Women's Health Initiative
2006 Annual Progress Report

Data as of: August 18, 2006

Prepared by
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Fred Hutchinson Cancer Research Center

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(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 field center follow-up of non-responders after seven months. Form 33–*Medical History Update* is viewed as the primary indicator of response. Response rates to the first follow-up year are high (84.8% respond to the first mailing, 92.5% respond overall), as shown in Table 1.5. Response rates for other data collection instruments are similar to Form 33. Response rates are somewhat lower in the clinical trial components than in the observational study, presumably because this follow-up plan is new to CT participants.

Field centers are responsible for data collection from women that cannot be followed by mail and from non-responders to the three CCC mailings. Among those women for whom the CCC mailing interval has expired, 5.9% require field center follow-up and of these, 65.5% have provided a Form 33 (Table 1.6), giving an estimated overall response rate of over 97%. The response rates for Form 151 are somewhat lower than for other instruments at this stage because field center follow-up for this form is optional. Differences between study components are small with the exception that follow-up of HT participants appears to be somewhat more difficult.

1.3 Study Performance Reports

Reports summarizing field center activities were updated to reflect field center activities in the WHI ES. (See Tables 7.1 to 7.6.) These reports 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.

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 7.7).

1.4 Outcomes

Outcomes adjudication for the WHI-ES is now 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, which will

involve double adjudication of at least 10% of the cases by another adjudicator from the same committee, are currently being implemented.

The detailed procedures for processing are still being refined. The current status indicates that outcomes processing by the field centers is excellent with timeliness of documenting and forwarding cases better than it ever was during WHI. Table 7.8 shows the status of outcomes cases identified at the field centers through Sept. 1, 2006, as well as the number of outcomes cases at the CCC. There is a working backlog for the adjudication committees and the CCC, with the largest backlog in the administrative processing of the outcomes designated as other hospitalizations (see Table 7.9).

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

- Angina and CHF are no longer adjudicated
- Outpatient stroke is adjudicated (not adjudicated during WHI)
- Hip fracture continues to be adjudicated but no others (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

Venous thromboembolism (VTE) events continue to be investigated only for (former) HT participants. For each outcome type, only the first occurrence since the beginning of WHI is investigated. For example, a woman who has a confirmed MI during WHI will not be investigated for MI during the WHI-ES. A complete list of adjudicated outcomes for the WHI-ES may be found in the WHI-ES protocol.

In future reports we will provide tables of the agreement rates between self-reports and adjudications for the WHI-ES.

1.5 Specimen Repository

The current inventory of the WHI specimen repository are described in Tables 8.1–*CT Outcomes Cases with Blood* and 8.2–*OS Outcomes Cases with Blood* by tabulations of 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. Specimen availability is not shown for women who have not experienced one of these outcomes because of the large supply of potential controls. Urine samples, collected at the three bone mineral densitometry clinics, are also not shown but these resources have not yet been used for any purpose.

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 below); and (3) that which is reserved for use by WHI investigators at the end of the Extension Follow-up period.

1.6 Core and Ancillary Study Activities

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 9.1.

In January 2006, the NHLBI released their Broad Agency Announcement (BAA) to the larger scientific community, requesting proposals designed to use WHI specimens. These applications are currently under review at NHLBI. Those selected will receive funding and appropriate specimens beginning in January 2007.

WHI investigators and their colleagues continue to propose ancillary studies to use WHI resources. To date, the ancillary study use of blood specimens has been limited to OS participants because the CT specimens were reserved for use in explanatory studies by the program. No timeline has yet been established to provide CT specimens for testing non-intervention related hypotheses but this topic is under discussion.

Together these efforts are aimed to maximize the use of these resources to provide insight into the causes and mechanisms of disease.

Table 10.1 lists all proposed ancillary studies along with their WHI approval and funding status. Table 10.2 provides additional information on ancillary studies that are approved to use WHI biospecimens.

Participant enrollments to ancillary studies requiring a separate consent are tabulated by center and shown in Table 10.3. Over 31,000 participant enrollments have occurred in WHI. Table 10.4 provides the distribution of enrollments per participant. Approximately 14% of participants are enrolled in one or more ancillary study, and of these the majority participate in only one.

A 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, 610 manuscript proposals have been received and 418 approved for development by the Publications and Presentations committee. Of these, 168 have been published or are in press, including 24 since January 2006 (Table 11.1).

Table 1.1
WHI Centers and Principal Investigators

Principal Investigator	Institution	Location
Annlouise Assaf, PhD	Memorial Hospital of Rhode Island	Pawtucket, RI
Shirley Beresford, PhD	Fred Hutchinson Cancer Research Center	Seattle, WA
Henry Black, MD	Rush Presbyterian/St. Luke's Medical Ctr.	Chicago, IL
Denise Bonds, MD	Wake Forest University	Winston-Salem/Greensboro, NC
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
David Curb, MD	University of Hawaii	Honolulu, HI
Margery Gass, MD	University of Cincinnati	Cincinnati, OH
Jennifer Hays, PhD	Baylor College of Medicine	Houston, TX
Gerardo Heiss, MD MPH	University of North Carolina, Chapel Hill	Chapel Hill, NC
Susan Hendrix, DO	Wayne State University	Detroit, MI
Barbara Howard, PhD	MedStar Research Institute	Washington, D.C.
Judith Hsia, MD	George Washington University	Washington, DC
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
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
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
John Robbins, MD	University of California, Davis	Sacramento, CA
Gloria Sarto, MD	University of Wisconsin	Madison, WI
Sylvia Smoller, PhD	Albert Einstein College of Medicine	Bronx, NY
Marcia Stefanick, PhD	Stanford University	San Jose, CA
Cyndi Thomson, PhD RD	University of Arizona	Tucson and Phoenix, AZ
Linda Van Horn, PhD RD	Northwestern University	Chicago and Evanston, IL
Jean Wactawski-Wende, PhD	State University of New York, Buffalo	Buffalo, NY
Robert Wallace, MD	University of Iowa	Iowa City/Bettendorf, IA
Evelyn Whitlock, MD	Kaiser Foundation Research Institute	Portland, OR
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 18, 2006

WHI Enrollment	Enrolled in WHI	Eligible for extension[1]	Consented N	Consented %
Hormone Therapy	27347	25192	20415	81.0
With Uterus	16608	15407	12778	82.9
E+P	8506	7877	6539	83.0
Placebo	8102	7530	6239	82.9
Without Uterus	10739	9785	7637	78.0
E-alone	5310	4851	3775	77.8
Placebo	5429	4934	3862	78.3
Dietary Modification	48835	45558	37837	83.0
Intervention	19541	18206	14763	81.1
Comparison	29294	27352	23071	84.3
Calcium and Vitamin D	36282	34447	29841	86.6
Active	18176	17280	15013	86.9
Placebo	18106	17167	14828	86.4
Clinical Trial Total	68132	63329	52139	82.3
Observational Study	93676	86744	63134	72.8
Total	161808	150073	115273	76.8

[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 18, 2006

WHI Enrollment	Enrolled in WHI	Eligible for extension[1]	Consented N	Consented %
Clinical Trial	68132	63329	52139	82.3
Age				
50-54	9188	8754	7230	82.6
55-59	14661	13940	11710	84.0
60-69	31389	29288	24521	83.7
70-79	12894	11347	8678	76.5
Race/Ethnicity				
American Indian	292	260	185	71.2
Asian/Pacific Islander	1519	1414	1105	78.1
Black	6983	6423	4768	74.2
Hispanic	2875	2686	1786	66.5
White	55525	51679	43649	84.5
Unknown	938	867	646	74.5
Observational Study	93676	86744	63134	72.8
Age				
50-54	12381	11969	8977	75.0
55-59	17329	16565	12705	76.7
60-69	41200	38502	28545	74.1
70-79	22766	19708	12907	65.5
Race/Ethnicity				
American Indian	421	372	215	57.8
Asian/Pacific Islander	2671	2444	1290	52.8
Black	7635	6868	3571	52.0
Hispanic	3609	3333	1590	47.7
White	78016	72504	55697	76.8
Unknown	1324	1223	771	63.0

[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 18, 2006

	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	1828	79.1
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	2309	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	628	72.0	494	353	71.5	785	605	77.1	1225	881	71.9	1881	1018	54.1
Chicago	1121	952	84.9	518	443	85.5	759	687	90.5	1493	1266	84.8	1754	1368	78
Cincinnati	966	880	91.1	494	442	89.5	859	802	93.4	1297	1174	90.5	2076	1611	77.6
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	706	77.2	470	359	76.4	806	649	80.5	1220	936	76.7	1911	1415	74
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	524	452	86.3	813	745	91.6	1442	1244	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	1402	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	911	78.8	554	410	74.0	971	802	82.6	1559	1212	77.7	2056	1615	78.6
La Jolla	1525	962	63.1	682	323	47.4	1080	710	65.7	1986	1176	59.2	3188	1858	58.3
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	1166	867	74.4	666	486	73.0	841	663	78.8	1561	1150	73.7	2250	1246	55.4
Miami	1009	729	72.2	544	387	71.1	500	378	75.6	1377	987	71.7	1254	689	54.9
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	1947	75.6
Nevada	980	849	86.6	572	479	83.7	923	815	88.3	1362	1162	85.3	1957	1550	79.2
Newark	1269	1007	79.4	490	393	80.2	836	711	85.0	1600	1273	79.6	2369	1685	71.1
New Brunswick	375	328	87.5	368	326	88.6	436	399	91.5	657	576	87.7	779	651	83.6
NY-City	1223	1003	82.0	698	560	80.2	827	718	86.8	1767	1435	81.2	2710	1521	56.1
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	2684	79.1
Pittsburgh	1096	1005	91.7	595	540	90.8	804	754	93.8	1528	1395	91.3	1733	1381	79.7
Portland	1110	949	85.5	591	523	88.5	826	749	90.7	1522	1322	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	1069	70.6
Stanford	1226	1071	87.4	633	558	88.2	948	866	91.4	1639	1445	88.2	2465	2044	82.9

Table 1.4 (continued)
Extension Consent Summary by Field Center

Data as of August 18, 2006

	DM			HT			CaD			CT			OS		
	Eligible	Consent	%	Eligible	Consent	%	Eligible	Consent	%	Eligible	Consent	%	Eligible	Consent	%
Stonybrook	936	801	85.6	473	400	84.6	572	509	89	1266	1083	85.5	1915	1467	76.6
Torrance	743	550	74.0	287	203	70.7	507	404	79.7	914	669	73.2	1385	865	62.5
Tucson	1387	1077	77.6	714	506	70.9	1007	815	80.9	1929	1459	75.6	2544	1650	64.9
UC Davis	1358	1135	83.6	642	542	84.4	1033	904	87.5	1790	1488	83.1	2107	1392	66.1
Worcester	1153	1045	90.6	568	514	90.5	833	778	93.4	1553	1408	90.7	2105	1759	83.6
Total	45558	37834	83.0	25192	20415	81.0	34447	29841	86.6	63329	52139	82.3	86744	63134	72.8

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

Data as of August 18, 2006

	1st Mailing Period				2nd Mailing Period						3rd Mailing Period					
Study	Form	Sent Mail 1	Response within 0 to 3 months		Mail 1 > 5 mos ago	Sent Mail 2		Response within 3 - 5 mos		Cumulative response	Mail 1 > 7 mos ago	Sent Mail 3		Response within 5 - 7 mos		Cumulative Response
Total	33	109649	93028	84.8%	93803	14432	15.4%	7016	48.6%	92.2%	63494	3923	6.2%	587	15.0%	93.4%
	134	109656	91630	83.6%	93805	15596	16.6%	7777	49.9%	91.8%	63492	4143	6.5%	638	15.4%	93.0%
	150	18662	14643	78.5%	15165	3411	22.5%	1455	42.7%	87.7%	7981	817	10.2%	72	8.8%	88.7%
	151	77561	63932	82.4%	61707	11323	18.3%	5417	47.8%	90.8%	31393	2533	8.1%	356	14.1%	92.1%
HT	33	18660	14630	78.4%	15165	3418	22.5%	1453	42.5%	87.6%	7981	822	10.3%	73	8.9%	88.7%
	134	18662	14472	77.5%	15165	3555	23.4%	1531	43.1%	87.2%	7981	837	10.5%	72	8.6%	88.3%
	150	18662	14643	78.5%	15165	3411	22.5%	1455	42.7%	87.7%	7981	817	10.2%	72	8.8%	88.7%
	151	18663	14623	78.4%	15165	3426	22.6%	1463	42.7%	87.6%	7981	819	10.3%	70	8.5%	88.7%
DM	33	34504	28166	81.6%	27864	5478	19.7%	2577	47.0%	90.3%	14556	1205	8.3%	138	11.5%	91.4%
	134	34505	27780	80.5%	27864	5740	20.6%	2736	47.7%	89.8%	14556	1244	8.5%	148	11.9%	91.0%
	150	5557	4262	76.7%	4513	1122	24.9%	479	42.7%	86.6%	2487	289	11.6%	18	6.2%	87.5%
	151	34506	27970	81.1%	27864	5568	20.0%	2650	47.6%	90.1%	14556	1214	8.3%	139	11.4%	91.2%
CaD	33	27199	22108	81.3%	22046	4369	19.8%	2031	46.5%	90.0%	11482	982	8.6%	103	10.5%	91.0%
	134	27201	21872	80.4%	22046	4554	20.7%	2133	46.8%	89.6%	11482	1005	8.8%	107	10.6%	90.7%
	150	11812	9341	79.1%	9628	2118	22.0%	915	43.2%	88.1%	5114	514	10.1%	44	8.6%	89.1%
	151	27202	22022	81.0%	22046	4423	20.1%	2079	47.0%	89.9%	11482	984	8.6%	100	10.2%	90.9%
OS	33	62042	54544	87.9%	55287	6657	12.0%	3459	52.0%	94.2%	43432	2190	5.0%	395	18.0%	95.2%
	134	62046	53596	86.4%	55289	7459	13.5%	4010	53.8%	93.7%	43430	2355	5.4%	436	18.5%	94.9%
	151	29949	25602	85.5%	23191	3450	14.9%	1785	51.7%	93.0%	11331	790	7.0%	164	20.8%	94.4%

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

Data as of August 18, 2006

Study	Form	Eligible for FC Follow-up	Respondents		Total Estimated Response Rate
Total	33	1917	1256	65.5%	97.7%
	134	2154	1349	62.6%	97.4%
	150	195	105	53.8%	94.8%
	151	1232	112	9.1%	92.8%
HT	33	197	121	61.4%	95.6%
	134	208	123	59.1%	95.2%
	150	195	105	53.8%	94.8%
	151	197	17	8.6%	89.6%
DM	33	265	184	69.4%	97.4%
	134	290	201	69.3%	97.2%
	150	71	43	60.6%	95.1%
	151	270	16	5.9%	91.7%
CaD	33	213	149	70.0%	97.3%
	134	237	160	67.5%	97.0%
	150	120	66	55.0%	95.1%
	151	219	12	5.5%	91.4%
OS	33	1528	999	65.4%	98.4%
	134	1729	1071	61.9%	98.0%
	151	836	88	10.5%	95.0%

Table 2.1
Hormone Therapy Component Age – and Race/Ethnicity

Data as of August 18, 2006

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 18, 2006; Extension Participants Only

	Without Uterus (N=7,637)		With Uterus (N=12,778)		HT Participants (N=20,415)	
	N	%	N	%	N	%
Vital Status/Participation						
Deceased	94	1.2	132	1.0	226	1.1
Alive: Current Participation[1]	6874	90.0	11648	91.2	18522	90.7
Alive: Recent Participation[2]	642	8.4	946	7.4	1588	7.8
Alive: Past/Unknown Participation[3]	0	0.0	1	<0.1	1	<0.1
Stopped Follow-Up[4]	27	0.4	51	0.4	78	0.4
Lost to Follow-Up[5]	0	0.0	0	0.0	0	0.0

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 18, 2006

Outcomes	Total		Age 50-54		Age 55-59		Age 60-69		Age 70-79	
Number randomized	27347		3420		5413		12360		6154	
Mean follow-up (months)	104.3		110.2		107.3		103.8		99.5	
Cardiovascular										
CHD[1]	1083	(0.46%)	53	(0.17%)	115	(0.24%)	498	(0.47%)	417	(0.82%)
CHD death[2]	325	(0.14%)	13	(0.04%)	25	(0.05%)	130	(0.12%)	157	(0.31%)
Total MI[3]	857	(0.36%)	42	(0.13%)	97	(0.20%)	399	(0.37%)	319	(0.63%)
Clinical MI	823	(0.35%)	41	(0.13%)	95	(0.20%)	382	(0.36%)	305	(0.60%)
CABG/PTCA	1303	(0.55%)	59	(0.19%)	169	(0.35%)	650	(0.61%)	425	(0.83%)
Carotid artery disease	222	(0.09%)	5	(0.02%)	23	(0.05%)	118	(0.11%)	76	(0.15%)
Stroke	740	(0.31%)	27	(0.09%)	70	(0.14%)	328	(0.31%)	315	(0.62%)
Non-disabling stroke[4]	410	(0.17%)	21	(0.07%)	48	(0.10%)	173	(0.16%)	168	(0.33%)
Fatal/disabling stroke[4]	272	(0.11%)	3	(0.01%)	16	(0.03%)	125	(0.12%)	128	(0.25%)
Unknown status from stroke[4]	58	(0.02%)	3	(0.01%)	6	(0.01%)	30	(0.03%)	19	(0.04%)
PVD	214	(0.09%)	9	(0.03%)	20	(0.04%)	114	(0.11%)	71	(0.14%)
DVT	421	(0.18%)	24	(0.08%)	59	(0.12%)	194	(0.18%)	144	(0.28%)
Pulmonary embolism	303	(0.13%)	20	(0.06%)	44	(0.09%)	145	(0.14%)	94	(0.18%)
Coronary disease[5]	2774	(1.17%)	147	(0.47%)	326	(0.67%)	1299	(1.22%)	1002	(1.96%)
DVT/PE	585	(0.25%)	32	(0.10%)	79	(0.16%)	284	(0.27%)	190	(0.37%)
Total cardiovascular disease	4068	(1.71%)	209	(0.67%)	481	(0.99%)	1910	(1.79%)	1468	(2.88%)
Cancer										
Breast cancer	975	(0.41%)	97	(0.31%)	177	(0.37%)	461	(0.43%)	240	(0.47%)
Invasive breast cancer	782	(0.33%)	71	(0.23%)	143	(0.30%)	365	(0.34%)	203	(0.40%)
Non-invasive breast cancer	197	(0.08%)	26	(0.08%)	35	(0.07%)	99	(0.09%)	37	(0.07%)
Ovarian cancer	78	(0.03%)	3	(0.01%)	15	(0.03%)	41	(0.04%)	19	(0.04%)
Endometrial cancer[6]	96	(0.04%)	5	(0.02%)	23	(0.05%)	51	(0.05%)	17	(0.03%)
Colorectal cancer	331	(0.14%)	19	(0.06%)	36	(0.07%)	165	(0.15%)	111	(0.22%)
Other cancer[7]	1282	(0.54%)	96	(0.31%)	177	(0.37%)	603	(0.56%)	406	(0.80%)
Total cancer	2646	(1.11%)	213	(0.68%)	418	(0.86%)	1259	(1.18%)	756	(1.48%)
Fractures										
Hip fracture	396	(0.17%)	4	(0.01%)	23	(0.05%)	123	(0.12%)	246	(0.48%)
Deaths										
Cardiovascular deaths	570	(0.24%)	23	(0.07%)	42	(0.09%)	222	(0.21%)	283	(0.55%)
Cancer deaths	741	(0.31%)	37	(0.12%)	90	(0.19%)	351	(0.33%)	263	(0.52%)
Other known cause	352	(0.15%)	16	(0.05%)	45	(0.09%)	138	(0.13%)	153	(0.30%)
Unknown cause	55	(0.02%)	4	(0.01%)	4	(0.01%)	27	(0.03%)	20	(0.04%)
Not yet adjudicated	206	(0.09%)	6	(0.02%)	22	(0.05%)	79	(0.07%)	99	(0.19%)
Total death	1924	(0.81%)	86	(0.27%)	203	(0.42%)	817	(0.76%)	818	(1.60%)

[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 2.3 (continued)
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Hormone Therapy

Data as of: August 18, 2006

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)	99.1	98.9	102.2	99.2	105.2	99.9
Cardiovascular						
CHD[1]	5 (0.47%)	13 (0.30%)	112 (0.48%)	31 (0.24%)	900 (0.47%)	22 (0.69%)
CHD death[2]	2 (0.19%)	5 (0.12%)	54 (0.23%)	6 (0.05%)	255 (0.13%)	3 (0.09%)
Total MI[3]	4 (0.37%)	11 (0.25%)	72 (0.31%)	26 (0.20%)	724 (0.37%)	20 (0.62%)
Clinical MI	4 (0.37%)	10 (0.23%)	71 (0.30%)	24 (0.19%)	695 (0.36%)	19 (0.59%)
CABG/PTCA	7 (0.65%)	13 (0.30%)	115 (0.49%)	48 (0.38%)	1102 (0.57%)	18 (0.56%)
Carotid artery disease	1 (0.09%)	1 (0.02%)	8 (0.03%)	2 (0.02%)	208 (0.11%)	2 (0.06%)
Stroke	5 (0.47%)	14 (0.32%)	99 (0.42%)	22 (0.17%)	588 (0.30%)	12 (0.37%)
Non-disabling stroke[4]	3 (0.28%)	8 (0.18%)	48 (0.21%)	13 (0.10%)	332 (0.17%)	6 (0.19%)
Fatal/disabling stroke[4]	2 (0.19%)	6 (0.14%)	40 (0.17%)	6 (0.05%)	214 (0.11%)	4 (0.12%)
Unknown status from stroke[4]	0 (0.00%)	0 (0.00%)	11 (0.05%)	3 (0.02%)	42 (0.02%)	2 (0.06%)
PVD	2 (0.19%)	1 (0.02%)	23 (0.10%)	2 (0.02%)	186 (0.10%)	0 (0.00%)
DVT	2 (0.19%)	2 (0.05%)	45 (0.19%)	7 (0.06%)	363 (0.19%)	2 (0.06%)
Pulmonary embolism	3 (0.28%)	1 (0.02%)	38 (0.16%)	4 (0.03%)	255 (0.13%)	2 (0.06%)
Coronary disease[5]	12 (1.12%)	32 (0.74%)	310 (1.33%)	102 (0.80%)	2278 (1.18%)	40 (1.25%)
DVT/PE	5 (0.47%)	2 (0.05%)	66 (0.28%)	9 (0.07%)	500 (0.26%)	3 (0.09%)
Total cardiovascular disease	20 (1.86%)	46 (1.06%)	454 (1.95%)	132 (1.04%)	3367 (1.74%)	49 (1.53%)
Cancer						
Breast cancer	3 (0.28%)	22 (0.51%)	86 (0.37%)	32 (0.25%)	823 (0.43%)	9 (0.28%)
Invasive breast cancer	3 (0.28%)	16 (0.37%)	69 (0.30%)	24 (0.19%)	663 (0.34%)	7 (0.22%)
Non-invasive breast cancer	0 (0.00%)	6 (0.14%)	17 (0.07%)	8 (0.06%)	164 (0.08%)	2 (0.06%)
Ovarian cancer	0 (0.00%)	1 (0.02%)	6 (0.03%)	0 (0.00%)	69 (0.04%)	2 (0.06%)
Endometrial cancer[6]	1 (0.09%)	0 (0.00%)	5 (0.02%)	5 (0.04%)	84 (0.04%)	1 (0.03%)
Colorectal cancer	1 (0.09%)	8 (0.18%)	28 (0.12%)	14 (0.11%)	274 (0.14%)	6 (0.19%)
Other cancer[7]	7 (0.65%)	24 (0.55%)	97 (0.42%)	40 (0.31%)	1100 (0.57%)	14 (0.44%)
Total cancer	12 (1.12%)	55 (1.27%)	213 (0.91%)	85 (0.67%)	2252 (1.17%)	29 (0.90%)
Fractures						
Hip fracture	1 (0.09%)	4 (0.09%)	10 (0.04%)	7 (0.06%)	372 (0.19%)	2 (0.06%)
Deaths						
Cardiovascular deaths	3 (0.28%)	10 (0.23%)	93 (0.40%)	11 (0.09%)	448 (0.23%)	5 (0.16%)
Cancer deaths	5 (0.47%)	14 (0.32%)	66 (0.28%)	25 (0.20%)	622 (0.32%)	9 (0.28%)
Other known cause	4 (0.37%)	2 (0.05%)	31 (0.13%)	6 (0.05%)	303 (0.16%)	6 (0.19%)
Unknown cause	0 (0.00%)	2 (0.05%)	12 (0.05%)	2 (0.02%)	38 (0.02%)	1 (0.03%)
Not yet adjudicated	0 (0.00%)	2 (0.05%)	14 (0.06%)	7 (0.06%)	179 (0.09%)	4 (0.12%)
Total Death	12 (1.12%)	30 (0.69%)	216 (0.93%)	51 (0.40%)	1590 (0.82%)	25 (0.78%)

[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) for HT Participants Without and With Uterus

Data as of: August 18, 2006

Outcomes	Without Uterus		With Uterus	
Number randomized	10739		16608	
Mean follow-up (months)	103.4		104.9	
Cardiovascular				
CHD[1]	510	(0.55%)	573	(0.39%)
CHD death[2]	175	(0.19%)	150	(0.10%)
Total MI[3]	392	(0.42%)	465	(0.32%)
Clinical MI	377	(0.41%)	446	(0.31%)
CABG/PTCA	609	(0.66%)	694	(0.48%)
Carotid artery disease	117	(0.13%)	105	(0.07%)
Stroke	325	(0.35%)	415	(0.29%)
Non-disabling stroke[4]	169	(0.18%)	241	(0.17%)
Fatal/disabling stroke[4]	124	(0.13%)	148	(0.10%)
Unknown status from stroke[4]	32	(0.03%)	26	(0.02%)
PVD	100	(0.11%)	114	(0.08%)
DVT	164	(0.18%)	257	(0.18%)
Pulmonary embolism	109	(0.12%)	194	(0.13%)
Coronary disease[5]	1346	(1.46%)	1428	(0.98%)
DVT/PE	228	(0.25%)	357	(0.25%)
Total cardiovascular disease	1892	(2.05%)	2176	(1.50%)
Cancer				
Breast cancer	325	(0.35%)	650	(0.45%)
Invasive breast cancer	265	(0.29%)	517	(0.36%)
Non-invasive breast cancer	61	(0.07%)	136	(0.09%)
Ovarian cancer	20	(0.02%)	58	(0.04%)
Endometrial cancer[6]	0	N/A	96	(0.07%)
Colorectal cancer	136	(0.15%)	195	(0.13%)
Other cancer[7]	507	(0.55%)	775	(0.53%)
Total cancer	959	(1.04%)	1687	(1.16%)
Fractures				
Hip fracture	146	(0.16%)	250	(0.17%)
Deaths				
Cardiovascular deaths	281	(0.30%)	289	(0.20%)
Cancer deaths	317	(0.34%)	424	(0.29%)
Other known cause	137	(0.15%)	215	(0.15%)
Unknown cause	25	(0.03%)	30	(0.02%)
Not yet adjudicated	87	(0.09%)	119	(0.08%)
Total death	847	(0.92%)	1077	(0.74%)

[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
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 18, 2006

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	27347	3420	5413	12360	6154
Mean follow-up (months)	104.3	110.2	107.3	103.8	99.5
Hospitalizations					
Ever	14791 (6.22%)	1332 (4.24%)	2359 (4.87%)	6915 (6.47%)	4185 (8.20%)
Two or more	8647 (3.64%)	640 (2.04%)	1241 (2.56%)	4034 (3.77%)	2732 (5.35%)
Other					
Diabetes (treated)	2557 (1.14%)	359 (1.19%)	498 (1.09%)	1192 (1.18%)	508 (1.06%)
Gallbladder disease[1, 2]	2117 (1.11%)	282 (1.09%)	443 (1.12%)	988 (1.17%)	404 (1.01%)
Hysterectomy	778 (0.54%)	66 (0.35%)	154 (0.49%)	391 (0.60%)	167 (0.56%)
Glaucoma[2]	3203 (1.47%)	287 (0.97%)	548 (1.21%)	1519 (1.55%)	849 (1.87%)
Osteoporosis[2]	6115 (2.83%)	477 (1.61%)	962 (2.13%)	2955 (3.05%)	1721 (3.89%)
Osteoarthritis[3]	5387 (3.64%)	693 (2.90%)	1090 (3.22%)	2474 (3.86%)	1130 (4.35%)
Rheumatoid arthritis[2]	1698 (0.78%)	211 (0.73%)	341 (0.76%)	764 (0.78%)	382 (0.83%)
Intestinal polyps	4419 (2.00%)	468 (1.54%)	838 (1.81%)	2206 (2.22%)	907 (2.01%)
Lupus	305 (0.13%)	35 (0.11%)	65 (0.13%)	138 (0.13%)	67 (0.13%)
Kidney stones[2, 3]	769 (0.40%)	94 (0.38%)	143 (0.36%)	346 (0.39%)	186 (0.44%)
Cataracts[2, 3]	8650 (5.05%)	505 (2.01%)	1345 (3.46%)	4578 (5.84%)	2222 (7.68%)
Pills for hypertension	8019 (4.74%)	913 (3.60%)	1561 (4.17%)	3682 (4.96%)	1863 (5.80%)

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)	99.1	98.9	102.2	99.2	105.2	99.9
Hospitalizations						
Ever	71 (6.61%)	211 (4.86%)	1494 (6.41%)	648 (5.10%)	12171 (6.30%)	196 (6.11%)
Two or more	50 (4.66%)	105 (2.42%)	885 (3.80%)	315 (2.48%)	7183 (3.72%)	109 (3.40%)
Other						
Diabetes (treated)	13 (1.39%)	54 (1.36%)	392 (1.92%)	226 (1.93%)	1834 (0.99%)	38 (1.28%)
Gallbladder disease[1, 2]	13 (1.64%)	32 (0.84%)	187 (0.93%)	129 (1.40%)	1730 (1.13%)	26 (1.02%)
Hysterectomy	2 (0.44%)	6 (0.20%)	51 (0.53%)	37 (0.51%)	675 (0.55%)	7 (0.36%)
Glaucoma[2]	16 (1.65%)	60 (1.50%)	410 (1.98%)	190 (1.60%)	2480 (1.40%)	47 (1.64%)
Osteoporosis[2]	32 (3.26%)	141 (3.52%)	349 (1.61%)	338 (2.95%)	5162 (2.95%)	93 (3.19%)
Osteoarthritis[3]	35 (4.80%)	111 (3.61%)	543 (3.83%)	372 (4.22%)	4242 (3.57%)	84 (4.05%)
Rheumatoid arthritis[2]	15 (1.64%)	30 (0.75%)	272 (1.33%)	220 (1.88%)	1126 (0.63%)	35 (1.20%)
Intestinal polyps	23 (2.32%)	67 (1.69%)	457 (2.10%)	208 (1.71%)	3615 (2.02%)	49 (1.66%)
Lupus	2 (0.19%)	4 (0.09%)	34 (0.15%)	24 (0.19%)	240 (0.12%)	1 (0.03%)
Kidney stones[2, 3]	9 (1.08%)	25 (0.69%)	82 (0.43%)	62 (0.60%)	583 (0.37%)	8 (0.30%)
Cataracts[2, 3]	44 (5.48%)	143 (4.52%)	790 (4.63%)	450 (4.49%)	7110 (5.15%)	113 (4.87%)
Pills for hypertension	48 (6.32%)	142 (4.67%)	718 (6.19%)	495 (5.20%)	6521 (4.59%)	95 (4.53%)

[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 2.6

Selected Medication Use after Stopping of the HT Intervention

Data as of: August 18, 2006

	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	3775		3862		6539		6239	
% missing medication information	9.6%		10.0%		8.8%		8.8%	
Any prescription hormone	222	6.7	121	3.6	242	4.2	180	3.3
E-alone use	156	4.7	82	2.4	160	2.7	128	2.3
E+P use	20	0.6	17	0.5	104	1.8	42	0.8
Non-prescription (natural) hormone	95	2.9	89	2.7	178	3.1	155	2.8
Osteoporosis[4]	567	17.4	699	21.1	1271	22.4	1474	27.1
SERM	76	2.3	99	3.0	231	4.0	167	3.0

[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 first year of extension.
[4] Bisphosphonate, calcitonin, or PTH.

Table 3.1
Dietary Modification Component Age – and Race/Ethnicity

Data as of August 18, 2006

	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 18, 2006; Extension Participants Only

	DM Participants (N =37,834)	
	N	%
Vital Status/Participation		
Deceased	280	0.7
Alive: Current Participation[1]	35167	93.0
Alive: Recent Participation[2]	2294	6.1
Alive: Past/Unknown Participation[3]	8	<0.1
Stopped Follow-Up[4]	84	0.2
Lost to Follow-Up[5]	1	<0.1

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
Verified Outcomes (Annualized Percentages) by Age for Dietary Modification

Data as of: August 18, 2006

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	48835		6961		11037		22715		8122	
Mean follow-up (months)	107.4		114.6		110.7		105.7		101.8	
Cancer										
Breast cancer	2310	(0.53%)	281	(0.42%)	529	(0.52%)	1090	(0.54%)	410	(0.60%)
Invasive breast cancer	1855	(0.42%)	204	(0.31%)	430	(0.42%)	887	(0.44%)	334	(0.48%)
Non-invasive breast cancer	477	(0.11%)	80	(0.12%)	104	(0.10%)	212	(0.11%)	81	(0.12%)
Ovarian cancer	185	(0.04%)	22	(0.03%)	38	(0.04%)	85	(0.04%)	40	(0.06%)
Endometrial cancer[1]	309	(0.07%)	34	(0.05%)	74	(0.07%)	148	(0.07%)	53	(0.08%)
Colorectal cancer	515	(0.12%)	32	(0.05%)	84	(0.08%)	255	(0.13%)	144	(0.21%)
Other cancer[2]	2087	(0.48%)	177	(0.27%)	360	(0.35%)	1055	(0.53%)	495	(0.72%)
Total cancer	5165	(1.18%)	525	(0.79%)	1035	(1.02%)	2509	(1.25%)	1096	(1.59%)
Cardiovascular										
CHD[3]	1492	(0.34%)	82	(0.12%)	180	(0.18%)	709	(0.35%)	521	(0.76%)
CHD death[4]	413	(0.09%)	20	(0.03%)	32	(0.03%)	194	(0.10%)	167	(0.24%)
Total MI[5]	1210	(0.28%)	64	(0.10%)	156	(0.15%)	574	(0.29%)	416	(0.60%)
Clinical MI	1155	(0.26%)	58	(0.09%)	149	(0.15%)	548	(0.27%)	400	(0.58%)
CABG/PTCA	1919	(0.44%)	91	(0.14%)	262	(0.26%)	1016	(0.51%)	550	(0.80%)
Carotid artery disease	298	(0.07%)	11	(0.02%)	35	(0.03%)	158	(0.08%)	94	(0.14%)
Stroke	1081	(0.25%)	46	(0.07%)	116	(0.11%)	503	(0.25%)	416	(0.60%)
PVD	269	(0.06%)	14	(0.02%)	35	(0.03%)	130	(0.06%)	90	(0.13%)
Coronary disease[6]	4081	(0.93%)	230	(0.35%)	538	(0.53%)	2045	(1.02%)	1268	(1.84%)
Total cardiovascular disease	5287	(1.21%)	282	(0.42%)	685	(0.67%)	2639	(1.32%)	1681	(2.44%)
Fractures										
Hip fracture	530	(0.12%)	13	(0.02%)	35	(0.03%)	212	(0.11%)	270	(0.39%)
Deaths										
Cardiovascular deaths	745	(0.17%)	33	(0.05%)	52	(0.05%)	319	(0.16%)	341	(0.49%)
Cancer deaths	1169	(0.27%)	72	(0.11%)	163	(0.16%)	580	(0.29%)	354	(0.51%)
Other known cause	504	(0.12%)	28	(0.04%)	54	(0.05%)	208	(0.10%)	214	(0.31%)
Unknown cause	64	(0.01%)	1	(<0.01%)	6	(0.01%)	34	(0.02%)	23	(0.03%)
Not yet adjudicated	278	(0.06%)	16	(0.02%)	25	(0.02%)	142	(0.07%)	95	(0.14%)
Total death	2760	(0.63%)	150	(0.23%)	300	(0.29%)	1283	(0.64%)	1027	(1.49%)

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 3.3 (continued)
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Dietary Modification

Data as of: August 18, 2006

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)	103.9	103.7	104.1	100.1	108.4	102.2
Cancer						
Breast cancer	5 (0.29%)	55 (0.58%)	185 (0.41%)	59 (0.38%)	1981 (0.55%)	25 (0.45%)
Invasive breast cancer	4 (0.23%)	42 (0.44%)	138 (0.30%)	46 (0.30%)	1605 (0.45%)	20 (0.36%)
Non-invasive breast cancer	1 (0.06%)	13 (0.14%)	48 (0.11%)	13 (0.08%)	397 (0.11%)	5 (0.09%)
Ovarian cancer	1 (0.06%)	6 (0.06%)	11 (0.02%)	7 (0.05%)	157 (0.04%)	3 (0.05%)
Endometrial cancer[1]	0 (0.00%)	3 (0.03%)	20 (0.04%)	8 (0.05%)	273 (0.08%)	5 (0.09%)
Colorectal cancer	4 (0.23%)	8 (0.08%)	56 (0.12%)	18 (0.12%)	422 (0.12%)	7 (0.12%)
Other cancer[2]	6 (0.34%)	32 (0.34%)	162 (0.35%)	43 (0.28%)	1817 (0.51%)	27 (0.48%)
Total cancer	15 (0.86%)	99 (1.04%)	413 (0.90%)	127 (0.82%)	4450 (1.24%)	61 (1.09%)
Cardiovascular						
CHD[3]	4 (0.23%)	16 (0.17%)	163 (0.36%)	27 (0.18%)	1261 (0.35%)	21 (0.37%)
CHD death[4]	0 (0.00%)	3 (0.03%)	63 (0.14%)	9 (0.06%)	328 (0.09%)	10 (0.18%)
Total MI[5]	4 (0.23%)	15 (0.16%)	119 (0.26%)	21 (0.14%)	1034 (0.29%)	17 (0.30%)
Clinical MI	4 (0.23%)	15 (0.16%)	114 (0.25%)	20 (0.13%)	986 (0.27%)	16 (0.28%)
CABG/PTCA	6 (0.34%)	15 (0.16%)	181 (0.40%)	40 (0.26%)	1657 (0.46%)	20 (0.36%)
Carotid artery disease	2 (0.11%)	1 (0.01%)	22 (0.05%)	3 (0.02%)	266 (0.07%)	4 (0.07%)
Stroke	4 (0.23%)	19 (0.20%)	153 (0.34%)	27 (0.18%)	863 (0.24%)	15 (0.27%)
PVD	3 (0.17%)	2 (0.02%)	49 (0.11%)	2 (0.01%)	209 (0.06%)	4 (0.07%)
Coronary disease[6]	15 (0.86%)	45 (0.47%)	515 (1.13%)	102 (0.66%)	3352 (0.93%)	52 (0.93%)
Total cardiovascular disease	22 (1.26%)	66 (0.69%)	663 (1.45%)	130 (0.84%)	4337 (1.21%)	69 (1.23%)
Fractures						
Hip fracture	2 (0.11%)	3 (0.03%)	16 (0.04%)	10 (0.06%)	494 (0.14%)	5 (0.09%)
Deaths						
Cardiovascular deaths	2 (0.11%)	10 (0.10%)	108 (0.24%)	15 (0.10%)	599 (0.17%)	11 (0.20%)
Cancer deaths	6 (0.34%)	17 (0.18%)	102 (0.22%)	32 (0.21%)	993 (0.28%)	19 (0.34%)
Other known cause	8 (0.46%)	7 (0.07%)	59 (0.13%)	12 (0.08%)	411 (0.11%)	7 (0.12%)
Unknown cause	0 (0.00%)	1 (0.01%)	14 (0.03%)	1 (0.01%)	46 (0.01%)	2 (0.04%)
Not yet adjudicated	1 (0.06%)	4 (0.04%)	27 (0.06%)	3 (0.02%)	238 (0.07%)	5 (0.09%)
Total death	17 (0.97%)	39 (0.41%)	310 (0.68%)	63 (0.41%)	2287 (0.64%)	44 (0.78%)

[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 3.4
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 18, 2006

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	48835	6961	11037	22715	8122
Mean follow-up (months)	107.4	114.6	110.7	105.7	101.8
Hospitalizations					
Ever	26054 (5.96%)	2787 (4.19%)	4996 (4.91%)	12692 (6.35%)	5579 (8.10%)
Two or more	14712 (3.37%)	1264 (1.90%)	2527 (2.48%)	7320 (3.66%)	3601 (5.23%)
Other					
DVT[1]	592 (0.14%)	34 (0.05%)	90 (0.09%)	285 (0.15%)	183 (0.28%)
Pulmonary embolism	409 (0.09%)	28 (0.04%)	63 (0.06%)	211 (0.11%)	107 (0.16%)
Diabetes (treated)	4185 (1.00%)	592 (0.91%)	957 (0.97%)	1945 (1.02%)	691 (1.06%)
Gallbladder disease[2, 3]	3830 (1.10%)	573 (1.01%)	902 (1.09%)	1802 (1.15%)	553 (1.04%)
Hysterectomy	1676 (0.67%)	244 (0.65%)	402 (0.65%)	795 (0.71%)	235 (0.63%)
Glaucoma[3]	5318 (1.32%)	567 (0.91%)	1098 (1.15%)	2589 (1.42%)	1064 (1.74%)
Osteoporosis[3]	10221 (2.60%)	1129 (1.81%)	1969 (2.10%)	5021 (2.81%)	2102 (3.56%)
Osteoarthritis[4]	10413 (3.85%)	1588 (3.19%)	2460 (3.53%)	4781 (4.10%)	1584 (4.60%)
Rheumatoid arthritis[3]	2849 (0.71%)	399 (0.65%)	631 (0.67%)	1319 (0.72%)	500 (0.80%)
Intestinal polyps	8587 (2.11%)	1135 (1.76%)	1944 (2.01%)	4238 (2.30%)	1270 (2.07%)
Lupus	503 (0.12%)	82 (0.12%)	116 (0.11%)	237 (0.12%)	68 (0.10%)
Kidney stones[3, 4]	1319 (0.38%)	175 (0.34%)	281 (0.35%)	654 (0.40%)	209 (0.37%)
Cataracts[3, 4]	15485 (4.86%)	1157 (2.21%)	2859 (3.56%)	8462 (5.77%)	3007 (7.61%)
Pills for hypertension	13590 (4.45%)	1821 (3.41%)	3056 (3.98%)	6447 (4.80%)	2266 (5.53%)

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)	103.9	103.7	104.1	100.1	108.4	102.2
Hospitalizations						
Ever	101 (5.78%)	421 (4.41%)	2734 (5.99%)	796 (5.17%)	21679 (6.03%)	323 (5.75%)
Two or more	64 (3.66%)	190 (1.99%)	1604 (3.51%)	404 (2.62%)	12264 (3.41%)	186 (3.31%)
Other						
DVT[1]	2 (0.12%)	0 (0.00%)	55 (0.12%)	10 (0.07%)	516 (0.15%)	9 (0.17%)
Pulmonary embolism	2 (0.12%)	1 (0.01%)	42 (0.09%)	5 (0.03%)	354 (0.10%)	5 (0.09%)
Diabetes (treated)	19 (1.17%)	115 (1.28%)	746 (1.84%)	227 (1.57%)	3013 (0.87%)	65 (1.22%)
Gallbladder disease[2, 3]	14 (1.16%)	60 (0.73%)	304 (0.78%)	152 (1.36%)	3250 (1.14%)	50 (1.09%)
Hysterectomy	5 (0.61%)	31 (0.51%)	105 (0.52%)	51 (0.62%)	1473 (0.70%)	11 (0.35%)
Glaucoma[3]	30 (1.87%)	108 (1.23%)	763 (1.86%)	201 (1.40%)	4152 (1.25%)	64 (1.27%)
Osteoporosis[3]	43 (2.68%)	272 (3.16%)	679 (1.61%)	409 (2.97%)	8678 (2.69%)	140 (2.81%)
Osteoarthritis[4]	45 (4.49%)	242 (3.49%)	1066 (3.89%)	433 (4.14%)	8471 (3.83%)	156 (4.50%)
Rheumatoid arthritis[3]	23 (1.52%)	49 (0.56%)	506 (1.24%)	222 (1.57%)	1998 (0.60%)	51 (1.00%)
Intestinal polyps	45 (2.77%)	180 (2.06%)	945 (2.22%)	271 (1.84%)	7026 (2.11%)	120 (2.32%)
Lupus	4 (0.23%)	8 (0.08%)	72 (0.16%)	20 (0.13%)	392 (0.11%)	7 (0.13%)
Kidney stones[3, 4]	9 (0.66%)	27 (0.35%)	137 (0.37%)	58 (0.46%)	1071 (0.37%)	17 (0.38%)
Cataracts[3, 4]	61 (4.91%)	306 (4.32%)	1510 (4.46%)	537 (4.48%)	12867 (4.94%)	204 (4.95%)
Pills for hypertension	48 (4.27%)	281 (4.38%)	1392 (6.09%)	553 (4.84%)	11146 (4.29%)	170 (4.50%)

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

Data as of August 18, 2006

	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 18, 2006; Extension Participants Only

	CaD Participants (N = 29,841)	
	N	%
Vital Status/Participation		
Deceased	246	0.8
Alive: Current Participation[1]	27670	92.7
Alive: Recent Participation[2]	1855	6.2
Alive: Past/Unknown Participation[3]	2	<0.1
Stopped Follow-Up[4]	67	0.2
Lost to Follow-Up[5]	1	<0.1

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 18, 2006

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number of participants	36282	5153	8269	16519	6341
Mean follow-up (months)	95.5	101.6	98.5	94.0	90.5
Fractures					
Hip fracture	398 (0.14%)	7 (0.02%)	36 (0.05%)	136 (0.11%)	219 (0.46%)
Cancer					
Colorectal cancer	350 (0.12%)	23 (0.05%)	50 (0.07%)	171 (0.13%)	106 (0.22%)
Breast cancer	1464 (0.51%)	179 (0.41%)	346 (0.51%)	680 (0.53%)	259 (0.54%)
Invasive breast cancer	1163 (0.40%)	130 (0.30%)	278 (0.41%)	546 (0.42%)	209 (0.44%)
Non-invasive breast cancer	312 (0.11%)	49 (0.11%)	70 (0.10%)	138 (0.11%)	55 (0.11%)
Ovarian cancer	127 (0.04%)	15 (0.03%)	35 (0.05%)	52 (0.04%)	25 (0.05%)
Endometrial cancer[1]	187 (0.06%)	22 (0.05%)	46 (0.07%)	85 (0.07%)	34 (0.07%)
Other cancer[2]	1425 (0.49%)	119 (0.27%)	237 (0.35%)	710 (0.55%)	359 (0.75%)
Total cancer	3411 (1.18%)	348 (0.80%)	691 (1.02%)	1622 (1.25%)	750 (1.57%)
Cardiovascular					
CHD[3]	1039 (0.36%)	57 (0.13%)	126 (0.19%)	494 (0.38%)	362 (0.76%)
CHD death[4]	283 (0.10%)	13 (0.03%)	23 (0.03%)	118 (0.09%)	129 (0.27%)
Total MI[5]	842 (0.29%)	46 (0.11%)	107 (0.16%)	415 (0.32%)	274 (0.57%)
Clinical MI	791 (0.27%)	42 (0.10%)	102 (0.15%)	391 (0.30%)	256 (0.54%)
CABG/PTCA	1354 (0.47%)	69 (0.16%)	187 (0.28%)	708 (0.55%)	390 (0.82%)
Carotid artery disease	221 (0.08%)	10 (0.02%)	21 (0.03%)	124 (0.10%)	66 (0.14%)
Stroke	753 (0.26%)	34 (0.08%)	81 (0.12%)	333 (0.26%)	305 (0.64%)
PVD	203 (0.07%)	7 (0.02%)	25 (0.04%)	100 (0.08%)	71 (0.15%)
Coronary disease[6]	2864 (0.99%)	163 (0.37%)	388 (0.57%)	1410 (1.09%)	903 (1.89%)
Total cardiovascular disease	3745 (1.30%)	204 (0.47%)	493 (0.73%)	1833 (1.42%)	1215 (2.54%)
Deaths					
Cardiovascular deaths	508 (0.18%)	23 (0.05%)	38 (0.06%)	210 (0.16%)	237 (0.50%)
Cancer deaths	772 (0.27%)	56 (0.13%)	106 (0.16%)	383 (0.30%)	227 (0.47%)
Other known cause	324 (0.11%)	16 (0.04%)	41 (0.06%)	139 (0.11%)	128 (0.27%)
Unknown cause	48 (0.02%)	3 (0.01%)	6 (0.01%)	26 (0.02%)	13 (0.03%)
Not yet adjudicated	225 (0.08%)	10 (0.02%)	29 (0.04%)	95 (0.07%)	91 (0.19%)
Total death	1877 (0.65%)	108 (0.25%)	220 (0.32%)	853 (0.66%)	696 (1.46%)

[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 4.3 (continued)
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Calcium and Vitamin D

Data as of August 18, 2006

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)	93.6	90.9	92.7	91.3	96.2	90.6
Fractures						
Hip fracture	2 (0.17%)	5 (0.09%)	7 (0.03%)	3 (0.03%)	380 (0.16%)	1 (0.03%)
Cancer						
Colorectal cancer	3 (0.26%)	5 (0.09%)	32 (0.13%)	10 (0.09%)	297 (0.12%)	3 (0.09%)
Breast cancer	4 (0.34%)	31 (0.57%)	105 (0.41%)	40 (0.35%)	1270 (0.53%)	14 (0.42%)
Invasive breast cancer	3 (0.26%)	21 (0.38%)	80 (0.31%)	31 (0.27%)	1015 (0.42%)	13 (0.39%)
Non-invasive breast cancer	1 (0.09%)	10 (0.18%)	26 (0.10%)	9 (0.08%)	265 (0.11%)	1 (0.03%)
Ovarian cancer	0 (0.00%)	5 (0.09%)	7 (0.03%)	5 (0.04%)	108 (0.04%)	2 (0.06%)
Endometrial cancer[1]	1 (0.09%)	2 (0.04%)	8 (0.03%)	4 (0.03%)	169 (0.07%)	3 (0.09%)
Other cancer[2]	5 (0.43%)	24 (0.44%)	93 (0.36%)	30 (0.26%)	1260 (0.52%)	13 (0.39%)
Total cancer	12 (1.03%)	64 (1.17%)	235 (0.92%)	82 (0.72%)	2984 (1.23%)	34 (1.02%)
Cardiovascular						
CHD[3]	5 (0.43%)	8 (0.15%)	98 (0.38%)	23 (0.20%)	888 (0.37%)	17 (0.51%)
CHD death[4]	1 (0.09%)	2 (0.04%)	41 (0.16%)	7 (0.06%)	225 (0.09%)	7 (0.21%)
Total MI[5]	5 (0.43%)	7 (0.13%)	67 (0.26%)	19 (0.17%)	730 (0.30%)	14 (0.42%)
Clinical MI	5 (0.43%)	7 (0.13%)	64 (0.25%)	18 (0.16%)	684 (0.28%)	13 (0.39%)
CABG/PTCA	4 (0.34%)	12 (0.22%)	119 (0.46%)	41 (0.36%)	1161 (0.48%)	17 (0.51%)
Carotid artery disease	1 (0.09%)	1 (0.02%)	11 (0.04%)	3 (0.03%)	203 (0.08%)	2 (0.06%)
Stroke	5 (0.43%)	18 (0.33%)	85 (0.33%)	19 (0.17%)	614 (0.25%)	12 (0.36%)
PVD	2 (0.17%)	2 (0.04%)	26 (0.10%)	1 (0.01%)	171 (0.07%)	1 (0.03%)
Coronary disease[6]	9 (0.77%)	28 (0.51%)	312 (1.22%)	88 (0.77%)	2392 (0.99%)	35 (1.05%)
Total cardiovascular disease	14 (1.20%)	45 (0.82%)	404 (1.58%)	110 (0.96%)	3125 (1.29%)	47 (1.41%)
Deaths						
Cardiovascular deaths	1 (0.09%)	10 (0.18%)	72 (0.28%)	14 (0.12%)	403 (0.17%)	8 (0.24%)
Cancer deaths	2 (0.17%)	16 (0.29%)	57 (0.22%)	20 (0.18%)	665 (0.28%)	12 (0.36%)
Other known cause	6 (0.52%)	4 (0.07%)	29 (0.11%)	7 (0.06%)	273 (0.11%)	5 (0.15%)
Unknown cause	0 (0.00%)	1 (0.02%)	11 (0.04%)	0 (0.00%)	35 (0.01%)	1 (0.03%)
Not yet adjudicated	1 (0.09%)	2 (0.04%)	12 (0.05%)	5 (0.04%)	200 (0.08%)	5 (0.15%)
Total death	10 (0.86%)	33 (0.60%)	181 (0.71%)	46 (0.40%)	1576 (0.65%)	31 (0.93%)

[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
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 18, 2006

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	36282	5153	8269	16519	6341
Mean follow-up (months)	95.5	101.6	98.5	94.0	90.5
Hospitalizations					
Ever	18122 (6.28%)	1884 (4.32%)	3453 (5.09%)	8695 (6.72%)	4090 (8.55%)
Two or more	9753 (3.38%)	794 (1.82%)	1704 (2.51%)	4752 (3.67%)	2503 (5.23%)
Other					
DVT[1]	420 (0.15%)	24 (0.06%)	77 (0.12%)	184 (0.15%)	135 (0.29%)
Pulmonary embolism	280 (0.10%)	22 (0.05%)	51 (0.08%)	144 (0.11%)	63 (0.13%)
Diabetes (treated)	3081 (1.11%)	460 (1.08%)	679 (1.04%)	1434 (1.16%)	508 (1.12%)
Gallbladder disease[2, 3]	2485 (1.07%)	367 (0.99%)	602 (1.08%)	1157 (1.13%)	359 (0.96%)
Hysterectomy	1067 (0.63%)	144 (0.57%)	264 (0.63%)	501 (0.67%)	158 (0.59%)
Glaucoma[3]	3730 (1.40%)	401 (0.97%)	770 (1.22%)	1773 (1.50%)	786 (1.84%)
Osteoporosis[3]	7136 (2.72%)	736 (1.79%)	1362 (2.17%)	3451 (2.95%)	1587 (3.81%)
Osteoarthritis[4]	7277 (4.03%)	1110 (3.39%)	1712 (3.66%)	3307 (4.30%)	1148 (4.69%)
Rheumatoid arthritis[3]	1879 (0.71%)	267 (0.66%)	435 (0.69%)	834 (0.71%)	343 (0.79%)
Intestinal polyps	5918 (2.20%)	782 (1.85%)	1330 (2.05%)	2851 (2.38%)	955 (2.24%)
Lupus	352 (0.12%)	57 (0.13%)	82 (0.12%)	149 (0.12%)	64 (0.13%)
Kidney stones[3, 4]	819 (0.34%)	111 (0.32%)	180 (0.32%)	383 (0.35%)	145 (0.36%)
Cataracts[3, 4]	11122 (5.28%)	818 (2.38%)	2096 (3.91%)	5937 (6.24%)	2271 (8.25%)
Pills for hypertension	10260 (4.97%)	1384 (3.88%)	2315 (4.42%)	4734 (5.32%)	1827 (6.20%)

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)	93.6	90.9	92.7	91.3	96.2	90.6
Hospitalizations						
Ever	71 (6.11%)	264 (4.84%)	1652 (6.45%)	601 (5.26%)	15324 (6.34%)	210 (6.32%)
Two or more	50 (4.30%)	118 (2.16%)	921 (3.60%)	282 (2.47%)	8263 (3.42%)	119 (3.58%)
Other						
DVT[1]	4 (0.35%)	1 (0.02%)	40 (0.16%)	9 (0.08%)	362 (0.15%)	4 (0.12%)
Pulmonary embolism	3 (0.26%)	0 (0.00%)	27 (0.11%)	4 (0.04%)	242 (0.10%)	4 (0.12%)
Diabetes (treated)	13 (1.20%)	77 (1.50%)	454 (1.98%)	203 (1.89%)	2285 (0.98%)	49 (1.58%)
Gallbladder disease[2, 3]	10 (1.17%)	39 (0.82%)	169 (0.76%)	121 (1.43%)	2118 (1.10%)	28 (1.04%)
Hysterectomy	2 (0.41%)	17 (0.48%)	54 (0.49%)	38 (0.60%)	949 (0.65%)	7 (0.37%)
Glaucoma[3]	20 (1.88%)	59 (1.18%)	472 (2.05%)	177 (1.66%)	2969 (1.33%)	33 (1.09%)
Osteoporosis[3]	30 (2.81%)	156 (3.10%)	409 (1.73%)	299 (2.90%)	6160 (2.81%)	82 (2.76%)
Osteoarthritis[4]	42 (5.70%)	144 (3.61%)	652 (4.19%)	352 (4.50%)	5987 (3.98%)	100 (4.58%)
Rheumatoid arthritis	17 (1.71%)	29 (0.58%)	304 (1.34%)	152 (1.45%)	1349 (0.61%)	28 (0.94%)
Intestinal polyps	34 (3.18%)	94 (1.87%)	577 (2.41%)	193 (1.76%)	4953 (2.20%)	67 (2.19%)
Lupus	4 (0.35%)	3 (0.06%)	41 (0.16%)	16 (0.14%)	286 (0.12%)	2 (0.06%)
Kidney stones[3, 4]	7 (0.74%)	18 (0.39%)	73 (0.35%)	46 (0.49%)	667 (0.33%)	8 (0.29%)
Cataracts[3, 4]	51 (5.84%)	178 (4.42%)	909 (4.79%)	440 (4.95%)	9409 (5.36%)	135 (5.42%)
Pills for hypertension	37 (5.06%)	178 (4.73%)	928 (6.98%)	471 (5.35%)	8538 (4.80%)	108 (5.13%)

[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

Data as of August 18, 2006

	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 18, 2006; Extension Participants Only

	OS Participants (N = 63,134)	
	N	%
Vital Status/Participation		
Deceased	470	0.7
Alive: Current Participation[1]	61332	97.1
Alive: Recent Participation[2]	1054	1.7
Alive: Past/Unknown Participation[3]	164	0.3
Stopped Follow-Up[4]	112	0.2
Lost to Follow-Up[5]	2	<0.1

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 18, 2006

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number enrolled	93676	12381	17329	41200	22766
Mean follow-up (months)	101.5	107.0	105.6	101.1	96.3
Cardiovascular					
CHD[1]	2575 (0.32%)	89 (0.08%)	201 (0.13%)	1026 (0.30%)	1259 (0.69%)
CHD death[2]	849 (0.11%)	21 (0.02%)	42 (0.03%)	277 (0.08%)	509 (0.28%)
Clinical MI	1979 (0.25%)	74 (0.07%)	171 (0.11%)	829 (0.24%)	905 (0.50%)
Angina	2836 (0.36%)	124 (0.11%)	318 (0.21%)	1320 (0.38%)	1074 (0.59%)
CABG/PTCA	3268 (0.41%)	123 (0.11%)	333 (0.22%)	1570 (0.45%)	1242 (0.68%)
Carotid artery disease	592 (0.07%)	29 (0.03%)	49 (0.03%)	251 (0.07%)	263 (0.14%)
Congestive heart failure	2304 (0.29%)	81 (0.07%)	174 (0.11%)	886 (0.26%)	1163 (0.64%)
Stroke	2043 (0.26%)	52 (0.05%)	163 (0.11%)	796 (0.23%)	1032 (0.57%)
PVD	551 (0.07%)	17 (0.02%)	50 (0.03%)	233 (0.07%)	251 (0.14%)
Coronary disease[3]	6939 (0.88%)	278 (0.25%)	660 (0.43%)	2994 (0.86%)	3007 (1.65%)
Total cardiovascular disease	9449 (1.19%)	359 (0.33%)	873 (0.57%)	4001 (1.15%)	4216 (2.31%)
Cancer					
Breast cancer	4241 (0.54%)	467 (0.42%)	730 (0.48%)	1959 (0.56%)	1085 (0.59%)
Invasive breast cancer	3530 (0.45%)	379 (0.34%)	597 (0.39%)	1624 (0.47%)	930 (0.51%)
Non-invasive breast cancer	734 (0.09%)	94 (0.09%)	136 (0.09%)	344 (0.10%)	160 (0.09%)
Ovarian cancer	374 (0.05%)	38 (0.03%)	64 (0.04%)	169 (0.05%)	103 (0.06%)
Endometrial cancer[4]	573 (0.07%)	47 (0.04%)	91 (0.06%)	264 (0.08%)	171 (0.09%)
Colorectal cancer	922 (0.12%)	51 (0.05%)	98 (0.06%)	413 (0.12%)	360 (0.20%)
Other cancer[5]	4149 (0.52%)	286 (0.26%)	543 (0.36%)	1901 (0.55%)	1419 (0.78%)
Total cancer	9765 (1.23%)	858 (0.78%)	1460 (0.96%)	4475 (1.29%)	2972 (1.63%)
Fractures					
Hip fracture	1198 (0.15%)	31 (0.03%)	75 (0.05%)	392 (0.11%)	700 (0.38%)
Deaths					
Cardiovascular deaths	1842 (0.23%)	46 (0.04%)	105 (0.07%)	594 (0.17%)	1097 (0.60%)
Cancer deaths	2707 (0.34%)	150 (0.14%)	315 (0.21%)	1178 (0.34%)	1064 (0.58%)
Other known cause	1398 (0.18%)	61 (0.06%)	119 (0.08%)	506 (0.15%)	712 (0.39%)
Unknown cause	238 (0.03%)	12 (0.01%)	19 (0.01%)	90 (0.03%)	117 (0.06%)
Not yet adjudicated	648 (0.08%)	29 (0.03%)	54 (0.04%)	251 (0.07%)	314 (0.17%)
Total death	6833 (0.86%)	298 (0.27%)	612 (0.40%)	2619 (0.75%)	3304 (1.81%)

[1] "CHD" includes clinical MI and CHD death.
[2] "CHD death" includes definite and possible CHD death.
[3] "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.
[4] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[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 5.3 (continued)
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for OS Participants

Data as of August 18, 2006

Outcomes	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)	93.5	96.1	93.6	90.3	103.1	97.6
Cardiovascular						
CHD[1]	16 (0.49%)	43 (0.20%)	238 (0.40%)	46 (0.17%)	2194 (0.33%)	38 (0.35%)
CHD death[2]	9 (0.27%)	16 (0.07%)	117 (0.20%)	14 (0.05%)	677 (0.10%)	16 (0.15%)
Clinical MI	9 (0.27%)	32 (0.15%)	148 (0.25%)	37 (0.14%)	1726 (0.26%)	27 (0.25%)
Angina	18 (0.55%)	40 (0.19%)	250 (0.42%)	80 (0.29%)	2414 (0.36%)	34 (0.32%)
CABG/PTCA	17 (0.52%)	47 (0.22%)	208 (0.35%)	81 (0.30%)	2869 (0.43%)	46 (0.43%)
Carotid artery disease	3 (0.09%)	6 (0.03%)	25 (0.04%)	11 (0.04%)	536 (0.08%)	11 (0.10%)
Congestive heart failure	16 (0.49%)	22 (0.10%)	235 (0.39%)	42 (0.15%)	1955 (0.29%)	34 (0.32%)
Stroke	12 (0.37%)	50 (0.23%)	202 (0.34%)	45 (0.17%)	1702 (0.25%)	32 (0.30%)
PVD	3 (0.09%)	4 (0.02%)	59 (0.10%)	6 (0.02%)	467 (0.07%)	12 (0.11%)
Coronary disease[3]	44 (1.34%)	100 (0.47%)	632 (1.06%)	163 (0.60%)	5909 (0.88%)	91 (0.84%)
Total cardiovascular disease	53 (1.62%)	159 (0.74%)	873 (1.47%)	216 (0.80%)	8011 (1.19%)	137 (1.27%)
Cancer						
Breast cancer	12 (0.37%)	92 (0.43%)	281 (0.47%)	102 (0.38%)	3711 (0.55%)	43 (0.40%)
Invasive breast cancer	11 (0.34%)	77 (0.36%)	227 (0.38%)	85 (0.31%)	3093 (0.46%)	37 (0.34%)
Non-invasive breast cancer	1 (0.03%)	16 (0.07%)	56 (0.09%)	18 (0.07%)	636 (0.09%)	7 (0.06%)
Ovarian cancer	1 (0.03%)	5 (0.02%)	19 (0.03%)	12 (0.04%)	335 (0.05%)	2 (0.02%)
Endometrial cancer[4]	0 (0.00%)	9 (0.04%)	19 (0.03%)	9 (0.03%)	526 (0.08%)	10 (0.09%)
Colorectal cancer	3 (0.09%)	16 (0.07%)	99 (0.17%)	21 (0.08%)	772 (0.12%)	11 (0.10%)
Other cancer[5]	15 (0.46%)	77 (0.36%)	269 (0.45%)	81 (0.30%)	3649 (0.54%)	58 (0.54%)
Total cancer	31 (0.94%)	189 (0.88%)	654 (1.10%)	219 (0.81%)	8557 (1.28%)	115 (1.07%)
Fractures						
Hip fracture	5 (0.15%)	12 (0.06%)	26 (0.04%)	12 (0.04%)	1125 (0.17%)	18 (0.17%)
Deaths						
Cardiovascular deaths	14 (0.43%)	42 (0.20%)	224 (0.38%)	39 (0.14%)	1492 (0.22%)	31 (0.29%)
Cancer deaths	12 (0.37%)	55 (0.26%)	223 (0.37%)	66 (0.24%)	2317 (0.35%)	34 (0.32%)
Other known cause	21 (0.64%)	28 (0.13%)	128 (0.21%)	58 (0.21%)	1147 (0.17%)	16 (0.15%)
Unknown cause	1 (0.03%)	5 (0.02%)	45 (0.08%)	9 (0.03%)	175 (0.03%)	3 (0.03%)
Not yet adjudicated	5 (0.15%)	5 (0.02%)	46 (0.08%)	15 (0.06%)	569 (0.08%)	8 (0.07%)
Total death	53 (1.62%)	135 (0.63%)	666 (1.12%)	187 (0.69%)	5700 (0.85%)	92 (0.85%)

[1] "CHD" includes clinical MI and CHD death.
[2] "CHD death" includes definite and possible CHD death.
[3] "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.
[4] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[5] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin.

Table 5.4
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 18, 2006

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	93676	12381	17329	41200	22766
Mean follow-up (months)	101.5	107.0	105.6	101.1	96.3
Hospitalizations					
Ever	47067 (5.94%)	4351 (3.94%)	7001 (4.59%)	21304 (6.14%)	14411 (7.89%)
Two or more	25316 (3.19%)	1894 (1.71%)	3209 (2.10%)	11416 (3.29%)	8797 (4.82%)
Other					
DVT[1]	849 (0.11%)	56 (0.05%)	104 (0.07%)	386 (0.12%)	303 (0.17%)
Pulmonary embolism	554 (0.07%)	49 (0.04%)	74 (0.05%)	247 (0.07%)	184 (0.10%)
Diabetes (treated)	5768 (0.76%)	724 (0.67%)	1073 (0.73%)	2635 (0.79%)	1336 (0.76%)
Gallbladder disease[2,3]	5690 (0.95%)	835 (0.96%)	1153 (0.99%)	2549 (0.99%)	1153 (0.85%)
Hysterectomy	3685 (0.47%)	504 (0.46%)	692 (0.45%)	1705 (0.49%)	784 (0.43%)
Glaucoma[3]	8516 (1.26%)	852 (0.88%)	1379 (1.05%)	3910 (1.32%)	2375 (1.56%)
Osteoporosis[3]	20767 (3.20%)	2110 (2.22%)	3384 (2.63%)	9540 (3.39%)	5733 (4.01%)
Osteoarthritis[4]	17424 (3.78%)	2303 (2.89%)	3300 (3.30%)	7816 (4.03%)	4005 (4.56%)
Rheumatoid arthritis[3]	4607 (0.69%)	638 (0.67%)	885 (0.68%)	1898 (0.65%)	1186 (0.76%)
Intestinal polyps	14625 (2.04%)	1758 (1.67%)	2893 (2.03%)	6813 (2.19%)	3161 (2.01%)
Lupus	1001 (0.13%)	143 (0.13%)	200 (0.13%)	440 (0.13%)	218 (0.12%)
Kidney stones[3,4]	2327 (0.39%)	292 (0.36%)	436 (0.39%)	996 (0.38%)	603 (0.43%)
Cataracts[3,4]	27206 (5.32%)	1735 (2.13%)	4109 (3.71%)	14089 (6.17%)	7273 (8.06%)
Pills for hypertension	23600 (4.16%)	2774 (3.02%)	4214 (3.54%)	10493 (4.34%)	6119 (5.33%)

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)	93.5	96.1	93.6	90.3	103.1	97.6
Hospitalizations						
Ever	227 (6.92%)	863 (4.04%)	3629 (6.09%)	1344 (4.95%)	40382 (6.02%)	622 (5.77%)
Two or more	129 (3.93%)	356 (1.67%)	1923 (3.23%)	599 (2.21%)	21978 (3.28%)	331 (3.07%)
Other						
DVT[1]	4 (0.13%)	5 (0.02%)	79 (0.14%)	11 (0.04%)	739 (0.11%)	11 (0.11%)
Pulmonary embolism	2 (0.06%)	4 (0.02%)	39 (0.07%)	5 (0.02%)	500 (0.08%)	4 (0.04%)
Diabetes (treated)	51 (1.81%)	200 (0.98%)	838 (1.59%)	351 (1.39%)	4229 (0.65%)	99 (0.96%)
Gallbladder disease[2,3]	31 (1.31%)	81 (0.45%)	377 (0.78%)	232 (1.19%)	4892 (0.98%)	77 (0.95%)
Hysterectomy	17 (0.52%)	69 (0.32%)	227 (0.38%)	165 (0.61%)	3148 (0.47%)	59 (0.55%)
Glaucoma[3]	45 (1.63%)	253 (1.35%)	997 (1.98%)	312 (1.32%)	6787 (1.19%)	122 (1.31%)
Osteoporosis[3]	92 (3.35%)	630 (3.50%)	1078 (2.07%)	739 (3.21%)	17902 (3.29%)	326 (3.66%)
Osteoarthritis[4]	63 (3.45%)	538 (3.57%)	1360 (3.94%)	771 (4.32%)	14429 (3.74%)	263 (4.01%)
Rheumatoid arthritis[3]	38 (1.38%)	98 (0.52%)	664 (1.33%)	385 (1.66%)	3333 (0.59%)	89 (0.98%)
Intestinal polyps	51 (1.70%)	356 (1.86%)	1149 (2.11%)	441 (1.74%)	12444 (2.06%)	184 (1.90%)
Lupus	8 (0.25%)	18 (0.08%)	104 (0.18%)	50 (0.19%)	806 (0.12%)	15 (0.14%)
Kidney stones[3,4]	18 (0.72%)	41 (0.24%)	266 (0.56%)	125 (0.58%)	1832 (0.36%)	45 (0.54%)
Cataracts[3,4]	105 (4.88%)	685 (4.89%)	1951 (4.78%)	905 (4.56%)	23165 (5.42%)	395 (5.65%)
Pills for hypertension	102 (4.85%)	617 (4.10%)	1740 (5.95%)	939 (4.61%)	19842 (4.02%)	360 (4.77%)

[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 5.5
First Reported Verified Outcomes Before and After AV-3[1] for OS Participants

Data as of August 18, 2006

Outcome	Number of Events	
	Before AV-3	After AV-3
Cardiovascular		
CHD[2]	759	1816
CHD death[3]	177	672
Clinical MI	639	1340
Angina	1270	1566
CABG/PTCA	1165	2103
Carotid artery disease	225	367
Congestive heart failure	719	1585
Stroke	596	1447
PVD	196	355
Coronary disease[4]	2584	4355
Total cardiovascular disease	3465	5984
Cancer		
Breast cancer	1604	2637
Invasive breast cancer	1335	2195
Non-invasive breast cancer	275	459
Ovarian cancer	136	238
Endometrial cancer	214	359
Colorectal cancer	333	589
Other cancer[5]	1433	2716
Total cancer	3643	6122
Fractures		
Hip fracture	295	903
Deaths		
Cardiovascular deaths	367	1475
Cancer deaths	616	2091
Deaths: other known cause	223	1175
Deaths: unknown cause	58	180
Deaths: not yet adjudicated	1	647
Total death	1265	5568

[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 5.6
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 18, 2006

Outcome	Number of Events	
	Before AV-3	After AV-3
Ever hospitalized	19160	27907
DVT[2]	227	622
Pulmonary embolism	130	424
Diabetes (treated)	1740	4028
Gallbladder disease[3, 4]	2137	3553
Hysterectomy	1358	2327
Glaucoma[4]	2755	5761
Osteoporosis[4]	8703	12064
Osteoarthritis[5]	6339	11085
Rheumatoid arthritis[4]	1723	2884
Intestinal polyps	4397	10228
Lupus	348	653
Kidney stones[4, 5]	646	1681
Cataracts[4, 5]	9145	18061
Pills for hypertension	8141	15459

[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 18, 2006

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	68132	9188	14661	31389	12894
Mean follow-up (months)	106.3	113.3	109.7	104.9	100.8
Cardiovascular					
CHD[1]	2281 (0.38%)	121 (0.14%)	259 (0.19%)	1047 (0.38%)	854 (0.79%)
CHD death[2]	656 (0.11%)	30 (0.03%)	48 (0.04%)	282 (0.10%)	296 (0.27%)
Total MI[3]	1827 (0.30%)	95 (0.11%)	222 (0.17%)	843 (0.31%)	667 (0.62%)
Clinical MI	1747 (0.29%)	89 (0.10%)	214 (0.16%)	805 (0.29%)	639 (0.59%)
Angina[4]	2413 (0.40%)	129 (0.15%)	331 (0.25%)	1213 (0.44%)	740 (0.68%)
CABG/PTCA	2859 (0.47%)	136 (0.16%)	373 (0.28%)	1461 (0.53%)	889 (0.82%)
Carotid artery disease	467 (0.08%)	14 (0.02%)	54 (0.04%)	243 (0.09%)	156 (0.14%)
Congestive heart failure[4]	1750 (0.29%)	81 (0.09%)	172 (0.13%)	746 (0.27%)	751 (0.69%)
Stroke	1606 (0.27%)	58 (0.07%)	160 (0.12%)	730 (0.27%)	658 (0.61%)
PVD	425 (0.07%)	21 (0.02%)	52 (0.04%)	210 (0.08%)	142 (0.13%)
Coronary disease[5]	6076 (1.01%)	334 (0.39%)	764 (0.57%)	2917 (1.06%)	2061 (1.90%)
Total cardiovascular disease	7898 (1.31%)	403 (0.46%)	971 (0.72%)	3792 (1.38%)	2732 (2.52%)
Cancer					
Breast cancer	2964 (0.49%)	340 (0.39%)	639 (0.48%)	1399 (0.51%)	586 (0.54%)
Invasive breast cancer	2380 (0.39%)	250 (0.29%)	521 (0.39%)	1127 (0.41%)	482 (0.44%)
Non-invasive breast cancer	610 (0.10%)	93 (0.11%)	124 (0.09%)	284 (0.10%)	109 (0.10%)
Ovary cancer	243 (0.04%)	23 (0.03%)	51 (0.04%)	116 (0.04%)	53 (0.05%)
Endometrial cancer[6]	376 (0.06%)	36 (0.04%)	88 (0.07%)	186 (0.07%)	66 (0.06%)
Colorectal cancer	734 (0.12%)	41 (0.05%)	106 (0.08%)	365 (0.13%)	222 (0.20%)
Other cancer[7]	2996 (0.50%)	228 (0.26%)	486 (0.36%)	1477 (0.54%)	805 (0.74%)
Total cancer	6992 (1.16%)	644 (0.74%)	1317 (0.98%)	3375 (1.23%)	1656 (1.53%)
Fractures					
Hip fracture	834 (0.14%)	16 (0.02%)	53 (0.04%)	301 (0.11%)	464 (0.43%)
Deaths					
Cardiovascular deaths	1167 (0.19%)	48 (0.06%)	80 (0.06%)	471 (0.17%)	568 (0.52%)
Cancer deaths	1689 (0.28%)	96 (0.11%)	227 (0.17%)	825 (0.30%)	541 (0.50%)
Other known cause	773 (0.13%)	40 (0.05%)	82 (0.06%)	314 (0.11%)	337 (0.31%)
Unknown cause	109 (0.02%)	5 (0.01%)	9 (0.01%)	54 (0.02%)	41 (0.04%)
Not yet adjudicated	429 (0.07%)	22 (0.03%)	43 (0.03%)	189 (0.07%)	175 (0.16%)
Total death	4167 (0.69%)	211 (0.24%)	441 (0.33%)	1853 (0.68%)	1662 (1.53%)

[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 6.1 (continued)
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for CT Participants

Data as of: August 18, 2006

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)	101.8	102.3	103.3	99.5	107.2	101.3
Cardiovascular						
CHD[1]	8 (0.32%)	28 (0.22%)	234 (0.39%)	48 (0.20%)	1927 (0.39%)	36 (0.45%)
CHD death[2]	2 (0.08%)	8 (0.06%)	101 (0.17%)	13 (0.05%)	520 (0.10%)	12 (0.15%)
Total MI[3]	7 (0.28%)	25 (0.19%)	163 (0.27%)	39 (0.16%)	1563 (0.32%)	30 (0.38%)
Clinical MI	7 (0.28%)	24 (0.19%)	158 (0.26%)	37 (0.16%)	1493 (0.30%)	28 (0.35%)
Angina[4]	12 (0.48%)	30 (0.23%)	298 (0.50%)	80 (0.34%)	1963 (0.40%)	30 (0.38%)
CABG/PTCA	12 (0.48%)	26 (0.20%)	264 (0.44%)	74 (0.31%)	2450 (0.49%)	33 (0.42%)
Carotid artery disease	3 (0.12%)	2 (0.02%)	29 (0.05%)	4 (0.02%)	423 (0.09%)	6 (0.08%)
Congestive heart failure[5]	5 (0.20%)	17 (0.13%)	244 (0.41%)	49 (0.21%)	1411 (0.28%)	24 (0.30%)
Stroke	7 (0.28%)	31 (0.24%)	212 (0.35%)	43 (0.18%)	1290 (0.26%)	23 (0.29%)
PVD	5 (0.20%)	3 (0.02%)	62 (0.10%)	4 (0.02%)	347 (0.07%)	4 (0.05%)
Coronary disease[5]	24 (0.97%)	73 (0.56%)	713 (1.19%)	172 (0.72%)	5014 (1.01%)	80 (1.01%)
Total cardiovascular disease	34 (1.37%)	104 (0.80%)	925 (1.54%)	217 (0.91%)	6516 (1.31%)	102 (1.29%)
Cancer						
Breast cancer	7 (0.28%)	71 (0.55%)	241 (0.40%)	76 (0.32%)	2539 (0.51%)	30 (0.38%)
Invasive breast cancer	6 (0.24%)	53 (0.41%)	185 (0.31%)	61 (0.26%)	2051 (0.41%)	24 (0.30%)
Non-invasive breast cancer	1 (0.04%)	18 (0.14%)	57 (0.09%)	15 (0.06%)	513 (0.10%)	6 (0.08%)
Ovary cancer	1 (0.04%)	7 (0.05%)	15 (0.02%)	7 (0.03%)	208 (0.04%)	5 (0.06%)
Endometrial cancer[6]	1 (0.04%)	3 (0.02%)	24 (0.04%)	11 (0.05%)	331 (0.07%)	6 (0.08%)
Colorectal cancer	5 (0.20%)	13 (0.10%)	73 (0.12%)	25 (0.10%)	607 (0.12%)	11 (0.14%)
Other cancer[7]	11 (0.44%)	50 (0.39%)	220 (0.37%)	73 (0.31%)	2609 (0.53%)	33 (0.42%)
Total cancer	24 (0.97%)	139 (1.07%)	549 (0.91%)	180 (0.75%)	6022 (1.21%)	78 (0.98%)
Fractures						
Hip fracture	3 (0.12%)	7 (0.05%)	25 (0.04%)	14 (0.06%)	779 (0.16%)	6 (0.08%)
Deaths						
Cardiovascular deaths	5 (0.20%)	19 (0.15%)	169 (0.28%)	23 (0.10%)	937 (0.19%)	14 (0.18%)
Cancer deaths	9 (0.36%)	28 (0.22%)	144 (0.24%)	49 (0.21%)	1436 (0.29%)	23 (0.29%)
Other known cause	9 (0.36%)	9 (0.07%)	77 (0.13%)	17 (0.07%)	650 (0.13%)	11 (0.14%)
Unknown cause	0 (0.00%)	3 (0.02%)	23 (0.04%)	3 (0.01%)	77 (0.02%)	3 (0.04%)
Not yet adjudicated	1 (0.04%)	4 (0.03%)	38 (0.06%)	10 (0.04%)	367 (0.07%)	9 (0.11%)
Total death	24 (0.97%)	63 (0.49%)	451 (0.75%)	102 (0.43%)	3467 (0.70%)	60 (0.76%)

[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 6.2
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 18, 2006

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	68132	9188	14661	31389	12894
Mean follow-up (months)	106.3	113.3	109.7	104.9	100.8
Hospitalizations					
Ever	36466 (6.04%)	3649 (4.21%)	6552 (4.89%)	17467 (6.37%)	8798 (8.12%)
Two or more	20765 (3.44%)	1686 (1.94%)	3341 (2.49%)	10054 (3.66%)	5684 (5.25%)
Other					
DVT[1]	880 (0.15%)	51 (0.06%)	129 (0.10%)	408 (0.15%)	292 (0.28%)
Pulmonary embolism	577 (0.10%)	40 (0.05%)	85 (0.06%)	285 (0.10%)	167 (0.16%)
Diabetes (treated)	5836 (1.01%)	807 (0.96%)	1238 (0.96%)	2729 (1.05%)	1062 (1.04%)
Gallbladder disease[2,3]	5248 (1.09%)	746 (1.02%)	1195 (1.09%)	2463 (1.14%)	844 (1.00%)
Hysterectomy	2249 (0.64%)	282 (0.57%)	514 (0.62%)	1092 (0.69%)	361 (0.59%)
Glaucoma[3]	7570 (1.37%)	745 (0.91%)	1457 (1.16%)	3664 (1.46%)	1704 (1.77%)
Osteoporosis[3]	14702 (2.70%)	1453 (1.79%)	2636 (2.13%)	7143 (2.91%)	3470 (3.73%)
Osteoarthritis[4]	14126 (3.79%)	2032 (3.12%)	3171 (3.44%)	6478 (4.03%)	2445 (4.48%)
Rheumatoid arthritis[3]	4012 (0.72%)	538 (0.67%)	866 (0.70%)	1823 (0.73%)	785 (0.80%)
Intestinal polyps	11632 (2.08%)	1434 (1.71%)	2490 (1.95%)	5752 (2.27%)	1956 (2.04%)
Lupus	732 (0.12%)	111 (0.13%)	166 (0.12%)	335 (0.12%)	120 (0.11%)
Kidney stones[3,4]	1877 (0.39%)	241 (0.36%)	379 (0.36%)	898 (0.40%)	359 (0.40%)
Cataracts[3,4]	21575 (4.93%)	1468 (2.14%)	3732 (3.52%)	11651 (5.79%)	4724 (7.65%)
Pills for hypertension	19207 (4.52%)	2421 (3.45%)	4074 (3.99%)	8999 (4.82%)	3713 (5.62%)

Outcome	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)	101.8	102.3	103.3	99.5	107.2	101.3
Hospitalizations						
Ever	153 (6.17%)	590 (4.56%)	3689 (6.13%)	1223 (5.13%)	30350 (6.12%)	461 (5.82%)
Two or more	101 (4.08%)	274 (2.12%)	2155 (3.58%)	612 (2.57%)	17361 (3.50%)	262 (3.31%)
Other						
DVT[1]	4 (0.17%)	2 (0.02%)	88 (0.15%)	16 (0.07%)	760 (0.16%)	10 (0.13%)
Pulmonary embolism	4 (0.16%)	2 (0.02%)	56 (0.09%)	7 (0.03%)	502 (0.10%)	6 (0.08%)
Diabetes (treated)	26 (1.16%)	157 (1.29%)	984 (1.85%)	379 (1.70%)	4201 (0.88%)	89 (1.20%)
Gallbladder disease[2,3]	22 (1.25%)	86 (0.77%)	420 (0.81%)	243 (1.39%)	4403 (1.12%)	74 (1.14%)
Hysterectomy	6 (0.55%)	37 (0.44%)	140 (0.53%)	77 (0.58%)	1973 (0.66%)	16 (0.35%)
Glaucoma[3]	40 (1.77%)	153 (1.29%)	1008 (1.88%)	338 (1.52%)	5932 (1.30%)	99 (1.39%)
Osteoporosis[3]	66 (2.90%)	389 (3.31%)	911 (1.64%)	639 (2.99%)	12488 (2.80%)	209 (2.95%)
Osteoarthritis[4]	69 (4.64%)	337 (3.59%)	1391 (3.85%)	688 (4.21%)	11422 (3.75%)	219 (4.39%)
Rheumatoid arthritis[3]	32 (1.49%)	74 (0.62%)	683 (1.27%)	358 (1.63%)	2788 (0.61%)	77 (1.07%)
Intestinal polyps	58 (2.54%)	232 (1.96%)	1223 (2.18%)	403 (1.77%)	9562 (2.08%)	154 (2.11%)
Lupus	6 (0.24%)	12 (0.09%)	96 (0.16%)	40 (0.17%)	570 (0.12%)	8 (0.10%)
Kidney stones[3,4]	15 (0.78%)	47 (0.44%)	190 (0.39%)	100 (0.51%)	1501 (0.38%)	24 (0.37%)
Cataracts[3,4]	92 (5.14%)	428 (4.49%)	2003 (4.52%)	828 (4.44%)	17931 (5.02%)	293 (5.03%)
Pills for hypertension	80 (4.96%)	396 (4.49%)	1833 (6.09%)	871 (4.90%)	15792 (4.37%)	235 (4.47%)

[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 6.3
Verified Other Cancers (Annualized Percentages): CT and OS Participants

Data as of: August 18, 2006

	CT		OS	
Number of participants	68132		93676	
Mean follow-up time (months)	106.3		101.5	
Ppts with other cancer	2936	(0.49%)	4074	(0.51%)
Accessory sinus	1	(<0.01%)	1	(<0.01%)
Adrenal gland	1	(<0.01%)	6	(<0.01%)
Anus	12	(<0.01%)	18	(<0.01%)
Appendix	6	(<0.01%)	9	(<0.01%)
Biliary tract, parts of (other/unspecified)	40	(0.01%)	42	(0.01%)
Bladder	173	(0.03%)	218	(0.03%)
Bones/joints/articular cartilage (limbs)	4	(<0.01%)	8	(<0.01%)
Bones/joints/articular cartilage (other)	5	(<0.01%)	2	(<0.01%)
Brain	76	(0.01%)	87	(0.01%)
Cervix	50	(0.01%)	44	(0.01%)
Central Nervous System (excludes brain)	0	(0.00%)	3	(<0.01%)
Connective/subcutaneous/soft tissues	27	(<0.01%)	41	(0.01%)
Endocrine glands, related structures	6	(<0.01%)	7	(<0.01%)
Esophagus	34	(0.01%)	37	(<0.01%)
Eye and adnexa	14	(<0.01%)	13	(<0.01%)
Genital organs	35	(0.01%)	25	(<0.01%)
Kidney	135	(0.02%)	182	(0.02%)
Larynx	14	(<0.01%)	11	(<0.01%)
Leukemia	135	(0.02%)	185	(0.02%)
Liver	32	(0.01%)	41	(0.01%)
Lung	580	(0.10%)	772	(0.10%)
Lymph nodes	12	(<0.01%)	9	(<0.01%)
Lymphoma, Hodgkins	16	(<0.01%)	17	(<0.01%)
Lymphoma, Non-Hodgkins	262	(0.04%)	380	(0.05%)
Melanoma of the skin	399	(0.07%)	510	(0.06%)
Multiple myeloma	102	(0.02%)	96	(0.01%)
Oral (mouth)	21	(<0.01%)	16	(<0.01%)
Palate	5	(<0.01%)	7	(<0.01%)
Pancreas	144	(0.02%)	186	(0.02%)
Parotid gland (Stensen's duct)	9	(<0.01%)	20	(<0.01%)
Peripheral nerves and autonomic nervous system	1	(<0.01%)	5	(<0.01%)
Pyriform sinus	0	(0.00%)	4	(<0.01%)
Respiratory system, intrathoracic, other	9	(<0.01%)	16	(<0.01%)
Salivary glands, major (other/unspecified)	3	(<0.01%)	11	(<0.01%)
Stomach	44	(0.01%)	56	(0.01%)
Thyroid	86	(0.01%)	106	(0.01%)
Tongue, part of (other/unspecified)	19	(<0.01%)	21	(<0.01%)
Urinary organs (other/unspecified)	12	(<0.01%)	25	(<0.01%)
Uterus, not otherwise specified	41	(0.01%)	80	(0.01%)
Other/unknown site of cancer	245	(0.04%)	309	(0.04%)
Other/unknown cancers reported on death form	224	(0.04%)	539	(0.07%)

Table 6.4
Locally Verified Other Fractures (Annualized Percentages): CT and OS Participants

Data as of: August 18, 2006
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%)
Shaft 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	1	(<0.01%)	0	(0.00%)

Data as of August 18, 2006

	CT		OS	
Number of participants	68132		93676	
Mean follow-up time (months)	106.3		101.5	
Self-Reports				
Elbow	610	(0.10%)	766	(0.10%)
Foot	2116	(0.35%)	2680	(0.34%)
Hand	501	(0.08%)	531	(0.07%)
Hip	964	(0.16%)	1386	(0.17%)
Knee	717	(0.12%)	962	(0.12%)
Lower arm	3031	(0.50%)	3766	(0.48%)
Lower leg	2401	(0.40%)	2976	(0.38%)
Pelvis	494	(0.08%)	827	(0.10%)
Tailbone	168	(0.03%)	244	(0.03%)
Upper arm	1335	(0.22%)	1677	(0.21%)
Upper leg	329	(0.05%)	511	(0.06%)
Spine	1419	(0.24%)	2113	(0.27%)
Other	2605	(0.43%)	2805	(0.35%)
Total fracture	11942	(1.98%)	15033	(1.90%)

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

Table 6.5
Cause of Death (Annualized Percentages): CT and OS Participants

Data as of: August 18, 2006

	CT		OS	
Number Randomized	68132		93676	
Mean Follow-up Time (months)	106.3		101.5	
Total death	4167	(0.69%)	6833	(0.86%)
Adjudicated death	3738	(0.62%)	6185	(0.78%)
Centrally adjudicated death	3676	(0.61%)	206	(0.03%)
Locally adjudicated death (final)	24	(<0.01%)	5859	(0.74%)
Temporary adjudicated death	0	(0.00%)	0	(0.00%)
Identified by NDI search	38	(0.01%)	120	(0.02%)
Cardiovascular				
Atherosclerotic cardiac	656	(0.11%)	849	(0.11%)
CHD deaths locally adjudicated before 10/99	0	(0.00%)	82	(0.01%)
Definite CHD deaths	314	(0.05%)	344	(0.04%)
Possible CHD deaths	342	(0.06%)	423	(0.05%)
Cerebrovascular	282	(0.05%)	478	(0.06%)
Pulmonary embolism	38	(0.01%)	48	(0.01%)
Other cardiovascular	173	(0.03%)	381	(0.05%)
Unknown cardiovascular	18	(<0.01%)	86	(0.01%)
Total cardiovascular deaths	1167	(0.19%)	1842	(0.23%)
Cancer				
Breast cancer	110	(0.02%)	392	(0.05%)
Ovarian cancer	117	(0.02%)	190	(0.02%)
Endometrial cancer	26	(<0.01%)	50	(0.01%)
Colorectal cancer	162	(0.03%)	233	(0.03%)
Other cancer	1179	(0.20%)	1704	(0.21%)
Unknown cancer site	95	(0.02%)	138	(0.02%)
Total cancer deaths	1689	(0.28%)	2707	(0.34%)
Accident/injury				
Homicide	7	(<0.01%)	10	(<0.01%)
Accident	106	(0.02%)	118	(0.01%)
Suicide	14	(<0.01%)	26	(<0.01%)
Other injury	4	(<0.01%)	16	(<0.01%)
Total accidental deaths	131	(0.02%)	170	(0.02%)
Other				
Other known cause	642	(0.11%)	1228	(0.15%)
Unknown cause	538	(0.09%)	886	(0.11%)
Total deaths – other causes	1180	(0.20%)	2114	(0.27%)

Table 7.1
Form 33/33D - Medical History Update/(Detail) Workload
Data as of 8-15-06

	Form 33 - Medical History Update 5-1-05 thru 4-30-06									Form 33D - Medical History Update (Detail) Cummulative							
	Total		CCC Mailings Not Collected		FC Collections # Due Not Collected			Outstanding Info Errors (Cum)		# Due	Missing		Incomplete		Ave Coll'd per Month last 6 mo	Form 33D Workload (miss + incomp)	
	# Due	% Collected	#	%	#	#	%	#	%		#	%	#	%	#	# cases	# months
Atlanta	3,031	92.2	261	8.6	25	1	4.0	105	3.8	419	33	7.9	2	0.5	37	35	1.0
Birmingham	2,558	93.5	329	12.9	166	3	1.8			376	1	0.3	1	0.3	38	2	0.1
Bowman	2,520	94.8	172	6.8	43	3	7.0	1	0.0	376	6	1.6	1	0.3	34	7	0.2
Brigham	4,074	97.9	159	3.9	77	5	6.5	3	0.1	595	10	1.7			52	10	0.2
Buffalo	2,975	97.2	159	5.3	78	2	2.6	2	0.1	458	2	0.4			42	2	0.0
ChapelHill	2,731	96.4	186	6.8	92	4	4.3	7	0.3	381	7	1.8			34	7	0.2
Chicago-Rush	1,829	89.5	234	12.8	44	2	4.5	5	0.3	270	37	13.7	1	0.4	30	38	1.3
Chicago	2,513	96.4	121	4.8	31	1	3.2	6	0.2	447	34	7.6			40	34	0.8
Cincinnati	2,686	95.2	160	6.0	30			5	0.2	415	56	13.5			40	56	1.4
Columbus	2,798	97.7	114	4.1	51	1	2.0	7	0.3	451	6	1.3			44	6	0.1
Detroit	2,246	94.9	184	8.2	71	1	1.4	2	0.1	349	10	2.9			32	10	0.3
Gainesville	3,776	94.5	390	10.3	187	3	1.6	1	0.0	637	5	0.8	7	1.1	63	12	0.2
GWU-DC	2,804	95.2	183	6.5	51	2	3.9	20	0.7	355	16	4.5			39	16	0.4
Honolulu	1,913	95.5	138	7.2	54	2	3.7			195					23		
Houston	2,157	95.1	129	6.0	25	1	4.0	30	1.5	327	28	8.6			29	28	1.0
IC-Bettendorf	1,948	98.5	60	3.1	36	5	13.9	1	0.1	316	12	3.8			26	12	0.5
IC-Des Moines	1,945	98.2	49	2.5	14			6	0.3	290	24	8.3			25	24	1.0
Irvine	2,836	96.3	136	4.8	32			3	0.1	326	13	4.0	3	1.0	36	16	0.4
LA	2,725	96.0	161	5.9	54	2	3.7	1	0.0	369	40	10.8			34	40	1.2
LaJolla	2,940	93.3	201	6.8	5			21	0.8	412	40	9.7			63	40	0.6
Madison	2,659	97.0	100	3.8	21	1	4.8	3	0.1	404	20	5.0			45	20	0.4
Medlantic	2,490	92.4	339	13.6	153	4	2.6	5	0.2	350	6	1.7			34	6	0.2
Memphis	2,302	95.0	202	8.8	92	6	6.5	4	0.2	292	3	1.0			28	3	0.1
Miami	1,598	89.8	203	12.7	40			1	0.1	190	14	7.4			21	14	0.7
Milwaukee	2,808	98.0	71	2.5	16			7	0.3	442	6	1.4			41	6	0.1

Table 7.1 (continued)
Form 33/33D - Medical History Update/(Detail) Workload
Data as of 8-15-06

	Form 33 - Medical History Update 5-1-05 thru 4-30-06									Form 33D - Medical History Update (Detail) Cummulative							
	Total		CCC Mailings Not Collected		FC Collections # Due Not Collected			Outstanding Info Errors (Cum)		# Due	Missing		Incomplete		Ave Coll'd per Month last 6 mo	Form 33D Workload (miss + incomp)	
	# Due	% Collected	#	%	#	#	%	#	%		#	%	#	%	#	# cases	# months
Minneapolis	3,426	97.3	114	3.3	26	3	11.5	2	0.1	471	22	4.7			44	22	0.5
Nevada	2,613	95.8	164	6.3	62	8	12.9	2	0.1	396	11	2.8			40	11	0.3
Newark	2,840	94.3	220	7.7	62	3	4.8	4	0.1	409	15	3.7			41	15	0.4
New Brunswick	1,169	92.4	135	11.5	49	3	6.1	36	3.3	155	26	16.8			11	26	2.4
NYC	2,823	94.6	301	10.7	164	15	9.1	2	0.1	410	4	1.0			36	4	0.1
Oakland	2,665	97.3	135	5.1	64	2	3.1	6	0.2	327	4	1.2			30	4	0.1
Pawtucket	4,666	94.7	337	7.2	90	2	2.2	14	0.3	737	29	3.9			78	29	0.4
Pittsburgh	2,649	96.0	161	6.1	57	2	3.5	4	0.2	510	5	1.0			53	5	0.1
Portland	2,771	94.5	156	5.6	3			81	3.1	375	20	5.3			39	20	0.5
San Antonio	1,745	92.8	137	7.9	13	1	7.7			101	8	7.9			8	8	1.0
Seattle	2,307	96.0	96	4.2	3					333	2	0.6			28	2	0.1
Stanford	3,325	97.3	164	4.9	79	5	6.3	1	0.0	461	2	0.4			42	2	0.0
StonyBrook	2,451	96.2	155	6.3	67	4	6.0	3	0.1	484	5	1.0			50	5	0.1
Torrance	1,454	93.7	130	8.9	43	4	9.3	71	5.2	188	9	4.8			17	9	0.5
Tucson	2,964	94.2	234	7.9	71	9	12.7	21	0.8	457	24	5.3			45	24	0.5
UCDavis	2,737	95.5	155	5.7	32			52	2.0	398	47	11.8	1	0.3	43	48	1.1
Worcester	3,047	97.2	165	5.4	84	3	3.6	10	0.3	436	5	1.1			39	5	0.1
All FCs	110,514	95.4	7,400	6.7	2,457	113	4.6	555	0.5	16,090	667	4.1	16	0.1	1,566	683	0.4

1- Excludes absolutely no contact and deceased participants

Table 7.2
Outcomes Processing Workload
Data as of 8-15-06

	Open Cases						Closed Cases	Outcomes Workload			Deaths			
	Open Cases	No Docs Request	No Docs Receive	No Docs Process	≥ 1 Doc Process	Open > 12 Mos	Ave # Closed Mo last 6 mo	Est # Months to Process Open Cases	Est Workload for Open cases and Form 33D		Cum[1] (Ext)	Unresolved[1] (Ext)		# Open cases with Deaths
	#	#	#	#	#	#			# cases	# months	#	#	%	
Atlanta	101	31	62	7	1	24	35	2.9	136	3.9	16	8	50.0	10
Birmingham	40	4	34		2	2	37	1.1	42	1.1	22	7	31.8	12
Bowman	66	35	30	1		6	36	1.8	73	2.0	23	10	43.5	13
Brigham	93	13	80			2	40	2.4	103	2.5	16	8	50.0	18
Buffalo	107	15	72	19	1	1	43	2.5	109	2.5	23	10	43.5	16
ChapelHill	29	4	19	6			31	0.9	36	1.1	18	2	11.1	5
Chicago-Rush	121	25	88	7	1		24	5.1	159	6.4	9	8	88.9	12
Chicago	88	14	52	22		1	35	2.5	122	3.3	26	17	65.4	25
Cincinnati	78	5	72	1		1	44	1.8	134	3.2	21	14	66.7	10
Columbus	48	2	45	1		1	53	0.9	54	1.0	27	8	29.6	16
Detroit	85	20	56	9		4	28	3.1	95	3.4	9	5	55.6	6
Gainesville	165	56	95	14		1	65	2.6	177	2.7	22	10	45.5	19
GWU-DC	96	13	77	6		1	27	3.5	112	3.9	19	12	63.2	21
Honolulu	12	1	10	1			18	0.7	12	0.7	8	2	25.0	3
Houston	126	29	85	11	1		18	7.1	154	8.0	11	11	100.0	14
IC-Bettendorf	45	9	31	5			23	2.0	57	2.4	8	4	50.0	4
IC-Des Moines	64	10	43	10	1	2	22	2.9	88	3.8	7	3	42.9	12
Irvine	85	31	49	5		2	19	4.5	101	5.0	15	14	93.3	16
LA	105	17	69	19		21	26	4.1	145	5.3	13	13	100.0	17
LaJolla	162	46	69	46	1	1	37	4.4	202	5.1	3	3		11
Madison	91	20	40	31			40	2.3	111	2.7	27	21	77.8	22
Medlantic	47	7	22	14	4	5	24	2.0	53	2.2	14	9	64.3	15
Memphis	29	5	23	1			28	1.0	32	1.2	23	7	30.4	20
Miami	36	18	15	3		10	16	2.3	50	3.0	9	3	33.3	7
Milwaukee	59	29	28	1	1	13	33	1.8	65	1.9	17	7	41.2	3

Table 7.2 (continued)
Outcomes Processing Workload
Data as of 8-15-06

	Open Cases						Closed Cases	Outcomes Workload			Deaths			
	Open Cases	No Docs Request	No Docs Receive	No Docs Process	≥ 1 Doc Process	Open > 12 Mos	Ave # Closed Mo last 6 mo	Est # Months to Process Open Cases	Est Workload for Open cases and Form 33D		Cum[1] (Ext)	Unresolved[1] (Ext)		# Open cases with Deaths
	#	#	#	#	#	#			# cases	# months	#	#	%	
Minneapolis	71	1	61	9			32	2.2	93	2.7	13	6	46.2	5
Nevada	164	55	95	12	2	11	33	5.0	175	5.3	30	21	70.0	30
Newark	122	33	86	2	1	2	32	3.8	137	4.2	13	13	100.0	21
New Brunswick	64	10	46	8		5	11	5.7	90	8.1	11	11	100.0	12
NYC	87	23	59	4	1	2	35	2.5	91	2.6	17	10	58.8	22
Oakland	76	3	45	28			28	2.7	80	2.9	23	16	69.6	26
Pawtucket	226	2	221	2	1	6	53	4.3	255	4.7	42	33	78.6	40
Pittsburgh	87	21	64		2	2	60	1.5	92	1.6	34	9	26.5	19
Portland	119	71	38	8	2	11	26	4.6	139	5.1	21	16	76.2	15
San Antonio	24	1	14	9			7	3.4	32	4.4	19	19	100.0	9
Seattle	48	11	14	23		1	31	1.5	50	1.6	16	8	50.0	15
Stanford	31	8	10	13			41	0.8	33	0.8	31	1	3.2	4
StonyBrook	100	11	87	1	1	2	49	2.0	105	2.1	21	9	42.9	21
Torrance	55	6	46		3	16	14	4.0	64	4.5	7	6	85.7	3
Tucson	66	11	36	18	1	5	49	1.4	90	1.9	25	9	36.0	13
UCDavis	120	90	18	11	1		27	4.5	168	5.6	31	31	100.0	24
Worcester	79	52	17	9	1	26	40	2.0	84	2.1	20	4	20.0	15
All FCs	3,517	868	2,223	397	29	163	1,364	2.6	4,200	3.0	780	438	56.2	621

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

Table 7.3
Closure Codes for Closed Outcomes Cases
Data as of 8-15-06

	Closed Cases	Forwarded to CCC C-9		Not Adjudicated C-10		Duplicate C-11		No Doc in 12 Months C-12		No ROI C13		Admin C-14	
	#	#	%	#	%	#	%	#	%	#	%	No	%
Atlanta	317	270	85.2	28	8.8	14	4.4	5	1.6				
Birmingham	334	285	85.3	44	13.2	4	1.2					1	0.3
Bowman	280	252	90.0	22	7.9	5	1.8			1	0.4		
Brigham	383	290	75.7	53	13.8	40	10.4						
Buffalo	360	314	87.2	34	9.4	10	2.8	1	0.3	1	0.3		
ChapelHill	319	304	95.3	7	2.2	7	2.2			1	0.3		
Chicago-Rush	156	99	63.5	37	23.7	10	6.4	9	5.8	1	0.6		
Chicago	332	291	87.7	21	6.3	18	5.4					2	0.6
Cincinnati	311	266	85.5	15	4.8	30	9.6						
Columbus	410	367	89.5	38	9.3	5	1.2						
Detroit	230	191	83.0	28	12.2	6	2.6	2	0.9	3	1.3		
Gainesville	503	433	86.1	48	9.5	17	3.4	5	1.0				
GWU-DC	224	176	78.6	32	14.3	12	5.4	4	1.8				
Honolulu	153	138	90.2	10	6.5	4	2.6	1	0.7				
Houston	155	127	81.9	7	4.5	9	5.8	3	1.9	9	5.8		
IC-Bettendorf	256	222	86.7	16	6.3	17	6.6	1	0.4				
IC-Des Moines	191	156	81.7	27	14.1	5	2.6	2	1.0			1	0.5
Irvine	160	130	81.3	18	11.3	10	6.3	1	0.6	1	0.6		
LA	212	167	78.8	38	17.9	4	1.9	3	1.4				
LaJolla	231	161	69.7	37	16.0	27	11.7	6	2.6				
Madison	309	256	82.8	27	8.7	16	5.2	4	1.3	6	1.9		
Medlantic	206	167	81.1	29	14.1	9	4.4	1	0.5				
Memphis	231	210	90.9	19	8.2	1	0.4			1	0.4		
Miami	147	111	75.5	29	19.7	7	4.8						
Milwaukee	308	279	90.6	25	8.1	4	1.3						

Table 7.3 (continued)
Closure Codes for Closed Outcomes Cases
Data as of 8-15-06

	Closed Cases	Forwarded to CCC C-9		Not Adjudicated C-10		Duplicate C-11		No Doc in 12 Months C-12		No ROI C13		Admin C-14	
	#	#	%	#	%	#	%	#	%	#	%	No	%
Minneapolis	268	238	88.8	21	7.8	7	2.6			2	0.7		
Nevada	298	224	75.2	54	18.1	20	6.7						
Newark	283	199	70.3	69	24.4	9	3.2	3	1.1	3	1.1		
New Brunswick	93	79	84.9	1	1.1	1	1.1	12	12.9				
NYC	287	262	91.3	14	4.9	6	2.1	3	1.0	2	0.7		
Oakland	244	190	77.9	36	14.8	18	7.4						
Pawtucket	480	409	85.2	57	11.9	9	1.9			5	1.0		
Pittsburgh	496	418	84.3	38	7.7	38	7.7			2	0.4		
Portland	248	187	75.4	30	12.1	26	10.5	3	1.2	1	0.4		
San Antonio	70	57	81.4	8	11.4	2	2.9					3	4.3
Seattle	275	220	80.0	32	11.6	17	6.2	5	1.8	1	0.4		
Stanford	395	327	82.8	46	11.6	22	5.6						
StonyBrook	435	312	71.7	70	16.1	47	10.8	1	0.2	2	0.5	3	0.7
Torrance	120	94	78.3	24	20.0	2	1.7						
Tucson	396	309	78.0	45	11.4	23	5.8	12	3.0	6	1.5	1	0.3
UCDavis	199	158	79.4	20	10.1	21	10.6						
Worcester	372	302	81.2	57	15.3	13	3.5				0		
All FCs	11,677	9,647	82.6	1,311	11.2	572	4.9	87	0.7	48	0.4	11	0.1

Table 7.4
Participant Follow-up Status[1]
Data as of 8-15-06

	# Participants	Full		Partial/Custom		Proxy		Lost		No Follow-up		Absolutely No Contact		Deceased	
		#	%	#	%	#	%	#	%	#	%	#	%	#	%
Atlanta	3,126	2,755	88.1	353	11.3					1	0.0			17	0.5
Birmingham	2,677	2,559	95.6	77	2.9	1	0.0			4	0.1	11	0.4	25	0.9
Bowman	2,660	2,533	95.2	83	3.1					13	0.5	2	0.1	29	1.1
Brigham	4,215	4,020	95.4	161	3.8	8	0.2			3	0.1	4	0.1	19	0.5
Buffalo	3,128	2,939	94.0	125	4.0	29	0.9			1	0.0	3	0.1	31	1.0
ChapelHill	2,848	2,716	95.4	86	3.0	18	0.6			3	0.1	2	0.1	23	0.8
Chicago-Rush	1,899	1,729	91.0	157	8.3			1	0.1			3	0.2	9	0.5
Chicago	2,634	2,267	86.1	325	12.3	9	0.3			2	0.1	3	0.1	28	1.1
Cincinnati	2,785	2,656	95.4	104	3.7	3	0.1							22	0.8
Columbus	2,904	2,733	94.1	137	4.7	2	0.1			1	0.0	2	0.1	29	1.0
Detroit	2,351	2,104	89.5	232	9.9	2	0.1					3	0.1	10	0.4
Gainesville	3,947	3,420	86.6	482	12.2	15	0.4					6	0.2	24	0.6
GWU-DC	2,925	2,784	95.2	108	3.7	7	0.2			2	0.1	2	0.1	22	0.8
Honolulu	1,987	1,905	95.9	69	3.5	1	0.1					4	0.2	8	0.4
Houston	2,231	2,087	93.5	129	5.8					1	0.0	2	0.1	12	0.5
Iowa City-Bettendorf	2,032	1,877	92.4	140	6.9	2	0.1					2	0.1	11	0.5
Iowa City - Des Moines	2,029	1,857	91.5	152	7.5	3	0.1			1	0.0	8	0.4	8	0.4
Irvine	2,939	2,690	91.5	221	7.5					2	0.1	9	0.3	17	0.6
LA	2,827	2,639	93.3	164	5.8	2	0.1					8	0.3	14	0.5
LaJolla	3,034	2,816	92.8	213	7.0	1	0.0					1	0.0	3	0.1
Madison	2,763	2,589	93.7	131	4.7	9	0.3			4	0.1	1	0.0	29	1.0
Medlantic	2,613	2,411	92.3	186	7.1	2	0.1							14	0.5
Memphis	2,396	2,208	92.2	151	6.3	3	0.1					9	0.4	25	1.0
Miami	1,676	1,450	86.5	211	12.6					6	0.4			9	0.5
Milwaukee	2,938	2,792	95.0	116	3.9	3	0.1					9	0.3	18	0.6

Table 7.4 (continued)
Participant Follow-up Status[1]
Data as of 8-15-06

	# Participants	Full		Partial/Custom		Proxy		Lost		No Follow-up		Absolutely No Contact		Deceased	
		#	%	#	%	#	%	#	%	#	%	#	%	#	%
Minneapolis	3,553	3,354	94.4	173	4.9	5	0.1			4	0.1			17	0.5
Nevada	2,712	2,588	95.4	80	2.9	3	0.1					1	0.0	40	1.5
Newark	2,958	2,807	94.9	132	4.5	2	0.1	1	0.0	2	0.1			14	0.5
New Brunswick	1,226	962	78.5	247	20.1	4	0.3			1	0.1			12	1.0
NYC	2,956	2,781	94.1	147	5.0							9	0.3	19	0.6
Oakland	2,776	2,717	97.9	21	0.8	8	0.3					1	0.0	29	1.0
Pawtucket	4,871	4,418	90.7	391	8.0	7	0.1			3	0.1	1	0.0	51	1.0
Pittsburgh	2,776	2,595	93.5	133	4.8	1	0.0			6	0.2	5	0.2	36	1.3
Portland	2,887	2,773	96.1	90	3.1					1	0.0	1	0.0	22	0.8
San Antonio	1,837	1,731	94.2	64	3.5	2	0.1			10	0.5	7	0.4	23	1.3
Seattle	2,427	2,180	89.8	219	9.0	8	0.3			1	0.0	1	0.0	18	0.7
Stanford	3,489	3,243	92.9	200	5.7	4	0.1			3	0.1	1	0.0	38	1.1
StonyBrook	2,550	2,405	94.3	119	4.7							2	0.1	24	0.9
Torrance	1,534	1,342	87.5	175	11.4	1	0.1	1	0.1	1	0.1	7	0.5	7	0.5
Tucson	3,109	2,710	87.2	337	10.8	6	0.2			25	0.8	4	0.1	27	0.9
UCDavis	2,880	2,594	90.1	240	8.3	1	0.0			2	0.1	10	0.3	33	1.1
Worcester	3,166	3,100	97.9	9	0.3	28	0.9			1	0.0	2	0.1	26	0.8
All FCs	115,271	106,836	92.7	7,090	6.2	200	0.2	3	0	104	0.1	146	0.1	892	0.8

1 - Follow-up Status from *Form 9-WHI ES Participation Status , Ver. 8*; Lost from *Form 23-Search to Locate*; Deceased from *Form 120-Initial Notification of Death* (all versions)

Table 7.5
Form 85 - Mammogram (HT) Task Completeness
Data as of 8-15-06

	First Mammogram			Second Mammogram			Total Collected
	# Due[1]	Missing		# Due[1,2]	Missing		
		#	%		#	%	#
Atlanta	440	21	4.8	211	52	24.6	578
Birmingham	573	18	3.1	324	66	20.4	813
Bowman	420	128	30.5	154	94	61.0	352
Brigham	658	199	30.2	270	167	61.9	562
Buffalo	572	58	10.1	253	77	30.4	690
ChapelHill	483	94	19.5	197	174	88.3	412
Chicago-Rush	349	199	57.0	96	72	75.0	174
Chicago	435	80	18.4	200	84	42.0	471
Cincinnati	438	46	10.5	237	161	67.9	468
Columbus	449	51	11.4	205	95	46.3	508
Detroit	355	73	20.6	127	48	37.8	361
Gainesville	796	106	13.3	342	138	40.4	894
GWU-DC	451	90	20.0	177	84	47.5	454
Honolulu	283	14	4.9	136	24	17.6	381
Houston	269	164	61.0	43	37	86.0	111
IC-Bettendorf	616	137	22.2	225	93	41.3	611
IC-Des Moines	615	155	25.2	221	94	42.5	587
Irvine	445	128	28.8	152	122	80.3	347
LA	404	132	32.7	126	96	76.2	302
LaJolla	323	233	72.1	46	31	67.4	105
Madison	557	116	20.8	206	81	39.3	566
Medlantic	445	91	20.4	141	77	54.6	418
Memphis	476	91	19.1	149	75	50.3	459
Miami	385	158	41.0	117	103	88.0	241
Milwaukee	584	144	24.7	237	131	55.3	546

Table 7.5 (continued)
Form 85 - Mammogram (HT) Task Completeness
Data as of 8-15-06

	First Mammogram			Second Mammogram			Total Collected
	# Due[1]	Missing		# Due[1,2]	Missing		
		#	%		#	%	#
Minneapolis	650	292	44.9	170	98	57.6	430
Nevada	476	71	14.9	144	45	31.3	504
Newark	391	124	31.7	120	73	60.8	314
New Brunswick	319	120	37.6	94	73	77.7	220
NYC	554	129	23.3	228	133	58.3	520
Oakland	507	55	10.8	141	43	30.5	550
Pawtucket	770	121	15.7	315	163	51.7	801
Pittsburgh	525	70	13.3	207	59	28.5	603
Portland	515	238	46.2	150	109	72.7	318
San Antonio	439	78	17.8	153	50	32.7	464
Seattle	538	119	22.1	189	127	67.2	481
Stanford	548	84	15.3	193	92	47.7	565
StonyBrook	398	80	20.1	143	59	41.3	402
Torrance	201	36	17.9	70	36	51.4	199
Tucson	494	58	11.7	240	75	31.3	601
UCDavis	534	45	8.4	242	56	23.1	675
Worcester	507	40	7.9	216	71	32.9	612
All FCs	20,187	4,486	22.2	7,607	3,638	47.8	19,670

1 - Excludes lost to follow-up, no follow-up, absolutely no contact, and deceased
2 - Need first mammogram before 2nd is due

Table 7.6
Form Collection: Form 134, 150, 151
Data as of 8-15-06

Collections for 5-1-05 thru 4-30-06	Form 134-Addendum to Medical History Update								
	Total		CCC Mailings Not Collected		FC Collections			Outstanding Info Errors (Cum)	
	# Due[1]	% Collected	#	%	# Due[1]	Not Collected #	Not Collected %	#	%
Atlanta	2,732	92.1	238	8.7	23			21	0.8
Birmingham	2,332	93.4	299	12.8	154	9	5.8		
Bowman	2,370	94.7	167	7.0	41				
Brigham	3,775	97.9	158	4.2	83	3	3.6		
Buffalo	2,822	97.4	147	5.2	75	1	1.3	8	0.3
ChapelHill	2,569	96.6	188	7.3	101	1	1.0		
Chicago-Rush	1,751	89.4	229	13.1	44			2	0.1
Chicago	2,370	96.5	114	4.8	30				
Cincinnati	2,512	95.2	150	6.0	30				
Columbus	2,697	97.8	106	3.9	49	1	2.0	2	0.1
Detroit	2,147	95.0	179	8.3	72				
Gainesville	3,529	94.7	375	10.6	189			3	0.1
GWU-DC	2,608	95.6	164	6.3	48			4	0.2
Honolulu	1,797	95.9	125	7.0	52				
Houston	2,040	94.8	131	6.4	24			4	0.2
IC-Bettendorf	1,879	98.6	66	3.5	39				
IC-Des Moines	1,873	98.3	45	2.4	14				
Irvine	2,681	96.2	131	4.9	30				
LA	2,535	95.9	159	6.3	55				
LaJolla	2,741	93.3	193	7.0	8				
Madison	2,518	97.2	88	3.5	19	1	5.3		
Medlantic	2,314	92.8	321	13.9	155				
Memphis	2,195	95.2	194	8.8	89	1	1.1		
Miami	1,528	89.6	192	12.6	33			2	0.1
Milwaukee	2,561	98.2	63	2.5	16			1	0.0

Table 7.6 (continued)
Form Collection: Form 134, 150, 151
Data as of 8-15-06

Collections for 5-1-05 thru 4-30-06	Form 134-Addendum to Medical History Update								
	Total		CCC Mailings Not Collected		FC Collections			Outstanding Info Errors (Cum)	
	# Due[1]	% Collected	#	%	# Due[1]	Not Collected #	%	#	%
Minneapolis	3,245	97.4	104	3.2	19				
Nevada	2,477	96.3	155	6.3	64	1	1.6	7	0.3
Newark	2,742	94.0	221	8.1	59	2	3.4		
New Brunswick	1,137	91.9	131	11.5	39			3	0.3
NYC	2,606	95.0	292	11.2	163	1	0.6		
Oakland	2,476	97.3	127	5.1	61	1	1.6		
Pawtucket	4,279	95.0	299	7.0	84				
Pittsburgh	2,505	96.2	155	6.2	59			1	0.0
Portland	2,643	94.4	149	5.6	1			15	0.6
San Antonio	1,703	92.8	140	8.2	17				
Seattle	2,255	96.0	93	4.1	2			1	0.0
Stanford	3,075	97.6	150	4.9	75				
StonyBrook	2,231	96.5	147	6.6	69				
Torrance	1,336	92.1	123	9.2	18			6	0.5
Tucson	2,714	94.3	220	8.1	66			1	0.0
UCDavis	2,596	95.5	150	5.8	33			8	0.3
Worcester	2,834	97.7	147	5.2	83	1	1.2		
All FCs	103,730	95.5	7,025	6.8	2,385	23	1.0	89	0.1

1 - Excludes absolutely no contact and deceased participants

Table 7.6 (continued)
Form Collection: Forms 134, 150, and 151
Data as of 8-15-06

Collections for 5-1-05 thru 4-30-06	Form 150- Hormone Use Update (HT)							Form 151 - Activities of Daily Living			
	Total		CCC Mailings Not Collected		FC Collections			Total		CCC Mailings Not Collected	
	# Due[1]	% Collected	#	%	# Due[1]	Not Collected #	Not Collected %	# Due[1]	% Collected	#	%
Atlanta	414	87.9	53	12.8	3			3,028	72.4	835	27.6
Birmingham	541	91.9	77	14.2	33			2,541	73.3	678	26.7
Bowman	381	88.2	48	12.6	3			2,512	71.3	721	28.7
Brigham	625	96.0	36	5.8	12	1	8.3	4,070	69.8	1,231	30.2
Buffalo	519	95.4	37	7.1	14	1	7.1	2,965	72.0	829	28.0
ChapelHill	442	93.4	48	10.9	22	3	13.6	2,726	68.3	865	31.7
Chicago-Rush	319	81.5	64	20.1	5			1,827	73.3	487	26.7
Chicago	407	92.9	34	8.4	5			2,508	72.4	692	27.6
Cincinnati	398	92.7	30	7.5	1			2,682	64.5	953	35.5
Columbus	420	97.6	19	4.5	9			2,791	68.1	890	31.9
Detroit	312	88.1	46	14.7	9			2,244	71.6	637	28.4
Gainesville	725	91.9	95	13.1	37	1	2.7	3,770	69.7	1,142	30.3
GWU-DC	421	91.4	44	10.5	8			2,796	69.1	864	30.9
Honolulu	261	90.8	36	13.8	12			1,904	68.8	595	31.3
Houston	242	89.7	33	13.6	8			2,153	62.4	809	37.6
IC-Bettendorf	568	97.4	31	5.5	17	1	5.9	1,947	66.5	653	33.5
IC-Des Moines	580	96.7	25	4.3	6			1,939	69.6	589	30.4
Irvine	414	91.3	40	9.7	4			2,830	71.4	810	28.6
LA	384	94.8	32	8.3	13	1	7.7	2,718	70.2	810	29.8
LaJolla	297	93.3	21	7.1	1			2,940	92.2	228	7.8
Madison	529	95.3	32	6.0	7			2,649	68.7	829	31.3
Medlantic	398	87.7	73	18.3	25	1	4.0	2,484	65.8	850	34.2
Memphis	450	90.2	58	12.9	14			2,295	70.7	672	29.3
Miami	350	80.3	90	25.7	21			1,589	72.2	442	27.8
Milwaukee	525	97.5	17	3.2	4			2,806	74.4	719	25.6

Table 7.6 (continued)
Form Collection: Forms 134, 150, and 151
Data as of 8-15-06

Collections for 5-1-05 thru 4-30-06	Form 150- Hormone Use Update (HT)							Form 151 - Activities of Daily Living			
	Total		CCC Mailings Not Collected		FC Collections			Total		CCC Mailings Not Collected	
	# Due[1]	% Collected	#	%	# Due[1]	Not Collected #	Not Collected %	# Due[1]	% Collected	#	%
Minneapolis	603	96.2	27	4.5	4			3,423	78.1	749	21.9
Nevada	449	92.2	48	10.7	16	3	18.8	2,606	67.2	856	32.8
Newark	356	90.7	36	10.1	3			2,839	66.2	961	33.8
New Brunswick	287	86.4	56	19.5	19	2	10.5	1,166	63.6	424	36.4
NYC	499	91.0	67	13.4	22			2,813	69.2	865	30.8
Oakland	468	97.2	27	5.8	14			2,653	68.8	829	31.2
Pawtucket	704	92.6	57	8.1	5			4,661	78.0	1,027	22.0
Pittsburgh	502	93.0	40	8.0	5			2,646	74.6	672	25.4
Portland	472	90.7	44	9.3				2,766	67.1	909	32.9
San Antonio	399	84.7	62	15.5	1			1,742	65.2	607	34.8
Seattle	494	93.1	35	7.1	1			2,305	74.4	589	25.6
Stanford	505	95.6	36	7.1	15	1	6.7	3,316	70.9	965	29.1
StonyBrook	364	94.0	40	11.0	18			2,438	66.7	812	33.3
Torrance	182	89.0	21	11.5	1			1,451	63.3	533	36.7
Tucson	450	89.3	59	13.1	11			2,953	73.3	788	26.7
UCDavis	503	94.6	32	6.4	5			2,732	77.2	622	22.8
Worcester	479	96.7	34	7.1	18			3,043	69.8	918	30.2
All FCs	18,638	92.5	1,840	9.9	451	15	3.3	110,267	71.0	31,956	29.0

1 - Excludes absolutely no contact and deceased participants

Table 7.7
CCC Data Entry Volume
9-1-05 to 8-18-06

Form	Forms					Sheets Scanned	Forms with Comments	
	Total	Key-Entered		Scanned				
	#	#	%	#	%	#	#	%
33 – Medical History Update	108,764	1,300	1.2	107,464	98.8	214,928	18,378	16.9
120 – Initial Notice of Death	204	204	100					
134 – Addendum to Medical History Update	88,512	921	1.0	87,591	99.0	87,591	116	0.1
150 – Hormone Use Update	18,404	140	0.8	18,264	99.2	73,056	80	0.4
151 – Activities of Daily Living	95,987	1,125	1.2	94,862	98.8	94,862	275	0.3
Totals	311,871	3,690	1.2	308,181	98.8	470,437	18,849	6.0

Table 7.8
Status of Adjudication
Data as of 9-1-06

Committees	Total # Cases in WHIX (from Form 33D)	Cases at FCs Not Yet Forwarded to CCC					Cases at CCC				
		Completed				Total	Referred from				Total
		< 14 Days	14-29 Days	≥ 30 Days	Other		FCs	Form 125 Review	Other Committee	QA	
Extension											
Cancer	1,727	75	36	21	1	133	1,568	25	1	412	2,006
CVD (plus PE, DVT)	1,878	51	35	17		103	1,429	337	9		1,775
Fatal Events	630	37	14	7		58	570	1	1		572
Form 125-Hospital	6,614	240	112	59	1	412	6,202				6,202
Other Cancer	1						1				1
Stroke	744	27	16	4		47	625	61	11		697
Fracture	306	15	11	1		27	270	5	4		279
Extension Total	11,900	445	224	109	2	780	10,665	429	26	412	11,532
WHI											
Cancer	11,351				1	1	11,284			70	11,354
CVD (plus PE, DVT)	10,192				3	3	10,187		2		10,189
Fatal Events	5,616				8	8	5,607		1		5,608
Stroke	2,844						2,842	1	1		2,844
Fracture	2,559				1	1	2,558				2,558
WHI Total	32,562				13	13	32,478	1	4	70	32,553
Extension + WHI Total	44,462	445	224	109	15	793	43,143	430	30	482	44,085

Table 7.9
CCC Adjudication Workload
Data as of 9-1-06

Committees	# Cases at CCC			CCC Action Required		
	Total	Closed	To Adjudicate	Forward to Adjudicator	Wait for Return from Adjudicator	Data Enter and Close
Extension						
Cancer	1,594	494	1,100	982	66	52
CVD (plus PE, DVT)	1,775	868	907	533	315	59
Fatal Events	572	302	270	201	54	15
Form 125-Hospital	6,202	2,367	3,835	3,675	141	19
Other Cancer	1		1	1		
Stroke	697	75	622	498	112	12
Fracture	279	149	130	67	57	6
Extension Total	11,120	4,255	6,865	5,957	745	163
WHI[2]						
Cancer	11,354	11,305	49	22	2	25
CVD (plus PE, DVT)	10,189	10,171	18	7	2	9
Fatal Events	5,608	5,583	25	17		8
Stroke	2,844	2,765	79	67	11	1
Fracture	2,558	2,551	7	7		
WHI Total	32,553	32,375	178	120	15	43
Extension + WHI[2] Total	43,673	36,630	7,043	6,077	760	206

1 - WHI Other Cancer not adjudicated at CCC; not included in Closed and To Adjudicate totals
2 - WHI totals To Adjudicate adjusted to remove Not Required cases

Table 8.1
CT Outcomes Cases with Blood Sample by Estimated Volume
After Accounting for Approved Core and Ancillary Studies

					Volume of Designated Blood Components (ml)																	
					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	Total Ppts	No Draw	Blood Type	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%
Base-line	Breast Cancer	2786	10	Serum	15	1%	1	0%	1	0%	16	1%	3	0%	36	1%	4	0%	180	6%	1	0%	2534	91%
				Citrate	23	1%			1	0%	42	2%	12	0%	190	7%			2526	91%				
				EDTA	39	1%					10	0%			200	7%			2524	91%				
	CHD	2129	11	Serum	15	1%					39	2%	3	0%	228	11%	39	2%	232	11%	1	0%	1572	74%
				Citrate	29	1%	19	1%	11	1%	185	9%	51	2%	267	13%			1567	74%				
				EDTA	33	2%	8	0%	18	1%	58	3%	180	8%	256	12%			1576	74%				
	Colorectal Cancer	722	2	Serum	3	0%					8	1%			11	2%	2	0%	59	8%	2	0%	637	88%
				Citrate	12	2%					21	3%			55	8%			634	88%				
				EDTA	16	2%			1	0%	6	1%	3	0%	62	9%			634	88%				
	Endometrial Cancer	370	2	Serum	4	1%					2	1%			7	2%	3	1%	18	5%	1	0%	335	91%
				Citrate	5	1%					12	3%			15	4%			335	91%				
				EDTA	6	2%					3	1%	3	1%	24	6%			331	89%				
	Fracture (general)	8391	33	Serum	53	1%	4	0%	2	0%	76	1%	4	0%	160	2%	33	0%	566	7%	5	0%	7494	89%
				Citrate	102	1%	1	0%	5	0%	227	3%	27	0%	567	7%			7462	89%				
				EDTA	129	2%					65	1%	57	1%	647	8%			7487	89%				
	Fracture Hip	792	2	Serum	3	0%	1	0%	1	0%	9	1%	3	0%	29	4%	8	1%	51	6%	1	0%	691	87%
				Citrate	11	1%					42	5%	9	1%	56	7%			680	86%				
				EDTA	6	1%					6	1%			75	9%			694	88%				
	MI	1695	10	Serum	12	1%					32	2%	2	0%	192	11%	31	2%	176	10%	1	0%	1249	74%
				Citrate	23	1%	17	1%	9	1%	152	9%	42	2%	210	12%			1242	73%				
				EDTA	26	2%	8	0%	13	1%	49	3%	140	8%	205	12%			1254	74%				
	Stroke	1516	6	Serum	9	1%	1	0%			27	2%	4	0%	177	12%	20	1%	157	10%	2	0%	1119	74%
				Citrate	46	3%	4	0%	3	0%	284	19%	4	0%	274	18%			901	59%				
				EDTA	24	2%	1	0%	2	0%	38	3%	14	1%	326	22%			1111	73%				
	VTE	577	3	Serum	3	1%					8	1%	1	0%	37	6%	8	1%	153	27%	24	4%	343	59%
				Citrate	32	6%	8	1%	2	0%	197	34%	2	0%	42	7%			294	51%				
				EDTA	9	2%	3	1%	3	1%	30	5%	9	2%	220	38%			303	53%				

*Participants with no draw included in 0 volume column
Includes sample reserved for BAA (2 ml serum, 1 ml citrate, and 1 ml EDTA)
Represents conservative estimate of 1 ml in each aliquot collected

Table 8.1 (continued)
CT Outcomes Cases with Blood Sample by Estimated Volume (in ml)
After Accounting for Approved Core and Ancillary Studies

					Volume of Designated Blood Components (ml)																	
Visit	Outcome	Total Ppts	No Draw	Blood Type	0* Ppt	0* %	>0 - <.5 Ppt	>0 - <.5 %	.5 - <1 Ppt	.5 - <1 %	1 - <1.5 Ppt	1 - <1.5 %	1.5 - <2 Ppt	1.5 - <2 %	2 - <2.5 Ppt	2 - <2.5 %	2.5 - <3 Ppt	2.5 - <3 %	3 - <3.5 Ppt	3 - <3.5 %	3.5 - <4 Ppt	3.5 - <4 %	4+ Ppt	4+ %
AV1	Breast Cancer	2786	182	Serum	184	7%	1	0%			16	1%	5	0%	28	1%	5	0%	167	6%	21	1%	2365	85%
				Citrate	193	7%					32	1%			176	6%			2384	86%				
				EDTA	214	8%					10	0%			191	7%			2366	85%				
	CHD	2129	238	Serum	241	11%					30	1%	1	0%	150	7%	25	1%	203	10%	16	1%	1463	69%
				Citrate	260	12%	15	1%	7	0%	107	5%	44	2%	226	11%			1470	69%				
				EDTA	266	12%	5	0%	8	0%	42	2%	95	4%	234	11%			1479	69%				
	Colorectal Cancer	722	68	Serum	68	9%	1	0%			7	1%			6	1%	11	2%	53	7%	48	7%	528	73%
				Citrate	74	10%					17	2%	1	0%	48	7%			582	81%				
				EDTA	76	11%			1	0%	5	1%	4	1%	49	7%	1	0%	586	81%				
	Endometrial Cancer	370	22	Serum	22	6%					2	1%	1	0%	9	2%	1	0%	18	5%	7	2%	311	84%
				Citrate	25	7%					9	2%	3	1%	15	4%			320	86%				
				EDTA	25	7%					2	1%			22	6%			318	86%				
	Fracture (general)	8391	550	Serum	555	7%	6	0%	2	0%	62	1%	7	0%	120	1%	43	1%	539	6%	197	2%	6860	82%
				Citrate	617	7%	6	0%	1	0%	167	2%	16	0%	549	7%			7035	84%				
				EDTA	670	8%	2	0%	4	0%	58	1%	32	0%	591	7%			7034	84%				
	Fracture Hip	792	53	Serum	53	7%	1	0%	1	0%	6	1%	3	0%	17	2%	13	2%	62	8%	55	7%	581	73%
				Citrate	63	8%					36	5%	3	0%	54	7%			636	80%				
				EDTA	63	8%			2	0%	10	1%	4	1%	66	8%			647	82%				
	MI	1695	156	Serum	158	9%					27	2%	1	0%	126	7%	18	1%	165	10%	14	1%	1186	70%
				Citrate	177	10%	14	1%	5	0%	90	5%	36	2%	182	11%			1191	70%				
				EDTA	180	11%	5	0%	6	0%	37	2%	76	4%	191	11%			1200	71%				
	Stroke	1516	148	Serum	150	10%					24	2%	1	0%	112	7%	28	2%	146	10%	12	1%	1043	69%
				Citrate	178	12%	3	0%	2	0%	195	13%	5	0%	285	19%			848	56%				
				EDTA	170	11%					29	2%	13	1%	245	16%			1059	70%				
	VTE	577	52	Serum	52	9%					4	1%	1	0%	26	5%	9	2%	102	18%	19	3%	364	63%
				Citrate	76	13%	7	1%	2	0%	114	20%			48	8%			330	57%				
				EDTA	58	10%	2	0%	2	0%	23	4%	7	1%	151	26%			334	58%				

*Participants with no draw included in 0 volume column
Includes sample reserved for BAA (2 ml serum, 1 ml citrate, and 1 ml EDTA)
Represents conservative estimate of 1 ml in each aliquot collected

Table 8.2 (continued)
OS Outcomes Cases with Blood Sample by Estimated Volume (in ml)
After Accounting for Approved Core and Ancillary Studies

					Volume of Designated Blood Components (ml)																	
Visit	Outcome	Total Ppts	No Draw	Blood Type	0* Ppt	0* %	>0 - <.5 Ppt	>0 - <.5 %	.5 - <1 Ppt	.5 - <1 %	1 - <1.5 Ppt	1 - <1.5 %	1.5 - <2 Ppt	1.5 - <2 %	2 - <2.5 Ppt	2 - <2.5 %	2.5 - <3 Ppt	2.5 - <3 %	3 - <3.5 Ppt	3 - <3.5 %	3.5 - <4 Ppt	3.5 - <4 %	4+ Ppt	4+ %
Base-line	Breast Cancer	3877	7	Serum	13	0%	1	0%			15	0%	10	0%	157	4%	231	6%	509	13%	482	12%	2459	63%
				Citrate	35	1%					15	0%	23	1%	171	4%	25	1%	3608	93%				
				EDTA	64	2%			1	0%	54	1%	42	1%	263	7%	115	3%	3338	86%				
	CHD	2471	3	Serum	7	0%	5	0%	10	0%	51	2%	28	1%	259	10%	57	2%	208	8%	329	13%	1517	61%
				Citrate	30	1%					27	1%	23	1%	350	14%	26	1%	2015	82%				
				EDTA	49	2%			1	0%	148	6%	54	2%	455	18%	39	2%	1725	70%				
	Colorectal Cancer	908	1	Serum	3	0%					5	1%			59	6%	77	8%	140	15%	229	25%	395	44%
				Citrate	10	1%					13	1%	4	0%	39	4%	7	1%	835	92%				
				EDTA	23	3%					20	2%	11	1%	60	7%	27	3%	767	84%				
	Endometrial Cancer	533	1	Serum	3	1%					5	1%	1	0%	34	6%	48	9%	86	16%	144	27%	212	40%
				Citrate	6	1%					1	0%	4	1%	36	7%	3	1%	483	91%				
				EDTA	15	3%					12	2%	10	2%	36	7%	12	2%	448	84%				
	Fracture (general)	1933	9	Serum	11	1%	2	0%	2	0%	8	0%	11	1%	55	3%	27	1%	101	5%	74	4%	1642	85%
				Citrate	27	1%					7	0%	9	0%	136	7%	21	1%	1733	90%				
				EDTA	36	2%					49	3%	30	2%	167	9%	65	3%	1586	82%				
	Fracture Hip	1132	1	Serum	2	0%					37	3%	74	7%	127	11%	152	13%	102	9%	52	5%	586	52%
				Citrate	11	1%					6	1%	9	1%	99	9%	18	2%	989	87%				
				EDTA	23	2%					23	2%	21	2%	112	10%	39	3%	914	81%				
	MI	1898	2	Serum	5	0%	4	0%	9	0%	40	2%	24	1%	211	11%	49	3%	170	9%	308	16%	1078	57%
				Citrate	21	1%					21	1%	16	1%	292	15%	23	1%	1525	80%				
				EDTA	37	2%			1	0%	120	6%	44	2%	376	20%	31	2%	1289	68%				
	Stroke	1843	1	Serum	2	0%			1	0%	15	1%	16	1%	66	4%	38	2%	146	8%	274	15%	1285	70%
				Citrate	15	1%	1	0%	2	0%	82	4%	188	10%	675	37%	103	6%	777	42%				
				EDTA	25	1%	1	0%	8	0%	319	17%	394	21%	347	19%	23	1%	726	39%				
	VTE	36	0	Serum											2	6%	1	3%			2	6%	31	86%
				Citrate											3	8%			33	92%				
				EDTA	2	6%					1	3%			3	8%			30	83%				

*Participants with no draw included in 0 volume column
Includes sample reserved for BAA (2 ml serum, 1 ml citrate, and 1 ml EDTA)
Represents conservative estimate of 1 ml in each aliquot collected

Table 8.2 (continued)
OS Outcomes Cases with Blood Sample by Estimated Volume (in ml)
After Accounting for Approved Core and Ancillary Studies

					Volume of Designated Blood Components (ml)																	
		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	Outcome	Ppts	Draw	Type	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%
AV3	Breast Cancer	3877	619	Serum	621	16%					7	0%			26	1%	1	0%	59	2%	23	1%	3140	81%
				Citrate	659	17%					18	0%			41	1%			3159	81%				
				EDTA	689	18%					16	0%	1	0%	45	1%			3126	81%				
	CHD	2471	719	Serum	721	29%					6	0%			16	1%	13	1%	57	2%	30	1%	1628	66%
				Citrate	732	30%					8	0%			89	4%			1642	66%				
				EDTA	756	31%					12	0%			92	4%	4	0%	1607	65%				
	Colorectal Cancer	908	236	Serum	237	26%					2	0%			6	1%			7	1%	2	0%	654	72%
				Citrate	241	27%									10	1%			657	72%				
				EDTA	243	27%					6	1%	2	0%	36	4%	66	7%	555	61%				
	Endometrial Cancer	533	80	Serum	80	15%									4	1%			9	2%	7	1%	433	81%
				Citrate	82	15%					2	0%			11	2%			438	82%				
				EDTA	87	16%					2	0%	1	0%	12	2%	1	0%	430	81%				
	Fracture (general)	1933	309	Serum	312	16%					8	0%			12	1%			22	1%	10	1%	1569	81%
				Citrate	320	17%					8	0%			18	1%			1587	82%				
				EDTA	337	17%					8	0%			25	1%	3	0%	1560	81%				
	Fracture Hip	1132	248	Serum	252	22%					2	0%			11	1%			15	1%	7	1%	845	75%
				Citrate	259	23%					7	1%			10	1%			856	76%				
				EDTA	267	24%					4	0%			19	2%			842	74%				
	MI	1898	441	Serum	442	23%					5	0%			15	1%	11	1%	47	2%	24	1%	1354	71%
				Citrate	451	24%					7	0%			75	4%			1365	72%				
				EDTA	471	25%					9	0%			79	4%	4	0%	1335	70%				
	Stroke	1843	473	Serum	473	26%					2	0%			14	1%	2	0%	19	1%	9	0%	1324	72%
				Citrate	486	26%					8	0%			26	1%			1323	72%				
				EDTA	505	27%					10	1%			30	2%	4	0%	1294	70%				
	VTE	36	5	Serum	6	17%					1	3%											29	81%
				Citrate	6	17%													30	83%				
				EDTA	7	19%									1	3%			28	78%				

*Participants with no draw included in 0 volume column
Includes sample reserved for BAA (2 ml serum, 1 ml citrate, and 1 ml EDTA)
Represents conservative estimate of 1 ml in each aliquot collected

Table 9.1
Core Study[1] Report

Ref #	Title	Status	Study Pop	Blood	Blood Usage	Used in Approved Publications
W1	CT Core Analytes	Complete	CT, 6% subsample *Baseline, Y1, Y3, and Y6	Y	Citrate 1.05ml: Factor VII Ag (antigen); Factor VIIC; Fibrinogen EDTA 1.05ml: Apolipoprotein(a); High-density lipoprotein cholesterol; High-density lipoprotein-2; High-density lipoprotein-3; Low-density lipoprotein cholesterol; Total Cholesterol; Triglyceride Serum 1.05ml: 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
W2	OS-Measurement Precision Study	Complete	OS, n = 1061 *Baseline and 3 month repeat	Y	Citrate 1.05ml: Factor VII Ag (antigen); Factor VIIC; Fibrinogen EDTA 1.05ml: Apolipoprotein(a); High-density lipoprotein cholesterol; High-density lipoprotein-2; High-density lipoprotein-3; Low-density lipoprotein cholesterol; Total Cholesterol; Triglyceride Serum 1.05ml: Alpha-Carotene; Alpha-tocopherol; Beta-Carotene; Beta-Cryptoxanthine; Gamma-tocopherol; Glucose; Insulin; Lutein and Zeaxanthin; Lycopene; Retinol	442, 524
W4	National Validation and Quality Control Assurance of Vitamin D Absorption from CaD Tablets for WHI	Complete	CaD, n=448	Y	Serum 1.05ml: Vitamin D3, 25-Hydroxy	
W5	Correlates of Endogenous Sex Hormone Concentrations in WHI	Complete	DM, n=300 *Baseline and Y1	Y	Serum 3.05ml: Albumin; Androstenedione; Bioavailable Estradiol; Dehydroepiandrosterone; Dehydroepiandrosterone Sulfate (SO4); Dihydrotestosterone; Estradiol; Estrone; Estrone-sulfate; Progesterone; Prolactin; Sex Hormone Binding Globulin; Testosterone	20, 280
W6	CVD Biomarkers - Phase I	Funded	HT Cases: n=402 CHD, 272 stroke, 223 VTE Controls: n=877 *Baseline and Y1	Y	Citrate 1.05ml: ATIII; C-reactive protein; D-dimers; FIX Conc; Factor VIII Activity; Fibrinogen; PAI-1 Antigen; PAP; Protein C; Protein S Total; Prothrombin antigen; Prothrombin fragment 1+2; Thrombin activatable fibrinolysis inhibitor concentration; von Willebrand Factor activity or concentration DNA 3ug: 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)	204, 210, 222, 273, 345, 347, 350, 380, 429, 445, 526

Table 9.1 (continued)
Core Study[1] Report

Ref #	Title	Status	Study Pop	Blood	Blood Usage	Used in Approved Publications
W6 (Con't)	CVD Biomarkers - Phase I	Funded	HTCases: n=402 CHD, 272 stroke, 223 VTEControls: n=877 *Baseline and Y1	Y	DNA 3ug: FXIII val34leu; Factor V Leiden; FactorV-HR2; Methylenetetrahydrofolate reductase polymorphism; Plasminogen Activator Inhibitor 1; Prothrombin 19911 - PT19911; Prothrombin 20210 - PT20210 EDTA .25ml: HDL Particles (total); HDL Size; High-density lipoprotein cholesterol; IDL; LDL Particles (total); LDL Size; Large HDL; Large LDL; Large VLDL/Chylomicrons; Medium HDL; Medium Small LDL; Medium VLDL; Small HDL; Small LDL (total); Small VLDL; Triglyceride; VLDL Particles (total); VLDL Size; VLDL-TG; Very Small LDL; VLDL particles (total), Large VLDL, Medium VLDL. Small VLDL, LDL Particles (total), IDL, Large LDL, Small LDL (Total), Medium small LDL, Very small LDL, HDL Particles (total), Large HDL, Medium HDL, Small HDL, VLDL size, LDL size, HDL size, Total triglycerides, VLDL trigglycerides, HDL Cholesterol EDTA 1.05ml: Apolipoprotein(a); E-Selectin; High-density lipoprotein cholesterol; High-density lipoprotein-2; High-density lipoprotein-3; Homocysteine; Interluekin 6, ultrasensitive; Low-density lipoprotein cholesterol; Total Cholesterol; Triglyceride Serum 1.05ml: Matrix metalloproteinases	
W7	Genome-Wide Scan on Breast Cancer, CHD, and Stroke	Funded	OS/HT Phase I (OS) Cases: n=1000 breast cancer, 1000 CHD, 1000 stroke Controls: n=same Phase II (OS) Cases: n=800 breast cancer, 800 CHD, 721 stroke Controls: n=same Phase III (HT) Cases: n=345 breast cancer, 319 CHD, 494 stroke Controls: n=same	Y	DNA 2ug: genome-wide scan	

Table 9.1 (continued)
Core Study[1] Report

Ref #	Title	Status	Study Pop	Blood	Blood Usage	Used in Approved Publications
W8	Nutritional Biomarkers Study	Funded	DM, n=544, with 111 of these in repeat sample	Y	NBS-24hr Urine: 24hr urine volume, unirary nitrogen g/day, urinary nitrogen g/L NBS-Spot Urine 4ml: %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 .20ml: alpha-carotene, alpha-tocopherol, beta-carotene, folate, gamma-tocopherol, total cholesterol	464
W9	Biological Markers of the Effect of HT on Risk of Fractures in the Women's Health Initiative Clinical Trial	Funded	HT Cases: n=750 Controls: n=750 *All hip fractures plus non spine other fractures to make 750	Y	DNA 1ug: CYP19; SHBG; HSD17B1; HSD17B2; HSD17B3); HSD17B4; CYP1A1; CYP1A2; CYP1B1; CYP3A4; COMT; SULT1A1; SULT1E1; UGT1A1; ESR1; ESR2; PGR; NCOA1; NCOA2; NCOA3 Serum .75ml: Estradiol; Sex Hormone Binding Globulin Serum .35ml: PINP (Amino-terminal polypeptide of Type I procollagen); CTx	
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=576 Controls: n=576	Y	DNA 2ug: ER-a, ER-b, PGR, SHBP, CYP19, CYP1A1, CYP1A2, CYP1B1, CYP3A4, COMT, HSD17B1, HSD17B2, HSD17B3, HSD17B4, SULT1A1, SULT1E1, UGT1A1, NCOA1, NCOA2, NCOA3 Serum .55ml: MPA Serum .35ml: Glucose, insulin, IGF-1, IGFBP-3 Serum 1.25ml: Total estradiol, bioavailable estradiol, estradiol sulfate, estrone sulfate, estrone, SHBG, testosterone	
W11	CVD Biomarkers - Phase II: Strokes after Feb 2001	Funded	HT Cases: n=316 Controls: n=316 *Baseline and Y1	Y	Citrate .35ml: Free TFPI; TFPI activity; Total TFPI Citrate .65ml: APC-ETP DNA 1ug: 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) EDTA .35ml: C-reactive protein; E-Selectin; Interluekin 6, ultrasensitive Serum .25ml: Glucose; Insulin	

Table 9.1 (continued)
Core Study[1] Report

Ref #	Title	Status	Study Pop	Blood	Blood Usage	Used in Approved Publications
W14	CVD Biomarkers Phase I-additional assays	Funded	HT Cases: n=390 CHD, 270 stroke, 220 VTE Controls: n=390 CHD, 270 stroke, 220 VTE *Baseline and Y1	Y	Citrate .35ml: Free TFPI; TFPI activity; Total TFPI Citrate .65ml: APC-ETP Serum .25ml: Glucose; Insulin;	
W15	CaD Vitamin D Levels in CaD Participants with Colorectal cancer or Fractures	Funded	CaD Cases: n=1830 Controls: n=1830	Y	Serum .2ml: 25-OH-Vitamin D3	450, 451
W18	HT Hormone Pretest	Funded	HT, n=200 *Baseline and Y1	Y	Serum .95ml: Estradiol, estrone, SHBG on both E-Alone and E+P samples; progesterone and testosterone on E+P only samples.	
W19	WHI HT Proteomic Pilot Study	Funded	HT, n=200 *Baseline and Y1	Y	Serum .55ml: proteomics	
W20	WHI-EDRN Pilot Study for the Identification of Circulating Biomarkers for Colon Cancer in Pre-Clinical Specimens	Funded	OS Cases: n=100 Controls: n=100	Y	EDTA .2ml: Calibration for Wayne State lab. EDTA .55ml: Proteomics	
W21	Cancer Genetic Markers of Susceptibility (CGEMS)	Funded	OS Cases: n=2952 Controls: n=2952	Y	DNA 2ug: Genome-wide scan	
W22	Vitamin D levels in 6% blood subsample of CaD	Proposed	CaD	Y	Serum .25ml: Vitamin D	
W23	Genotyping to Explore CaD intervention effect on hip fracture	Funded	CaD Cases: n=357 Controls: n=357	Y	DNA 1ug:	
W24	CaD Vitamin D and Breast Cancer	Funded	CaD Cases: n=1376 Controls: n=1376	Y	Serum .2ml: Vitamin D	

Table 9.1 (continued)
Core Study[1] Report

Ref #	Title	Status	Study Pop	Blood	Blood Usage	Used in Approved Publications
W25	WHI Coronary Artery Calcification Study in E-Alone	Funded	HT (E-Alone), n = 1141	N		503, 506
W26	Food Grouping in WHI by FHCRC Nutrition Shared Resource Group	Funded	DM	N		
W27	Nutrition and Physical Activity Assessment Study (AS218) lab assays	Funded	OS, n=450	Y		
W28	Medicare Claims Data	Proposed	OS/CT, participants aged 65+	N		
W29	NCI Pancreatic Cancer Cohort Consortium	Funded	OS/CT Cases: n=300 Controls: n=300	Y	DNA 5ug: genome-wide scan	
W30	Dietary Assessment Study	Complete	DM, n=166	N		

[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.

Table 10.1
All Ancillary Studies

AS	Title	PIs	Status	Study dates	Study Population*	Blood study
1	Arterial Disease Artherosclerosis Prevention Trial (ADAPT)	Anc: Crouse WHI: Burke	Dropped		DM	N
2	Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial (PLCO-OS)	Anc: Weissfeld WHI: Kuller	Dropped		OS/CT	N
3	PLCO Offer to WHI-Partners (PLCO-Partners)	Anc: Weissfeld WHI: Kuller	Dropped			N
4	Dietary Modification and Prostate Cancer in WHI Husbands	Anc: Shikany WHI: Oberman	Dropped			N
5	Explanations for the Development of Fat Distaste	Anc: Green WHI: Bowen	Complete		DM	N
6	Incidence and Impact of Arthritis in Older Women	Anc: Hughes WHI: Greenland	Dropped		OS/CT	N
7	Effect of HRT on Cardiovascular Morbidity and Mortality in Postmenopausal Women with a low Ankle/Arm BPI	Anc: Kuller WHI: Kuller	Dropped		HT	N
8	Partner's Health Study	Anc: Langer WHI: Langer	Dropped			N
9	Oral Bone Loss	Anc: Jeffcoat WHI: Lewis	Complete	05/29/95- 11/30/04	OS/CT 450 Ppts@Birming	N
10	Urinary Estrogen Metabolites and Breast Cancer Risk	Anc: Meilahn WHI: Kuller	Dropped		DM	N
11	Validation and Exploration of Sleep and Mood Predictors	Anc: Kripke WHI: Langer	Complete		OS/CT	N
12	Empowerment/Nutritional Counseling	Anc: Mouton WHI: Lasser	Dropped		DM	N
13	Prevalence and Correlates of Lumbar Spinal Stenosis	Anc: Vogt WHI: Kuller	Complete		CT	N
14	High Density Lipoprotein Metabolism	Anc: Going WHI: Moon	Complete		OS/CT	N
15	The Relationship between Osteopenia and Periodontitis	Anc: Wactawski-Wend WHI: Trevisan	Complete		OS/CT 1468 Ppts@Buffalo	N
16	Lower Extremity Atherosclerotic Disease	Anc: McDermott WHI: Greenland	Dropped		OS/CT	N
17	Domestic Violence in Older Women	Anc: Mouton WHI: Lasser	Complete		OS/CT	N
18	WHT:FSMP DM follow-up	Anc: Grizzle WHI: Bowen	Dropped		OS/CT	N
19	Coagulation Proteins, Anticardiolipin Antibodies and Stroke in Women	Anc: Orencia WHI: Greenland	Dropped		OS/CT	N
20	Coronary Screening of Postmenopausal Women Using EBCT	Anc: Detrano WHI: Chlebowski	Dropped		OS/CT	N

Table 10.1 (continued)
All Ancillary Studies

AS	Title	PIs	Status	Study dates	Study Population*	Blood study
21	Effect of DM, HRT and CaD Admin on Progression of Coronary Atherosclerosis Assessed by EBCT	Anc: Detrano WHI: Chlebowski	Dropped		CT	N
22	Vascular Compliance as a Predictor of Cardiovascular Disease in Postmenopausal Women	Anc: Robinson WHI: Grimm	Dropped		CT	N
23	Non-steroidal Anti-inflammatory Drugs and Cancers of the Breast and Colon	Anc: Harris WHI: Jackson	Dropped		OS/CT	N
24	Cross-ethnic Comparisons of Skeletal Health of Postmenopausal Women in San Diego County	Anc: Schneider WHI: Langer	Complete		OS/CT	N
25	Ankle-Arm Blood Pressure Index Measurement	Anc: Masaki WHI: Curb	Complete		OS/CT	N
26	HRT and Knee/Hip Osteoarthritis	Anc: Cerhan WHI: Wallace	Dropped		HT	N
27	Vitamin D, Calcium, and Breast Cancer	Anc: Hulka WHI: Sheps	Dropped		OS/CT	N
28	Perspectives on Aging	Anc: Smoller WHI: Smoller	Dropped		OS/CT	N
29	HRT and Cardiovascular Biomarkers Related to Oxidation Status and Platelet Function	Anc: Gaziano WHI: Manson	Dropped		HT	N
30	The Role of Endocrine Factors in the Etiology of Lung Cancer in Women	Anc: Kabat WHI: Smoller	Dropped		OS/CT	N
31	Eye Care Use	Anc: Kleinstein WHI: Oberman	Complete		OS/CT	N
32	Recruitment Techniques in getting Minority Women to participate in Breast Cancer Clinical Trials	Anc: Boe WHI: Langer	Dropped		OS/CT	N
33	The Association of HRT with Abdominal and Total Body Fat in Postmenopausal Women	Anc: Mayo WHI: Oberman	Complete		OS/CT	N
34	Ethnic Differences in Hip Bone Geometry by DXA and QCT	Anc: Nelson WHI: Hendrix	Complete		HT 311 Ppts@Detroit	N
35	Risk Factors for Fatigue in Women Ages 50 to 75	Anc: Hartz WHI: Kotchen	Dropped		CT	N
36	HRT and changes in Mammographic Density	Anc: Hulka WHI: Heiss	Complete	01/31/98- 12/31/02	OS/CT 857 Ppts@19 clinics	N
37	Lipid Markers of Atherosclerotic Disease in Post Menopausal Women	Anc: Manson WHI: Manson	Dropped		OS/CT	N
38	Hemostatic/Thrombotic and Genetic Markers for Coronary Disease in Postmenopausal Women	Anc: Ridker WHI: Manson	Dropped		OS/CT	N
39	The Effects of HRT on the Development and Progression of Dementia (WHIMS)	Anc: Shumaker WHI:	Complete	06/01/96- 05/31/05	HT 7528 Ppts@48 clinics	N
40	Ethnic and age differences in use of Mammography	Anc: Smoller WHI: Smoller	Complete		OS/CT	N

Table 10.1 (continued)
All Ancillary Studies

AS	Title	PIs	Status	Study dates	Study Population*	Blood study
41	Metabolism of Lipoprotein and HRT	Anc: Morrisett WHI: Foreyt	Dropped		OS/CT	N
42	Impact of Insurance Status on Health Outcomes and Health Services Utilization in the WHI	Anc: Hsia WHI: Miller	Dropped		OS/CT	N
43	Decrease of Bone Mass in Older Women	Anc: Goodman WHI: Judd	Dropped		CT	N
44	Estrogen and Vaginal pH	Anc: Schaeffer WHI: Greenland	Dropped		HT	N
45	Response Set Biases in Dietary Self-Report in the WHI DM	Anc: Herbert WHI: Herbert	Dropped		DM	N
46	Prostate & Colorectal Cancer in WHI Dietary Arm Husbands	Anc: Oberman WHI: Oberman	Dropped			N
47	Effect of diet intervention on motivation to make other health-related changes	Anc: WHI: Langer	Complete		HT	N
48	Prostate Ca Survey of Spouses of WHI Screened Women	Anc: Smoller WHI: Smoller	Complete		OS/CT	N
49	Applying Creative Self-Monitoring in the WHI	Anc: Rahmani WHI: Rahmani	Dropped		DM	N
50	Nutrition Practice Guidelines for Maintaining Low-Fat Dietary Change in Post Menopausal Women	Anc: Burrows WHI: Grimm	Complete		DM	N
51	Cross-Sectional & Longitudinal Evaluation of Bone Quality	Anc: LeBlanc WHI: Foreyt	Dropped		OS/CT	N
52	Genetic Polymorphisms in the Hormonal Etiology of Breast Cancer	Anc: McTiernan WHI:	Dropped		OS/CT	N
53	A Prospective Study of Diet and Hormones in the Development of Prostate Cancer	Anc: Kabat WHI: Smoller	Dropped		OS/CT	N
54	Women & Minority Recruitment / Retention: A Community-Based Intervention	Anc: Fouad WHI: Oberman	Dropped		DM	N
55	Predictors of Participation Among Latinos in Clinical Trials	Anc: Talavera WHI: Talavera	Dropped		OS/CT	N
56	Behavioral and psychosocial predictors of dietary change in postmenopausal women	Anc: Pleuss WHI: Burke	Complete		DM	N
57	Hispanic Women's Advocacy and Retention Strategies	Anc: Ritenbaugh WHI: Ritenbaugh	Complete		OS/CT	N
58	Enrollment of Hispanic Women in Prevention Trials	Anc: Trapido WHI: Baum	Dropped		OS/CT	N
59	Prevalence and Natural History of Autoimmune Thyroid Disease (AITD) in Postmenopausal Women	Anc: Zakarija WHI:	Dropped		OS/CT	N
60	Fat Intake in Husbands of WHI Dietary Arm Participants	Anc: Shikany WHI: Oberman	Complete			N

Table 10.1 (continued)
All Ancillary Studies

AS	Title	PIs	Status	Study dates	Study Population*	Blood study
61	Longitudinal Assessment of Memory Functioning in the WHI Clinical Trial	Anc: Ober WHI: Robbins	Funded		HT	N
62	Prevention of age-related maculopathy in the WHI HRT CT: WHI-SE	Anc: Haan WHI: Robbins	Funded		HT 4430 Ppts@21 clinics	N
63	Development and Evaluation of Eating Style Index	Anc: Haines WHI: Heiss	Complete		OS/CT	N
64	Examine Mammography Sensitivity in WHI Women	Anc: Foreyt WHI:	Dropped		CT	N
65	Benign Breast Disease	Anc: Rohan WHI:	Complete	04/01/98- 06/30/99	OS/CT 101 Ppts@12 clinics	N
66	Quantitative, Patient-Specific serially comparable (QPS) mammography	Anc: Morrisett WHI: Foreyt	Dropped		OS/CT	N
67	Prevalence and Natural History of Autoimmune Thyroid Disease in Postmenopausal Women	Anc: Zakarija WHI: O'Sullivan	Funded		OS/CT	N
68	Coronary artery calcification detected with Ultrafast CT as an indication of CAD in OS participants	Anc: Hsia WHI: Hsia	Complete		OS/CT 735 Ppts@2 clinics	N
69	Birth Place and CVD Risk in Women	Anc: Wylie-Rosett WHI	Dropped		OS/CT	N
70	The Prevalence & Prognostic Importance of Myocardial Ischemia During Daily Life, & its Relationship to Migraine Status:WHI	Anc: Sheps WHI: Heiss	Complete		OS/CT	N
71	Assessing Stages of Change in Postmenopausal Women Enrolled in the Dietary Modification Arm if the WHI	Anc: Brewer WHI: Applegate	Dropped		DM	N
72	Ethnicity, Body Composition, Bone Density and Breast Cancer	Anc: Chen WHI: Ritenbaugh	Analysis		OS/CT	N
73	Psychosocial and Cultural Determinants of NIDDM in Latinas	Anc: Ritenbaugh WHI: Langer	Complete		OS/CT	N
74	The Effectiveness of Individual Versus Group Behavioral Strategies to Increase Participants Adherence	Anc: Wodarski WHI: Trevisan	Complete		DM	N
75	Adherence to Dietary Modification in the WHI	Anc: Rosal WHI: Ockene	Analysis		DM	N
76	Tailored Messages to Enhance Adherence of Older Women to Dietary Programs for Breast Cancer control	Anc: Chlebowski WHI: Chlebowski	Complete		DM	N
77	HRT Decision Project	Anc: Kerner WHI: Langer	Dropped		OS/CT	N
78	Community Strategy to Retain Women Enrolled in Research	Anc: Fouad WHI: Oberman	Complete		CT	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	Dropped		OS/CT	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: Psaty	Dropped		HT	N

Table 10.1 (continued)
All Ancillary Studies

AS	Title	PIs	Status	Study dates	Study Population*	Blood study
81	Androgeneic Hair Growth in Postmenopausal Women	Anc: Freeman WHI: Smoller	Dropped		OS/CT	N
82	Extension of Bone Mineral Density Assessment in WHI Native American Women	Anc: Chen WHI: Ritenbaugh	Complete		OS/CT	N
83	Thrombotic, Inflammatory and Genetic Markers for Coronary Heart Disease in Postmenopausal Women: A WHI Umbrella Study	Anc: Ridker WHI:	Complete	09/01/99-08/31/03	OS	Y
84	Estrogen, Vitamin E and Cognitive Change in Women	Anc: Dunn WHI: Van Horn	Funded		OS/CT 546 Ppts@2 clinics	N
85	Brain Imaging with Fluorometatyrosine in Post-Menopausal Women on or off Hormonal Replacement Therapy - Implications for Schizophrenia	Anc: Nordahl WHI:	Dropped			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	Complete		HT	N
87	The Effect of Dietary Change on Blood Flavonoid and F2-Isoprostane Levels	Anc: Simon WHI: Hendrix	Dropped		DM	N
88	Cholesterol distribution in lipoprotein particles in WHI Dietary Modification Intervention participants consuming a low-fat dietary pattern compared to Comparison participants consuming their usual fa	Anc: Tinker WHI: Grimm	Dropped		DM	N
89	Effect of HRT on plasma homocysteine concentration	Anc: Manson WHI: Manson	Dropped		HT	N
90	WHI Sex Hormone and Genetic Risk Factors for Hip Fracture	Anc: Cummings WHI Cummings	Funded	04/01/04-03/31/07	OS	Y
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:	Dropped		CT	N
92	Fasting glucose in baseline plasma from all CT participants	Anc: Howard WHI: Howard	Tabled		CT	N
93	The Epidemiology of Venous Disease	Anc: Criqui WHI: Langer	Complete		OS/CT	N
94	The Effect of Lowfat Dietary Modification on Markers of Bone Turnover and Bone Mineral Density	Anc: Jackson WHI:	Dropped		DM	N
95	Work organization, psychological distress, and health among minority older women	Anc: Rodriguez WHI: Curb	Complete		OS/CT	N
96	Longitudinal Insulin Sensitivity and Postmenopausal HRT	Anc: Cottrell WHI:	Dropped		OS/CT	N
97	Modeling serum markers for cost-effective ovarian cancer screening	Anc: Anderson WHI: Anderson	Funded	09/30/01-06/30/09	OS	Y
98	Bone mineral density as a predictor for periodontitis	Anc: Wactawski-Wend WHI: Trevisan	Funded		OS/CT 969 Ppts@Buffalo	N
99	GENNID Study	Anc: Chlebowski WHI: Chlebowski	Complete		OS/CT	N

Table 10.1 (continued)
All Ancillary Studies

AS	Title	PIs	Status	Study dates	Study Population*	Blood study
100	Genetic, Biochemical and Behavioral Determinants of Obesity	Anc: Hays WHI: Hays	Funded		OS/CT 797 Ppts@3 clinics	N
101	Women's Health Oral History Project	Anc: Allen WHI: Allen	Dropped			N
102	Quality of Life Improvements and Willingness to Pay: An Investigation of Selective Estrogen Receptor Modulators	Anc: Fouad WHI: Oberman	Complete		OS/CT	N
103	Effects of Hormone Replacement Therapy on Cognitive Aging: Women's Health Initiative Study of Cognitive Aging (WHISCA)	Anc: Shumaker WHI: Shumaker	Funded		HT 2266 Ppts@15 clinics	N
104	Tamoxifen Prevention: Is it acceptable to women at risk?	Anc: Melnikow WHI: Robbins	Complete		OS/CT	N
105	Carotenoids in Age-Related Eye Disease Study	Anc: Mares-Perlman WHI: Sarto	Complete	06/01/00-04/30/04	OS 2007 Ppts@15 clinics	Y
106	Gene-Diet Interactions in Human Breast Cancer Risk	Anc: Hu WHI: Paskett	Dropped		OS/CT	N
108	Gene-environment effects and Colorectal Cancer	Anc: Lin WHI: Chlebowski	Complete	04/01/03-03/31/04	OS	Y
110	Sex steroid hormones and risk of coronary heart disease: A nested case control study	Anc: Rexrode WHI: Manson	Complete	09/01/00-08/31/03	OS	Y
112	Motivators and Barriers to Exercise in Older Women	Anc: Haan WHI: Haan	Dropped		OS/CT	N
113	Some Aspects of Mediterranean Diet in Relation to Risk of Chronic Diseases among Postmenopausal Women	Anc: Hakim WHI: Bassford	Complete		OS/CT	N
114	Effects of Hormone Replacement Therapy on Cardiac Function and Ischemia	Anc: Haan WHI: Robbins	Dropped		HT	N
115	Diabetes In Postmenopausal Women	Anc: Howard WHI:	Dropped		OS/CT	N
116	National validation and quality assurance of vitamin D absorption from CaD tablets	Anc: Garland WHI:	Dropped			N
117	Risk Factors for Dry Eye Syndrome in Postmenopausal Women	Anc: Nichols WHI: Jackson	Analysis		OS/CT 217 Ppts@Columbus	N
118	Accuracy of Food Portion Estimation Among Postmenopausal Women	Anc: Coy WHI: Hubble	Complete		DM	N
119	The Longevity Consortium	Anc: Langer WHI: Langer	Dropped			N
120	Epidemiology of Cervical and Lumbar Stenosis	Anc: Vogt WHI: Kuller	Dropped		OS/CT	N
121	Hyperinsulinemia and Ovarian Cancer	Anc: Modugno WHI: Kuller	Complete	09/01/02-08/31/04	OS	Y
122	Feasibility Study of Computerized Tailored Dietary Feedback	Anc: Glanz WHI: Curb	Complete		HT	N

Table 10.1 (continued)
All Ancillary Studies

AS	Title	PIs	Status	Study dates	Study Population*	Blood study
123	Genetic and Ethnic Determinants of Nicotine Addiction in Postmenopausal Women	Anc: David WHI:	Dropped			N
124	Sociocultural Influences on Motivation for and Maintenance of Health-Related Dietary Change Among Women	Anc: Namic WHI: Langer	Complete		DM	N
125	Osteoporosis in Caribbean Hispanic Women	Anc: Cohen WHI: Smoller	Dropped		OS/CT	N
126	Stroke Risk Factors and Molecular Markers in Postmenopausal Women	Anc: Smoller WHI:	Complete	08/01/03-07/31/06	OS	Y
127	CHD Risk Perception Study	Anc: Barnhart WHI: Smoller	Funded		OS/CT	N
128	Mismatch Repair Gene Associated Malignancies in Women	Anc: Weber WHI: Smoller	Expired	04/01/04-03/31/08	OS	Y
129	Association of Diabetes and Insulin-Like Growth Factor-I (IGF-I) with Risks of Colorectal, Breast, and Endometrial Cancer	Anc: Strickler WHI: Smoller	Complete	02/01/02-12/31/05	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	Funded	07/01/01-06/30/06	CT 3889 Ppts@49 clinics	N
131	Sex Steroid Hormones, Inflammatory Cytokines and the Risk of Rheumatoid Arthritis: A Nested Case Control Study	Anc: Shadick WHI: Manson	Dropped		OS	Y
132	A Prospective Study of Genetic and Biochemical Predictors of Type 2 Diabetes Mellitus	Anc: Liu WHI: Manson	Funded	08/01/02-07/30/07	OS	Y
133	Biochemical and Genetic Predictors of Incident Hypertension in White and Black Women	Anc: Sesso WHI: Manson	Funded	08/01/04-07/31/08	OS	Y
134	Serum Estrogen Hormone Metabolites, Hormone Replacement Therapy and the Risk of Breast Cancer	Anc: Modugno WHI: Kuller	Complete	07/01/02-06/30/04	OS	Y
135	Natural History of Pelvic Organ Prolapse in WHI Women	Anc: Nygaard WHI: Wallace	Funded		HT	N
136	The Natural History of Female Pelvic Organ Prolapse	Anc: Handa WHI: Robbins	Dropped		HT	N
137	Postmenopause CHD risk: platelet genes and hormone therapy	Anc: Bray WHI: Hays	Funded	09/27/03-08/31/07	OS	Y
138	The Study of Tamoxifen, Raloxifene, and Cognition (Co-STAR)	Anc: Shumaker WHI:	Dropped		HT	N
139	Follow-up of Healthy Breast Cancer Survivors in the WHI Observational Study	Anc: Paskett WHI: Burke	Complete		OS/CT	N

Table 10.1 (continued)
All Ancillary Studies

AS	Title	PIs	Status	Study dates	Study Population*	Blood study
140	Air Pollution and Electrocardiographic Abnormalities	Anc: Whitsel WHI: Heiss	Funded	09/01/03-05/31/08	OS/CT	N
141	Periodontal Disease and Subclinical Cardiovascular Disease in Post-Menopausal Women	Anc: Dorn WHI: Trevisan	Complete		OS/CT	N
142	Thrombosis-related Genes in Population Subgroups Narrowly Defined by Race, Ethnicity, and Place of Birth	Anc: Kaplan WHI: Smoller	Dropped		OS	Y
143	Treatment of Elevated Cholesterol Among US Postmenopausal Women	Anc: Kaplan WHI: Smoller	Dropped		OS	Y
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:	Dropped		OS	Y
145	Pancreatic Cancer	Anc: Whitcomb WHI:	Dropped		OS	Y
146	A Prospective Study of Pancreatic Cancer Pathogenesis	Anc: Fuchs WHI: Manson	Complete	03/01/03-12/31/04	OS	Y
147	Gene-gene and gene-environment interactions and breast cancer risk	Anc: Eng WHI: Jackson	Dropped		OS	Y
148	Relationship Between Monoclonal Hemopoiesis and other Molecular Abnormalities and the Development of Leukemia in Older Women	Anc: Preisler WHI: Black	Expired		OS	Y
149	Gene-Environment Interactions and Human Breast Cancer Risk	Anc: Hu WHI:	Dropped	06/01/04-05/31/06	OS	Y
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:	Funded	05/01/02-05/31/06	OS/CT	N
151	Behavioral Management of Urinary Incontinence in African-American Women	Anc: Ruff WHI: Howard	Dropped		OS/CT	N
152	Growth Factor Genes and Female Breast, Colorectal, and Endometrial Cancers	Anc: Ho WHI Smoller	Funded	08/01/03-07/31/07	OS	Y
153	Longitudinal Changes in Hip Geometry and Skeletal Muscle	Anc: Chen WHI: Bassford	Funded	08/15/03-06/30/08	OS/CT 47 Ppts@Tucson	N
155	Carotenoids, Transforming Growth Factors, and Breast Cancer Risk	Anc: Rohan WHI: Smoller	Dropped		OS	Y
156	The Effect of Domestic Violence on Health Care Costs and Utilization	Anc: Mouton WHI: Schenken	PO Approved		OS/CT	N
157	Prediction of CHD Among Postmenopausal Women Using NMR Spectrscopy Lipoproteins	Anc: Kuller WHI: Kuller	Dropped		OS	Y
158	Potential Mediators of the Association of Depression with CVD	Anc: Wylie-Rosett WHI: Smoller	Dropped		OS	Y
159	The Insulin-like Growth Factor (IGF) System and Coronary Heart Disease	Anc: Kaplan WHI: Smoller	Dropped		OS	Y

Table 10.1 (continued)
All Ancillary Studies

AS	Title	PIs	Status	Study dates	Study Population*	Blood study
160	An Assessment of Symptoms and Symptom Self-Management for Women Abruptly stopping Hormone Replacement Study Pills	Anc: Valanis WHI: Ritenbaugh	Complete		CT	N
161	Bone Mass Response to Termination of Estrogen + Progestin	Anc: Cauley WHI: Kuller	Funded		CT	N
162	Interactive Telephone Strategy to Maintain Diet Change	Anc: Beresford WHI:	Tabled		CT	N
163	Hormone Use Following the WHI E+P Trial Termination: A Pilot Study	Anc: Hays WHI: Hays	SC Approved		OS/CT	N
164	The IGF System and Coronary Heart Disease	Anc: Kaplan WHI: Smoller	Expired	01/01/06- 12/31/06	OS	Y
165	Subclinical Thyroid Dysfunction and Risk of Myocardial Infarction and Stroke	Anc: Hartmann WHI: Heiss	Funded	09/01/04- 07/31/07	OS	Y
166	Estrogen Replacement Therapy and Autoantibodies	Anc: Mackay WHI: Smoller	Dropped		OS	Y
167	Sex Hormones, Risk Factors, and Risk of ER+ and ER- Breast Cancer	Anc: Cummings WHI:	Funded	01/01/05- 12/31/06	OS	Y
168	Plasma Inflammatory Markers and Colorectal Cancer	Anc: Ho WHI: Smoller	Dropped		OS	Y
169	Risk Factors for Hemorrhagic Stroke Among Postmenopausal Women	Anc: Kaplan WHI: Smoller	Not Funded	04/01/06- 07/30/10	OS	Y
170	WHI Nutrition and Diabetes Study (WHINDS)	Anc: Margolis WHI: Margolis	Dropped		DM	N
171	Analysis of Heart Rate Variability from Ultra-short Records: The WHI Study	Anc: Michael WHI: Ritenbaugh	Complete		CT	N
172	Estrogen Receptor Polymorphisms and Cardiovascular Effects of HRT	Anc: Herrington WHI: Burke	Dropped		CT	N
173	Relationship of Biomarkers and Genetic Markers to Risk of Congestive Heart Failure	Anc: Chae WHI: Manson	Not Approved		OS	Y
174	Proinflammatory Markers and Colorectal Cancer	Anc: Ho WHI: Smoller	Not Approved		OS	Y
175	Physical Function Determinants in Minority Women	Anc: Nicholas WHI: Bassford	Funded		OS/CT	N
176	Long Term Breast and Colorectal Cancer Survivors in the OS	Anc: Rahmani WHI: Smoller	Dropped		OS/CT	N
177	Relative Risk Differences Between FFQs and Food Records	Anc: Subar WHI: Patterson	Funded		DM	N
178	Mammographic Density and Invasive Breast Cancer	Anc: Pisano WHI: Heiss	Funded	03/12/04- 02/28/07	CT 793 Ppts@34 clinics	N
179	Frailty in WHI: Drugs, Inflammatory and Genetic Markers	Anc: LaCroix WHI:	Funded	09/15/05- 07/31/08	OS	Y

Table 10.1 (continued)
All Ancillary Studies

AS	Title	PIs	Status	Study dates	Study Population*	Blood study
180	Gene-environment Interaction for Diabetic Complications in Postmenopausal Women	Anc: Li WHI: Johnson	Expired	12/01/05-11/30/09	OS	Y
181	Estradiol, Cytokines, and Bone Turnover: Effects on Hip Fracture	Anc: Cauley WHI: Kuller	Funded	07/01/05-06/30/08	OS	Y
182	Genetic and Epigenetic Markers of Lung Cancer Risk in Post-menopausal Women	Anc: Schlecht WHI: Smoller	Submitted	04/01/07-03/30/10	OS	Y
183	WHIMS MRI study	Anc: Shumaker WHI:	Funded		OS/CT	N
184	Measures for Changes in Skeletal Muscle Mass	Anc: Chen WHI: Bassford	PO Approved		OS/CT	N
185	An Assessment of Symptoms and Symptom Self-Management for Women Abruptly Stopping Hormone Replacement Study Pills	Anc: Ritenbaugh WHI: Ritenbaugh	Funded		HT	N
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	Not Approved		OS	Y
187	Serum Fatty Acids and Salicylic Acid in Relation to Incidence of Ischemic Stroke in Postmenopausal Women	Anc: He WHI: Van Horn	Submitted	04/01/07-03/31/09	OS	Y
188	Inflammation and the Risk of Hormonally-Linked Cancer	Anc: Modugno WHI: Kuller	Submitted	07/01/07-06/30/10	OS	Y
189	Biochemical and Anthropometric Heterogeneity among Morbid Obese Women in the Women's Health Initiative Observational Study	Anc: Mackey WHI: Kuller	Funded	05/01/06-04/30/09	OS	Y
190	Insulin resistance and vitamin D	Anc: Hsia WHI: Hsia	Not Approved		CaD	Y
191	Cytokines, Hormones and Sarcopenia in Older Women	Anc: Chen WHI: Bassford	Submitted	07/01/07-06/30/12	OS	Y
192	Estrogen and progesterone-related genes and colorectal cancer risk	Anc: Zhang WHI: Manson	Funded	07/01/06-06/30/10	OS	Y
193	Immune Dysregulation in the Pathogenesis of Non Hodgkin's Lymphoma	Anc: DeRoos WHI: LaCroix	Not Approved		OS	Y
194	Genetic Epidemiology of Hip Fracture in WHI & SOF	Anc: Zmuda WHI: Kuller	Proposed		OS	Y
195	Candidate pathways in colorectal carcinogenesis: one-carbon metabolism and inflammation	Anc: Ulrich WHI: Prentice	Submitted	03/01/06-02/28/11	OS	Y
196	Heart failure evaluation in post-menopausal women: the Women's Health Initiative Study	Anc: Klein WHI: Van Horn	Not Funded		HT	N
197	Validity of self-reported diabetes mellitus in the Women's Health Initiative	Anc: Margolis WHI: Margolis	Funded		CT	N
198	Women's Thoughts and Feelings About Participating In a Clinical Trial	Anc: Furniss WHI: Lasser	PO Approved		HT	N
199	Genetic Factors of Muscle Loss	Anc: Chen WHI: Bassford	Not Funded		OS	Y

Table 10.1 (continued)
All Ancillary Studies

AS	Title	PIs	Status	Study dates	Study Population*	Blood study
200	Women's Health Initiative Cancer Survivor Cohort: Biological, Psychosocial, and Behavioral Predictors of Survival	Anc: Paskett WHI: Jackson	Not Approved		OS	Y
201	Effect of hormone therapy on angiotensin II and Microalbuminuria Among Postmenopausal Women	Anc: Agarwal WHI: Bonds	Not Approved		HT	Y
202	Insulin/IGF and risk of BBD: a cohort study	Anc: Rohan WHI: Smoller	Not Approved		CT	Y
203	Infection of Helicobacter pylori, other Helicobacter species and the risk of pancreatic cancer among postmenopausal women	Anc: Ye WHI: Margolis	Not Approved		OS	Y
204	Genetic Susceptibility of Chronic Kidney Disease	Anc: Vupputuri WHI: Heiss	Not Approved		OS	Y
205	Genome-wide scan of cardiovascular disease and breast cancer and combined postmenopausal hormone therapy	Anc: Prentice WHI: Grimm	Tabled			Y
206	Selenium, Genetic Variation in Selenoenzymes and Colorectal Cancer	Anc: Peters WHI: Prentice	Funded	07/01/06-06/30/09	OS	Y
207	IGF and Multiple Myeloma	Anc: Colditz WHI: Manson	Submitted		OS	Y
208	Proinflammatory Markers and Colorectal Cancer	Anc: Ho WHI: Smoller	Submitted	04/01/07-03/31/10	OS	Y
209	Red blood cell omega-3 and trans fatty levels and the risk of coronary heart disease death	Anc: Harris WHI: Wallace	Not Funded		OS	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	Not Approved		DM	Y
211	Homocysteine Levels, B Vitamins and Bone Health in Women	Anc: LeBoff WHI: Manson	Submitted	12/01/07-11/30/10	OS	Y
212	Biochemical Antecedents of Fracture in Minority Women	Anc: Cauley WHI: Kuller	Not Funded	07/01/07-06/30/11	OS	Y
213	Assays for Early Detection of Cancer	Anc: Hendrix WHI: Hendrix	Not Approved		OS	Y
214	A Prospective Study of Pancreatic Cancer Pathogenesis - extension	Anc: Fuchs WHI: Manson	Not Funded	07/01/07-06/30/12	OS	Y
215	UGTs, NSAIDs, and breast cancer risk in the WHI Observational Study	Anc: Lampe WHI: Prentice	Not Funded	12/01/05-11/30/09	OS	Y
216	Decision-making about cancer screening among older women	Anc: Messina WHI: Lane	Funded		OS/CT 334 Ppts@Stonybrk	N
217	Validation of the self-report of Rheumatoid Arthritis and Systemic Lupus Erythematosus: The Women's Health Initiative	Anc: Wallitt WHI: Howard	PO Approved		CT	N
218	WHI Nutrition and Physical Activity Assessment Study (NPAAS)	Anc: Prentice WHI: Neuhouser	Funded	07/12/06-06/30/09	OS/CT	N
219	Diet And Eye Health In The WHI: End Of Trial Study	Anc: Mares WHI: Sarto	Not Funded		DM 195 Ppts@Madison	N

Table 10.1 (continued)
All Ancillary Studies

AS	Title	PIs	Status	Study dates	Study Population*	Blood study
220	Neighborhoods, Women, and Coronary Heart Disease: A Prospective Study	Anc: Bird WHI: Margolis	Not Funded	12/01/06-11/30/09	OS/CT	N
221	Dietary modification, calcium/vitamin D supplementation, and change in breast density	Anc: Rohan WHI: Smoller	Submitted		DM/CaD	N
222	Developmental Research of Air Pollution as a Cause of Common Cancers	Anc: DeRoos WHI: LaCroix	Not Approved		OS/CT	N
223	Women's Health Initiative Cancer Survivor Cohort: Biological, Psychosocial and Behavioral Predictors of Survival	Anc: Paskett WHI: Jackson	Not Funded		OS/CT	N
224	Genome-wide Association Study for Nonsynonymous NSPs in Colon Cancer	Anc: Peters WHI: Prentice	Submitted	08/01/06-08/01/10	OS	Y
225	Potential gene-environment interaction on the association between chronic ai pollution exposure and incident MI in the WHI-OS	Anc: Sullivan WHI: Beresford	Not Approved		OS/CT	N
226	Socioeconomic and environmental disparities in sleep disturbance	Anc: WHI: Heiss	Submitted		OS/CT	N
227	Risk factors and biomarkers for Parkinson¿s disease	Anc: WHI: Manson	Proposed		OS/CT	Y
228	Obesity, diet, physical activity and medicare costs	Anc: Yan WHI: Van Horn	PO Approved	01/01/07-12/31/11	OS/CT	N
229	Genome wide, case-control analysis of SNP associations with cardiovascular disease in African American women	Anc: Carlson WHI: LaCroix	Submitted	09/20/06-09/20/09	OS/CT	N
230	Markers of inflammation and renal function and hte risk of coronary heart disease and mortality in women with diabetes	Anc: Rajpathak WHI: Smoller	Not Approved	10/20/08-10/20/10	OS	Y
231	Relationship between circulating nutrient biomarkers and death from coronar heart disease or myocardial infarct	Anc: Lichtenstein WHI: Van Horn	Proposed	09/01/07-08/31/09	OS	Y
233	WHIMS Extension	Anc: WHI:	Proposed		HT 2860 Ppts@31 clinics	N
R1	Glycemic Index/Glycemic Load and Blood Lipids in the WHI	Anc: Shikany WHI: Lewis	Complete	07/01/03-06/30/05		N

* Number of clinics includes number of satellite sites

Table 10.2
Approved Ancillary Studies Using Specimens by Outcome

Disease	Anc ID	Title	PIs	Status	Study Dates	Study Population	Blood Usage
Breast Cancer	129	Association of Diabetes and Insulin-Like Growth Factor-I (IGF-I) with Risks of Colorectal, Breast, and Endometrial Cancer	Anc: Strickler WHI: Smoller	Complete	02/01/02-12/31/05	OS Breast Cancer:900 Colorectal Cancer:500 Endometrial Cancer:300 Controls:900 *same as AS152	Serum .2ml: Total Estradiol Vitros Assay Serum .25ml: Glucose; Insulin Serum .25ml: IGF Free; IGF binding protein-3; IGF-I competitive binding DSL
Breast Cancer	134	Serum Estrogen Hormone Metabolites, Hormone Replacement Therapy and the Risk of Breast Cancer	Anc: Modugno WHI: Kuller	Complete	07/01/02-06/30/04	OS Breast Cancer: 200 Controls: 200	Serum .25ml: 16a-OH estrone; 2-OH estrone
Breast Cancer	152	Growth Factor Genes and Female Breast, Colorectal, and Endometrial Cancers	Anc: Ho	Funded	08/01/03-07/31/07	OS Colorectal Cancer:500 Endometrial Cancer:300 Controls:900 *Same as AS129	DNA 3ug: IGF-1; IGFBP-3; insulin, insulin receptor substrate 1; ERK1, ERK2, PIK3R1, AKT1, AKT2
Breast Cancer	167	Sex Hormones, Risk Factors, and Risk of ER+ and ER- Breast Cancer	Anc: Cummings	Funded	01/01/05-12/31/06	OS Breast Cancer:400 Controls: 600	Serum .95ml: Estradiol; Sex Hormone Binding Globulin; Testosterone
Breast Cancer	188	Inflammation and the Risk of Hormonally-Linked Cancer	Anc: Modugno WHI: Kuller	Submitted	07/01/07-06/30/10	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	DNA 1ug: TNFalpha-308 (AA);IL-6 -597/-572/-373/-174;IL-1B-31 (TT); IL-1B-511 (TT); IL-1RNVNTR*2;TGFalpha1 29 (CC); TGFalphaR1*6A;IL-10-1082/-819/-592 (GCC/GCC);Il-8-251-A-T;IGF-1 (CA)n 192/192 EDTA .35ml: IL-1 cluster, IL-2, IL-4, IL-5, IL-6, IL-8, IL-10, IL-12p40, IL-13, IL-15, IL-17, TNFa, IFNs, FGF, GCSF, GMCSF, EGF, VEGF, MCP, MIPs, eot, sIL-6r I; sIL-2r; EGFR, and TNFa soluble receptors I and II; CRP Serum .25ml: Estradiol

Table 10.2 (continued)
Approved Ancillary Studies Using Specimens by Outcome

Disease	Anc ID	Title	PIs	Status	Study Dates	Study Population	Blood Usage
Breast Cancer	215	UGTs, NSAIDs, and breast cancer risk in the WHI Observational Study	Anc: Lampe WHI: Prentice	Not Funded	12/01/05-11/30/09	OS Breast Cancer:3398 Controls:3398 *all ppts diagnosed with breast cancer at least one year after enrollment	DNA .4ug: UGT1A1*28, UGT1A3(W11R), UGT1A3(V47A), UGT1A3(M270V), UGT1A6*2, UGT1A6*3, UGT1A7*2, UGT1A7*3, UGT1A7*4, UGT1A8*2, UGT1A8*3, UGT1A9(T[10]), UGT1A9*3, UGT2B4(D458E), UGT2B7(H268Y), CYP2C9*2, CYP2C9*3
CHD	83	Thrombotic, Inflammatory and Genetic Markers for Coronary Heart Disease in Postmenopausal Women: A WHI Umbrella Study	Anc: Ridker WHI: LaCroix	Complete	09/01/99-08/31/03	OS CHD: 650 Controls: 650	Citrate 1ml: D-dimers; tPA - Tissue type plasminogen act EDTA 1ml: Apolipoprotein(a); C-reactive protein; High-density lipoprotein cholesterol; Homocysteine; Interluckin 6, ultrasensitive; Low-density lipoprotein cholesterol; Soluble intracellular adhesion molecule; Total Cholesterol; Triglyceride
CHD	110	Sex steroid hormones and risk of coronary heart disease: A nested case control study	Anc: Rexrode	Complete	09/01/00-08/31/03	OS CHD: 385 Controls: 385 *79 matched cases-controls and 92 cases (but not controls) overlap with AS83.	Citrate 1ml: Factor VII Ag (antigen); Factor VIIC; Fibrinogen EDTA 1ml: Apolipoprotein(a); High-density lipoprotein cholesterol; High-density lipoprotein-2; High-density lipoprotein-3; Low-density lipoprotein cholesterol; Total Cholesterol; Triglyceride Serum 1ml: Dehydroepiandrosterone Sulfate (SO4); Estradiol; Estrone-sulfate; Sex Hormone Binding Globulin; Testosterone Serum .25ml: Glucose; Insulin
CHD	137	Postmenopause CHD risk: platelet genes and hormone therapy	Anc: Bray WHI: Hays	Funded	09/27/03-08/31/07	OS CHD:1060 Controls:2120	DNA 3ug: GPIIIa (integrin beta3); integrin alpha2 (platelet GPIa); GPI b alpha; ER beta; ER alpha; alpha2-adrenergic receptor; beta 3 subunit of G protein; GPVI
CHD	164	The IGF System and Coronary Heart Disease	Anc: Kaplan WHI: Smoller	Expired		OS CHD: 350 Controls: 350	Serum .2ml: Total IGF-I, IGFBP-3
CHD	165	Subclinical Thyroid Dysfunction and Risk of Myocardial Infarction and Stroke	Anc: Hartmann WHI: Heiss	Funded	09/01/04-07/31/07	OS CHD:800 Stroke:591 Controls:3136	Serum .25ml: Anti-thyroid peroxidase autoantibodies; Free thyroxine Serum .3ml: Thyroid Stimulating Hormone

Table 10.2 (continued)
Approved Ancillary Studies Using Specimens by Outcome

Disease	Anc ID	Title	PIs	Status	Study Dates	Study Population	Blood Usage
CHD	189	Biochemical and Anthropometric Heterogeneity among Morbid Obese Women in the Women's Health Initiative Observational Study	Anc: Mackey WHI: Kuller	Funded	05/01/06-04/30/09	OS CHD:150 Controls:1300	EDTA .2ml: NMR lipoproteins Serum .57ml: Adiponectin; ghrelin; glucose; insulin; leptin
CHD	209	Red blood cell omega-3 and trans fatty levels and the risk of coronary heart disease death	Anc: Harris WHI: Wallace	Not Funded		Ppts: OS CHD:800 Controls:800 *cases are CHD deaths	RBC .3ml: EPA, DHA, ALA, trans fatty acids
Cancer of Lung	182	Genetic and Epigenetic Markers of Lung Cancer Risk in Post-Menopausal Women	Anc: Schlecht WHI: Smoller	Submitted	04/01/07-03/30/10	OS Cancer of Lung:720 Controls:1440	Citrate .3ml: Folate, B12, B6, homocysteine DNA 1ug: Dnmt1; Dnmt3b; MSS; MS; MTHFR
Colorectal Cancer	108	Gene-environment effects and Colorectal Cancer	Anc: Lin WHI: Chlebowski	Complete	04/01/03-03/31/04	OS Colorectal Cancer:50 Controls:150	DNA 1ug: Hematopoietic prostaglandin D synthase - val187ile; Post-transcriptional gene silencing
Colorectal Cancer	128	Mismatch Repair Gene Associated Malignancies in Women	Anc: Weber WHI: Smoller	Expired		OS Colorectal Cancer:1025 Endometrial Cancer:710 Ovarian Cancer:405 Controls: 1000	DNA 3ug case: DNA mismatch repair genes: hMSH2, hMLH1, hMSH6. Experimental methods for cases: DHPLC, Automated DNA sequencing. 1 ug control: Experimental methods for controls: pyrosequencing
Colorectal Cancer	129	Association of Diabetes and Insulin-Like Growth Factor-I (IGF-I) with Risks of Colorectal, Breast, and Endometrial Cancer	Anc: Strickler WHI: Smoller	Complete	02/01/02-12/31/05	OS Breast Cancer:900 Colorectal Cancer:500 Endometrial Cancer:300 Controls:900 *same as AS152	Serum .2ml: Total Estradiol Vitros Assay Serum .25ml: Glucose; Insulin Serum .25ml: IGF Free; IGF binding protein-3; IGF-I competitive binding DSL
Colorectal Cancer	152	Growth Factor Genes and Female Breast, Colorectal, and Endometrial Cancers	Anc: Ho WHI: Smoller	Funded	08/01/03-07/31/07	OS Breast Cancer:900 Colorectal Cancer:500 Endometrial Cancer:300 Controls:900	DNA 3ug: IGF-1; IGFBP-3; insulin, insulin receptor substrate 1; ERK1, ERK2, PIK3R1, AKT1, AKT2

Table 10.2 (continued)
Approved Ancillary Studies Using Specimens by Outcome

Disease	Anc ID	Title	PIs	Status	Study Dates	Study Population	Blood Usage
Colorectal Cancer	192	Estrogen and progesterone-related genes and colorectal cancer risk	Anc: Zhang WHI: Manson	Funded	07/01/06-06/30/10	OS Colorectal Cancer:800 Controls:1600	DNA 2ug: ESR1 (PVII; Xbal); ESR2 (CA repeat; G1730A); PGR (G+331A); CYP1A1 (MspI; Ile462Val); CYP1B1 (Leu432Val; Asn453Ser); CYP17A1 (T-34C); CYP19A1 ([TTTA]n repeat; G240A); COMT (Val158Met); HSD17B2 (Ser312Gly); 100 SNPs for haplotype analyses
Colorectal Cancer	195	Candidate pathways in colorectal carcinogenesis: one-carbon metabolism and inflammation	Anc: Ulrich WHI: Prentice	Submitted	03/01/06-02/28/11	OS Colorectal Cancer:1000 Controls:1500 *Same cases/controls as AS 206	DNA .8ug: Candidate polymorphisms in one-carbon metabolism (MTHFR, thymidylate synthase, reduced folate carrier, trifunctional enzyme, gamma-glutamyl-hydrolase, methionine synthase, methionine synthase reductase, serine hydroxyl-methyl-transferase, holo-transcobalamin II, DNA methyltransferase, alcohol dehydrogenase II) and in prostaglandin synthesis/pro-inflammatory cytokines (Cyclooxygenases 1 and 2, 5-Lipoxygenase, Prostacyclin synthase, TGFbeta, C-reactive protein, TNF alpha and interleukin 6); global DNA methylation EDTA .85ml: Plasma homocysteine, folate, pyridoxal-5-phosphate (vitamin B6), vitamin B12, and holotranscobalamin II RBC .25ml: Red blood cell folate Serum .25ml: C-reactive protein, serum-amyloid A, creatinine
Colorectal Cancer	206	Selenium, Genetic Variation in Selenoenzymes and Colorectal Cancer	Anc: Ulrich WHI: Prentice	Funded	07/01/06-06/30/09	OS Colorectal Cancer:805 Controls: 805 *Same cases/controls as AS195	DNA: 0.8ug: about 40 tagging polymorphisms in the following 6 selenoenzypes: GPX1, GPX2, GPX3, GPX4, TXNRD1, SEPP1 Serum .13ml: Selenium levels with atomic absorption spectrometry
Colorectal Cancer	208	Proinflammatory Markers and Colorectal Cancer	Anc: Ho WHI: Smoller	Submitted	04/01/07-03/31/10	OS Colorectal Cancer:500 Controls:900 *same cases/controls as AS 129	DNA 1ug: TNFa,TNFR1,TNFR2,IkBa, IkBb, IKKBb, IL6, gp130, STAT3 EDTA .55ml: TNFa, IL-6, CRP

Table 10.2 (continued)
Approved Ancillary Studies Using Specimens by Outcome

Disease	Anc ID	Title	PIs	Status	Study Dates	Study Population	Blood Usage
Endometrial Cancer	128	Mismatch Repair Gene Associated Malignancies in Women	Anc: Weber WHI: Smoller	Expired		OS Colorectal Cancer:1025 Endometrial Cancer:710 Ovarian Cancer:405 Controls: 1000	DNA 3ug case: DNA mismatch repair genes: hMSH2, hMLH1, hMSH6. Experimental methods for cases: DHPLC, Automated DNA sequencing. 1 ug control: Experimental methods for controls: pyrosequencing
Endometrial Cancer	129	Association of Diabetes and Insulin-Like Growth Factor-I (IGF-I) with Risks of Colorectal, Breast, and Endometrial Cancer	Anc: Strickler WHI: Smoller	Complete	02/01/02-12/31/05	OS Breast Cancer:900 Colorectal Cancer:500 Endometrial Cancer:300 Controls:900 *same as AS152	Serum .2ml: Total Estradiol Vitros Assay Serum .25ml: Glucose; Insulin Serum .25ml: IGF Free; IGF binding protein-3; IGF-I competitive binding DSL
Endometrial Cancer	152	Growth Factor Genes and Female Breast, Colorectal, and Endometrial Cancers	Anc: Ho WHI: Smoller	Funded	08/01/03-07/31/07	OS Breast Cancer:900 Colorectal Cancer:500 Endometrial Cancer:300 Controls:900	DNA 3ug: IGF-1; IGFBP-3; insulin, insulin receptor substrate 1; ERK1, ERK2, PIK3R1, AKT1, AKT2
Endometrial Cancer	188	Inflammation and the Risk of Hormonally-Linked Cancer	Anc: Modugno WHI: Kuller	Submitted	07/01/07-06/30/10	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	DNA 1ug: TNFalpha-308 (AA);IL-6 -597/-572/-373/-174;IL-1B-31 (TT); IL-1B-511 (TT); IL-1RNVNTR*2;TGFalpha1 29 (CC); TGFalphaR1*6A;IL-10-1082/-819/-592 (GCC/GCC);Il-8-251-A-T;IGF-1 (CA)n 192/192 EDTA .35ml: IL-1 cluster, IL-2, IL-4, IL-5, IL-6, IL-8, IL-10, IL-12p40, IL-13, IL-15, IL-17, TNFa, IFNs, FGF, GCSF, GMCSF, EGF, VEGF, MCP, MIPs, eot, sIL-6r I; sIL-2r; EGFR, and TNFa soluble receptors I and II; CRP Serum .25ml: Estradiol

Table 10.2 (continued)
Approved Ancillary Studies Using Specimens by Outcome

Disease	Anc ID	Title	PIs	Status	Study Dates	Study Population	Blood Usage
Eye	105	Carotenoids in Age-Related Eye Disease Study	Anc: Mares-Perlman WHI: Sarto	Complete	06/01/00-04/30/04	OS Eye:1350 Controls:1350	Serum .3ml: Total Cholesterol; Triglyceride Serum .3ml: Alpha-Carotene; Beta-Carotene, all trans; Beta-carotene, 13cis; Beta-carotene, 9cis; Cryptoxanthine (alpha + beta); Lutein cis isomer 1; Lutein cis isomer 2; Lutein cis isomer 3; Lutein, all trans; Lycopene, 13 cis; Lycopene, 15 cis; Lycopene, 5 cis; Lycopene, 9 cis; Lycopene, all trans; Lycopene, total (trans + cis); Retinol; Tocopherol, Alpha; Tocopherol, Delta; Tocopherol, Gamma; Zeaxanthin; Zeaxanthin cis isomer; retinyl palmitate; 12/04 add CRP, 25-OH vit D
Fracture (general)	211	Homocysteine Levels, B Vitamins and Bone Health in Women	Anc: LeBoff WHI: Manson	Submitted	12/01/07-11/30/10	OS Fracture (general):2500 Controls:2500 *2500 cases/2500 controls for EDTA plasma (B+Y3) and DNA; 400 cases/400 controls for serum and urine	DNA 1ug: MTHFR C677T and A1298C; CBS G919A and T833C; MTR A2756; MTRR G66A EDTA .55ml: Homocysteine Serum 1.05ml: BSAP, osteocalcin, OPG, RANKL, TRACP Urine .55ml: N-telopeptides
Fracture (general)	212	Biochemical Antecedents of Fracture in Minority Women	Anc: Cauley WHI: Kuller	Not Funded	07/01/07-06/30/11	OS Fracture (general):1320 Controls: 1320	EDTA .25ml: PTH Serum .7ml: Estradiol, testosterone, SHBG; 25-OH Vitamin D Serum .4ml: PINP, CTx
Fracture - Hip	90	WHI Sex Hormone and Genetic Risk Factors for Hip Fracture	Anc: Cummings WHI: Cummings	Funded	04/01/04-03/31/07	OS Fracture - Hip:400 Controls:400 *same as AS181	DNA 3ug: Apolipoprotein-E4; Collagen Ialpha1 Sp1 polymorphism; Transforming growth factor - Beta Leu10Pro; androgen receptor (AR); aromatase (CYP19); ESR1; ESR2; LDL receptor-related protein 5 (LRP5); SHBG;Vitamin D receptor start codon polymorphism (VDRFOK1) Serum .85ml: Estradiol; IGF-I competitive binding RIA; Sex Hormone Binding Globulin; Testosterone Serum .5ml: Cystatin-C; Homocysteine HPLC; Thyroid Stimulating Hormone

Table 10.2 (continued)
Approved Ancillary Studies Using Specimens by Outcome

Disease	Anc ID	Title	PIs	Status	Study Dates	Study Population	Blood Usage
Fracture - Hip	181	Estradiol, Cytokines, and Bone Turnover: Effects on Hip Fracture	Anc: Cauley WHI: Kuller	Funded	07/01/05-06/30/08	OS Fracture - Hip:400 Controls:400 *same as AS90	Serum .55ml: Vitamin D 25OH Serum .3ml: Aminoterminal procollagen extension propetide; C-Terminal Telopeptide of Type I Collagen Serum 0ml: Interluekin 6, soluble receptor; Osteoprotegerin; TNFalpha SR1; TNFalpha SR2
Fraility-disability	179	Frailty in WHI: Drugs, Inflammatory and Genetic Markers	Anc: LaCroix WHI: LaCroix	Funded	09/15/05-07/31/08	OS Fraility: 900 Controls:9000	Citrate .75ml: D-dimers; Factor VIII Activity; Fibrinogen; tPA - Tissue type plasminogen act DNA 1ug: ACE gene insertion (I) polymorphism; two promotor polymorphisms (-174G/C and -572G/C) of the IL-6 gene EDTA .3ml: C-reactive protein; Interluekin 6, ultrasensitive
Hyperten-sion	133	Biochemical and Genetic Predictors of Incident Hypertension in White and Black Women	Anc: Sesso WHI: Manson	Funded	08/01/04-07/31/08	OS Hypertension:800 Controls:800	DNA 2ug: CRP, sICAM-1,IL-6,TNF-alpha; IL-1beta; MMP-9, Adiponectin, PPAR-gamma2 EDTA .85ml: C-reactive protein; IL-1Beta (interluekin); Interluekin 6, ultrasensitive; Matrix metalloproteinases; Soluble intracellular adhesion molecule; Tumor necrosis factor Alpha
Leukemia	148	Relationship between Monoclonal Hemopoiesis and other Molecular Abnormalities and the Development of Leukemia in Older Women	Anc: Priesler WHI: Black	Expired		OS Leukemia: 59 Controls: 177	DNA 3ug: Clonality of hemopoiesis, presence of N-ras mutation and methylation of the of p15 gene
Lung Cancer	182	Genetic and Epigenetic Markers of Lung Cancer Risk in Post-menopausal Women	Anc: Schlecht WHI: Smoller	Submitted	04/01/07-03/30/10	OS Cancer of Lung:720 Controls:1440	Citrate .3ml: Folate, B12, B6, homocysteine DNA 1ug: Dnmt1; Dnmt3b; MSS; MS; MTHFR
Ovarian Cancer	97	Modeling serum markers for cost-effective ovarian cancer screening	Anc: Anderson WHI: Anderson	Funded	09/30/01-06/30/09	OS Ovarian Cancer:240 Controls:480	Serum .35ml: Cancer antigen 125; Macrophage colony-stimulating factor; Ovarian tumor marker
Ovarian Cancer	121	Hyperinsulinemia and Ovarian Cancer	Anc: Modugno WHI: Kuller	Complete	09/01/02-08/31/04	OS Ovarian Cancer: 225 Controls:225 *originally a subset of AS97	Serum .25ml: Glucose; Insulin Serum .25ml: IGF binding protein-1; IGF binding protein-3; IGF-I

Table 10.2 (continued)
Approved Ancillary Studies Using Specimens by Outcome

Disease	Anc ID	Title	PIs	Status	Study Dates	Study Population	Blood Usage
Ovarian Cancer	128	Mismatch Repair Gene Associated Malignancies in Women	Anc: Weber WHI: Smoller	Expired		OS Colorectal Cancer:1025 Endometrial Cancer:710 Ovarian Cancer:405 Controls: 1000	DNA 3ug case: DNA mismatch repair genes: hMSH2, hMLH1, hMSH6. Experimental methods for cases: DHPLC, Automated DNA sequencing. 1 ug control: Experimental methods for controls: pyrosequencing
Ovarian Cancer	188	Inflammation and the Risk of Hormonally-Linked Cancer	Anc: Modugno WHI: Kuller	Submitted	07/01/07-06/30/10	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	DNA 1ug: TNFalpha-308 (AA);IL-6 -597/-572/-373/-174;IL-1B-31 (TT); IL-1B-511 (TT); IL-1RNVNTR*2;TGFalpha1 29 (CC); TGFalphaR1*6A;IL-10-1082/-819/-592 (GCC/GCC);Il-8-251-A-T;IGF-1 (CA)n 192/192 EDTA .35ml: IL-1 cluster, IL-2, IL-4, IL-5, IL-6, IL-8, IL-10, IL-12p40, IL-13, IL-15, IL-17, TNFa, IFNs, FGF, GCSF, GMCSF, EGF, VEGF, MCP, MIPs, eot, sIL-6r I; sIL-2r; EGFR, and TNFa soluble receptors I and II; CRP Serum .25ml: Estradiol
Pancreatic Cancer	146	A Prospective Study of Pancreatic Cancer Pathogenesis	Anc: Fuchs WHI: Manson	Complete	03/01/03-12/31/04	OS Pancreatic Cancer:106 Controls:318	DNA 3ug: N-acetyltransferase-1; N-acetyltransferase-2; CYP1A1, GSTM1, MTHFR-667, MTHFR-1287 EDTA .7ml: C-Peptide; Folate; Homocysteine; IGF binding protein-1; IGF binding protein-3; IGF-I; IGF-II; Insulin; Pyridoxal-5'-phosphate; Vitamin B12
Pancreatic Cancer	214	A Prospective Study of Pancreatic Cancer Pathogenesis - Extension	Anc: Fuchs WHI: Manson	Not Funded	07/01/07-06/30/12	OS Pancreatic Cancer:200 Controls:400	DNA 1ug: IRS1, IRS2, IGF1, IGF2, IGF1R, IGF2R, GH1, GHR, IGFBP1, IGFBP3, ACDC, IL1B, IL1RN, IL6, IL8, IL10, TNF, TGFB1, PPARD, NFKB1, NFKBIA, NFKBIL1, PTGS1, PTGS2, VDR EDTA 1.25ml: C-peptide, insulin, proinsulin, adiponectin, leptin, CRP, IL-6, TNF-alpha-receptor II, H. pylori whole cell and CagA antibodies, gastrin, carotenoids, retinol, 25(OH)vitamin D

Table 10.2 (continued)
Approved Ancillary Studies Using Specimens by Outcome

Disease	Anc ID	Title	PIs	Status	Study Dates	Study Population	Blood Usage
Sarcopenia	191	Cytokines, Hormones and Sarcopenia in Older Women	Anc: Chen WHI: Bassford	Submitted	07/01/07-06/30/12	OS Sarcopenia:800 Controls:2000 *Identification of cases done in AS153	DNA .5ug: IL-6 (3 marker SNPs and 1 minisatellite); IL1beta, IL1alpha, and IL1ra gene cluster (5 SNPs); TNF-alpha (4 sites); IGF-1 (8 tag snps); GH1 (3 SNPs) EDTA .35ml: CRP, Insulin, leptin, Acid Labile Subunit (ALS), IL-1a, IL-1b, IL-1ra, IL-6, IL-6sR, IL-10, TNF-alpha, TNFRII, IGF-1, IGFBP-1, IGFBP-3
Sarcopenia	199	Genetic Factors of Muscle Loss	Anc: Chen WHI: Bassford	Not Funded		OS Sarcopenia:800 Controls:2000 *Add to AS191	DNA.5ug:See AS 191
Stroke	126	Stroke Risk Factors and Molecular Markers in Postmenopausal Women	Anc: Smoller WHI: Smoller	Complete	08/01/03-07/31/06	OS Stroke: 1100 Controls: 1100	Citrate 1.25ml: D-dimers; Factor VII Ag (antigen); Factor VIIC; Fibrinogen; PAI-1 Antigen; Prothrombin fragment 1+2; Tumor necrosis factor Alpha; tPA - Tissue type plasminogen act EDTA .1ml: Lp-PLA2 or lipoprotein-associated phospholipase A2 EDTA .2ml: HDL Particles (total); HDL Size; High-density lipoprotein cholesterol; IDL; LDL Particles (total); LDL Size; Large HDL; Large LDL; Large VLDL/Chylomicrons; Medium HDL; Medium Small LDL; Medium VLDL; Small HDL; Small LDL (total); Small VLDL; Triglyceride; VLDL Particles (total); VLDL Size; VLDL-TG; Very Small LDL EDTA 1.22ml: Apolipoprotein(a); C-reactive protein; Glucose; High-density lipoprotein cholesterol; Homocysteine; Insulin; Interluekin 6, ultrasensitive; Neopterin; Total Cholesterol; Triglyceride; Vascular cell adhesion molecule-1
Stroke	165	Subclinical Thyroid Dysfunction and Risk of Myocardial Infarction and Stroke	Anc:Hartmann WHI: Heiss	Funded	09/01/04-07/31/07	OS CHD:800 Stroke:591 Controls:3136	Serum .25ml: Anti-thyroid peroxidase autoantibodies; Free thyroxine Serum .3ml: Thyroid Stimulating Hormone

Table 10.2 (continued)
Approved Ancillary Studies Using Specimens by Outcome

Disease	Anc ID	Title	PIs	Status	Study Dates	Study Population	Blood Usage
Stroke	169	Risk Factors for Hemorrhagic Stroke Among Postmenopausal Women	Anc: Kaplan WHI: Smoller	Not Funded	04/01/06-07/30/10	OS Stroke:357 Controls:757	Citrate .2ml: fibrinogen, vWF Citrate .4ml: Elastase, MMP-2, MMP-3, MMP-9, MMP-12, MMP activity, MMP-2/TIMP-1 Complex (activated MMP2), MMP-9/TIMP-2 Complex (activated MMP-9), TIMP-1 DNA 1ug: ApoE EDTA .95ml: HDL cholesterol, Total cholesterol, LDL cholesterol, Triglycerides, Glucose, CRP
Stroke	187	Serum Fatty Acids and Salicylic Acid in Relation to Incidence of Ischemic Stroke in Postmenopausal Women	Anc: He WHI: Van Horn	Submitted	04/01/07-03/31/09	OS Stroke:1050 Controls:1050 shares cases and controls *with AS 126	Serum .65ml: fatty acids: myristic acid, palmitic acid, trans-elaidic acid, trans-linoleic acid; alpha-linolenic acid, eicosapentaenoic acid, docasahexaenoic acid; salicylic acid
Type 2 Diabetes	132	A Prospective Study of Genetic and Biochemical Predictors of Type 2 Diabetes Mellitus	Anc: Liu WHI: Manson	Funded	08/01/02-07/30/07	OS Type 2 Diabetes:2150 Controls:2150	DNA 3ug: Adiopocyte 2; Calpain 10 gene; E-Selectin 128Arg Polymorphisms; Nitric oxide synthase 3; Peroxisome proliferator activated receptor; Tumor necrosis factor Alpha G308A; Uncoupling protein 2 EDTA .75ml: C-reactive protein; E-Selectin; Glucose; Insulin; Interluekin 6, ultrasensitive; Soluble intracellular adhesion molecule; Tumor necrosis factor Alpha; Vascular cell adhesion molecule-1
Type 2 Diabetes	180	Macrovascular Complications of Diabetes in Postmenopausal Women	Anc: Li WHI: Johnson	Expired		OS Cases: 3164	DNA 1ug: AGT, AGTR1, ACE, NOS3, GNB3, ADRB2, PPARG, RETN, TNF and UCP3

Table 10.3
Recruitment to Ancillary Studies Requiring Separate Consents by Field Centers

	9	15	34	36	39	62	65	68	84	98	100	103
	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 Participants	Estrogen, Vitamin E and Cognitive Change in Women	Bone Mineral Density as a Predictor for Periodontitis	Genetic, Biochemical and Behavioral Determinants O\of Obesity	Effects of Hormone Replacement Therapy on Cognitive Aging: WHI Studyof Cognitive Aging(WHISCA)
Total	**450**	**1468**	**311**	**857**	**7528**	**4430**	**101**	**735**	**546**	**969**	**797**	**2266**

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Table 10.3 (continued)
Recruitment to Ancillary Studies Requiring Separate Consents by Field Centers

	105	117	130	153	178	216	219	233	W25	W30	Total
	Carotenoids in Age-Related Eye Disease Study	Risk Factors for Dry Eye Syndrome in Postmenopausal Women	Randomized Controlled Trial of Fat Reduction, Calcium/ Vitamin D Supplementation, Hormone Replacement Therapy, and Risk of Proliferative Forms of Benign Breast Disease	Longitudinal Changes in Hip Geometry and Skeletal Muscle	Mammographic Density and Invasive Breast Cancer	Decision-making About Cancer Screening Among Older Women	Diet and Eye Health in the WHI: End of Trial Study	WHIMS Extension	WHI Coronary Artery Calcification Study in E-Alone	Dietary Assessment Study	
Total	**2007**	**217**	**3899**	**47**	**793**	**334**	**195**	**2860**	**1141**	**134**	**32085**

Table 10.4
Participant Enrollment in WHI Ancillary Studies
Requiring Separate Consents

CT+OS			
	Ppts	**%**	
CT+OS	161808		
Not Enrolled in Ancillary Studies	139214	86.04	
Enrolled in Ancillary Studies	22594	13.96	
Number of Studies	**Ppts**	**%**	**Enrollments**
1	15981	9.88	15981
2	4380	2.71	8760
3	1655	1.02	4965
4	513	0.32	2052
5	63	0.04	315
6	2	0	12
Total	**22594**	**13.96**	**32085**

Extension			
	Ppts	**%**	
Consented to Extension	115305		
Not Enrolled in Ancillary Studies	96867	84.01	
Enrolled in Ancillary Studies	18438	15.99	
Number of Studies	**Ppts**	**%**	**Enrollments**
1	12530	10.87	12530
2	3788	3.29	7576
3	1551	1.35	4653
4	505	0.44	2020
5	62	0.05	310
6	2	0	12
Total	**18438**	**15.99**	**27101**

Table 10.5
Ancillary Study PI List

Investigator		PI for	Sponsoring WHI PI for	Supporting CCC PI for
Last Name	First Name	Ancillary Study #	Ancillary Study #	Ancillary Study #
Agarwal	Mamta	201		
Allen	Catherine	101	101	
Anderson	Garnet	97	97	97, 121, 150, 140, 129
Applegate	Bill		71	
Barnhart	Janice	127		
Bassford	Tamsen		153, 191, 175, 210, 184, 113,	
Baum	Marianna		58	
Beresford	Shirley	162	225	
Bird	Cloe	220		
Black	Henry		148	
Boe	Kathryn	32		
Bonds	Denise		201	
Bowen	Deborah		18, 5	39
Bray	Paul	137		
Brewer	Amy	71		
Burke	Greg		56, 139, 172, 1	
Burrows	Beth	50		
Carlson	Chris	229		
Cauley	Jane	212, 161, 181		
Cerhan	James	26		
Chae	Claudia	173		
Chen	Chu	199		164
Chen	Zhao	153, 191, 72, 82,		
Chiu	Brian	186		
Chlebowski	Rowan	99, 76	108, 20, 21, 99, 76	
Cochrane	Barbara			133, 149, 167, 192, 214, 196,
Cohen	Ellen	125		
Colditz	Graham	207		
Cottrell	Daryl	96		
Coy	Christine	118		
Criqui	Michael	93		
Crouse	John	1		
Cummings	Steve	90, 167	90	
Curb	David		25, 95, 122	
David	Sean	123		
DeRoos	Anneclaire	222, 193		
Detrano	Robert	20, 21		
Dorn	Joan	141		
Dunn	Julie	84		
Eng	Charis	147		
Forevt	John	64	41, 51, 66	
Fouad	Mona	54, 78, 102		
Freeman	Ruth	81		
Fuchs	Charles	214, 146		
Furniss	Kathleen	198		
Garland	Cedric	116		
Gaziano	Michael	29		
Glanz	Karen	122		
Going	Scott	14		
Goodman	William	43		
Green	Pamela	5		
Greenland	Phil		6, 16, 19, 44	
Grimm	Richard		50, 88, 22, 205	
Grizzle	Jim	18		
Haan	Mary	112, 114, 62	112	

Table 10.5 (continued)
Ancillary Study PI List

Investigator		PI for Acillary Study #	Sponsoring WHI PI for Ancillary Study #	Supporting CCC PI for Ancillary Study #
Last Name	First Name			
Haines	Pam	63		
Hakim	Iman	113		
Handa	Victoria	136		
Harris	Randall	23		
Harris	William	209		
Hartmann	Katherine	165		
Hartz	Arthur	35		
Hays	Jennifer	100, 163	137, 100, 163	
He	Ka	187		
Heiss	Gerardo		36, 140, 165, 178, 63, 70, 204, 226	
Hendrix	Susan	213	34, 87, 213	
Herbert	James	45	45	
Herrington	David	172		
Ho	Gloria	152, 208, 168, 174		
Howard	Barbara	115, 92	92, 151, 217	
Hsia	Judith	42, 190, 68	190, 68	
Hu	Jennifer	149, 106		
Hubble	Allan		118	
Hughes	Susan	6		
Hulka	Barbara	36, 27		
Hunt	Julie			220
Jackson	Rebecca	94	23, 117, 147, 200, 223	
Jeffcoat	Marjorie	9		
Johnson	Karen		180	
Judd	Howard		43	
Kabat	Geoffrey	30, 53		
Kaplan	Robert	142, 159, 169, 143, 164		
Kaufman	Joel	150		
Kerner	David	77		
Kerwin	Diana	235		
Klein	Liviu	196		
Kleinstein	Robert	31		
Kooperberg	Charles			90, 126, 169
Kotchen	Jane		35, 235	
Kripke	Daniel	11		
Kuller	Lew	7, 157	121, 189, 194, 188, 212, 2, 3, 7, 10, 13, 120, 157, 134, 161, 181	
LaCroix	Andrea	179	222, 229, 193	153, 137, 165, 179, 191, 211, 212, 83, 181, 199
Lampe	Johanna	215		
Lane	Dorothy		216	
Langer	Robert	8, 119	11, 24, 73, 77, 93, 124, 8, 47, 32, 119	
Lasser	Norm		12, 17, 198	
LeBlanc	Adrian	51		
LeBoff	Meryl	211		
Lester	Gayle	91		
Lewis	Beth		9, R1	

Table 10.5 (continued)
Ancillary Study PI List

Investigator		PI for	Sponsoring WHI PI for	Supporting CCC PI for
Last Name	First Name	Acillary Study #	Ancillary Study #	Ancillary Study #
Li	Rongling	180		
Lichtenstein	Alice	231		
Lin	Henry	108		
Liu	James	144		
Liu	Simin	132		
Lund	Bernedine			195, 206
Mackay	Meggan	166		
Mackey	Rachel	189		
Manson	JoAnn	37	133, 192, 211, 214, 37, 89, 207, 132, 227, 29, 38, 146, 110, 131, 173	
Manson	JoAnn	89		
Mares	Julie	219		
Mares-Perlman	Julie	105, 232		
Margolis	Karen	170, 197	170, 203, 220, 197	
Masaki	Kamal	25		
Mayo	Charlotte	33		
McDermott	Mary	16		
McTiernan	Anne	52		36, 178
Meilahn	Elaine	10		
Melnikow	Joy	104		
Messina	Catherine	216		
Michael	Yvonne	171		
Miller	Vallery		42	
Modugno	Francesmary	121, 188, 134		
Moon	Tom		14	
Morrisett	Joel	41, 66		
Mouton	Charles	12, 17, 156		
Namie	Joylin	124		
Nelson	Dorothy	34		
Neuhouser	Marian	234	218	130, 188
Nicholas	J.	175		
Nichols	Kelley	117		
Nordahl	Thomas	85		
Nygaard	Ingrid	135		
O'Sullivan	Mary Jo		67	
Ober	Beth	61		
Oberman	Albert	46	4, 33, 54, 60, 78, 102, 31, 46	
Ockene	Judith		75	
Orencia	Anthony	19		
Parra-Medina	Deborah			
Paskett	Electra	139, 200, 223	149, 106	
Patterson	Ruth		177	128, 108, 65
Peters	Ulrike	206, 224		
Pisano	Etta	178		
Pleuss	Joan	56		
Polk	M.J.	86		
Preisler	Harvey	148		
Prentice	Ross	205, 218	195, 206, 215, 224, 234	84
Psaty	Bruce	80	80	
Rahmani	Yasmin	49, 176	49	
Rajpathak	Swapnil	230		

Table 10.5 (continued)
Ancillary Study PI List

Investigator		PI for	Sponsoring WHI PI for	Supporting CCC PI for
Last Name	First Name	Acillary Study #	Ancillary Study #	Ancillary Study #
Rexrode	Kathryn	110		
Ridker	Paul	38, 83		
Ritenbaugh	Cheryl	57, 73, 185	57, 72, 82, 160, 185, 171	
Robbins	John		61, 114, 104, 62, 136	
Robinson	Jennifer	22		
Rodriguez	Beatriz	95		
Rohan	Tom	130, 65, 155, 202, 221		
Rosal	Milagros	75		
Ruff	Coralese	151		
Sarto	Gloria		219, 105, 232	
Schaeffer	Anthony	44		
Schenken	Robert		86, 156	
Schlecht	Nicolas	182		
Schneider	Diane	24		
Sesso	Howard	133		
Shadick	Nancy	131		
Sheps	David	70	27	
Shikany	James	R1, 4, 60		
Shumaker	Sally	39, 183, 103, 138	103	
Simon	Michael	87		
Smoller	Sylvia	126, 28, 40, 48	128, 130, 152, 155, 208, 28, 30, 79, 125, 127, 142, 158, 159, 168, 174, 176, 202, 221, 53, 182, 230, 169, 40, 48, 81, 143, 129, 164, 166	
Strickler	Howard	129		
Subar	Amy	177		
Sullivan	Jeffrey	225		
Talavera	Gregory	55	55	
Thomson	Cynthia	210		
Tinker	Lesley	88		152, 115, R1, 180, 189, 208, 209, 219, 132, 105, 218, 187
Trapido	Edward	58		
Trevisan	Maurizio		141, 74, 15, 98	
Ulrich	Cornelia	195		
Valanis	Barbara	160		
Van Horn	Linda		84, 186, 196, 228, 231, 187	
Vogt	Molly	13, 120		
Vupputuri	Suma	204		
Wactawski-Wende	Jean	15, 98		
Wallace	Robert		26, 135, 209	
Wallitt	Brian	217		
Wang	C.Y.			9
Weber	Tom	128		
Weissfeld	Joel	2, 3		

Table 10.5 (continued)
Ancillary Study PI List

Investigator		PI for Acillary Study #	Sponsoring WHI PI for Ancillary Study #	Supporting CCC PI for Ancillary Study #
Last Name	First Name			
Whitcomb	David	145		
Whitsel	Eric	140		
Wodarski	Lois	74		
Wylie-Rosett	Judith	79, 158, 69		
Yan	Lijing	228		
Ye	Weimin	203		
Zakarija	Margita	59, 67		
Zhang	Shumin	192		
Zmuda	Joseph	194		

Table 11.1
Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
1	Informed consent in the Women's Health Initiative clinical trial and observational study	**McTiernan**, Rossouw, Manson, Franzi, Taylor, Carleton, Johnson, Nevitt	11	Gen	J Womens Health 1995;4(5):519-29
4	The Women's Health Initiative: Overview of the nutrition component	**Tinker**, Burrows, Henry, Patterson, Van Horn, Rupp	11	Gen	Nutrition and Women's Health 1996;510-542
5	Women's Health Initiative: Why now? What is it? What's new?	**Matthews**, Shumaker, Bowen, Langer, Hunt, Kaplan, Klesges, Ritenbaugh	11	Gen	Am Psychol 1997;52(2):101-116
6	Low-fat diet practices of older women: Prevalence and implications for dietary assessment	**Patterson**, Kristal, Coates, Tylavsky, Ritenbaugh, Van Horn, Caggiula, Snetselaar	11	Gen	J Am Diet Assoc 1996;7:670-9
7	The evolution of the Women's Health Initiative: Perspectives from the NIH	**Rossouw**, Finnegan, Harlan, Pinn, Clifford, McGowan	11	Gen	J Am Med Womens Assoc 1995;50(2):50-5
8	Design of the WHI clinical trial and observational study: The WHI Study Group	**Prentice**, Rossouw, Furberg, Johnson, Henderson, Cummings, Manson, Freedman, Oberman, Kuller, Anderson	11	Gen	Control Clin Trials 1998;19:61-109
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	11	CT	Control Clin Trials 1996;Dec 17(6):509-25
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	11	CT	Menopause 1996;3(2):71-76

Table 11.1 (continued)
Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
12	Factors associated with insurance status among participants in the WHI	**Hsia**, Sofaer, Kiefe, Zapka, Bowen, Mason, Limacher, Pettinger, Lillington	11	Gen	J Womens Health Gend Based Med 2000;9(8):881-889
13	Depression and cardiovascular sequelae in postmenopausal women	**Wassertheil-Smoller**, Shumaker, Ockene, Talavera, Greenland, Cochrane, Robbins, Aragaki, Dunbar	11	Gen	Arch Intern Med 2004;164:289-298
16	Differences between estimated caloric requirements and self-reported caloric intake in the WHI	**Hebert**, Patterson, Gorfine, Ebbeling, St. Jeor, Chlebowski	11	Gen	Ann Epidemiol 2003;13:1-9
17	Sexual orientation and health: Comparisons in the Women's Health Initiative sample	**Valanis**, Bowen, Bassford, Whitlock, Charney, Carter	11	CT	Arch Fam Med 2000;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	11	Gen	Clin J Womens Health 2001;Dec 1(5):225-34
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	11	OS	Hypertension 2000;36:780-89
22	Pelvic organ prolapse in the WHI: Gravity and gravidity	**Hendrix**, Clark, Nygaard, Aragaki, Barnabei, McTiernan	11	CT	Am J Obstet Gynecol 2002;186:1160-6
24	Estimation of the correlation between nutrient intake measures under restricted sampling	**Wang**, Anderson, Prentice	11	Gen	Biometrics 1999; 55:711-717
25	Estrogen and progestin use and the QT interval in postmenopausal women	**Kadish**, Greenland, Limacher, Frishman, Daugherty, Parker, Schwartz	11	CT	Ann Noninvasive Electrocardiol 2004;9(4):366-74

Table 11.1 (continued)
Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
26	Special populations recruitment for the WHI: Successes and limitations	**Fouad**, Corbie-Smith, Curb, Howard, Mouton, Simon, Talavera, Thompson, Wang, White, Young	11	Gen	Control Clin Trials 2004;335-352
27	The effects of insurance coverage and ethnicity on mammography utilization in a postmenopausal population	**Bush**, Langer	11	Gen	West J Med 1998;168:236-40
35	Measurement characteristics of the WHI food frequency questionnaire	**Patterson**, Kristal, Carter, Tinker, Bolton, Agurs-Collins	11	Gen	Ann Epidemiol 1999; (9):178-197
40	The health impact of domestic violence in older women	**Mouton**, Furniss, Lasser, Rovi	11	OS	J Womens Health Gend Based Med 1999;8(9):1173-1179
41	Cross-sectional correlates of fasting hyperinsulinaemia in post-menopausal women of different ethnic origin	**Pradhan**, Manson, Rodrigues, Johnson, Wagenknecht, Allen, LaCroix	11	Gen	Diabet Med 2006; 23: 77-85
43	Sleep complaints of postmenopausal women	**Kripke**, Brunner, Freeman, Hendrix, Jackson, Masaki, Carter	11	CT	Clin J Womens Health 2001;1(5):244-252
51	Relationship of social support and social burden to repeated breast cancer screening in the Women's Health Initiative	**Messina**, Lane, Glanz, Smith, Taylor, Frishman, Powell	11	Gen	Health Psychol 2004;23(6):582-594
55	Factor structure and measurement invariance of the Women's Health Initiative insomnia rating scale	**Levine**, Kaplan, Kripke, Bowen, Naughton, Shumaker	11	Gen	Psychol Assess 2003;15(2):123-136
59	Risk factors for kidney stones in postmenopausal women in the southern United States	**Hall**, Pettinger, Oberman, Watts, Johnson, Paskett, Limacher, Hays	11	Gen	Am J Med Sci 2001;322(1):1-7
60	WHIMS: A trial of the effect of estrogen therapy in preventing and slowing the progression of dementia	**Shumaker**, Reboussin, Espeland, Rapp, McBee, Dailey, Bowen, Terrell, Jones	11	WHIMS	Control Clin Trials 1998;19:604-621

Table 11.1 (continued)
Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
62	Self-reported urogential symptoms in postmenopausal women: Women's Health Initiative	**Pastore**, Carter, Hulka, Wells	11	Gen	Maturitas 2004;49(4):292-303
63	The importance of health insurance as a determinant of cancer screening: Evidence from the WHI	**Hsia**, Kemper, Kiefe, Zapka, Sofaer, Pettinger, Bowen, Limacher, Lillington, Mason	11	OS	Prev Med 2000;31:261-270
66	Walking compared with vigorous exercise for the prevention of cardiovascular events in women	**Manson**, Greenland, LaCroix, Stefanick, Mouton, Oberman, Perri, Sheps, Pettinger, Siscovick	11	OS	N Engl J Med 2002;347(10)
67	Yogurt consumption is associated with healthy behavior in postmenopausal women	**Mossavar-Rahmani**, Garland, Caan, Hebert, Wodarski, Vitolins, Himes, Parker	11	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	11	CT	Nutr Cancer, 2000:36:163-69
70	Correlates of serum alpha- and gamma-tocopherol in the WHI	**White**, Kristal, Shikany, Wilson, Chen, Mares-Perlman, Masaki, Caan	11	CT	Ann Epidemiol 2001;11:136-144
71	The Women's Health Initiative: Goals, rationale, and current status	**Liu**	11	Gen	Menopausal Medicine 1998;6(2):1-4
72	Postmenopausal bone loss and its relationship to oral bone loss	**Jeffcoat**, Lewis, Reddy, Wang, Redford	11	Gen	Periodontol 2000; June23(1):94-102
76	Differences in eating pattern labels between maintainers and nonmaintainers in the WHI	**Hopkins**, Burrows, Bowen, Tinker	11	CT	J Nutr Educ 2001;33:278-283
78	Lack of a relationship between antioxidants and BMD: Results from the WHI	**Wolf**, Cauley, Stone, Nevitt, Simon, Jackson, LaCroix, Lewis, Wactawski-Wende, LeBoff	11	Gen	Am J Clin Nutr 2005;82:581-588

Table 11.1 (continued)
Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
80	Insulin resistance and weight gain in postmenopausal women of diverse ethnic groups	**Howard**, Adams-Campbell, Allen, Black, Pasaro, Rodrigues, Safford, Stevens, Wagenknecht, Snetselaar	11	Gen	Int Journal Obesity 2004;28(8):1039-1047
83	Recreational physical activity and the risk of breast cancer in postmenopausal women	**McTiernan**, Kooperberg, White, Wilcox, Coates, Adams-Campbell, Woods, Ockene	11	Gen	JAMA 2003;290:1331-1336
84	Research staff turnover and participant adherence in the WHI	**Jackson**, Berman, Huber, Snetselaar, Granek, Boe, Milas, Spivak, Chlebowski	11	CT	Control Clin Trials 2003;24:422-435
85	The Women's Health Initiative: Rationale, design and progress report	**Johnson**, Anderson, Barad, Stefanick	11	CT	Journal of the British Menopause Society 1995;155-159
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	11	CT	J Am Diet Assoc 2002;102:789-800
88	Estimating normal hemogram values for postmenopausal women	**Assaf**, Carleton, Miller, Coccio	11	Gen	Clin J Womens Health 2000;1(1):23-28
91	Compliance with national cholesterol education program dietary and lifestyle guidelines among older women with self-reported hypercholesterolemia: The WHI	**Hsia**, Rodabough, Rosal, Cochrane, Howard, Snetselaar, Frishman, Stefanick	11	OS	Am J Med 2002;113;384-92
92	Comparison of self-report, hospital discharge codes, and adjudication of cardiovascular events in the WHI	**Heckbert**, Kooperberg, Safford, Psaty, Hsia, McTiernan, Gaziano, Frishman, Curb	11	Gen	Am J Epidemiol 2004;160:1152-1158
93	Fat intake in husbands of participants in the dietary modification component of the Women's Health Initiative	**Shikany**	11	Gen	Nutr Res 2002;22:577-86

Table 11.1 (continued)
Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
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	11	OS	Health Psychol 2003;22(5):513-522
98	Antioxidant supplement use in the Women's Health Initiative participants	**Shikany**, Patterson, Agurs-Collins, Anderson	11	Gen	Prev Med 2003;36(3):379-387
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	11	OS	Metabolism 2003;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	11	Gen	JNCI 2003;95(6):429-436
102	Association between cardiovascular outcomes and antihypertensive drug treatment in older women	**Wassertheil-Smoller**, Psaty, Greenland, Oberman, Kotchen, Mouton, Black, Aragaki, Trevisan	11	OS	JAMA 2004;292:2849-2859
103	The Women's Health Initiative: Recruitment complete - looking back and looking forward (guest editorial)	**Rossouw**, Hurd	11	CT	J Womens Health 1999;8:3-5
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	11	Gen	Control Clin Trials; 22(3):279-289
107	Vigorous leisure activity through women's adult life: The Women's Health Initiative	**Evenson**, Wilcox, Pettinger, Brunner, King, McTiernan	11	OS	Am J Epidemiol 2002;156:945-953
108	Cross-sectional geometry, bone strength, and bone mass in the proximal femur in black and white postmenopausal women	**Nelson**, Barondess, Hendrix, Beck	11	CT	J Bone Miner Res 2000;15(10):1992-1997

Table 11.1 (continued)
Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
109	Recruitment of women to the WHI: The case of Embajadoras in Arizona	**Larkey**, Staten, Ritenbaugh, Hall, Buller, Bassford, Altimari	11	Gen	Control Clin Trials 2002;23:289-298
112	Results of an adjunct dietary intervention program in the Women's Health Initiative	**Bowen**, Ehret, Pedersen, Snetselaar, Johnson, Tinker, Hollinger, Lichty, Sivertsen, Ocken, Staats, Beedoe	11	OS	J Am Diet Assoc 2002;102:1631-1637
113	Prior oral contraception and postmenopausal fracture: A Women's Health Initiative observational cohort study	**Barad**, Kooperberg, Wactawski-Wende, Liu, Hendrix, Watts	11	Gen	Fertility & Sterility 2005; 84(2):374-383
115	Prevalence and 3-year incidence of abuse among postmenopausal women	**Mouton**, Rodabough, Rovi, Hunt, Talamantes, Brzyski, Burge	11	OS	Am J Public Health 2004; 94(4)
120	Obesity, body size, and risk of postmenopausal breast cancer: The Women's Health Initiative	**Morimoto**, White, McTiernan, Chlebowski, Hays, Stefanick, Margolis, Manson, Kuller, Chen, Muti, Lopez	11	OS	Cancer Causes Control 2002;13:741-751
122	Does statin use reduce risk of osteoporotic fracture or improve 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	11	OS	Ann Intern Med 2003;129:97-104
126	Influences on older women's adherence to a low-fat diet in the Women's Health Initiative	**Kearney**, Rosal, Ockene, Churchill	11	CT	Psychosom Med 2002;64(3):450-7
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, Wallace, Jackson, Pettinger, Ridker	11	OS	JAMA 2002;288:980-987

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Ms ID	Title	Authors	Stage	Data Focus	Reference
129	Thrombotic markers for coronary heart disease in women	**Pradhan**, LaCroix, Trevisan, Lewis, Langer, Hsia, Oberman, Kotchen, Ridker	11	OS	Circulation 2004;110:292-300
130	Cross-sectional analysis of association between hormone replacement therapy and thrombotic and inflammatory markers for CHD in women	**Langer**, Manson, LaCroix, Lewis, Hendrix, Rossouw, Pradhan, Ridker	11	OS	Thromb Haemost 2005;93:1108-16
132	Association of nonmelanoma skin cancer with second malignancy: The Women's Health Initiative observational study	**Rosenberg**, Greenland, Khandekar, Ascensao, Lopez	11	Gen	Cancer 2004;100:130-8
134	Additional self-monitoring tools in the dietary modification component of the Women's Health Initiative	**Mossavar-Rahmani**, Henry, Rodabough, Bragg, Brewer, Freed, Kinzel, Soule, Vosburg	11	CT	J Am Diet Assoc 2004;104:76-85
135	Radiographic measurements, bone mineral density and the Singh Index in the proximal femur of white and African-American postmenopausal women	**Barondess**, Singh, Hendrix, Nelson	11		Clin J Womens Health 2001;1992-1997
137	Recruitment of hispanic women to the Women's Health Initiative: the Case of Embajadoras in Arizona	**Larkey**, Staten, Ritenbaugh, Buller, Bassford, Altimari	11	Gen	Control Clin Trials 2002;23(3):289-298
138	Baseline experience with the Modified Mini-Mental State exam: The Women's Health Initiative Memory Study	**Rapp**, Espeland, Hogan, Jones, Dugan	11	WHIMS	Aging Ment Health 2003;7(3):217-223
140	Usefulness of prior hysterectomy as an independent predictor of Framingham Risk Score (The WHI)	**Hsia**, Barad, Margolis, Rodabough, McGovern, Limacher, Oberman, Wassertheil-Smoller	11	Gen	Am J Cardiol 2003;92:264-9

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Ms ID	Title	Authors	Stage	Data Focus	Reference
142	Coronary artery calcification in black and white women	**Khurana**, Rosenbaum, Howard, Adams-Campbell, Detrano, Klouj, Hsia	11	OS	Am Heart J 2003;145 :724-9
144	Risk of cardiovascular disease by hysterectomy status, with and without oophorectomy: The WHI observational study	**Howard**, Kuller, Langer, Manson, Allen, Assaf, Cochrane, Larson, Lasser, Rainford, Van Horn, Stefanick, Trevisan	11	OS	Circulation 2005;111:1462-1470
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	11	OS	Cancer Res 2003;63:6096-6101
148	Incidence of cytologial abnormalities on cervical cytology with aging in the WHI estrogen plus progestin trial	**Yasmeen**, Romano, Hubbell, La Valluer, Johnson, Lane, McIntosh, Hendrix	11	CT	In Press: Obstetrics and Gynecology
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, Van Horn	11	CT	J Am Diet Assoc 2003;103(4):454-459
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	11	OS	JNCI 2005;97(6):439-448
164	Leukocyte count as a predictor of cardiovascular events and mortality in postmenopausal women	**Margolis**, Manson, Greenland, Rodabough, Bray, Safford, Grimm, Howard, Assaf, Prentice	11	OS	Arch Intern Med 2005;165:500-508

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Ms ID	Title	Authors	Stage	Data Focus	Reference
166	Habitual tea consumption and risk of osteoporosis: A prospective study in the WHI observational study	**Chen**, Pettinger, Ritenbaugh, LaCroix, Robbins, Caan, Barad, Hakim	11	OS	Am J Epidemiol 2003;158:772-781
169	Reliability and validity of the Women's Health Initiative insomnia rating scale	**Levine**, Kaplan, Kripke, Bowen, Naughton, Shumaker	11	Gen	Psychol Assess 2003;15(2):137-148
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	11	Gen	Arch Intern Med 2003;163:2041-2050
174	Statin use and breast cancer: Prospective results from the Women's Health Initiative	**Cauley**, LaCroix, Chlebowski, Margolis, McTiernan, Vitolins, Furberg, Bauer	11	OS	JNCI 2006; 98(10):700-707
177	Validity of self-reports of fractures among postmenopausal women in a prospective study results from the Women's Health Initiative	**Chen**, Kooperberg, Pettinger, Bassford, Cauley, LaCroix, Lewis, Kipersztok, Borne, Jackson	11	Gen	Menopause 2004;11(3):264-274
179	Progression and remission of pelvic organ prolapse: A longitudinal study of menopausal women	**Handa**, Garret, Hendrix, Gold, Robbins	11	CT	Am J Obstet Gynecol 2004;190:27-32
186	Physical activity and diabetes risk in postmenopausal women	**Hsia**, Wu, Allen, Oberman, Lawson, Torrens, Safford, Limacher, Howard	11	Gen	Am J Prev Med 2005;28(1):19-25
188	Electrocardiographic abnormalities that predict coronary heart disease events and mortality in postmenopausal women: The Women's Health Initiative	**Rautaharju**, Kooperberg, Larson, LaCroix	11	CT	Circulation 2006; 13(4): 473-480
189	Dietary adherence in the WHI dietary modification trial	**The Writing Group for the Women's Health Initiative Investigators**	11	CT	J Am Diet Assoc 2004;104(4):654-658

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Ms ID	Title	Authors	Stage	Data Focus	Reference
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	11	CT	Am J Cardio 2006; 97: 512-519
192	Bone mineral density of American Indian and Alaska Native women: Results from the Women's Health Initiative study	**Whampler**, Chen, Jacobsen, Henderson, Howard, Rossouw	11	Gen	Menopause 2005; 12(5):492-494
197	Predictors of angina pectoris vs myocardial infarction from the WHI observational study	**Hsia**, Aragaki, Bloch, LaCroix, Wallace	11	OS	Am J Cardiology 2004;93(6):673-8
198	The Women's Health Initiative: Aspects of the management and coordination	**Cochrane**, Lund, Anderson, Prentice	11	Gen	Diversity in Health Care Research: Strategies for Multisite, Multidisciplinary and Multi-ethnic Projects. J. W. Hawkins, L. A. Haggerty (eds.): 2003 pp.181-207 Springer
200	Expression and ambivalence over expression of negative emotion: Psychometric analysis in the Women's Health Initiative	**Michael**, Perrin, O'Connor, Cochrane, Wisdom, Brzyski, Ritenbaugh	11	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	11	Gen	Am J Cardiol 2006; 97(5):730-737
202	Depressive symptoms and heart rate variability in postmenopausal women: An ancillary study to the Women's Health Initiative	**Sheps**, Kim, McGorray, Bartholomew, Marsh, Dicken, Wassertheil-Smoller, Curb, Oberman, Barton, McMahon	11	Gen	Arch Intern Med 2005;165(11):1239-44

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Ms ID	Title	Authors	Stage	Data Focus	Reference
203	Influence of estrogen plus progestin on breast cancer and mammography in healthy postmenopausal women	**Chlebowski**, Hendrix, Langer, Stefanick, Gass, Lane, Rodabough, Gilligan, Cyr, Thomson, Khandekar, Petrovich, McTiernan	11	CT	JAMA 2003;289:3243-3253
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	11	CT	JAMA 2003;289(20):2673-84
206	Fracture risk among breast cancer survivors	**Chen**, Maricic, Bassford, Pettinger, Ritenbaugh, Lopez, Barad, Gass, LeBoff	11	Gen	Arch Intern Med 2005;165:552-558
208	The effects of estrogen plus progestin on the risk of fracture and bone mineral density: The Women's Health Initiative clinical trial	**Cauley**, Robbins, Chen, Cummings, Jackson, LaCroix, LeBoff, Lewis, McGowan, Neuner, Pettinger, Stefanick, Wactawski-Wende, Watts	11	CT	JAMA 2003;290:1729-1738
209	Obesity, hormone therapy, estrogen metabolism and risk of postmenopausal breast cancer	**Modugno**, Cochrane, Chlebowski, Kuller, Stefanick, Rohan, Lasser, Kip	11	OS	Int J Cancer 2005; 118: 1292-1301
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	11	CT	N Engl J Med 2003;349:523-34
211	Effects of estrogen plus progestin on health-related quality of life	**Hays**, Ockene, Brunner, Kotchen, Manson, Patterson, Aragaki, Shumaker, Brzyski, LaCroix, Granek, Valanis	11	CT	N Engl J Med 2003;348:1839-1854

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Ms ID	Title	Authors	Stage	Data Focus	Reference
212	Effect of oestrogen plus progestin on the incidence of diabetes in postmenopausal women: Results from the WHI hormone trial	**Margolis**, Bonds, Rodabough, Tinker, Phillips, Allen, Bassford, Burke, Torrens, Howard	11	CT	Diabetologia 2004;47(7):1175-1187
216	Effects of conjugated estrogen-progestin hormone therapy on cognition and affect: The Women's Health Initative Study of Cognitive Agingombination estrogen plus progestin hormone treatment on cognition and affect	**Resnick**, Maki, Rapp, Espeland, Brunner, Coker, Granek, Hogan, Ockene, Shumaker	11	CT	J Clin Endocrinol Metab 2006; 10.1210/jc: 2005-2097
221	Effects of estrogen plus progestin on gynecologic cancers and associated diagnostic procedures: The WHI randomized trial	**Anderson**, Judd, Kaunitz, Barad, Beresford, Pettinger, Liu, McNeeley, Lopez	11	CT	JAMA 2003;290:1739-1748
222	Estrogen plus progestin and risk of venous thrombosis	**Cushman**, Kuller, Prentice, Rodabough, Psaty, Stafford, Sidney, Rosendaal	11	CT	JAMA 2004;292(13):1573-1580
224	Estimation of dependence between paired correlated failure times in the presence of covariate measurement error	**Gorfine**, Hsu, Prentice	11	OS	J R Stat Soc [Ser B] 2003;65(3):633-661
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	**Shumaker**, Legault, Rapp, Thal, Wallace, Ockene, Hendrix, Jones, Assaf, Jackson, Kotchen, Wassertheil-Smoller, Wactawski-Wende	11	CT	JAMA.2003;289:2651-2662
226	The effect of estrogen with progestin treatment on global cognitive function in postmenopausal women: Results from the Women's Health Initiative Memory Study	**Rapp**, Espeland, Shumaker, Henderson, Brunner, Manson, Gass, Stefanick, Lane, Hays, Johnson, Coker, Dailey, Bowen	11	CT	JAMA.2003;289:2663-2672

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Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
229	Menopausal symptoms and treatment-related effects of estrogen and progestin in the WHI	**Barnabei**, Cochrane, Aragaki, Nygaard, Williams, McGovern, Young, Wells, O'Sullivan, Chen, Schenken, Johnson	11	CT	Obstet Gynecol 2005;105(5):1063-1073
232	Women's Health Initiative: Statistical aspects and early results	**Prentice**, Anderson	11	Gen	Encyclopedia of Biostatistics, 2nd Edition, Armitage P, Colton T (eds), 2005.
233	Estrogen plus progestin and colorectal cancer in postmenopausal women	**Chlebowski**, Wactawski-Wende, Ritenbaugh, Hubbell, Ascensao, Rodabough, Rosenberg, Taylor, Harris, Chen, Adams-Campbell, White	11	CT	N Engl J Med 2004;350:991-1004
234	Postmenopausal hormone therapy and body composition: A substudy of the estrogen and progestin trial of the Women's Health Initiative	**Chen**, Bassford, Green, LeBoff, LaCroix, Margolis, Jackson, Cauley, Stefanick	11	CT	Am J Clin Nutr 2005;82:651-6
235	Hormone replacement therapy and risk of cardiovascular disease: Implications of the results of the WHI	**Kuller**	11	CT	Arterioscler Thromb Vasc Biol 2003;23:11-16
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	**Resnick**, Coker, Maki, Rapp, Espeland, Shumaker	11	CT	Clinical Trials 2004; 1: 440-450
240	Risks and benefits of estrogen plus progestin in healthy post-menopausal women: Principal results of the Women's Health Initiative randomized controlled trial.	**The Writing Group for the Women's Health Initiative Investigators**	11	CT	JAMA 2002;288(3):321-333
242	Estrogen deficiency symptom management in breast cancer survivors in the changing context of menopausal hormone therapy	**Chlebowski**, Kim, Col	11	CT	Semin Oncol 2003;30(6):776-88

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Ms ID	Title	Authors	Stage	Data Focus	Reference
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	11	CT	Am J Epidemiol 2005;162:404-414
246	WHI response to Goodman, Goldzicher and Ayala's critique of the Women's Health Initiative report on the risks and benefits of estrogen plus progestin	**Hendrix**, Prentice	11	CT	Menopausal Medicine 2003;11:1-4
248	Progression of coronary calcification in healthy postmenopausal women	**Hsia**, Klouj, Prasad, Burt, Adams-Campbell, Howard	11	OS	BMC Cardiovasc Disord 2004;4:21
249	Effects of estrogen with and without progestin on urinary incontinence	**Hendrix**, Cochrane, Nygaard, Handa, Barnabei, Iglesia, Aragaki, Naughton, Wallace, McNeeley	11	CT	JAMA 2005;293:935-948
265	Comparing SF-36 scores of participants in the Women's Healthy Eating and Living Study, Women's Health Initiative, and Medical Outcomes Study	**Yost**, Haan, Levine, Gold	11	Gen	Qual Life Res 2005;14:1251–1261
271	Factors associated with treatment initiation after screening and diagnosis of osteoporosis	**Brennan**, Wactawski-Wende, Crespi, Dmochowski	11	CT	Am J Epidemiol 2004;160:475-483
272	Effect of estrogen therapy on gallbladder disease	**Cirillio**, Wallace, Rodabough, Greenland, LaCroix, Limacher, Larson	11	CT	JAMA 2005;293(3):330-339
273	Effects of conjugated equine estrogen in postmenopausal women with hysterectomy. The Women's Health Initiative randomized controlled trial	**The Women's Health Initiative Steering Committee**	11	CT	JAMA 2004;291:1701-1712

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Ms ID	Title	Authors	Stage	Data Focus	Reference
274	Association between self-reported alcohol intake and changes in cognition: Results from the Women's Health Initiative Memory Study (WHIMS)	**Espeland**, Gu, Masaki, Langer, Coker, Stefanick, Ockene, Rapp	11	CT	Am J Epidemiol 2005;161(3):228-238
277	Estrogen plus progestin and the risk of peripheral arterial disease: The WHI	**Hsia**, Criqui, Rodabough, Langer, Resnick, Phillips, Allison, Bonds, Masaki, Caralis, Kotchen	11	CT	Circulation 2004;109(5):620-626
279	Symptom experience after discontinuing use of estrogen plus progestin	**Ockene**, Barad, Cochrane, Larson, Gass, Manson, Barnabei, Lane, Brzyski, Rosal, Wylie-Rosette, Hays	11	CT	JAMA 2005;294(2):183-193
282	Improving dietary self-monitoring and adherence with hand-held computers: A pilot study	**Glanz**, Murphy, Moylan, Evensen, Curb	11	CT	Am J of Health Promot 2006;20(3):165-170
285	Estrogen plus progestin influence on mammogram density in healthy postmenopausal women in the Women's Health Initiative	**McTiernan**, Martin, Peck, Pisano, Wang, Aragaki, Chlebowski	11	CT	J Natl Cancer Inst 2005; 97:1366-1376.
287	Prior hormone therapy and breast cancer risk in the Women's Health Initiative randomized trial of estrogen plus progestin	**Anderson**, Chlebowski, Aggerwal, Hubbell, Khandekar, Lane, Lasser, Lopez, Potter, Ritenbaugh, Rossouw	11	CT	Maturitas 2006; [Epub ahead of print] (doi:10.1016/j.maturitas.2006.05.004)
288	Insulin, physical activity, and caloric intake in postmenopausal women: Breast cancer implications	**Chlebowski**, Pettinger, Stefanick, Howard, Mossavar-Rahmani, McTiernan	11	Gen	J Clin Oncol 2004;22:4507-4513
289	Cutaneous melanoma in postmenopausal women following nonmelanoma skin carcinoma: The Women's Health Initiative observational study	**Rosenberg**, Greenland, Khandekar, Rodabough, McTiernan	11	OS	Cancer 2006 Feb 1;106(3):654-63.

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Ms ID	Title	Authors	Stage	Data Focus	Reference
294	Weighted estimators for proportional hazards regression with missing covariates	**Qi**, Wang, Prentice	11	OS	J American Statistical Association 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	11	OS	Am J Epidemiol 2006 Jul 17; [Epub ahead of print]
302	Frailty: Emergence and consequences in women aged 65 and older in the WHI observational study	**Woods**, LaCroix, Gray, Aragaki, Cochrane, Brunner, Masaki, Murray, Newman	11	Gen	J Am Geriatr Soc 2005;53(8):1321-30
317	Pelvic organ prolapse in older women: Prevalence and risk factors	**Nygaard**, Bradley, Brandt	11	CT	Obstet Gynecol 2004;104(3):489-497
324	Mortality and cardiac and vascular outcomes in extremely obese women	**McTigue**, Larson, Valoski, Burke, Kotchen, Lewis, Stefanick, Van Horn, Kuller	11	OS	JAMA 2006;296(1):79-86
327	Effects of a 7-yr low-fat, high carbohydrate diet on body weight in postmenopausal women: The Women's Health Initiative dietary modification trial	**Howard**, Beresford, Frank, Jones, Manson, Prentice, Snetselaar, Stefanick, Thomson, Tinker, Vitolins	11	CT	JAMA 2006;295:39-49
332	Conjugated equine estrogens and global cognitive function in postmenopausal women: The Women's Health Initiative Memory Study	**Espeland**, Rapp, Shumaker, Brunner, Manson, Sherwin, Hsia, Margolis, Hogan, Wallace, Dailey, Freeman, Hays	11	WHIMS	JAMA 2004;291:2959-2968
336	Conjugated equine estrogens and incidence of probable dementia and mild cognitive impairment in postmenopausal women: WHIMS	**Shumaker**, Legault, Kuller, Rapp, Thal, Lane, Stefanick, Hendrix, Lewis, Masaki, Coker	11	WHIMS	JAMA 2004;291:2947-2958

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Ms ID	Title	Authors	Stage	Data Focus	Reference
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	11	CT	JAMA 2006;295:1647-1657
344	Postmenopausal hormone therapy does not influence hospitalization for non-specific chest pain or its prognosis	**Robinson**, Wallace, Cochrane, Ko, Limacher, Ockene, Wassertheil-Smoller, Blanchette	11	Gen	Accepted, J Women's Health
345	CEE and coronary heart disease: The Women's Health Initiative	**Hsia**, Langer, Manson, Kuller, Johnson, Hendrix, Pettinger, Heckbert, Greep, Crawford, Kostis, Caralis, Prentice	11	CT	Arch Intern Med 2006;166:357-365
347	Effect of CEE & estrogen plus progestin on stroke in the WHI	**Hendrix**, Wassertheil-Smoller, Aragaki, Bray, Criqui, Howard, Johnson, Kooperberg, Mouton, Rapp, Trevisan	11	CT	Circulation 2006;113:2425-2434
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**, Ockene, Aragaki, Assaf, Brzyski, Gass, Granek, LaCroix, Mason, Matthews, Wallace, Woods	11	CT	Arch Intern Med 2005;165:1976-1986
350	Hormone therapy and risk of venous thrombosis in the Women's Health Initiative trial of estrogen alone in women without a uterus	**Curb**, Prentice, Bray, Langer, Van Horn, Barnabei, Bloch, Cyr, Gass, Lepine, Rodabough, Sidney, Uwaifo, Rosendaal	11	CT	Arch Intern Med 2006; 166: 772-780

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Ms ID	Title	Authors	Stage	Data Focus	Reference
354	Effects of conjugated equine estrogen on risk of fractures and bone mineral density in postmenopausal women with hysterectomy: Results from the Women's Health Initiative randomized trial	**Jackson**, Wactawski-Wende, Bassford, Beresford, Ko, LaCroix, Lewis, Pettinger, Robbins, Satterfield, Watts	11	CT	In press, JBMR
357	Effect of conjugated equine estrogen in women without a uterus on the incidence of diabetes in postmenopausal women	**Bonds**, Lasser, Brzyski, Caan, Heiss, Limacher, Liu, Mason, Oberman, O'Sullivan, Phillips, Prineas, Tinker	11	CT	Diabetologia, 2006 Jan 27; [Epub ahead of print]
361	Estrogen therapy with and without progestin and the risk of hip and knee joint replacement in postmenopausal women	**Wallace**, Cirillio, Yood	11	CT	In press, Arthritis and Rheumatism
367	The Women's Health Initiative: A potential resource for future studies of autoimmune diseases	**Howard**	11	Gen	Autoimmunity 2004;37(4):265-268
368	Postmenopausal hormone therapy in relation to cardiovascular disease and cognition	**Prentice**	11	CT	Proceedings of the Forty Seventh Study Group of the Royal College of Obstetricians and Gynecologists, 2004
370	Performance of a longitudinal screening program to identify all-cause dementia: Results from the Women's Health Initiative Memory Study	**Espeland**, Bassford, Granek, Rapp	11	CT	Clin Trials 2006; 3 :99-106
373	Conjugated equine estrogens and peripheral arterial disease risk: The Women's Health Initiative	**Hsia**, Criqui, Herrington, Manson, Wu, Heckbert, Allison, McDermott, Robinson, Masaki	11	CT	Am Heart J 2006;152(1):170-6

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Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
385	Development of a glycemic index database for food frequency questionnaires used in epidemiologic studies	**Neuhouser**, Tinker, Thomson, Caan, Van Horn, Snetselaar, Parker, Patterson, Robinson, Beresford, Shikany	11	CT	J Nutr 2006;136:1604-1609
398	Osteoporosis and rate of bone loss among postmenopausal survivors of breast cancer: Results from a subcohort of WHI observational study	**Chen**, Maricic, Pettinger, Ritenbaugh, Lopez, Barad, Gass, LeBoff, Bassford	11	OS	Cancer 2005;104(7):1520-1530
418	Linear measurement error models with restricted sampling	**Gorfine**, Lipshtat, Freedman, Prentice	11	CT	In press, Biometrics
423	Combined analysis of Women's Health Initiative observational and clinical trial data on postmenopausal hormone treatment and cardiovascular disease	**Prentice**, Anderson, Barad, Curb, Howard, Kotchen, Kuller, Langer, Limacher, Pettinger, Stefanick, Wactawski-Wende	11	Gen	Am J Epidemio 2006; 163(7):589-599
447	Low-fat dietary pattern and risk of cardiovascular disease: The Women's Health Initiative randomized controlled dietary modification trial	**Howard**, Van Horn, Hsia, Manson, Stefanick, Wassertheil-Smoller, Kuller, LaCroix, Langer, Lasser, Lewis, Limacher, Margolis, Mysiw, et al	11	CT	JAMA 2006;295(6):655-666
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	11	CT	JAMA 2006;295(6):629-642
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	11	CT	JAMA 2006;295(6):643-654

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Ms ID	Title	Authors	Stage	Data Focus	Reference
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	11	CT	NEJM 2006;354(7):669-683
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	11	CT	NEJM 2006;354(7):684-696
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	11	CT	Int J Epidemiol 2006;35(4): 1011-1021
518	Baseline Monograph - foreword	**Rossouw**, Anderson, Oberman	11	Gen	Ann Epidemiol 2003;13:S1-S4
519	Baseline Monograph - Implementation of the WHI study design	**Anderson**, Manson, Wallace, Lund, Hall, Davis, Shumaker, Wang, Stein, Prentice	11	Gen	Ann Epidemiol 2003;13:S5-S17
520	The WHI recruitment methods and results	**Hays**, Hunt, Hubbell, Anderson, Limacher, Allen, Rossouw	11	OS	Ann Epidemiol 2003;13:S18-S77
521	The WHI postmenopausal hormone trials	**Stefanick**, Cochrane, Hsia, Barad, Liu, Johnson	11	Gen	Ann Epidemiol 2003;13:S78-S86
522	The WHI DM trial: Overview and baseline characteristics of participants	**Ritenbaugh**, Patterson, Chlebowski, Caan, Tinker, Howard, Ockene	11	Gen	Ann Epidemiol 2003;13:S87-S97
523	The WHI CaD trial: Overview and baseline characteristics of participants	**Jackson**, LaCroix, Cauley, McGowan	11	Gen	Ann Epidemiol 2003;13:S98-S106

Table 11.1 (continued)
Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
524	The WHI observational study: Baseline characteristics of participants and reliability of baseline measures	**Langer**, White, Lewis, Kotchen, Hendrix, Trevisan	11	OS	Ann Epidemiol 2003;13:S-107-S121
525	Outcomes ascertainment and adjudication methods in the WHI	**Curb**, McTiernan, Heckbert, Kooperberg, Stanford, Nevitt, Johnson, Proulx-Burns, Pastore, Criqui, Daugherty	11	Gen	Ann Epidemiol 2003;13:S122-S128
538	Electrocardiographic predictors of incident congestive heart failure and all-cause mortality in postmenopausal women: The Women's Health Initiative	**Rautaharju**, Kooperberg, Larson, LaCroix	11	CT	Circulation 2006;113(4): 481-489
183	Panic attacks, chest pain and ischemia in postmenopausal women	**Smoller**, Wassertheil-Smoller, Sheps, Brunner, Curb, Oberman, Hendrix, Hsia	10	Gen	
195	Predictors of calcium/Vitamin D supplementation adherence in the Women's Health Initiative	**Brunner**, Cauley, Snetselaar, Jackson, Cochrane, Granek, Wactawski-Wende	10	CT	
196	Intrapersonal, interpersonal, treatment, and organizational adherence predictors in the Women's Health Initiative dietary modification clinical trial	**Tinker**, Van Horn, Perri, Rosal, Ockene, Patterson, Assaf, Hays, Young	10	CT	
218	Psychological effects of physical and verbal abuse among postmenopausal women	**Mouton**, Rodabough, Cochrane, Brzyski, Rovi, Talamantes, Burge, Katerndahl	10	OS	Submitted, J of Gerontology
250	Treatment with estrogen + progestin and age-related maculopathy in the Women's Health Initiative Sight Exam Study (WHISE)	**Haan**, Wallace, Klein, Klein, Hendrix, Seddon, Musch, Hyman	10	CT	Submitted, JAMA

Table 11.1 (continued)
Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
275	Association of prior hormone therapy with cognition during the Women's Health Initiative Memory Study (WHIMS) estrogen / progestin clinical trial	**Espeland**, Hogan, Dailey, Gass, Hendrix, Murphy, Rapp, Shumaker, Wactawski-Wende	10	CT	Submitted, Arch Intern Med
280	Diet, physical activity, energy balance and endogenous sex hormone concentrations in the WHI	**McTiernan**, Wu, Chlebowski, Modugno, Mossavar-Rahmani, Perri, Stanczyk, Van Horn	10	CT	accepted, Obesity Research
325	Association between reported alcohol intake and cognition: Results from the Women's Health Initiative Study of Cognitive Aging	**Espeland**, Coker, Limacher, Messina, Powell, Rapp, Resnick, Wallace	10	CT	Submitted, J of Neuropeidemiol
341	Race, socioeconomic status, and morbidity burden in the WHI baseline data	**Gold**, Hubbell, Mason, Michael, Rodrigues, Safford, Whitlock	10	Gen	Submitted, Ethn Health
342	Other combinations of height and weight are better predictors of BMD then BMI	**Robbins**	10	OS	Submitted, JBMR
353	Effects of conjugated equine estrogens on colorectal cancer in postmenopausal women with hysterectomy: The Women's Health Initiative randomized controlled trial. [WHI priority paper]	**Ritenbaugh**, Stanford, Ascensao, Chlebowski, Frank, Garland, Lane, Mason, McNeeley, Shikany, Stefanick, Taylor, Wu	10	CT	Submitted NEJM
359	Fractures and osteoporosis in diabetics	**Bonds**, Johnson, Margolis, Robbins, Rodrigues, Strotmeyer	10	OS	
363	Air pollution and cardiovascular disease incidence in the Women's Health Initiative observational study	**Miller,** Siscovick, Sheppard, Shepherd, Sullivan, Anderson, Kaufman	10	CT	Submitted, NEJM

Table 11.1 (continued)
Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
378	Expression and ambivalence over expression of negative emotion: Cross-sectional associations with psychosocial factors and health related quality of life	**Michael**, Bowen, Brzyski, Cochrane, O'Connor, Perrin, Ritenbaugh, Wisdom	10	Gen	Submitted, Journal of Psychosomatic Research
383	Circulating levels of insulin/glucose/igf-axis proteins and risk of postmenopausal ovarian, peritoneal and fallopian tube cancers	**Modugno**, Anderson, Monk, Rohan, Shikany, Williams	10	OS	Submitted
387	Predictive role of the resting electrocardiogram in the WHI hormone therapy trial	**Denes**, Greenland, Limacher, Allison, Johnson, LaCroix, Larson, Oberman	10	CT	
417	Postmenopausal hormone therapy and CHD risk: Interaction with COX-2 inhibitors	**Hsia**, Manson, Kuller, Pettinger, Choe, Langer, Limacher, Oberman, Ockene, O'Sullivan, Robinson	10	CT	Submitted, PLOS Clinical Trials
440	Statistical aspects of monitoring and reporting of the Women's Health Initiative randomized hormone therapy trials	**Anderson**, Kooperberg, Rossouw, Pettinger, Prentice	10	CT	Submitted, Clinical Trials
441	Effect of calcium and vitamin D supplementation on weight change in postmenopausal women: Results from the WHI clinical trial of CaD supplementation	**Caan**, Neuhouser, Powell, LaCroix, Uwaifo, Lewis, Whitlock, Wylie-Rosette, Margolis, Jackson, LeBoff	10	CT	Submitted
20	Relation of demographic factors, menstrual history, reproduction and medication use to sex hormones in postmenopausal women	**McTiernan**, Chen, Rohan, Modugno, Hendrix, Wu	9	CT	
30	Completeness of purchase mailing lists for identifying older women	**Falkner**, Wactawski-Wende, Trevisan	9	CT	in revision
34	The relationship between smoking status, body weight, and waist-to-hip ratio: The WHI	**Johnson**, Klesges, Hays, Noonan, Black, Curb, Liu, Manson	9	Gen	

Table 11.1 (continued)
Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
39	Hormone replacement therapy and dietary fat intake influence on blood lipids and insulin in postmenopausal women	**Chlebowski**, Sparks, Stefanick, Howard, Mossavar-Rahmani, McTiernan	9	Gen	
73	Innovative strategies for monitoring and enhancing clinic performance in the WHI clinical trial: The creation of the Performance Monitoring Committee	**Pottern**, Naughton, Lund, Cochrane, Brinson, Kotchen, McTiernan, Shumaker	9	Gen	
87	Predictors of total hip replacement in a cohort of older women: Result from the WHI observational study	**Wallace**, Chang, Nevitt, LaCroix, Kaplan, Sturm	9	Gen	
105	Retention of low income and minority women in clinical trials: A focus group study	**Johnson**, Williams, Fouad	9	CT	
111	Effects of fat intake on fat hedonics: Cognition or taste?	**Bowen**, Green, Vizenor, Vu, Kreuter, Rolls	9	OS	
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	9		
147	Association of hormone replacement therapy with body fat distribution in postmenopausal women	**Mayo**, Heimburger, Gower, Goran, Fouad, Redden, Oberman, Lewis, McGwin	9	CT	
149	Health status of postmenopausal white women with back and leg pain living in the community: A pilot study	**Vogt**, Lauerman, Chirumbole, Kuller	9	OS	

Table 11.1 (continued)
Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
173	Relationships between blood pressure, hypertension, and hypertension therapy and measures of cognition among WHIMS women at baseline	**Johnson**, Espeland, Mouton, Margolis, Masaki, Murphy, Wassertheil-Smoller, Prineas	9	WHIMS	
187	Estrogens and cardiovascular disease	**Rossouw**	9	OS	
220	The Women's Health Initiative: A glimpse behind the scenes	**Furniss**	9	CT	
316	Coffee consumption and risk of nonmelanoma skin cancer in caucasian women	**Abel**, Fernandez, Johnson, Jones, Mossavar-Rahmani, Rosenberg, Vitolins, Wong	9	OS	
323	Correlation between pelvic organ prolapse, pelvic floor disorder, urinary incontinence, defecation disorder, voiding dysfunction	**Nygaard**, Bradley	9	OS	
326	The association between osteoporosis and oral bone loss in postmenopausal women	**Wactawski-Wende**, Hovey, Hausmann, Trevisan, Grossi, Genco	9	CT	
331	Pelvic floor symptoms in older, community-dwelling women	**Bradley**, Kennedy, Nygaard	9	CT	
337	Joint analyses of clinical trial and observational study data on E+P use and cancers of the breast	**Prentice**, Anderson, Chlebowski, Hendrix, Hubbell, Kooperberg, Kuller, Lane, Langer, Manson, McTiernan, O'Sullivan, Stefanick	9	Gen	
352	Body size, weight cycling and risk of renal cell carcinoma among post-menopausal women.	**Luo**, Margolis	9	Gen	

Table 11.1 (continued)
Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
362	Effects of postmenopausal hormone therapy on rheumatoid arthritis and systemic lupus erythematosus: The Women's Health Initiative randomized controlled trials	**Wallitt**, Howard, Foster, Torner, Wasko, Katz, Pettinger	9	CT	
371	Associations between age-related maculopathy and lutein and zeaxanthin in the diet and serum in the Carotenoids in Age-related Eye Disease Study, an ancillary study of the Women's Health Initiative	**Moeller**, Mares-Perlman	9	OS	
388	Accuracy of commercial geocoding in the envirnomental epidemiology of arrhythmogenesis in WHI	**Whitsel**	9	CT	
389	Error in estimating ambient particulate matter health effects in the environmental epidemiology of arrhythmogenesis in the WHI	**Whitsel**	9	CT	
415	Application of GIS to estimate residential daily ambient pollutant concentrations.	**Liao**, Peuquet, Dou, Lin, Smith, Whitsel	9	CT	
421	Associations of serum alpha tocopherol status, current supplemental vitamin E and past supplemental and dietary vitamin E with cognitive impairments in older women	**Dunn**	9	Gen	
429	Biomarkers, postmenopausal hormone therapy and the risk of stroke: The Women's Health Initiative trials of postmenopausal hormone therapy.	**Kooperberg**, Cushman, Hsia, Robinson, Lynch, Baird, Johnson, Kuller, Beresford, Rodrigues	9	Gen	

Table 11.1 (continued)
Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
444	Associations between age-related nuclear opacities and lutein and zeaxanthin in the diet and serum in the Carotenoids in Age-Related Eye Disease Study, an ancillary study of the WHI	**Moeller**, Voland, Tinker, Blodi, Klein, Gehrs, Johnson, Snodderly, Wallace, Chappell, Mehta, Ritenbaugh, Mares-Perlman	9	OS	
38	Relationship of select dietary components and colorectal cancer among postmenopausal women: The Women's Health Initiative	**Frank**, Pettinger, Paskett, Wylie-Rosette, Agurs-Collins	8	Gen	
74	Baseline characteristics of the WHI observational study breast cancer survivor cohort	**Paskett**, Sherman, Andersen, Hays, McDonald, Naughton	8	OS	
117	Correlates of session completion and self-monitoring of food intake among minority participants enrolled in the Women's Health Initiative (WHI) dietary modification intervention during the first year of intervention	**Rosal**, Ockene, Mossavar-Rahmani, Margolis, Paskett, Thomson	8	Gen	
127	Plasma homocysteine levels and coronary heart disease in women	**Siscovick**, Manson, Trevisan, Wallace, Howard, Burke, Ridker	8	OS	
154	Does acidogenic diet contribute to the incidence of hip fracture?	**Barzel**, Wylie-Rosette, Ritenbaugh, Aickin, LeBoff	8	OS	
181	The relationship between moderate alcohol use folic acid intake and breast cancer in the Women's Health Initiative observational study	**Assaf**, Coccio, Paskett, Lane, Rohan, McTiernan, Duffy, Burkholder	8	OS	
217	Associations with gun-related threats and household fear in postmenopausal women	**Mouton**, Tan, del Aguila	8	OS	

Table 11.1 (continued)
Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
228	Past hysterectomy as a risk factor for hypertension in the Women's Health Initiative observational study participants	**Barad**	8	OS	
230	Use of electric blankets increases risk of endometrial cancer	**Abel**, Johnson, Mohanka, Mossavar-Rahmani	8	OS	
253	Cardiovascular disease and age related maculopathy in the Women's Health Initiative Sight Exam Study	**Klein**, Klein, Hendrix, Seddon, Langer, Kuller, Brunner, Haan, Hyman, Tomany	8	CT	
310	Relationship of body fat level and distribution to age-related maculopathy in the Carotenoids in Age related Eye Disease Study (CAREDS)	**LaRowe**, Gehrs, Wallace, Chappel	8	OS	
312	Accuracy of food portion estimation among postmenopausal women	**Coy**, Frank, Lee, Meyskens	8	CT	
322	The influence of years since menopause on the effect of HT on cardiovascular disease	**Rossouw**, Barad, Barnabei, Ko, Manson, Margolis, Prentice, Stefanick, Wu	8	CT	
369	Markers of inflammation as predictors of type 2 diabetes mellitus in a multi-racial cohort of women	**Liu**, Bonds, Carnethon, Heiss, Howard, Margolis, Phillips, Robinson, Safford, Wylie-Rosette	8	OS	
376	Markers of endothelial activation as predictors of type 2 diabetes mellitus in a multi-racial cohort of women	**Liu**, Manson, Cook, Hotamisligil, Hu, Levitan, Margolis, Oberman, Ridker, Rifai, Rodrigues, Tinker	8	OS	
390	Using artificial neural networks to assess risks and benefits for the individual postmenopausal woman	**Bandelow**, Espeland, Henderson, Resnick, Wallace, Coker, Hogervorst	8	WHIMS	
414	The impact of prehypertension on cardiovascular disease risk	**Hsia**, Allison, Black, Eaton, LaCroix, Lasser, Margolis, Wenger	8	CT	

Table 11.1 (continued)
Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
471	Calcium/vitamin D supplementation and the risk of cardiovascular diseases: The WHI randomized trial	**Hsia**, Manson, Johnson, Heiss, Stefanick, Allison, Heckbert, Sidney, Trevisan, Greenland, Dolan	8	CT	
493	Panic attacks and risk of Incident cardiovascular events in postmenopausal women in the Women's Health Initiative observational study	**Smoller**, Pollack, Wassertheil-Smoller, Jackson, Oberman, Wong, Sheps	8	OS	
53	Dietary, physical activity, and exercise patterns among diabetics	**Agurs-Collins**, Dolan, Pasaro, Howard	7	Gen	
79	Databased tracking and statistical models of the clinical trial recruitment process	**Creech**	7	CT	
81	The prevalence of urinary incontinence in WHI women	**Hendrix**, Clark, Ling, Dugan, Salmieri, Hurtado, McNeeley, Laube, McTiernan, Francis	7	Gen	
193	Predictors of adherence to the Women's Health Initiative clinical trial interventions: A conceptual framework	**Rosal**, Shumaker, Snetselaar, Tinker, Cochrane, Bowen, Brunner, Ockene	7	CT	
194	Predictors of adherence to the hormone replacement therapy clinical trial in the Women's Health Initiative	**Cochrane**, Stefanick, Wallace, Granek, Lillington, Anderson, Woods, Naughton	7	CT	
314	Aspirin dose, inflammation and cardiovascular disease	**Berger**, Langer, Wong, Oberman, Burke, Kostis	7	OS	
315	Urethral changes in postmenopausal women	**Coughlin**	7	CT	
328	Leukocyte count as a predictor of cancer in postmenopausal women	**Margolis**, Lopez, McTiernan, Thomson	7	OS	
339	Validity of self-reported diabetes mellitus in the WHI	**Margolis**, Bonds, Brzyski, Howard, Phillips, Robinson, Safford, Tinker	7	Gen	

Table 11.1 (continued)
Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
372	Risk factors for hip fracture, WHI observational study	**Robbins**, Aragaki, Cauley, Chen, Jackson, Kooperberg, Lewis, Stefanick, Wactawski-Wende, Watts	7	OS	
386	Dietary predictors of ovarian cancer risk in postmenopausal women participating in WHI	**Thomson**, Caan, La Valluer, Modugno, Mossavar-Rahmani, Parker, Sarto, Shikany	7	Gen	
394	Smoking and colorectal cancer risk	**Paskett**, Allison, Hunt, Messina, Reeves, Rohan, Whitlock, Williams	7	Gen	
401	Association of depression with cancer screening and advanced cancer at the presentation	**Aggerwal**, Adams-Campbell, Bonds, Freund, Lessin, Lopez, Ockene, Wallace, Williams	7	OS	
404	Risk of falling and fracture after cancer diagnosis	**Chen**, Chlebowski, Lopez, Mouton	7	Gen	
409	Risk factors for fracture in minority women	**Cauley**, Allison, Talavera	7	OS	
492	Older women discharged as non-specific chest pain are at increased cardiovascular risk	**Robinson**, Wallace, Limacher, Sato, Konety, Cochrane, Wassertheil-Smoller, Ockene, Blanchette, Ko	7	CT	
539	Estrogen use and mild cognitive impairment: Baseline and retrospective data from the Cognitive Change in Women WHI Ancillary Study	**Dunn**, Stoddard, Harty, Gavett, Weintraub	7	CT	
303	Statin use and occurrence of frailty and disability in postmenopausal women	**LaCroix**, Gray, Woods, Allison, Black, Cochrane, Curb, Greenland, Newman	6	Gen	
393	BMI as a predictor of body image in older women, controlling for socio-demographic correlates	**Carrigan**, Robbins, Winward, Blanchette, Grosz, Hays, Hunt, Manson, Messina, Parker, Rosal	6	OS	

Table 11.1 (continued)
Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
420	Postmenopausal hormone use and the risk of nephrolithiasis: Results from the WHI	**Malouff**; Robbins, Cochrane, Moe, Sakhaee, Welch	6	CT	
475	CaD & physical function	**Brunner**, Lewis, Cochrane, Limacher, Mysiw, Rosal, Shumaker, Wallace	6	CT	
506	The effect of treatment with conjugated equine estrogen on the presence and extent of subclinical coronary atherosclerosis in women 50 – 59 years of age at enrollment in the Women's Health Initiative	**Manson,** Allison, Carr, Cochrane, Hsia, Hunt, Kuller, Lane, Langer, Ludlam, Margolis, Nathan, Ockene, Robbins, Rossouw, Stefanick	6	CT	
18	The relationship of dietary phytoestrogens to menopausal symptoms and major morbidity in postmenopausal women	**Assaf**, Cyr, Coccio, Hixson	5	CT	
45	Socio-demographic determinants of folic acid intake	**Beresford**, Kritchevsky, Vitolins, Wodarski	5	Gen	
54	Current treatment patterns in women with hypercholesterolemia	**Manson**, Freed, Chae	5	Gen	
118	Association between depressive symptomatology and physical activity in postmenopausal women	**Rosal**, Ockene, Haan, Brunner, Mouton, Lopez, Perri, Cochrane, Matthews, Jackson, Sato	5	Gen	
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, Van Horn	5	OS	
151	History of estrogen and oral contraceptive use and cognitive function: Results from the Women's Health Initiative Memory Study	**Rapp**, Dailey, Gass, Wactawski-Wende, Hendrix, Hogan, Jones, Murphy, Shumaker	5	WHIMS	

Table 11.1 (continued)
Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
152	The impact of magnesium intake on bone mass and risk of fracture in the Women's Health Initiative observational study	**Jackson**, LaCroix, Lewis, Wactawski-Wende, Cauley, Chen, Bassford	5	OS	
153	Metabolic syndrome and depression	**Wylie-Rosette**, Cochrane, Perri, Rapp, Rosal	5	CT	
156	Incidence of systemic lupus erythematosus in the Women's Health Initiative	**Assaf**, Cyr, Crowley, Coccio	5	OS	
159	Endogenous sex steroid hormone and risk of coronary heart disease in postmenopausal women	**Rexrode**, Manson, Kuller, McTiernan, Stefanick, Heckbert, White	5	OS	
160	Correlation of endogenous sex steroid hormones with inflammatory and thrombotic markers in postmenopausal women	**Rexrode**, Manson, Ridker, Cochrane, Ockene, Kotchen, Margolis, McGovern	5	OS	
172	Dietary glycemic Index/glycemic load assessed by food frequency questionnaire in relation to plasma lipid concentrations in Women's Health Initiative participants	**Shikany**, Tinker, Patterson, Liu, Neuhouser, Ma, Phillips	5	Gen	
176	Validating and improving the Gail and colleagues model of breast cancer risk in the WHI	**Chlebowski**, Anderson, McTiernan, Aragaki	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	
223	Physical activity and fracture in the Women's Health Initiative observational study	**Wactawski-Wende**, Cauley, Jackson, LeBoff	5	OS	

Table 11.1 (continued)
Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
268	The effects of estrogen plus progestin on the overall health of postmenopausal women as measured by a global index of disease events	**LaCroix**, Anderson, Beresford, Cauley, Chlebowski, Curb, Hendrix, Hubbell, Jackson, Margolis, O'Sullivan, Phillips, Wallace, Aragaki	5	CT	
284	The effect of estrogen and progestin on bone mineral density	**Jackson**, Cauley, Chen, LaCroix, Phillips, Robbins, Rodrigues, Tylavsky, Wactawski-Wende, Pettinger	5	CT	
296	Place of birth and migration within the United States and its effects on health behaviors and cardiovascular risk factors in postmenopausal women	**Johnson**, Connelly, Allison, Goldman, Langer, Limacher, Michael, Polanco-Paula, Sato	5	OS	
301	Ace-inhibitor use and occurrence of frailty and disability in postmenopausal women	**Gray**, LaCroix, Woods, Cochrane, McDermott, Murray, Rodrigues, Black	5	Gen	
304	The effect of E+P discontinuation on risk for fracture: The WHI	**Jackson**, Watts, Brzyski, Hubbell, Kuller, LaCroix, O'Sullivan, Sato, Stefanick	5	Gen	
307	Determinants of retinal levels of lutein and zeaxanthin in older women recruited to participate in the Carotenoids in Age-Related Eye Disease Study (CAREDS)	**Mares-Perlman**, Snodderly, Gruber, Moeller, Ficek, Klein, Wooten, Johnson, Chappel	5	OS	
308	Relationship between dietary fat and age related maculopathy in the CAREDS population	**Mehta**, Blodi, Chappel, Moeller	5	OS	
309	Correlates of dietary patterns in older women in the Carotenoids in Age related eye Disease Study (CAREDS)	**Moeller**, Ritenbaugh, Tinker, Moeller, Blodi, Chappel	5	OS	

Table 11.1 (continued)
Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
311	Relationship of supplement use to age related maculopathy	**Gruber**, Mares-Perlman, Wallace, Moeller, Oxton, Chappel	5	OS	
320	Endometrial cancer and NSAID use in the Women's Health Initiative	**Modugno**, Harris, Ness, Yasmeen, O'Sullivan, Rohan	5	OS	
334	Sexual function and the effect of discontinuation of E+P therapy among participants in WHI	**Gass**, Cochrane, Barad, Barnabei, Brzyski, Lane, LaValleur, Manson, Mouton, Ockene	5	CT	
346	Estrogen plus progestin & CEE influence on breast cancer diagnosis	**Chlebowski**, Anderson, Chen, Gilligan, Lane, Langer, McTiernan	5	CT	
358	Estrogen only influence on mammogram density in healthy postmenopausal women in the Women's Health Initiative randomized trial	**Martin**, McTiernan, Pisano, Chlebowski, Heiss	5	CT	
366	Association of vasomotor symptoms with cardiovascular outcomes	**Barad**, Allison, Barnabei, Brunner, Cochrane, Gass, Manson, Ockene, Robinson, Schatz, Stefanick, Woods, Rossouw	5	CT	
374	Tamoxifen and coronary heart disease (CHD) risk	**Chlebowski**, Allison, Brzyski, Greep, Kooperberg, O'Sullivan, Robinson	5	Gen	
375	Past weight cycling as a cause of immune related cancers	**DeRoos**, Caan, McTiernan, Mossavar-Rahmani, Rosenberg, Thomson, Ulrich	5	OS	
377	Medication utilization for the secondary prevention of cardiovascular disease in older women	**Robinson**, Wallace, Cochrane, Black, Ko, Masaki, O'Sullivan, Petrovich	5	Gen	

Table 11.1 (continued)
Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
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	5	CT	
381	Estimating ovarian cancer risk	**Anderson**, Chlebowski, Johnson, Kaunitz, Sato, Monk	5	Gen	
395	Hormone therapy, lean mass, falling and fracture risk among postmenopausal women: Results from the Women's Health Initiative hormone trials	**Chen**, Bassford, Cauley, Jackson, LaCroix, Lewis	5	CT	
406	Effect of HT on incidence of stroke in older women with atrial fibrillation	**Konety**, Robinson, Black, Frishman, Oberman, Sarto, Williams	5	CT	
422	Part 2 of Ms289	**Rosenberg**, Greenland, Khandekar, McTiernan, Rodabough, Sharma	5	Gen	
438	Walking speed and risk of strokes	**Kaplan**, Baird, Kooperberg, LaCroix, Lo, Lynch, Psaty, Rosenbaum, Verghese, Wassertheil-Smoller, Wolf, Xue	5	Gen	
445	Interaction of hormone therapy with biomarkers for cardiovascular outcomes.	**Bray**, Lawson, LaCroix, Langer, Lasser, Limacher, Manson, Margolis, Rossouw, Stefanick	5	Gen	
464	Use of nutritional biomarkers to describe participant-related measurement error from dietary self-report in the Women's Health Initiative	**Neuhouser**, Tinker, Assaf, Beresford, Bingham, Caan, Heiss, Kuller, Ockene, Prentice, Sarto, Satterfield, Schoeller, Stefanick, Thomson	5	CT	

Table 11.1 (continued)
Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
466	DM & QOL/depression	**Assaf**, Beresford, Brunner, Bowen, Naughton, Petrovich, Granek, Whitlock, Phillips, Haines, Rosal, Wenger, Snetselaar	5	CT	
470	CaD & breast and other cancers	**Chlebowski**, Johnson, Wactawski-Wende, Cummings, Kooperberg, Hubbell, Hiatt, Vitolins, Lane, Yasmeen, Shikany, Khandekar, O'Sullivan, Rohan	5	CT	
473	CaD & adverse effects and symptoms	**Wallace**, O'Sullivan, Wactawski-Wende, Masaki, Cochrane, Gass, Whitlock	5	CT	
479	Plasma homocysteine and risk of hip fracture among postmenopausal women in the WHI	**LeBoff**, Bauer, Cauley, Cummings, Jackson, Kooperberg, LaCroix, Lee, Lewis, Narweker, Thomas, Wu	5	OS	
480	Thyroid disease and risk for hip fracture in postmenopausal women	**Cummings**, Bauer, Cauley, Jackson, Kooperberg, LaCroix, LeBoff, Lee, Lewis, Thomas, Wu	5	OS	
481	Sex hormones, risk factors, and risk for hip fracture in postmenopausal women	**Cummings**, Cauley, Hendrix, Jackson, Kooperberg, LaCroix, LeBoff, Lee, Lewis, Robbins, Wallitt, Wu	5	OS	
503	Menopause, patterns of hormone therapy use and coronary artery calcium	**Allison,** Carr, Cochrane, Eaton, Gass, Greenland, Hendrix, Hsia, Hunt, Johnson, Kuller, Langer, Manson, Phillips, Robinson, Rossouw	5	CT	

Table 11.1 (continued)
Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
508	Alcohol and folate consumption and risk of benign proliferative epithelial disorders of the breast	**Cui**, Rohan, Beresford, Chlebowski, Hendrix, Lane	5	CT	
509	Cigarette smoking and risk of benign proliferative epithelial disorders of the breast	**Cui**, Rohan	5	CT	
541	Low-fat dietary pattern and risk of treated type 2 diabetes mellitus in postmenopausal women	**Tinker**, Bonds, Beresford, Howard, Manson, Margolis, Ockene, Parker, Perri, Robinson, Rodrigues, Safford, Stevens, Wenger	5	CT	
124	Relationships between nutritional intake and measures of cognition	**Espeland**, Bowen, Haan, Brunner, Snetselaar, Dunn	4	WHIMS	
185	Correlates of dietary lutein in older women recruited to participate in the Carotenoids in Age-related Eye Disease Study (CAREDS)	**Mares-Perlman**, Allen, Wallace, Ritenbaugh, Tinker	4	OS	
215	Stress, personality, and social support in the development of breast cancer	**Michael**, Ritenbaugh, Ockene, Weihs, Bowen, Chlebowski, Hays	4	OS	
251	History of hormone replacement therapy use, reproductive history and age-related maculopathy in the Women's Health Initiative Sight Exam Study	**Haan**, Wallace, Hendrix, Seddon, Klein, Klein, Musch, Langer, Brunner, Wactawski-Wende	4	CT	
252	Dietary and supplement intake of antioxidants in relation to age related maculopathy endpoints in the Women's Health Initiative Sight Exam Study	**Haan**, Seddon	4	CT	
256	Inflammation and ARM in the WHISE study	**Klein**, Klein, Knudtson, Seddon, Wallace, Hyman	4	CT	

Table 11.1 (continued)
Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
259	Alcohol, caffeine and ARM in the WHISE study	**Klein**, Seddon, Klein, Johnson, Tomany, Hyman, Musch, Johnson	4	CT	
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	4	OS	
267	Adherence to dietary modifcation: A theoretical framework	**Rosal**, Ockene, Fletcher	4	CT	
281	Prevalence of ST segment depression on Holtor monitoring in women in the observational study relationship to HRT	**Sheps**, Smoller, Wassertheil-Smoller	4	OS	
283	Baseline memory Impairment and HRT as moderators of the association between change in cognition and dementia in WHIMS	**Royall**	4	OS	
356	The cross-sectional relationship between relative body weight and cognitive function in older postmenopausal women participating in the Women's Health Initiative	**Kerwin**, Kotchen, Kooperberg, McTigue, Robinson, Van Horn, Coker, Espeland	4	CT	
360	Obesity and risk of dementia in postmenopausal women	**Kerwin**, Kotchen, Chlebowski, Coker, Espeland, Kuller, Vitolins	4	WHIMS	
396	Association between hypertension and change in cognitive function in postmenopausal women: Results from the Women's Health Initiative Memory Study (WHIMS)	**Margolis**, Espeland, Johnson	4	WHIMS	
411	Application of GIS to estimate residential daily ambient pollutant concentrations	**Liao**, Whitsel, Peuquet, Dou, Lin, Smith	4	Gen	

Table 11.1 (continued)
Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
426	Associations between Incident breast cancer and geographic location of residence in the Woman's Health Initiative observation study	**Millen**, Duffy; Freudenheim, Kuller, Lane, Langer, Lopez, McTiernan, Mossavar-Rahmani, Rosenberg, Wactawski-Wende	4	OS	
501	3 yr f/u E+P-primary paper	**Heiss**, Wallace, Brzyski, Gass, LaCroix, Rossouw, Stefanick	4	CT	
502	HT & ovarian cancer	**Anderson**, Barnabei, Brzyski, Chlebowski, Hendrix, Lane, Monk, Ockene, Rodriguez, Sarto	4	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	4	CT	
529	Ambient air pollution, myocardial ischemia and infarction: The environmental epidemiology of arrhythmogenesis in WHI,1999-2001	**Whitsel**, Anderson, Catellier, Chen, Crooks, Liao, Peuquet, Prineas, Quibrera, Smith	4	CT	
549	Improving estimation efficiency by exploiting covariate independence in outcome dependent sampling	**Dai**, LeBlanc, Kooperberg	4	Gen	
552	An application of mixed models in the analysis of periodontal data using a spatial covariance structure	**Cai**, Carter, Hutson, Wactawski-Wende, Wilding	4	OS	
588	Non-steroidal anti-inflammatory drugs and cognitive function in older women	**Dunn**, Gavett, Harty, Stoddard, Weintraub	4	Gen	
56	Psychometric evaluation of the urinary Incontinence scale	**Levine**, Shumaker, Naughton, Kaplan, Bowen	3	Gen	

Table 11.1 (continued)
Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
90	Passive smoke exposure in childhood and adulthood and prevalent coronary heart disease in women enrolled in the WHI	**Frishman**, Wagenknecht, Wong, Ockene	3	OS	
157	Type 2 diabetes and cognitive functioning in WHIMS	**Haan**, Wallace, Hogan, Coker, Ockene	3	WHIMS	
161	Reproductive history and cognitive function in WHIMS	**Haan**, Frishman, Stefanick	3	WHIMS	
205	Risk factors for sarcopenia among a multiethnic cohort of postmenopausal women	**Chen**, Cauley, Lewis, Phillips, Van Horn, Wallace	3	Gen	
207	Comparisons between never smokers, former smokers and current smokers in the observational study of the WHI	**Brunner**, Johnson, Hunt, Paskett, Stevens, Ockene, Bowen	3	OS	
245	Factors associated with self-reported severity of constipation in the Women's Health Initiative	**Morse**, Ockene, Nygaard, Crawford	3	Gen	
297	Racial/cthnic differences in menopausal symptoms in minority vs. White women in the observational study cohort of WHI at baseline	**Mossavar-Rahmani**, Cochrane, Brzyski, Schenken, Murphy, O'Sullivan, Potter, Kempainen	3	OS	
299	Association between hypertension and change in cognitive function in postmenopausal women: Results from the Women's Health Initiative Memory Study (WHIMS)	**Margolis**, Espeland, Johnson	3	WHIMS	
305	Serum sex hormone levels and risk of hypertension in postmenopausal women	**Joffe**, Rexrode, Cochrane, Allison, Kotchen, O'Sullivan, Safford	3	OS	

Table 11.1 (continued)
Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
351	Validation of the Gail Model for breast cancer risk in over age 70 women enrolled in WHI.	**Yasmeen**, Adams-Campbell, Barnabei, Chlebowski, Gilligan, Hendrix, Hubbell, Lopez, Melnikow, Sarto, Woods	3	Gen	
355	Spanish-language translation issues in clinical trials: The WHI experience	**Talavera**, Angelelli, Fernandez, Heinrich, Hunt, Mossavar-Rahmani	3	CT	
364	Hormone replacement therapy and chronic heart failure incidence and outcomes in post-menopausal women	**Greenland**, Chae, Howard, LaCroix, Limacher, Robinson, Wong	3	CT	
384	Frailty in WHI clinical trials participants: Comparison of self-report and physical performance measures	**Woods**, LaCroix, Brunner, Cochrane, O'Sullivan, Wallace	3	CT	
392	Family aggregation of macrovascular complications of diabetes in postmenopausal women	**Li**, Johnson, Curb, O'Sullivan, Robinson, Safford	3	OS	
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	3	WHIMS	
399	Subtypes of mild cognitive impairment: Prevalence, course, and effect of hormone therapy	**Rapp**	3	WHIMS	
410	Stress as a factor contributing to advanced breast cancer stage at the time of diagnosis in underserved minority women	**Moshesh**, Eaton, Hunt, Paskett, Woods	3	Gen	

Table 11.1 (continued)
Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
412	Validation of WHO model for absolute risk of fracture	**Cauley**, Watts, Chen, Cummings, Jackson, LeBoff, McGowan, O'Sullivan, Robbins, Wactawski-Wende	3	Gen	
427	Statin use and cognition in postmenopausal women:The Women's Health Initiative Memory Study (WHIMS)	**Legault**	3	CT	
428	Pelvic organ prolapse as a risk factor for postmenopausal osteoporotic fractures.	**Pal**, Barad, Wassertheil-Smoller, Barnabei, Freeman, Hailpern, Kipersztok	3	Gen	
430	Sleep quality and cardiovascular diseases of postmenopausal women	**Chen**, Brunner, Jain, Robinson, Stefanick	3	Gen	
433	Hormone therapy and fracture: Biological mechanisms in the Women's Health Initiative hormone trial	**Cauley**, Assaf, Chen, Frank, Jackson, LaCroix, McGowan, Neuner, Robbins, Wactawski-Wende, Wallace, Zmuda	3	CT	
458	BMI and prognostic features of endometrial cancer	**Paskett**, Cunyun, Lane, McNeeley, Reeves	3	Gen	
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, Van Horn	3	OS	
476	Dietary patterns, markers of inflammation and endothelial activation, and age related maculopathy (ARM) in a subset of Women's Health Initiative-Sight Exam (WHI-SE)	**Kannan**, Haan, Seddon, Blythe, Deng, Giacherio, Klein, Klein, McConnell, Moore, Wijeyesakere	3	CT	

Table 11.1 (continued)
Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
484	A prospective study of plasma insulin-like growth factor-1 (IGF-1), insulin-like growth factor-2 (IGF-2), insulin-like growth factor binding protein-3 (IGFBP-3) and the risk of pancreatic cancer	**Fuchs**, Cochrane, Manson, Rohan, Wolpin	3	OS	
486	Insulin sensitivity and insulin secretion determined by HOMA predict risk of type 2 diabetes mellitus in a multi racial cohort	**Liu**, Howard, Kuller, Manson, Nathan, Rifai, Song, Tinker	3	OS	
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	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	3	OS	
510	Drinking pattern and alcohol type and the risk of coronary heart disease among women with self-reported diabetes	**Rajpathak**, Wassertheil-Smoller, Rohan, Wylie-Rosette, Freiberg, Liu, Robinson	3	OS	
514	Selected micronutrients and risk of hormone receptor-defined breast cancers among postmenopausal women	**Cui**, Rohan, Liu, Shikany, Yasmeen	3	OS	
526	Biomarkers, postmenopausal HT and the risk of CHD	**Rossouw**, Bray, Cushman, Greenland, Hendrix, Hsia, Jones, Kooperberg, Robinson	3	CT	

Table 11.1 (continued)
Publications

Ms ID	Title	Authors	Stage	Data Focus	Reference
527	Predictors of change in calcium Intake and fortified food use after osteoporosis screening	**McCloud**	3	OS	
546	Predictors of incident dementia in postmenopausal women enrolled in a trial of hormone therapy: the Women's Health Initiative Memory Study (WHIMS)	**Coker**	3	WHIMS	
553	A pilot study of dopamine genotypes and their relation to physical activity, body mass index, body composition and energy intake in postmenopausal women: An ancillary pilot study from the Buffalo Clinical Center of the Women's Health Initiative	**Wactawski-Wende**, Epstein, Leddy, Salis	3	OS	
577	Effect of a long-term, low-fat, high fruit and vegetable diet on retinal carotenoids in the Women's Health Initiative	**Moeller**, Mares-Perlman	3	CT	

Stage

3=Writing group approved
4=Analysis proposed
5=Analysis in progress
6=Analysis completed
7=Draft manuscript
8=Final ms submitted to P&P & PO
9=Final ms approved
10=Submitted
11=In press/published

Appendix A

Women's Health Initiative Memory Study (WHIMS)

October 2006

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.

Women's Health Initiative Memory Study (WHIMS) Extension

Wake Forest University Health Sciences
Division of Public Health Sciences
Department of Social Sciences and Health Policy
Winston-Salem, North Carolina 27157

Study Activities:

The Women's Health Initiative Memory Study (WHIMS) Extension clinical centers have continued to enroll participants and collect data since the last report dated 9/9/2005. Clinical Center staff have conducted numerous home/off-site visits traveling over 18,000 miles this past year.

WHIMS Extension Enrollment Data: Currently, there are 4,116 participants enrolled in the WHIMS Extension. Enrollment rates for the WHIMS Extension average .80 percent for eligible WHI Extension participants across all sites. The WHIMS Enrollment Report which shows the cumulative number of participants recruited at each clinical center is attached. (Attachment A)

Supplemental Case Ascertainment (SCA) Protocol: In February 2006, WHIMS Site Monitors began conducting informant interviews. To date, 155 informant contacts have been made which have resulted in 73 completed interviews. The SCAP status report is attached (Attachment B).

Website: The WHIMS Extension website provides capabilities for study and participant management and participant form data entry via the internet. Extensive personnel effort has been put forth in establishing the following: Participant eligibility lists, Supplemental Case Ascertainment (SCA), Form 39 and Status Change data entry screens, Phase 1 – 4 and Adjudication tracking, Participant Follow-up status along with a Query Edit report. In addition, programming efforts have provided support to clinical center personnel regarding website access and operation.

Training Sessions: WHIMS Extension staff have utilized conference calls to train WHIMS technicians on various study procedures and instruments. These sessions have been well attended across all clinical centers and have been conducted with much success. Two training calls are offered on consecutive days, with one held in the morning (Northeast and Southwest clinics) and the other held in the afternoon (Midwest and West clinics). However, anyone can join the call that best meets their schedule. Over the past year, WHIMS Extension staff have conducted the following training sessions for the WHIMS technicians:

May 24 & 25, 2006 – WHIMS Phase 1 Tracking, Query Edit Report, Status Change Form

July 12 & 19, 2006 – WHIMS Phase 1 and Phase 2 Administration

Participating Clinical Centers/Field Centers: There are 38 WHI Extension clinical centers participating in the WHIMS Extension. They are as follows:

Atlanta Vanguard Clinical Center	Clinic ID# 19
Birmingham Vanguard Clinical Center	Clinic ID# 12
Boston Vanguard Clinical Center	Clinic ID# 14
Buffalo Vanguard Clinical Center	Clinic ID# 15
Chapel Hill Clinical Center	Clinic ID# 58
Chicago Vanguard Clinical Center	Clinic ID# 16
Evanston Hospital (Satellite)	Clinic ID# 20
Chicago-Rush Clinical Center	Clinic ID # 59 & 60
Cincinnati Clinical Center	Clinic ID# 61
Columbus Clinical Center	Clinic ID# 50
Davis Vanguard Clinical Center	Clinic ID# 30
Detroit Clinical Center	Clinic ID# 62
Gainesville Clinical Center	Clinic ID# 46
George Washington University	Clinic ID# 44
Honolulu Clinical Center	Clinic ID# 45
Houston Clinical Center	Clinic ID# 47
Iowa City Clinical Center	Clinic ID# 21
Des Moines Clinical Center (Satellite)	Clinic ID# 73
Irvine Clinical Center	Clinic ID# 63
Los Angeles Clinical Center	Clinic ID# 68
Madison Clinical Center	Clinic ID# 56
MedStar Clinical Center	Clinic ID# 51
Memphis Vanguard Clinical Center	Clinic ID# 24
Milwaukee Clinical Center	Clinic ID# 43
Minneapolis Clinical Center	Clinic ID# 25
Nevada Clinical Center	Clinic ID# 65
New Brunswick Clinical Center	Clinic ID# 72
New York City Clinical Center	Clinic ID# 49
Newark Vanguard Clinical Center	Clinic ID# 26
Oakland Clinical Center	Clinic ID# 53
Pawtucket Vanguard Clinical Center	Clinic ID# 23
Pittsburgh Vanguard Clinical Center	Clinic ID# 28
Portland Clinical Center	Clinic ID# 66
San Antonio Clinical Center	Clinic ID# 67
Stanford Clinical Center	Clinic ID# 42
Stony Brook Clinical Center	Clinic ID# 57
Torrance Clinical Center	Clinic ID# 55
Tucson Vanguard Clinical Center	Clinic ID# 29
Winston-Salem Clinical Center	Clinic ID# 71
Worcester Clinical Center	Clinic ID# 48

Findings to Date: Data collection is scheduled to end on September 30, 2007. Findings will not be known until after this time.

Publications and Ancillary Studies Committee (PASC): The WHIMS PASC held national conference calls to discuss current manuscript proposals, manuscripts under development and manuscripts that have been published. The committee reviewed abstracts, draft proposals and draft manuscripts. The PASC status report is attached (Attachment C).

Manual of Operating Procedures (MOP): An updated WHIMS Extension MOP was distributed to the WHIMS Clinical Centers (via the WHIMS Extension website) in January 2006. The WHIMS Extension website, which is located at https://www.phsapps.wfubmc.edu/whims/

WHI CCC Subcontract: In previous years, the WHIMS Extension has subcontracted with the WHI CCC to provide database management and statistical analysis for WHIMS participants. On July 13, 2006, the WHIMS CCC was notified by NHLBI the support for WHIMS had been added to the prime WHI contract with FHCRC. Therefore, the subcontract was no longer needed.

Attachment A

WHIMS Extension Enrollment
Number enrolled by clinic
Generated at 13:13 ET on 27OCT06

				WHI Extension		WHIMS Extension			
		Contacted^^		Enrolled		Enrolled		Denied Consent	
Clinic	Number eligible for Extension^	N	%	N	%	N	%^^^	N	%
ALL CLINICS	6579	6160	93.6%	5146	83.5%	4116	80.0%	1031	20.0%
11=Davenport	38	38	100%	28	73.7%	24	85.7%	4	14.3%
12=Birmingham	151	145	96.0%	114	78.6%	96	84.2%	18	15.8%
13=Greensboro	31	31	100%	26	83.9%	21	80.8%	5	19.2%
14=Boston	192	129	67.2%	105	81.4%	73	69.5%	32	30.5%
15=Buffalo	148	148	100%	133	89.9%	117	88.0%	17	12.8%
16=Chicago	9	9	100%	7	77.8%	5	71.4%	2	28.6%
19=Atlanta	94	93	98.9%	76	81.7%	70	92.1%	6	7.89%
20=Chicago-Evanston	19	18	94.7%	17	94.4%	13	76.5%	4	23.5%
21=Iowa City	48	45	93.8%	35	77.8%	21	60.0%	14	40.0%
23=Pawtucket	182	182	100%	158	86.8%	109	69.0%	49	31.0%
24=Memphis	92	92	100%	63	68.5%	47	74.6%	16	25.4%
25=Minneapolis	197	197	100%	161	81.7%	126	78.3%	35	21.7%
26=Newark	103	100	97.1%	82	82.0%	74	90.2%	8	9.76%
27=Phoenix	89	88	98.9%	59	67.0%	49	83.1%	10	16.9%
28=Pittsburgh	139	139	100%	125	89.9%	108	86.4%	17	13.6%
29=Tucson	138	127	92.0%	86	67.7%	57	66.3%	29	33.7%
30=Davis	199	194	97.5%	164	84.5%	120	73.2%	44	26.8%

				WHI Extension		WHIMS Extension			
		Contacted^^		Enrolled		Enrolled		Denied Consent	
Clinic	Number eligible for Extension^	N	%	N	%	N	%^^^	N	%
42=Stanford	240	239	99.6%	214	89.5%	193	90.2%	21	9.81%
43=Milwaukee	232	232	100%	193	83.2%	130	67.4%	63	32.6%
44=George Wash.	164	148	90.2%	125	84.5%	115	92.0%	10	8.00%
45=Honolulu	86	71	82.6%	62	87.3%	58	93.5%	4	6.45%
46=Gainesville	134	133	99.3%	128	96.2%	101	78.9%	27	21.1%
47=Houston	109	108	99.1%	66	61.1%	58	87.9%	8	12.1%
48=Worcester	263	261	99.2%	247	94.6%	197	79.8%	50	20.2%
49=New York	244	239	98.0%	200	83.7%	164	82.0%	36	18.0%
50=Columbus	264	264	100%	213	80.7%	139	65.3%	74	34.7%
51=Medlantic	149	140	94.0%	126	90.0%	114	90.5%	12	9.52%
53=Oakland	171	171	100%	141	82.5%	115	81.6%	26	18.4%
54=Jacksonville	81	79	97.5%	70	88.6%	62	88.6%	8	11.4%
55=Torrance	56	51	91.1%	40	78.4%	24	60.0%	16	40.0%
56=Madison	143	132	92.3%	116	87.9%	90	77.6%	26	22.4%
57=Stony Brook	232	232	100%	199	85.8%	154	77.4%	45	22.6%
58=Chapel Hill	223	216	96.9%	177	81.9%	147	83.1%	30	16.9%
59/60=Chicago -Rush	135	76	56.3%	76	100%	71	93.4%	5	6.58%
61=Cincinnati	147	147	100%	127	86.4%	117	92.1%	10	7.87%
62=Detroit	111	107	96.4%	75	70.1%	63	84.0%	12	16.0%
63=Irvine	177	152	85.9%	129	84.9%	87	67.4%	42	32.6%
65=Nevada	188	112	59.6%	112	100%	111	99.1%	1	0.89%

				WHI Extension		WHIMS Extension			
		Contacted^^		Enrolled		Enrolled		Denied Consent	
Clinic	Number eligible for Extension^	N	%	N	%	N	%^^^	N	%
66=Portland	181	171	94.5%	150	87.7%	130	86.7%	20	13.3%
67=San Antonio	98	50	51.0%	38	76.0%	38	100%	0	0.00%
68=Los Angeles	210	210	100%	151	71.9%	103	68.2%	48	31.8%
69=Fall River	123	122	99.2%	114	93.4%	95	83.3%	19	16.7%
70=Pauline	42	42	100%	30	71.4%	28	93.3%	2	6.67%
71=Bowman Gray	34	34	100%	23	67.6%	13	56.5%	10	43.5%
72=New Brunswick	187	160	85.6%	139	86.9%	124	89.2%	15	10.8%
73=Des Moines	286	286	100%	226	79.0%	145	64.2%	81	35.8%

^Based on most recent follow up status (Deceased, absolutely no follow-up, and proxy follow-up omitted)

^^Completed WHIMS Extension consent form

^^^Denominator is those participants that enrolled in WHI Extension

Click on link to get clinic specific information for reason for not consenting

Attachment B

	Clinical Center Contacts				CCC Contacts													
	Eligible	Contacted	Call Outcome		Attempts					Total Contacts		CCC Call Status						
Clinic	N	N	Agreed	Refused	Not Yet Attempted	1	2	3	4	Participant	Phone	DQ Completed	Declined	No Answer	Phone Disconnected	Unable to Locate	Other	Left a message (4th attempt only)
ALL CLINICS	705	348	276	72	122	76	27	36	16	155	302	73	3	49	13	2	9	6
11=Davenport	3	3	3	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0
12=Birmingham	21	18	12	6	1	4	1	4	2	11	26	9	0	1	1	0	0	0
13=Greensboro	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
14=Boston	12	10	10	0	0	3	2	2	3	10	25	5	0	1	1	0	1	2
15=Buffalo	12	10	9	1	5	2	2	0	0	4	6	0	1	2	0	0	1	0
16=Chicago	4	1	1	0	0	1	0	0	0	1	1	1	0	0	0	0	0	0
19=Atlanta	7	4	4	0	0	2	0	0	2	4	10	1	0	0	2	0	1	0
20=Chicago-Evanston	1	1	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
21=Iowa City	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
23=Pawtucket	28	21	16	5	0	13	1	2	0	16	21	10	2	2	0	2	0	0
24=Memphis	10	10	9	1	1	2	1	4	1	8	20	2	0	3	2	0	1	0
25=Minneapolis	18	16	15	1	15	0	0	0	0	0	0	0	0	0	0	0	0	0
26=Newark	9	2	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
27=Phoenix	13	8	7	1	7	0	0	0	0	0	0	0	0	0	0	0	0	0
28=Pittsburgh	17	16	12	4	1	1	1	5	4	11	34	6	0	2	0	0	1	2
29=Tucson	16	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
30=Davis	30	11	11	0	2	3	3	3	0	9	18	1	0	6	1	0	1	0
42=Stanford	34	26	21	5	21	0	0	0	0	0	0	0	0	0	0	0	0	0
43=Milwaukee	22	4	3	1	0	1	1	1	0	3	6	1	0	2	0	0	0	0
44=George Wash.	22	17	17	0	9	5	2	1	0	8	12	3	0	5	0	0	0	0
46=Gainesville	18	17	12	5	4	5	3	0	0	8	11	2	0	3	3	0	0	0
47=Houston	6	5	4	1	0	1	0	3	0	4	10	2	0	2	0	0	0	0
48=Worcester	37	36	34	2	19	12	4	0	0	16	20	4	0	11	0	0	1	0
49=New York	26	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
50=Columbus	28	2	2	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0
51=Mediantic	25	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

	Clinical Center Contacts				CCC Contacts													
	Eligible	Contacted	Call Outcome		Attempts					Total Contacts		CCC Call Status						
Clinic	N	N	Agreed	Refused	Not Yet Attempted	1	2	3	4	Participant	Phone	DQ Completed	Declined	No Answer	Phone Disconnected	Unable to Locate	Other	Left a message (4th attempt only)
53=Oakland	11	10	8	2	2	5	0	1	0	6	8	4	0	1	1	0	0	0
54=Jacksonville	5	5	3	2	0	1	0	0	2	3	9	1	0	0	1	0	0	1
55=Torrance	4	1	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
56=Madison	13	9	7	2	7	0	0	0	0	0	0	0	0	0	0	0	0	0
57=Stony Brook	24	17	7	10	0	2	1	3	1	7	17	3	0	4	0	0	0	0
58=Chapel Hill	25	3	3	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0
59/60=Chicago-Rush	11	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
61=Cincinnati	14	11	10	1	0	8	0	2	0	10	14	9	0	0	1	0	0	0
62=Detroit	12	3	2	1	0	1	0	1	0	2	4	2	0	0	0	0	0	0
63=Irvine	12	2	2	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0
65=Nevada	29	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
66=Portland	24	14	5	9	4	1	0	0	0	1	1	1	0	0	0	0	0	0
67=San Antonio	13	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
68=Los Angeles	17	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
69=Fall River	14	12	11	1	11	0	0	0	0	0	0	0	0	0	0	0	0	0
70=Pauline	6	6	3	3	0	2	1	0	0	3	4	3	0	0	0	0	0	0
71=Bowman Gray	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
72=New Brunswick	25	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
73=Des Moines	22	17	10	7	0	1	4	4	1	10	25	3	0	4	0	0	2	1

Attachment C

WHIMS/WHIMS-MRI/WHISCA/ WHISCA-CoStar/ WHI Ms#	Title	Convenor	Stage
Ms#2a/173	A prospective study of the effects of hypertension, antihypertensive treatment and blood pressure control on cognitive decline and dementia in postmenopausal women: results from the Women's Health Initiative Memory Study(WHIMS)	Johnson	6
Ms#8/157	Type 2 diabetes and change in cognitive functioning in the Women's Health Initiative Memory Study: the effects of diabetic risk factors and treatment for diabetes and hypertension (WHIMS)	Coker	1
Ms#11/595	Quality assurance and training in a low event long-term clinical trial: The Women's Health Initiative Memory Study (WHIMS)	Dailey	6
Ms#38/275	Prior use of hormone therapy and incident Alzheimer's disease: The Women's Health Initiative Memory Study (WHIMS) ***(Abstract under review by WHI P&P, with planned submission to the AAN)***	Henderson	9
Ms#40/283	Hormone therapy has no detrimental effects on the rate of cognitive change in postmenopausal women: The Women's Health Initiative Memory Study (WHIMS)	Royall	6
Ms#46/360	Body mass index, waist-hip ratio, and cognitive decline in postmenopausal women: results from the Women's Health Initiative Memory Study (WHIMS)	Kerwin	6
Ms#47/546	Predictors of incident dementia in postmenopausal women enrolled in a trial of hormone therapy: The Women's Health Initiative Memory Study (WHIMS)	Coker	6
Ms#49/390	Identifying risk factors for cognitive change in the WHIMS: a neural networks approach	Bandelow	10
Ms#50/399	Subtypes of mild cognitive impairment: prevalence, course and effect of hormone therapy (WHIMS)	Rapp	6
Ms#51/427	Statin use and cognition in postmenopausal women: The Women's Health Initiative Memory Study (WHIMS)	Legault	4
Ms#52/5	Associations between body mass index and domain-specific function among women enrolled in the Women's Health Initiative Study of Cognitive Aging (WHISCA)	Kerwin	1
Ms#53/1/542	Recruitment and consent into a brain magnetic resonance imaging study: results from the WHIMS-Magnetic Resonance Imaging Study (WHIMS-MRI) ***(WHI P&P request revision and resubmission)***	Jaramillo	7
Ms#54/558	Cognitive function and physical performance in the Women's Health Initiative Memory Study (WHIMS)	Atkinson	6
Ms#55/1	Relative effects of tamoxifen, raloxifene, and estrogen therapy on cognition: results from the Women's Health Initiative Study of Cognitive Aging (WHISCA) and the Cognition in the Study of Tamoxifen and Raloxifene (CoStar) clinical trials	Espeland	2

	***(Reviewed by WHI P&P on 7/13/06 awaiting results & "new" policy)*		
Ms#56/6/598	Effects of conjugated equine estrogens on cognition and affect in surgically menopausal women (WHISCA) ***(Revised and resubmitted to WHI P&P with a 10/26/06 review, awaiting results)*	Resnick	2
Ms#57/597	Prevalence of Anticholinergic Drug Use and Impact on Cognition and Function in Older Adults (WHIMS) ***(Revised and resubmitted to WHI P&P with a 10/26/06 review, awaiting results)*	Sink	2
Ms#58	COX-2 Inhibitor Use and Cognitive Function: Interaction with Postmenopausal Hormone Therapy (WHIMS) ***(Reviewed by PASC, awaiting revisions)*	Hsia	1
Ms#59/612	Impact of Prehypertension on Cognitive Function (WHIMS) ***(WHI P&P review yielded a request for revision and resubmission)*	Hsia	2
Resnick, S.M., Maki, P.M., Rapp, S.R., Espeland, M.A., Brunner, R.L., Coker, L.H., Granek, I., Hogan, P.E., Ockene, J.K., Shumaker, S.A. **The Journal of Clinical Endocrinology and Metabolism**, 2006; 91(5):1802	Effects of combination estrogen plus progestin hormone treatment on cognition and affect: The Women's Health Initiative Study of Cognitive Aging (WHISCA)	Resnick	11
Espeland, M.A., Coker, L.H., Limacher, M., Messina, C., Powell, L., Rapp, S.R., Resnick, S.M., Wallace, R. **Neuroepidemiology**, 2006;27:1-12	Association between reported alcohol intake and domain-specific cognitive function in older women: results from the Women's Health Initiative Study of Cognitive Aging (WHISCA)	Espeland	11
Espeland, M.A., Robertson, J., Albert, M., Bassford, T., Granek, I., Murphy, C., Rapp, S.R. **Clinical Trials**, 2006; 3: 99-106	Benchmarks for designing two-stage studies using modified mini-mental state examinations: experience from the Women's Health Initiative Memory Study (WHIMS)	Espeland	11
Espeland, M.A., Gu, L., Masaki, K.H., Langer, R.D., Coker, L.H., Stefanick, M.L., Ockene, J., Rapp, S.R. **American Journal of Epidemiology**, 2005; 161 (3): 228-238	Association between reported alcohol intake and changes in cognition: results from the Women's Health Initiative Memory Study (WHIMS)	Espeland	11
Resnick, S.M., Coker, L.H., Maki, P.M., Rapp, S.R., Espeland, M.A., Shumaker, S.A. **Clinical Trials**, 2004; 1:440-450.	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	Resnick	11
Shumaker, S.A., Legault, C., Kuller, L., Rapp, S.R., Thal, L., Lane, D.S., Fillit, H., Stefanick, M.L., Hendrix, S.L., Lewis, C.E., Masaki, K., Coker, L.H., **The Journal of the American Medical Association**, 2004, 291:2947-2958.	Conjugated equine estrogens and incidence of probable dementia and mild cognitive impairment in postmenopausal women: the Women's Health Initiative Memory Study	Shumaker	11

Espeland, M.A., Rapp, S.R., Shumaker, S.A., Brunner, R.L., Manson, J.E., Sherwin, B.B., Hsia, J., Margolis, K.L., Hogan, P.E., Wallace, R., Dailey, M., Freeman, R., Hays, J. **The Journal of the American Medical Association**, 2004, 291:2959-2968.	Conjugated equine estrogens and global cognitive function in postmenopausal women: the Women's Health Initiative Memory Study.	Espeland	11
Shumaker, S.A., Legault, C., Rapp, S.R., Thal, L., Wallace, R.B., Ockene, J.K., Hendrix, S.L., Jones, B.N., Assaf, A.R., Jackson, R.D., Kotchen, J.M., Wassertheil-Smoller, S. & Wactawski-Wende, J. **The Journal of the American Medical Association**, 2003, 289:2651-2662.	Estrogen plus progestin and the incidence of dementia and mild cognitive impairment in postmenopausal women: the Women's Health Initiative Memory Study	Shumaker	11
Rapp, S.R., Espeland, M.A., Shumaker, S.A., Henderson, V.W., Brunner, R.L., Manson, J.E., Gass, M.L.S., Stefanick, M.L., Lane, D.S., Hays, J., Johnson, K.C., Coker, L.H., Dailey, M. & Bowen, D. **The Journal of the American Medical Association**, 2003, 289:2663-2672.	The effect of estrogen plus progestin on global cognitive function in postmenopausal women: results from the Women's Health Initiative Memory Study.	Rapp	11
Rapp, S.R., Espeland, M.A., Hogan, P., Dugan, E. & Jones, B. **Aging and Mental Health**, 2003, 7:3:217-223.	Baseline experience with Modified Mini Mental State Exams: the Women's Health Initiative Memory Study.	Rapp	11
Shumaker, S.A., Reboussin, B.A., Espeland, M.A., Rapp, S.R., McBee, W.L., Dailey, M., Bowen, D., Terrell, T. & Jones, B.N. **Controlled Clinical Trials**, 1998, 19:604-621	The Women's Health Initiative Memory Study (WHIMS): A trial of the effects of estrogen therapy in preventing and slowing progression of dementia	Shumaker	11
McBee, W.L., Dailey, M.E., Dugan, E. & Shumaker, S.A. **Endocrinology & Metabolism Clinics of North America**, 1997, 26 (2):329-454.	Hormone replacement therapy and other potential treatments for dementias.	McBee	11

Effects of Hormone Therapy on Subclinical Neurological Pathology –
WHIMS-MRI Collaborative Study
Wake Forest University Health Sciences
Division of Public Health Sciences
Department of Social Sciences and Health Policy
Winston-Salem, North Carolina 27157

Study Activities:

Protocol Approval: The WHIMS-MRI protocol and informed consent were approved by the Wake Forest University Health Sciences (WFUHS) Internal Review Board for a period of 12 months beginning 7/29/2006.

No-Cost Extension Approved: Application to the NHLBI for a no-cost extension was approved on 7/31/06. The no-cost extension period is from 8/1/06 to 3/31/07. Activities to be completed during the extension are: central reading of MRI scans; data analyses; dissemination of study findings and publications.

WHIMS-MRI Coordinating Center Activities: Scanning was completed at all clinical centers by 4/28/2006. Focus is currently on completion of data entry, resolution of data entry errors, analysis of preliminary data, transmission of scans to Wake Forest University for archiving, and development of writing groups for study publications. We will soon begin to develop documentation for database closure and plans for dissemination activities.

Reports:

- WHIMS-MRI Enrollment Report: Clinical centers contacted 2,345 of 2,869 (82%) potential enrollees. 1,529 (65%) women across the clinical sites consented to enroll in the WHIMS-MRI study. Of the 2,345 women contacted, 3.4% were ineligible due to absolute contraindications and 31% refused (Attachment 1).

- Tracking Report for Completed MRI's: This report tracks scans from the time of completion, to acceptance by the Reading Center, and transmission to Wake Forest University. 1,425 scans have been received at the Reading Center. Of these, 1,133 (80%) have been reviewed and accepted. Ninety-two percent of the scans received by University of Pennsylvania have been transmitted to Wake Forest University for archival (Attachment 2).

Manual of Operating Procedures (MOP): The WHIMS-MRI Manual of Procedures was distributed to the WHIMS-MRI clinical centers via the website, which is located at: https://www.phsapps.wfubmc.edu/whims/

Committee and Administrative Activity:

- The WHIMS-MRI Working Group serves as an advisory committee for the study and is responsible for monitoring the conduct of the WHIMS-MRI study. This committee consists of technical experts, representatives from clinical centers, Magnetic Resonance Imaging Quality Control Center (MRIQCC) and the Coordinating Center (CoC). Also included are the Principal Investigator of WHIMS-Extension and representation from the NIH. Conference calls were held on September 26, 2005, December 12, 2005, February 20, 2006, April 28, 2006 and July 24, 2006. Primary issues discussed included the following: quality assurance of the MRI data by the Reading Center, data analysis, timeline and venues for presenting data, publications, MRI data flow, data cleaning, and archiving of images at WFUHS.

- The WHIMS-MRI Project Managers Committee held calls on October 19, 2005, December 14, 2005, February 22, 2006 and April 26, 2006. Primary issues discussed included: end of recruitment, completion of data entry, resolution of data entry errors, and dissemination of study results.

WHIMS-MRI Website: The WHIMS-MRI website is included within the larger WHIMS-Extension website. The site is password protected and includes: a directory of study personnel; committee rosters; study documents, forms and memorandums. The website provides capabilities for study and participant management and data entry of forms via the internet. Extensive reports are available to assist the Coordinating Center and clinical centers with project management and tracking data flow. Reports are also available to track missing data and to alert clinical center staff of data entry errors.

The CoC and clinical centers also reviewed and monitored alerts for serious adverse events (SAE) and/or urgent MRI findings (Level 4) via the website. Once a SAE or urgent finding was entered on the website, an email was generated to the clinical center PI and staff, CoC staff, study Safety Officer and the MRIQCC at the University of Pennsylvania. The email prompted the user to log on to the website to view the alert and record its resolution. The WHIMS-MRI Safety Officer monitored all serious adverse events and urgent findings as they were reported and conducted safety follow-up of participants.

Coordinating Center Archiving of Images: Image data for 1,313 of the 1,425 scans (93%) have been received at Wake Forest University from the University of Pennsylvania. Josh Tan from the Division of Radiologic Sciences at Wake Forest University Health Sciences joined the study to provide expertise on the transmission of images and to oversee the development of a central archive.

Study Forms and Materials: A bi-monthly electronic newsletter, the *WHIMS-MRI Link* provides helpful information regarding study policies and news. The newsletter is also placed on the website.

Data/Analysis: Data from the central reading of 924 scans have been received at Wake Forest University. A complete analysis database is expected to be available in late fall. Two WHIMS-MRI Coordinating Center biostatisticians serve as point persons for the data analyses. The Coordinating Center biostatisticians participated on a conference call with the University of Pennsylvania Reading Center on April 10, 2006 to plan data analyses. Conference calls with the WHIMS-MRI Working Group (see Committee Activity section above) are a primary venue for discussion of data analyses plans. Plans are underway for a meeting with principal investigators in January 2007 where preliminary findings will be disclosed and major study manuscripts will be framed, if funding for the meeting can be obtained.

Abstracts/Publications: Seven manuscript topics have been proposed, one of which is underway. Principal Investigators will be asked to make a total of 3 nominations across the 6 remaining topics.

- Topic underway - "Recruitment and Consent into a Brain Magnetic Resonance Study: Results from the Women's Health Initiative Memory Study Magnetic Resonance Imaging Study (WHIMS-MRI)". Approved by the WHIMS Suite of Studies and WHI P&P Committees in April 2006.
- Three abstracts were presented at the Society of Clinical Trials which was held May 21-24, 2006 in Orlando, Florida (Attachments 5, 6, 7):
    - "Utilization of DICOM Image Transmission in a Multi-Site Clinical Trial"
      Submitting Author: Lisa Desiderio, University of Pennsylvania
    - "Screening for a Magnetic Resonance Imaging Study"
      Submitting Author: Lee Ann Andrews, Wake Forest University Health Sciences
    - "Consent for an MRI Study Involving Women's Health Initiative Memory Study (WHIMS) Participants"
      Submitting Author: Sarah Jaramillo, Wake Forest University Health Sciences

WHIMS-MRIQCC

The Reading Center has received 1,425 MRI scans. Of these, 1,133 have been reviewed and accepted. Of the 1,425 scans received, 1,313 have been sent to WFU for archiving. Analysis data on 924 scans has been sent to the WHIMS-MRI Coordinating Center.

Participating Clinical Centers:

Institution (Site of Clinic)	Institution (Site of Clinic)
UNC-Chapel Hill (Durham, NC)	Medical College of Wisconsin (Milwaukee, WI)
Univ of Massachusetts (Worcester, MA)	Berman Center for Outcomes and Clinical Research (Minneapolis, MN)
Ohio State Univ Medical Center (Columbus, OH)	Univ of Nevada School of Medicine (Reno, NV)
Univ of California at Davis (Sacramento, CA)	Albert Einstein College of Medicine (Bronx, NY)
University of Iowa (Des Moines, IA)	Univ of Pittsburgh (Pittsburgh, Pa)
Univ of Florida (Gainesville and Jacksonville, FL)	Stanford University (San Jose, CA)
Univ of California at Los Angeles (Los Angeles, CA)	

WHIMS-MRI Reading Centers:

WHIMS-MRI Quality Control Center (MRIQCC)
University of Pennsylvania Medical Center
Philadelphia, PA

NIA Neuroimaging Group
Laboratory of Personality and Cognition
National Institute on Aging
Baltimore, MD 21224-6825

WHIMS-MRI CoC:

Wake Forest University School of Medicine
Winston-Salem, NC

Findings to Date: Data analyses will be completed in Fall 2006. Findings will be known at that time. The WHIMS-MRI Working Group will work with the clinical centers to develop a dissemination plan for study findings.

ATTACHMENT 1

WHIMS MRI Screening

Number screened by clinic

Generated at 12:57 ET on 18AUG06

			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	
Clinic	Potential Enrollees^	Contacted	N	%	N	%	N	%	N	%	N	%	N	%	N	%^^	N	%
ALL CLINICS	2869	2345	80	3.41%	730	31.13%	0	0.00%	0	0.00%	190	8.10%	1345	57.36%	1529	65.20%	1166	76.26%
25=Minneapolis	194	160	15	9.38%	39	24.38%	0	0.00%	0	0.00%	23	14.38%	83	51.88%	106	66.25%	77	72.64%
28=Pittsburgh	138	138	2	1.45%	44	31.88%	0	0.00%	0	0.00%	18	13.04%	74	53.62%	92	66.67%	0	0.00%
30=Davis	192	128	6	4.69%	14	10.94%	0	0.00%	0	0.00%	8	6.25%	100	78.13%	109	85.16%	82	75.23%
42=Stanford	234	151	7	4.64%	13	8.61%	0	0.00%	0	0.00%	0	0.00%	131	86.75%	127	84.11%	98	77.17%
43=Milwaukee	226	120	5	4.17%	7	5.83%	0	0.00%	0	0.00%	16	13.33%	92	76.67%	108	90.00%	104	96.30%
46=Gainesville	134	134	0	0.00%	58	43.28%	0	0.00%	0	0.00%	1	0.75%	75	55.97%	76	56.72%	67	88.16%
48=Worcester	257	186	5	2.69%	40	21.51%	0	0.00%	0	0.00%	9	4.84%	132	70.97%	141	75.81%	127	90.07%
49=New York	243	216	5	2.31%	87	40.28%	0	0.00%	0	0.00%	51	23.61%	73	33.80%	121	56.02%	80	66.12%
50=Columbus	264	263	5	1.90%	99	37.64%	0	0.00%	0	0.00%	40	15.21%	119	45.25%	159	60.46%	137	86.16%
54=Jacksonville	81	79	4	5.06%	23	29.11%	0	0.00%	0	0.00%	6	7.59%	46	58.23%	52	65.82%	38	73.08%
58=Chapel Hill	222	188	4	2.13%	75	39.89%	0	0.00%	0	0.00%	15	7.98%	94	50.00%	108	57.45%	86	79.63%
65=Nevada	189	99	9	9.09%	12	12.12%	0	0.00%	0	0.00%	1	1.01%	77	77.78%	79	79.80%	52	65.82%
68=Los Angeles	211	199	7	3.52%	88	44.22%	0	0.00%	0	0.00%	1	0.50%	103	51.76%	104	52.26%	89	85.58%
73=Des Moines	284	284	6	2.11%	131	46.13%	0	0.00%	0	0.00%	1	0.35%	146	51.41%	147	51.76%	129	87.76%

^Based on follow up status as of 02/28/2005 (Deceased, absolutely no follow-up, and proxy follow-up omitted)

^^ Denominator is # Contacted

Attachment 2

Tracking Report for Completed MRIs
By Clinic
Generated at 13:04 ET on 18AUG06

	Participants consented	Completed MRIs		Received at UPENN		Accepted by UPENN		Image Received at WFU	
Clinic	Number	Number	%	Number	%	Number	%	Number	%
25=Minneapolis	106	101	95%	101	100%	76	75%	89	117%
28=Pittsburgh	92	81	88%	81	100%	80	99%	81	101%
30=Davis	109	101	93%	101	100%	84	83%	101	120%
42=Stanford	127	123	97%	123	100%	76	62%	82	108%
43=Milwaukee	108	102	94%	106	104%	88	83%	99	113%
46=Gainesville	76	72	95%	72	100%	72	100%	70	97%
48=Worcester	141	132	94%	132	100%	123	93%	128	104%
49=New York	121	116	96%	116	100%	83	72%	103	124%
50=Columbus	159	144	91%	145	101%	137	94%	145	106%
54=Jacksonville	52	45	87%	45	100%	43	96%	41	95%
58=Chapel Hill	108	98	91%	98	100%	56	57%	88	157%
65=Nevada	79	65	82%	65	100%	46	71%	65	141%
68=Los Angeles	104	97	93%	97	100%	36	37%	78	217%
73=Des Moines	147	143	97%	143	100%	133	93%	143	108%
ALL CLINICS	1529	1420	93%	1425	100%	1133	80%	1313	116%