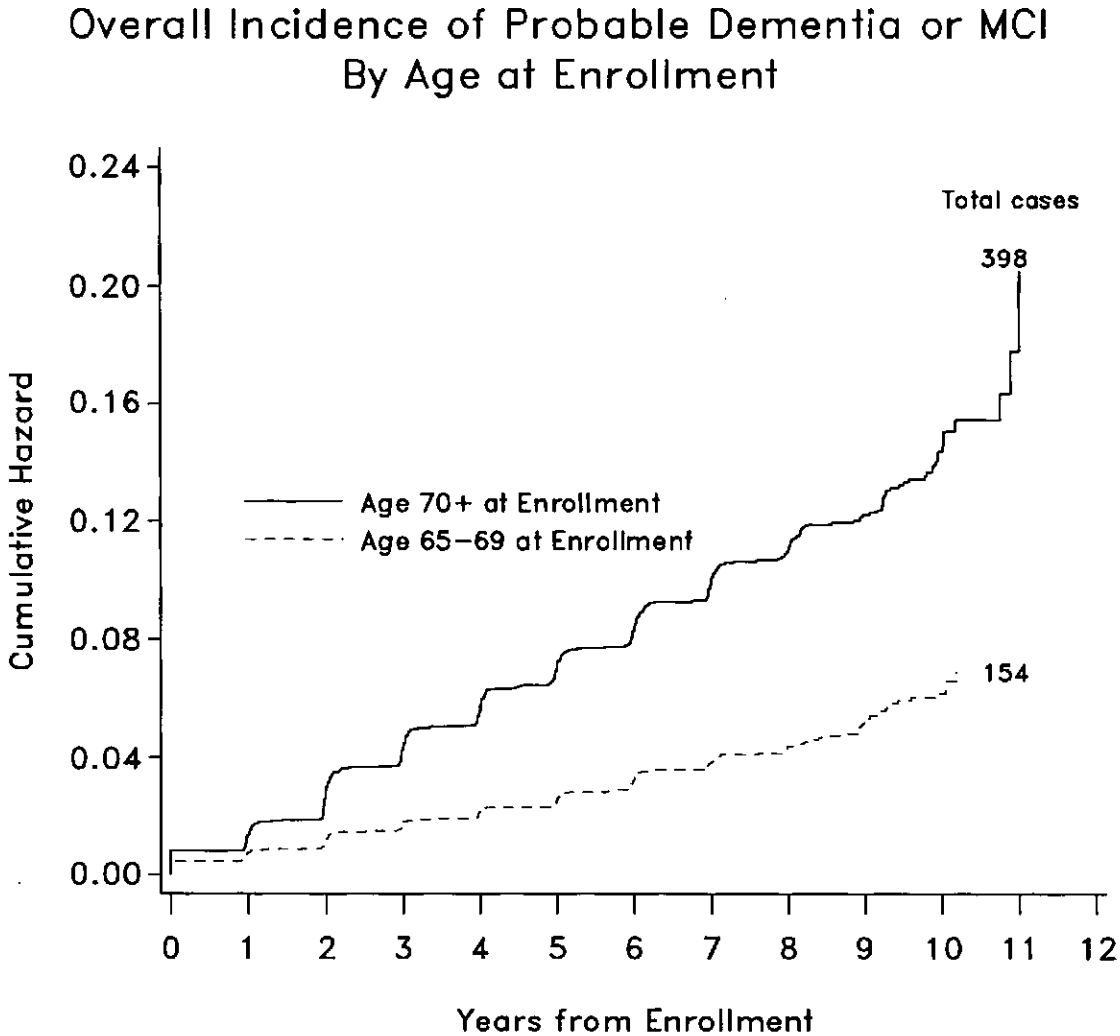
Cognitive Measure	Mean (SE) 6-Month Changes		p-value
	Face-to-Face	Telephone	
TICS	0.23 (0.14)	0.01 (0.14)	0.33
CVLT			
Total A	0.09 (0.14)	0.33 (0.14)	0.27
Total B	-0.15 (0.16)	0.04 (0.16)	0.43
Free recall short delay	0.36 (0.31)	0.38 (0.13)	0.90
Free recall long delay	0.06 (0.12)	0.62 (0.12)	0.03
Cued recall short delay	0.11 (0.14)	0.38 (0.14)	0.21
Cued recall long delay	0.45 (0.12)	0.24 (0.12)	0.29
Recognition	0.48 (0.16)	0.23 (0.16)	0.32
Perceived memory	-0.54 (0.13)	-0.42 (0.12)	0.54
Verbal fluency			
Letter	-0.01 (0.11)	0.13 (0.11)	0.41
Category	-0.23 (0.13)	0.28 (0.12)	0.01
Digit Span			
Forward	0.09 (0.14)	0.05 (0.14)	0.84
Backward	-0.00 (0.16)	0.24 (0.16)	0.31

6.1 Incidence of Probable Dementia from Time of WHIMS Enrollment

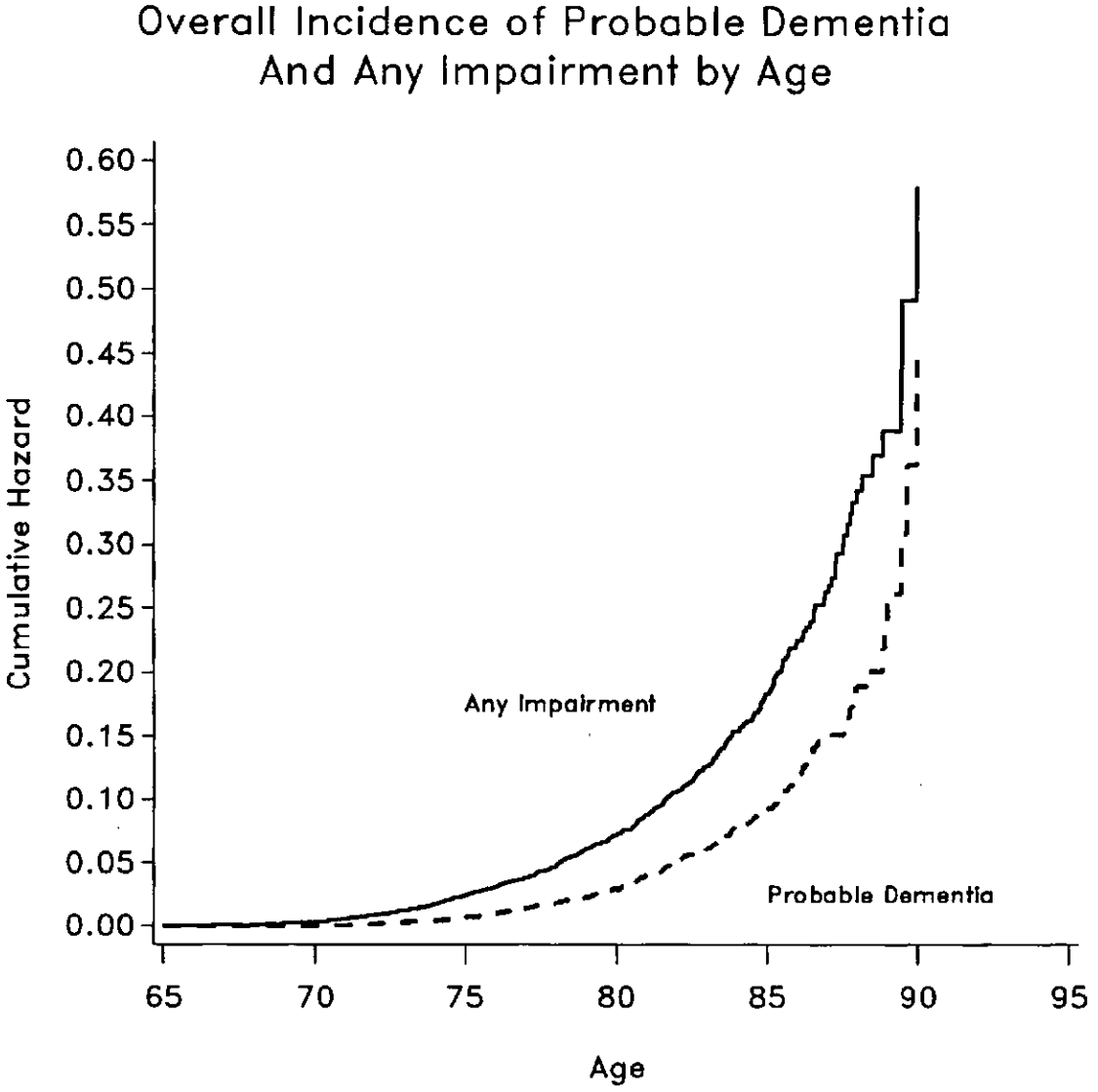
The following figures show the incidence of probable dementia and/or MCI over time.



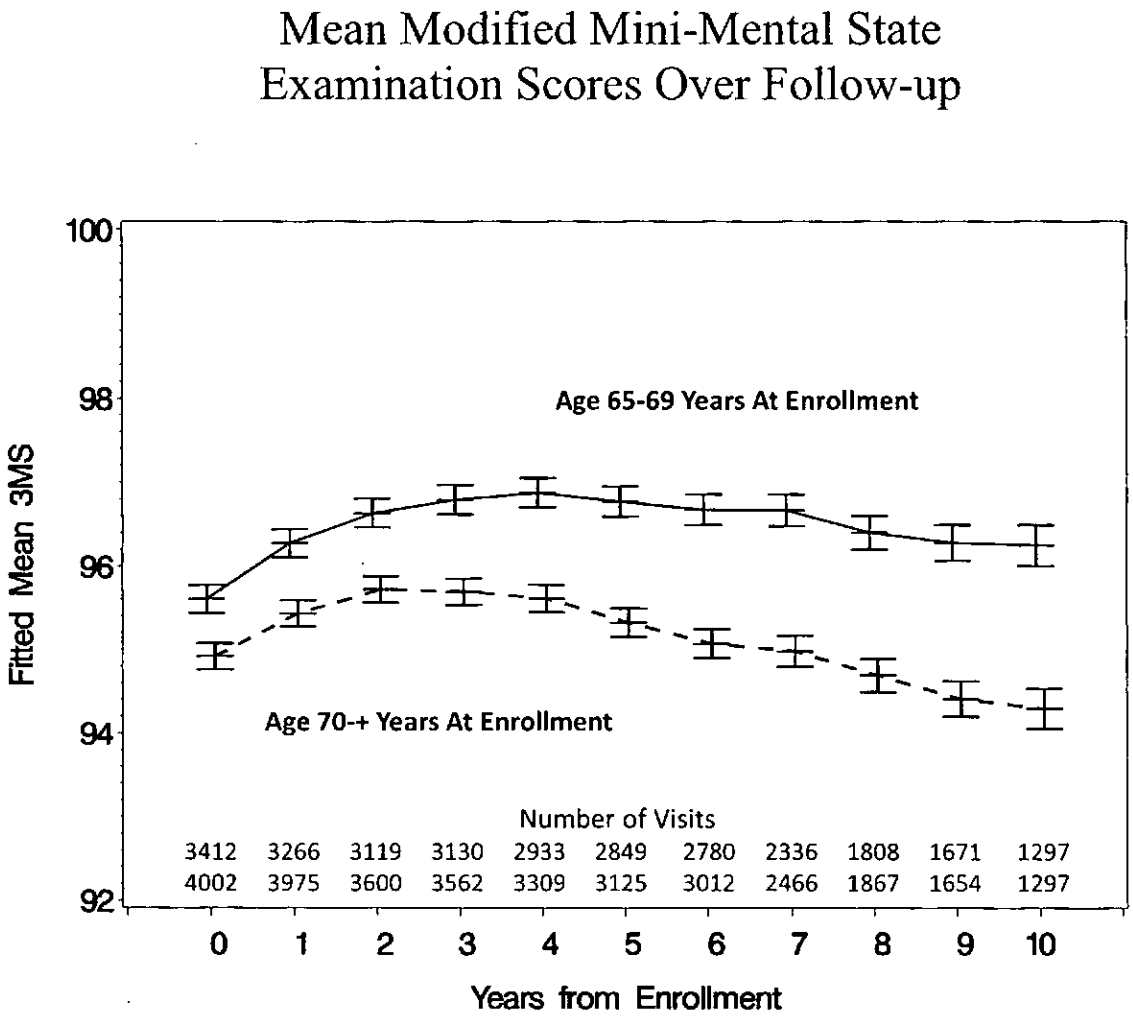
6.2 Incidence of Mild Cognitive Impairment from Time of WHIMS Enrollment



6.3 Overall Incidence of Probable Dementia



6.4 Mean Mini-Mental State Examination Scores over WHIMS Follow-Up



Section 7.

WHIMS-MRI2

7.1 WHIMS-MRI Summary

Between April, 2005 and January, 2006, 1,426 women underwent magnetic resonance imaging (MRI) across 13 Women's Health Initiative (WHI) field centers. The effort yielded N=1,403 scans that met central reading center quality control standards. WHIMS-MRI-1 women had been enrolled in the WHI Hormone Therapy (HT) randomized controlled clinical trials: until either July, 2002 (when the trial of combination therapy was halted due to an unfavorable risk-to-benefit ratio of its non-cognitive endpoints) or February, 2004 (when the trial of estrogen-alone therapy was halted due to an increased risk of stroke and embolic events and the lack of any favorable effect on cardiovascular disease). They also had been participants in the Women's Health Initiative Memory Study (WHIMS), which provided annual cognitive screening for dementia and mild cognitive impairment and had documented an increased risk for cognitive impairment among women who had been assigned to HT during the WHI trials. In addition, 73% had been participants in the Women's Health Initiative Study of Cognitive Aging (WHISCA), which provided more comprehensive annual assessments of cognitive function and mood. Cognitive testing continues on these women as part of the WHIMS- ECHO. WHISCA testing ended in the fall of 2007. Collectively, these rich data resources include characterizations, over extended periods of time, of risk factors for neuropathology and cognitive decline and psychometric and clinical assessments of cognitive function and cognitive status. WHIMS MRI-1 found that CEE+MPA and CEE-Alone were not associated with increased ischemic brain lesions, relative to placebo, on brain MRI conducted 8 years following randomization to CEE-based HT. However, both CEE+MPA and CEE-Alone were associated with lower mean total and regional brain volumes.

The WHIMS-MRI2 protocol is designed to collect a second MRI (approximately 4 years after the first MRI) from these women to assess incident neuropathology and the rate of atrophy.

7.2 WHIMS-MRI2 Progress Report

7.2.1 Progress with Study Coordination Activities:

Protocol Approval: The WHIMS-MRI2 protocol was submitted for continuing review to the Wake Forest University Health Sciences (WFUHS) Institutional Review Board and approved on 05/29/2009. IRB approval has been received for 12 of the 13 field centers.

Field Center Sub-Contracts:
Budgets have been approved and contracts have been sent to 11 of 13 field centers. Budgets have been approved and are in process at the WFUHS Controllers Office for the remaining two field centers.

7.2.2 WHIMS-MRI2 Coordinating Center Activities:

WHIMS-MRI2 Project Managers Committee:
Project managers have been identified at each of the 13 participating field centers. Conference calls were held on November 10, 2008, March 27 2009, and March 29, 2009 and July 7, 2009.

The primary focus of the calls was to provide an update on the status of each field center and to identify outstanding issues at each site that need to be addressed before scanning can begin. The University of Pennsylvania Magnetic Resonance Imaging Quality Control Center (MRIQCC) was also represented on the call.

Staff Training:
Centralized training was conducted at Wake Forest University Health Sciences on March 6, 2008. Additional training was provided by conference call on November 3, 2008 and April 15, 2009. Training slides are available for viewing and downloading on the WHIMS-MRI2 website. Project managers were trained on the study protocol and the following: rationale and design; recruitment and eligibility; administration and scoring of study forms; administration of the California Verbal Learning Test; safety monitoring and reporting; web-based data collection and reporting.

WHIMS-MRI2 Cognitive Testing:
Unlike WHIMS-MRI1, participants in WHIMS-MRI2 will be administered the California Verbal Learning Test (CVLT). The data from this cognitive testing will be used to examine associations between changes in MRI outcomes and learning and memory. Technicians are required to be certified by the WHIMS-MRI2 Coordinating Center prior to administering the CVLT to participants. Technicians at 10 of the 13 field centers have been certified.

WHIMS-MRI2 Website:
A report of eligible participants for each field center was made available on the website on April 7, 2009. This report provides project managers with important information about each participant as they begin recruitment (see below). It includes findings from the WHIMS-MRI1 study, WHI/WHIMS follow up status and an adjudication status of PD or MCI.

PPT	Date of Previous Scan	Previous QC Result	Previous Alert RC	Previous Alert CC	WHI Follow Status	WHIMS Follow Up Status	PD / MCI

Data entry was enabled in mid-April. Reporting will allow a project manager to view the progress of all participants enrolled in the WHIMS-MRI2 study at their field center (see below).

MRI2 Date Consent	Heart Attack last 2 months	MRI2 Date Sched	MRI2 Actual MRI	MRI2 QC Result	MRI2 Alert RC	MRI2 Alert CC

Forms and other study documents are posted on the website and are available for downloading.

7.2.3 WHIMS-MRIQCC Activities

All 14 scanning facilities have successfully installed the American College of Radiology Imaging Network (ACRIN) TRIAD software application for the WHIMS-MRI-2 trial. This image transmission replaces the previous image transmission application; Medical Image Resource Center (MIRC) used for WHIMS-MRI-1.

The MRIQCC has been working extensively with the 14 MRI facilities in preparation for recruitment. Each MRI facility must submit scans for approval by the MRIQCC prior to beginning scanning. Site approval involves data collection of a volunteer test scan from each site for evaluation of MRI protocol compliance and technical issues prior to analysis. In addition, a phantom test scan is acquired for scanner performance and quality control (QC). Ten sites have been approved. The MRIQCC will continue to monitor these QC scans for compliance with the ACR standards as the trial is on-going.

7.3 WHIMS-MRI2 Enrollment

Table 7-1 describes progress in WHIMS-MRI2 screening. Ten of the thirteen field centers have initiated contact and screening of potential enrollees. Of the 1,345 potential enrollees, 461 (34.28%) have been contacted by field center staff. Of these, 265 (57.48%) are eligible and willing to participate, 8 (1.74%) are ineligible due to absolute contraindications, 99 (21.48%) have refused, 1 needs additional follow up and 88 participants have indicated they are willing to participate and screening is in process. To date, 89 participants have provided informed consent. The WHIMS-MRI Recruitment Committee will meet periodically to review recruitment status, disseminate information on successful strategies, and examine the relative success of recruitment across important participant subgroups. The study website will contain real-time on-line reports for monitoring recruitment. Three sites currently have very high rates of refusals (New York, Columbus, and Des Moines). These are being contacted to identify and resolve issues.

7.3.1 Progress in obtaining scans:

To date, two field centers (Columbus and Minneapolis) have initiated MRI scanning. Of the 89 consented participants, scans have been completed on 34 participants.
MRI images are graded as the following:

- LEVEL 1 1 – Normal MRI Brain Scan
- LEVEL 2 – Age Related and Incidental Findings
  (MRI Abnormalities limited to age related white matter disease, leukoaraiosis, atrophy, etc and/or other incidental findings, such as sinus disease)
- LEVEL 3 – Non-Urgent Findings of Clinical Disease
  (Findings include remote stroke, small meningioma, or other processes of potential clinical significance).
- LEVEL 4 – Urgent, Disease Related Findings

(Findings include acute or subacute infarct, acute or chronic subdural or epidural hematoma, subarachnoid hemorrhage, arteriovenous malformation: obstructive hydrocephalus; brain tumor, brain abscess, or other lesion causing mass effect).

To date, one of the 34 completed images was Level 1, 29 were Level 2 and three are under review. To date no images have been found to require clinical follow-up (Level 4). Based on our WHIMS-MRI1 experience, it is anticipated that approximately 3 to 5% of images will require clinical follow-up. As these are encountered, WHIMS-MRI2 will follow the same safety protocol used in WHIMS-MRI1. The WHIMS-MRI Safety Committee is notified via e-mail and follow up procedures are employed to ensure that the Principal Investigator, participant, and participant's primary care physician are informed of the result within 72 hours.

Table 7-1 WHIMS MRI2 Screening – Number Screened by Field Center

			Ineligible due to absolute contraindication		Refusal		Missing screening status		Eligible with additional follow-up		Eligible and willing (MRI tech cleared device/condition)		Eligible and willing		Consented		Consented and WHISCA participant	
Field Center	Potential Enrollees	Contacted	N	%	N	%	N	%	N	%	N	%	N	%	N	%^	N	%
ALL FCs	1345	461	8	1.74%	99	21.48%	88	19.09%	1	0.22%	36	7.81%	229	49.67%	89	19.31%	69	77.53%
25=Minneapolis	94	1	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	100.0%	1	100.0%	1	100.0%
28=Pittsburgh	78	10	0	0.00%	0	0.00%	0	0.00%	0	0.00%	4	40.00%	6	60.00%	0	0.00%	0	0.00%
30=Davis	97	0	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
42=Stanford	117	106	2	1.89%	6	5.66%	0	0.00%	0	0.00%	0	0.00%	98	92.45%	0	0.00%	0	0.00%
43=Milwaukee	102	1	0	0.00%	0	0.00%	0	0.00%	1	100.0%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
46=Gainesville	71	0	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
48=Worcester	121	6	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	6	100.0%	0	0.00%	0	0.00%
49=New York	109	71	0	0.00%	17	23.94%	0	0.00%	0	0.00%	7	9.86%	47	66.20%	53	74.65%	37	69.81%
50=Columbus	136	124	3	2.42%	25	20.16%	0	0.00%	0	0.00%	25	20.16%	71	57.26%	35	28.23%	31	88.57%
54=Jacksonville	44	0	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
58=Chapel Hill	93	0	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
65=Nevada	64	8	0	0.00%	8	100.0%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
68=Los Angeles	87	6	0	0.00%	6	100.0%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
73=Des Moines	132	128	3	2.34%	37	28.91%	88	68.75%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%

8.1 WHIMS-Y Protocol Summary

Since the publication of WHIMS primary results showing increased risk of probable dementia and no protection of global cognitive functioning following initiation of post-menopausal hormone therapy (HT) speculation has occurred suggesting that HT may protect cognitive functioning in women if initiated during the peri-menopausal or recent postmenopausal period. This speculation has led to recent calls for studies of this 'critical window of opportunity' hypothesis. The Women's Health Initiative Memory Study of Younger Women (WHIMS-Y) provides a unique opportunity to evaluate this hypothesis by comparing cognitive outcomes of women enrolled in the WHI HT trials who were 50-54 years of age at study enrollment. It will assess the long-term impact of random assignment to postmenopausal HT among these women and thus adds critical information on the clinical treatment of peri-menopausal and early post-menopausal women and on potential mechanisms of action for how conjugated equine estrogen (CEE)-based therapy, with and without MPA) may affect cognition.

WHIMS-Y is designed to be conducted during the time period of the safety monitoring extension for the WHI HT trials. Women who were younger than 55 years of age when enrolled in the WHI HT trials, and who are currently enrolled in the WHI Extension study will be eligible for participation and will be solicited for their consent to undergo annual telephone-based assessments of their cognitive function. The assessment provides detailed global and specific neuro-cognitive data, thus enhancing our ability to ascertain subtler cognitive changes over time. It also serves to screen women for additional classification for PD and MCI.

Cognitive data on consenting women will be obtained through centralized cognitive telephone interviews conducted by trained and certified staff at the WHIMS Coordinating Center (WHIMS CoC). The proposed telephone-based protocol has been used successfully in other studies and proven to be a valid method for tracking changes in cognitive status, MCI and dementia. The same protocol is being used in the WHIMS ECHO study. WHIMS-Y participants will be contacted annually for a minimum of 2 years, and longer if funding permits.

Approximately 2,230 of the WHI HT trial participants who were 50-54 years old at the time of WHI enrollment are currently active in the WHI extension study. To be eligible for WHIMS-Y, a woman must provide informed consent and have adequate hearing acuity to participate in the telephone interviews. A brief hearing screening test, performed annually, will determine the participant's ability to hear over the telephone. The neuropsychological battery will take, on average, approximately 60 minutes to be administered. This hour includes the social exchange, hearing screen, test battery administration, scoring and review of scoring. The battery includes 5 validated neuropsychological tests and 3 validated questionnaires, one of which may be administered to a knowledgeable friend or family member (proxy). Only participants scoring below the predesignated cut-point on the global cognitive screener ($\leq$30 on TICSm), however, will have their proxy interviewed. All participants will receive the entire neuropsychological battery and self-reported questionnaires. Participants who score greater than 8 on the Geriatric Depression Scale (GDS) or whose responses suggest significant emotional distress will be administered the Emotional Distress Questionnaire and protocol. Together, the neuropsychological test and questionnaire data and the proxy interview will be submitted to the

WHIMS Adjudication Committee for final determination of ND, MCI, or PD – following the same procedures as are currently used in WHIMS ECHO and WHIMS SCAP.

8.2 WHIMS-Y Progress Report and Overall Enrollment

Currently, 772 WHIMS-Y eligible participants have agreed to contact by the WHIMS CoC. Of those participants who have agreed to contact, 396 have given written consent for participation. Thirty-two participants have declined consent and 344 of the WHIMS-Y participants who have agreed to contact have consents which are pending. Of the 396 participants who have given written consent, 49 completed test batteries have been conducted. Table 8-1 shows the current progress as outlined.

Table 8-1 WHIMS-Y Enrollment

		Consented to WHIMSY						Completed Test Batteries	
		Yes		Declined		Pending		Consented	
Field Center	Agreed to CoC contact	N	%	N	%	N	%	N	%
ALL FCs	772	396	51.30	32	4.15	344	44.56	49	12.04

Staff at the WHIMS CoC has mailed 760 consents, with 12 consents to be mailed. The WHIMS CoC has received 428 consents, including both agreed and refused, with 48 of those received coded as "incomplete". A re-mail has been conducted for the 48 incomplete consents. Table 8-2 shows the current progress as outlined.

Table 8-2 WHIMS-Y Consent Status

Field Center	Eligible Participants^	Consents Mailed	Completed Consents Received (Consent= Y or N)	Declined	Incomplete Consents Received
ALL FCs	772	760	428	32	48

The WHIMS CoC staff conducts follow-up phone calls to the WHIMS-Y eligible participant as part of the consenting process. The protocol calls for a maximum of 8 attempts to reach the participant. Of those who have given their consent, 264 consents have been received without any attempt. Eighty-nine consents have been received at the first attempt; 47 consents at the

second attempt; 21 consents at the third attempt; 5 consents at the fourth attempt; 1 consent at the fifth attempt and 1 consent at the seventh attempt. Table 8-3 shows the current progress as outlined.

Table 8-3	
Attempt	**N**
0	**264**
1	**89**
2	**47**
3	**21**
4	**5**
5	**1**
7	**1**

Of those who have declined their consent, 3 refusals have been received without any attempt. Twenty refusals have been received at the first attempt; 7 consents at the second attempt and 2 consents at the third attempt. Table 8-4 showing the current progress as outlined.

Table 8-4	
Attempt	**N**
0	**3**
1	**20**
2	**7**
3	**2**

8.3 WHIMS-Y Call Completion Rates

Table 8-5 WHIMS-Y Enrollment Tracking of Call Attempts for Visit 1 69 Participants Contacted Generated on 09/10/09		
Call Outcome		
Attempts at call completion ended	N	%
Call Completed	57	82.61
Declined	0	0.00
Phone Disconnected	0	0.00
Unable to locate	0	0.00
Left a message	5	7.25
Hearing Impaired	0	0.00
Discontinued	0	0.00
Deceased	0	0.00
Call completion possible		
No Answer	3	4.35
Busy	1	1.44
Scheduled	3	4.35
Re-Contact	0	0.00

9.1 Progress Report

The statisticians are organized to collaborate on writing groups from manuscripts based on WHIMS data. Listed in Exhibit 9.2 are the 26 WHIMS writing groups that have been approved by the WHI Publications Committee and are currently active.

September 10, 2009

Ms276: Social Support and Cognitive Functioning in Postmenopausal Women (WHIMS)
Chair: Catherine Messina
Biostatistical Collaborator: Sarah Gaussoin

Ms360: Body Mass Index, Waist-hip Ratio, and Cognitive Decline in Postmenopausal Women: Results from the WHIMS
Chair: Diana Kerwin
Biostatistical Collaborators: Mark Espeland and Sarah Gaussoin

Ms399: Subtypes of Mild Cognitive Impairment: Prevalence, Course and Effect of HT: The WHIMS
Chairs: Steve Rapp
Biostatistical Collaborator: Claudine Legault

Ms427: Statin Use & Cognition in Postmenopausal Women: The WHIMS
Chairs: Claudine Legault
Biostatistical Collaborator: Patricia Hogan

Ms546: Predictors of Incident Dementia in Postmenopausal Women Enrolled in a Trial of HT: The WHIMS
Chair: Laura Coker
Biostatistical Collaborator: Claudine Legault

Ms597: Prevalence of Anticholinergic Drug Use and Impact on Cognition and Function in Older Adults (WHIMS)
Chair: Kaycee Sink
Biostatistical Collaborators: Mark Espeland and James Lovato

Ms665: Ascertaining Dementia Related Outcomes for Deceased or Proxy-dependent Participants: An Overview of WHIMS Supplemental Case Ascertainment Protocol (WHIMS-SCAP)
Chair: Sarah Gaussoin
Biostatistical Collaborator: Mark Espeland

Ms670: Sleep Duration, Cognitive Function & Neurocognitive Impairment in Older Women (WHIMS)
Chair: Jiu-Chiuan Chen
Biostatistical Collaborators: Mark Espeland and Laura Lovato

Ms680: A Uniform Approach to Modeling Risk Factors Relationships for Ischemic Lesion Prevalence and Extent: WHIMS-MRI
Chair: Janet Tooze
Biostatistical Collaborators: Mark Espeland and Sarah Gaussoin

Ms683: Education, Neuropathology and Cognitive Performance in Older, Postmenopausal Women: The WHIMS
Chair: Steve Rapp
Biostatistical Collaborator: Mark Espeland

Ms695: Application of Hidden Markov Models for Longitudinal Measures of Cognition Collected by the WHISCA
Chair: Edward Ip
Biostatistical Collaborator: Mark Espeland

Ms696: Relationship of HTN, BP & BP Control with MRI Outcomes in the WHIMS-MRI
Chairs: Lew Kuller and Karen Margolis
Biostatistical Collaborator: Sarah Gaussoin

Ms881: Change in Cognitive Function in Cancer Patients among WHIMS Participants
Chair: Susan Resnick
Biostatistical Collaborator: Mark Espeland and Sarah Gaussoin

Ms884: Effects on Dementia & Cognitive Functioning 3 Years after Stopping E +/- Progestin: The WHIMS
Chairs: Claudine Legault, Sally Shumaker
Biostatistical Collaborator: Patricia Hogan

Ms899: Long Term Effects of Exposure to CEE Therapies on Domain-Specific Cognitive Function: Results from the WHISCA Extension
Chair: Mark Espeland
Biostatistical Collaborators: Patricia Hogan and Claudine Legault

Ms397v2: Is There an Association Between Macronutrient Intake and Changes in Cognition? Results from the WHIMS
Chair: Mara Vitolins
Biostatistical Collaborator: Laura Lovato

Ms909: Spatial Distribution of Ischemic Lesions in WHIMS-MRI and Effects of Postmenopausal Hormone Therapy
Chair: Christos Davatzikos
Biostatistical Collaborator: Ramon Casanova and Mark Espeland

Ms914: Relationships Between Changes in Weight & Waist Circumference with Domain-Specific Cognitive Function: Results from the WHISCA
Chair: Ira Driscoll
Biostatistical Collaborators: Mark Espeland and Sarah Gaussoin

Ms937: Psychological Attitudes, Neuroanatomy & Important Health Outcomes: WHIMS-MRI
Chair: Hilary Tindle
Biostatistical Collaborator: Patricia Hogan

Ms938: Insomnia, Snoring & Sleepiness and Risk of Cognitive Impairment in Older Women
Chair: Jiu-Chiuan Chen
Biostatistical Collaborators: Mark Espeland and Laura Lovato

Ms979: Depression & Cerebrovascular Changes in Postmenopausal Women: WHIMS-MRI
Chair: Joseph Goveas
Biostatistical Collaborators: Mark Espeland and Patricia Hogan

Ms980: Within-person Cross-domain Test Variability & Incident Dementia: WHISCA
Chair: Mark Espeland
Biostatistical Collaborators: Mark Espeland and Sarah Gaussoin

Ms1038: The Relation of Folate Intake & Cognitive Decline & Dementia in WHIMS
Chair: Sylvia Smoller
Biostatistical Collaborator: Patricia Hogan

Ms1042: Relationships That cognitive Function & Change in Cognitive Function Have with Incident Cardiovascular Disease: WHIMS
Chair: Sally Shumaker
Biostatistical Collaborators: Mark Espeland and Iris Leng

Ms1047: Effects of Conjugated Equine Estrogen Therapy on Region-Specific Brain Volumes: WHIMS-MRI
Chair: Ramon Casanova
Biostatistical Collaborators: Mark Espeland, Sarah Gaussoin

Ms1058: Omega-3 Fatty Acid Biomarkers & Brain Volumes: WHIMS-MRI
Chair: James Pottala
Biostatistical Collaborator: Mark Espeland

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Section 11.

Ancillary Studies

11.1 Omega 3 Fatty Acids

Project Summary

The offeror shall receive from the WHI CCC, frozen red blood cell samples from participants in the WHI Memory Study. The offeror is requesting a total of 9,407 samples comprised of 7,152 baseline samples, 1,400 1-yr samples, and 855 QA blind duplicate samples (the latter as required by the WHI CCC). The WHI CCC will also provide to the offeror relevant demographic and study outcome data to enable statistical analysis of the project Aims. The offeror's laboratory will analyze the fatty acid composition of the red blood cells. The offeror's biostatistician (Mr. Pottala) will, in collaboration with Drs. Mark Espeland (biostatistician on WHIMS) and Robert Wallace (University of Iowa), conduct the statistical analysis of the data. The offeror and co-investigators (Espeland, Shumaker, Robinson, and Wallace) will prepare reports providing the results of the analyses which will be sent to the NHLBI as the final product of this contract. In addition, these reports will be reduced to manuscripts for publication in the medical literature.

Project Hypotheses

Our primary hypothesis is that RBC omega-3 FA content is inversely correlated with risk for cognitive decline – whether measured by cognitive testing, case adjudication, or brain MRI - in postmenopausal women. The cognitive test data allow us to assess preclinical relationships that may signal early risk. WHIMS has demonstrated that even small mean changes in cognitive test scores may be associated with marked differences in the risk of clinical events. Associations with ischemic lesion volumes and atrophy, as assessed by MRI, allow us to assess both preclinical and clinical neuropathology and may help signal mechanisms. WHIMS PD cases have been sub-typed (Alzheimer's, vascular, mixed, etc.), which allows us to examine the consistency of FA relations among these classifications. Similarly, with WHISCA, we will examine the consistency of FA relations across various cognitive domains. The relations between RBC omega-3 FAs and time to incident CI and to the conversion from mild CI to PD will be explored. Together, these analyses permit a comprehensive examination of relations between a biomarker of tissue FA status and a spectrum of cognitive functional states and disease. Our secondary hypotheses include:

- Estrogen therapy (with or without progestin) increases RBC omega-3 FA content.
- The addition of RBC omega-3 FA content to dementia and CI prediction models will improve c-statistics (discrimination) and predictive models.
- The adverse effects of estrogen therapy on dementia are exacerbated in women with lower omega-3 FA levels.
- The relations between cognitive function and omega-3 FAs are stronger when using omega-3 biomarkers than when using omega-3 FA intakes estimated from food frequency questionnaires.

Project Objectives

Objective 1: Using data and samples from WHIMS, we will define the relations that RBC omega-3 FA content has with

a) baseline **global cognitive function,**
b) changes in global cognitive function over 10+ years,
c) time to incident probable dementia (PD) and combined cognitive impairment (CI; PD and/or mild CI), and
d) incidence of PD and CI over follow-up period.

Objective 2: Using data and samples from WHISCA, we will define the relations that RBC omega-3 FA content has with

a) domain-specific cognitive function and
b) changes in domain-specific cognitive function over 10+ years of follow-up.

Objective 3: Using data and samples from WHIMS-MRI, we will define the relations that RBC omega-3 FA content has with

c) total and region-specific **ischemic lesion volume**,
d) total and region-specific **brain volumes**, and

Objective 4: Using samples from WHIMS, we will determine the effects on RBC omega-3 FA content of random assignment to hormone therapy (HT) (both CEE and CEE+MPA).

11.2 Differences Among Women In How Postmenopausal Hormone Therapy Affects Cognitive Function: An Application of Machine Learning Methods to Data Within the Women's Health Initiative

An application in response to PA-08-190 Research Supplements to Promote Diversity in Health Related Research has recently been funded. It provides support for Dr. Ramon Casanova. The research aims of the grant are as follows:

The research program that Dr. Casanova will pursue has three main objectives:

- To refine and tailor machine learning methodology for use in assessing the impact of postmenopausal hormone therapy on cognition and MRI outcomes;
- To use this methodology to identify factors that contribute to heterogeneity in the responses of women to hormone therapy with respect to cognitive function and brain structure, using data collected by the WHIMS and WHIMS-MRI programs; and
- Using data on cognitive function that is being collected by the WHIMS-Y program, to examine how findings from older women may be replicated among younger women and how these may explain heterogeneity in their responses.

This research will benefit from a multidisciplinary team of mentors with expertise in neuroepidemiology, machine learning methodology, radiology, gerontology, biostatistics, and cognitive assessment.