Women's Health Initiative

2013 Annual Progress Report

Data as of: September 2013

The data, if any, contained in this report/deliverable 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

2013 Annual Progress Report

Data as of: September 2013

Prepared by
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Fred Hutchinson Cancer Research Center

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1. Overview

1.0 Background

Between 1993 and 1997, WHI investigators at 40 Clinical Centers recruited 161,808 women into the overall program; 68,132 were randomized into one or more arms of the clinical trial component (CT) and 93,676 were enrolled into the observational study (OS). During 2004-2005, the close-out period for the original program, 115,407 women consented to five additional years of follow-up, representing 76.9% of the 150,076 participants who were alive and in active follow-up at this time. At the end of the first extension period in 2010, participants were again offered the opportunity to continue and 86.9% of the 107,706 eligible women agreed (n=93,558).

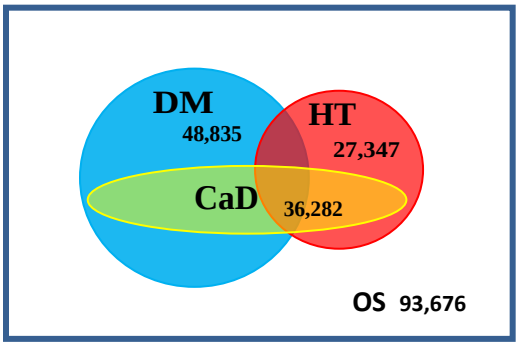


Figure 1: Original design of the WHI partial factorial trial and observational study of 161,808 postmenopausal women.

1.1 The 2010-2015 Extension Study

The follow-up protocol for 2010-2015 incorporates noteworthy streamlining from previous phases. All participants are contacted annually, primarily by mail, for health and selected exposure updates. For reports of designated health events, the effort to obtain documentation has been reduced to a subset. During 2010-2015, cardiovascular events and hip fractures will only be documented in a subset of participants referred to as the Medical Records Cohort (MRC). The MRC is comprised of former hormone trial (HT) participants and all African American and Hispanic participants, regardless of their previous enrollment status. Active outcome data collection for the remaining participants (the Self-Report Cohort or SRC) is limited to self-report with the exception of cancer, for which NCI is supporting the documentation and coding of all incident primary cancers.

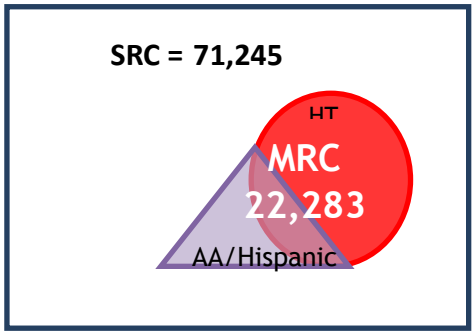


Figure 2: 2010-2015 Extension Study design reflecting differing levels of outcomes ascertainment: Medical Records Cohort (MRC) and the Self-Report Cohort (SRC). Total enrollment = 93,558.

This reduction in data collection prompted streamlining of the operational infrastructure. The 40 Field Centers were consolidated into 4 Regional Centers (RC) plus the Clinical Coordinating Center (CCC). Each RC has subcontracted with one or two former Field Centers in their geographic region to assist with the outcomes data collection (Table 1.1).

The CCC conducts annual mailings of follow-up questionnaires to all eligible participants. The RCs and their collaborating centers contact non-responders, collect and submit medical records for all of the designated outcomes to the CCC, and participate in a range of scientific endeavors. The CCC fulfills the RC role for two former Field Centers (Seattle and LaJolla).

1.2 Progress on primary study objectives

This report provides an update on study status through September 2013, including the reconsenting in 2005 and 2010 and recent follow-up rates. Follow-up rates have remained excellent. In the first follow-up year of this phase, we achieved an overall response rate of 97.1% (Table 1.8). Year 2 had only slight reductions in response rates, with 89.8% of women responding to mailings, and an overall 96.3% response rate including phone follow-up. Though not yet complete, year 3 response has been similarly high, with 88.2% of women responding to mailings, and an overall response rate of 94.8% including phone follow-up. Year 3 mailings to MRC participants also included a medications inventory form (Form 153), and the overall response rate for that form has been somewhat lower (84.7%). In the coming year, we will include an additional supplemental form (Form 156) with questions addressing health and safety issues of pronounced importance among older women.

For the designated WHI outcomes, clinical event rates using the fully adjudicated outcomes through the end of the first Extension Study (September 2010) are presented by original study component, age and race (Sections 2-6). Using the new study components, fully adjudicated events available through September 2013 are provided for the MRC (Table 7.2 and 7.3). For the SRC, fully adjudicated events are provided for the interval from enrollment to September 2010 (Table 7.4 and 7.5). Self-reported events for the subsequent interval (September 2010 to September 2013) are shown in Tables 7.6 and 7.7. A brief summary of other outcomes is also provided.

Table 8.1 provides a current summary of the agreement rates between self-reported events and the centrally adjudicated events among MRC participants. In general, 40% to 60% of self-reported outcomes are confirmed as the reported diagnosis. Often, however, a related diagnosis is found. Noteworthy variation in agreement rates across outcomes is seen, underscoring the importance of the adjudication process for outcomes of primary interest.

We recently completed an effort to centrally adjudicate self-reports of heart failure for all women who participated in the HT and all African-American and Hispanic women from the beginning of the study through 2010. All reports of suspected heart failure during this interval were sent for verification. This included multiple heart failure events for many participants. The review, conducted at University of North Carolina, confirmed 57.8% of reviewed events as possible or definite decompensated heart failure (Table 9.1), which agreed with 73.7% of the WHI events that had been previously adjudicated as heart failure (Table 9.2). UNC also verified that more than 28% of participants with possible or definite decompensated heart failure had 2 or more cases of heart failure (Table 9.3). UNC will continue to verify heart failure cases that are reported by this subset of participants (HT, African-American, Hispanic) during this extension period (2010-2015) and WHI investigators and analysts will now begin to curate these data in preparation for detailed analyses.

In recognition of the growing emphasis on studies of aging, a summary of the results from the year 2 form, Form 155, that queried on aging indicators are included (Tables 10.2 stratified by age and 10.3 stratified by race). Decline in physical functioning over time has been more rapid in the older age groups, particularly among women age 90 and older (Figure 10.1). Noting that more than 30% of women in the oldest age group

reported 3 or more falls in the last year, we plan to include an article on falls-prevention with a list of resources in the next WHI participant newsletter.

We also provide a brief summary of the most recently collected medication inventory data in Section 11, as a reminder of the data that is available. In the next year, we should have updated data available from the Medications Inventory that is included in the year 3 mailings to MRC participants.

Regional Center performance in follow-up and outcomes documentation is summarized in Section 13. Although there is some variability in specific items monitored across sites, we find that all centers are performing adequately in outcomes processing.

1.3 WHI Long-Life Study (LLS)

During the past year we have completed the WHI Long Life Study protocol which consists of an in-person visit among approximately 8,000 of the oldest women in the MRC (details in Section 12). The CCC contracted with a national-based organization, Examination Management Services, Inc (EMSI) to conduct home visits among consenting MRC participants to obtain clinical measures (blood pressure, pulse, height, weight), basic physical function measures, and a new blood collection. Women were preferentially sampled based on availability of GWAS data, CVD biomarkers and older ages.

We received signed consent from 9,246 women (65.7% of participants contacted) and 7,875 women completed the study visits (Table 12.1). Just under 95% of visits resulted in a successful blood collection. Approximately 52% of the enrolled participants were older than 80 years, and these women had lower body mass index and poorer physical functioning than younger women (Table 12.2). Biomarker data is available (Tables 12.4-12.5), and results of the complete blood count (CBC) were provided to women by mail with advice to consult with their doctor as appropriate. For women with CBC test values that indicated urgent action, WHI staff were instructed to call the women in advance of the letter, and counsel them to seek care from their doctor.

1.4 Engaging investigators

Information on the status of the WHI biorepository is presented in Section 14. Section 15 lists core, BAA and ancillary studies activities and Section 16 addresses publications. To streamline this report, we include only those ancillary studies approved and manuscripts published in the last year. A full listing and status of all proposed ancillary studies and manuscripts is available on the WHI website (www.whi.org). At this point WHI has reviewed 476 ancillary study proposals. More than 55% of these ancillary studies were led by non-WHI investigators, and more than 68% of the studies approved in the last year were led by non-WHI investigators. Of the 38 ancillary studies approved in the last year, 68% are led by non-WHI investigators, and half are already funded and in progress, of which 6 are already in the analysis phase.

Nearly 1,700 manuscript proposals have been approved and 762 are published or in press, 106 of which were published in the last year (Table 16.2). Investigators using WHI data continue to present high-quality science of broad interest, with publications in the last year in many high-impact journals including The New England Journal of Medicine,

Nature, JAMA, and Nature Genetics. In addition to manuscripts addressing cardiovascular disease among WHI participants, there have been a substantial number of manuscripts addressing topics in cancer, diabetes, genetics, and aging.

An ancillary study entitled "Objective Physical Activity and Cardiac Health [OPACH]" (PI: Andrea LaCroix) supports the collection of an objective measure of physical activity using actigraphy in conjunction with the LLS visit. A separate ancillary study (PI: Jeanette Beasley) funds the collection of a food frequency questionnaire after the visit. In the last year, the National Cancer Institute funded an ancillary study to follow a Cancer Survivor Cohort (PIs: Garnet Anderson, Bette Caan, Electra Paskett), which aims to expand the WHI data and biorepository for WHI participants diagnosed with cancer. Adding tumor tissue, treatment and recurrence data, and data on self-reported post-treatment effects will further increase the utility of the WHI resources for engaging investigators with an interest in tumor marker, treatment effects, and other issues affecting cancer survivors.

Various core studies have generated genetic data for over 30,000 WHI participants using a number of approaches (genome-wide association studies, exome sequencing, typing of ancestry informative markers, metabochip typing), along with CVD biomarker data. These data have been cleaned and annotated and then shared through dbGaP and BIOLINCCC, providing an opportunity for outside investigators to use these resources without a WHI sponsor. Despite heavy use of WHI biospecimens for core, ancillary, and BAA studies (Table 14.4), strong review protocols for these studies have ensured that adequate serum, plasma, and DNA samples remain for future research (Tables 14.1-14.3).

Another means of engaging new investigators during the 2010-2015 extension has been the establishment of 12 Scientific Interest Groups (SIGs), each covering an area such as aging, cancer, cardiovascular disease, and more. Each SIG is co-led by two WHI investigators with appropriate background in the interest-area, and conference calls for each group are held bimonthly. SIGs serve as a means of networking for investigators with common scientific interests and to engage outside investigators in learning about the resources available within the WHI and on-going activities. The SIGs each have a centralized means of communication and outreach through the publicly available WHI website, and SIG participants include many non-WHI investigators.

Table 1.1
WHI Centers and Principal Investigators

Clinical Coordinating Center

Principal Investigator	Institution	Location
Garnet Anderson, PhD	Fred Hutchinson Cancer Research Center	Seattle, WA

Regional Centers

Principal Investigator	Institution	Location
Barbara Howard, PhD	MedStar Research Institute	Washington, D.C.
Rebecca Jackson, MD	Ohio State University	Columbus, OH
Lewis Kuller, MD, DrPH	University of Pittsburgh	Pittsburgh, PA
Marian Limacher, MD	University of Florida	Gainesville/ Jacksonville, FL
JoAnn Manson, MD, DrPH	Brigham and Women's Hospital	Boston, MA
Sally Shumaker, PhD	Wake Forest University	Winston-Salem/Greensboro, NC
Marcia Stefanick, PhD	Stanford University	San Jose, CA
Cynthia Thomson, PhD, RD	University of Arizona	Tucson/ Phoenix, AZ
Jean Wactawski-Wende, PhD	State University of New York, Buffalo	Buffalo, NY
Jennifer Robinson, MD, MPH	University of Iowa	Iowa City/ Bettendorf, IA

Former Field Centers

Principal Investigator	Institution	Location
Shirley Beresford, PhD	Fred Hutchinson Cancer Research Center	Seattle, WA
Robert Brunner, PhD	University of Nevada	Reno, NV
Robert Brzyski, MD	University of Texas	San Antonio, TX
Bette Caan, PhD	Kaiser Foundation Research Institute	Oakland, CA
Rowan Chlebowski, MD, PhD	University of California, Los Angeles	Torrance, CA
J. David Curb, MD	University of Hawaii	Honolulu, HI
Charles Eaton, MD	Memorial Hospital of Rhode Island	Pawtucket, RI
Gerardo Heiss, MD MPH	University of North Carolina, Chapel Hill	Chapel Hill, NC
Hoda Anton-Culver, PhD	University of California, Irvine	Irvine, CA
Karen Johnson, MD, MPH	University of Tennessee	Memphis, TN
Jane Kotchen, MD, MPH	Medical College of Wisconsin	Milwaukee, WI
Andrea LaCroix, PhD	FHCRC for UNC/La Jolla	Seattle, WA
Dorothy Lane, MD, MPH	Research Foundation SUNY, Stony Brook	Stony Brook, NY
Norman Lasser, MD, PhD	University of Medicine and Dentistry	Newark, NJ
Erin LeBlanc, MD	Oregon Health & Science University	Portland, OR
Cora Lewis, MD, MSPH	University of Alabama at Birmingham	Birmingham, AL
Simin Liu, MD, ScD, MPH, MS	University of California, Los Angeles	Los Angeles, CA
Karen Margolis, MD	University of Minnesota	Minneapolis, MN
Lisa Martin, MD, FACC	George Washington University	Washington, DC
Mary-Jo O'Sullivan, MD	University of Miami	Miami, FL
Judith Ockene, PhD	University of Massachusetts	Worcester, MA
Larry Phillips, MD	Emory University	Atlanta, GA
Lynda Powell, PhD	Rush University Medical Center	Chicago, IL
Haleh Sangi-Haghpeykar, PhD	Baylor College of Medicine	Houston, TX

Table 1.1 (continued)
WHI Centers and Principal Investigators

Former Field Centers

Principal Investigator	Institution	Location
John Robbins, MD	University of California, Davis	Sacramento, CA
Gloria Sarto, MD	University of Wisconsin	Madison, WI
Michael Simon, MD	Wayne State University	Detroit, MI
Michael Thomas, MD	University of Cincinnati	Cincinnati, OH
Linda Van Horn, PhD, RD	Northwestern University	Chicago/ Evanston, IL
Mara Vitolins, PhD	Wake Forest University	Winston-Salem/Greensboro, NC
Sylvia Wassertheil-Smoller, PhD	Albert Einstein College of Medicine	Bronx, NY

Table 1.2
Consent Status by Study Component and Arm

Data as of: September 20, 2013

WHI Enrollment	Enrolled in WHI	Eligible for extension 2005-2010[1]	Consented N	Consented %
Hormone Therapy	27347	25194	20433	81.1
With Uterus	16608	15408	12788	83.0
E+P	8506	7878	6545	83.1
Placebo	8102	7530	6243	82.9
Without Uterus	10739	9786	7645	78.1
E-alone	5310	4851	3778	77.9
Placebo	5429	4935	3867	78.4
Dietary Modification	48835	45560	37858	83.1
Intervention	19541	18207	14769	81.1
Comparison	29294	27353	23089	84.4
Calcium and Vitamin D	36282	34447	29862	86.7
Active	18176	17280	15025	87.0
Placebo	18106	17167	14837	86.4
Clinical Trial Total	68132	63332	52176	82.4
Observational Study	93676	86744	63231	72.9
Total	161808	150076	115407	76.9

WHI Enrollment	Enrolled in extension 2005-2010	Eligible for extension 2010-2015[1]	Consented N	Consented %
Hormone Therapy	20433	18794	15583	82.9
With Uterus	12788	11789	9891	83.9
E+P	6545	6048	5047	83.4
Placebo	6243	5741	4844	84.4
Without Uterus	7645	7005	5692	81.3
E-alone	3778	3479	2833	81.4
Placebo	3867	3526	2859	81.1
Dietary Modification	37858	35594	30689	86.2
Intervention	14769	13922	12014	86.3
Comparison	23089	21672	18675	86.2
Calcium and Vitamin D	29862	27975	24231	86.6
Active	15025	14083	12242	86.9
Placebo	14837	13892	11989	86.3
Clinical Trial Total	52176	48697	41497	85.2
Observational Study	63231	59009	52065	88.2
Total	115407	107706	93562	86.9

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

Table 1.3
Consent Status by Age and Race/Ethnicity

Data as of: September 20, 2013

	Clinical Trial				Observational Study			
			Consented				Consented	
WHI Enrollment	**Enrolled in WHI**	**Eligible for extension 2005-2010[1]**	**N**	**%**	**Enrolled in WHI**	**Eligible for extension 2005-2010[1]**	**N**	**%**
Total	68132	63332	52176	82.4	93676	86744	63231	72.9
Age								
50-54	9188	8754	7237	82.7	12381	11969	8996	76.9
55-59	14661	13940	11724	84.1	17329	16565	12732	74.2
60-69	31389	29290	24528	83.7	41200	38502	28582	65.6
70-79	12894	11348	8687	76.6	22766	19708	12921	72.9
Race/Ethnicity								
American Indian	292	260	185	71.2	421	372	217	58.3
Asian/Pacific Islander	1519	1414	1105	78.1	2671	2444	1291	52.8
Black	6983	6423	4769	74.2	7635	6868	3585	52.2
Hispanic	2875	2686	1791	66.7	3609	3333	1598	47.9
White	55525	51682	43680	84.5	78016	72504	55767	76.9
Unknown	938	867	646	74.5	1324	1223	773	63.2

	Clinical Trial				Observational Study			
			Consented				Consented	
WHI Enrollment	**Enrolled in extension 2005-2010**	**Eligible for extension 2010-2015[1]**	**N**	**%**	**Enrolled in extension 2005-2010**	**Eligible for extension 2010-2015[1]**	**N**	**%**
Total	52176	48697	41497	85.2	63231	59009	52065	88.2
Age								
50-54	7237	7068	6249	88.4	8996	8802	8224	93.4
55-59	11724	11329	10054	88.7	12732	12400	11479	92.6
60-69	24528	22940	19642	85.6	28582	26820	23716	88.4
70-79	8687	7360	5552	75.4	12921	10987	8646	78.7
Race/Ethnicity								
American Indian	185	174	147	84.5	217	204	171	83.8
Asian/Pacific Islander	1105	1050	845	80.5	1291	1224	1035	84.6
Black	4769	4459	3420	76.7	3585	3358	2716	80.9
Hispanic	1791	1701	1226	72.1	1598	1527	1246	81.6
White	43680	40704	35361	86.9	55767	51969	46293	89.1
Unknown	646	609	498	81.8	773	727	604	83.1

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

Table 1.4
Extension 2010-2015 Consent by Current Age, Race/Ethnicity, and Cohort[1]

Data as of: September 20, 2013

	Enrolled in Extension 2005-2010	Eligible for Extension 2010-2015[2]	Consented	
			N	%
Total	115407	107706	93562	86.9
Age on 9/20/2013				
<80	56604	54826	49593	90.5
≥80	58803	52880	43969	83.1
80-84	26508	24834	21687	87.3
85-89	21047	18887	15546	82.3
90-94	9760	8108	6020	74.2
95-100	1488	1051	716	68.1
Race/Ethnicity				
American Indian	402	378	318	84.1
Asian/Pacific Islander	2396	2274	1880	82.7
Black	8354	7817	6136	78.5
Hispanic	3389	3228	2472	76.6
White	99447	92673	81654	88.1
Unknown	1419	1336	1102	82.5
Medical Record Cohort	29368	27221	22315	82.0
Age on 9/20/2013				
<80	15107	14481	12302	85.0
≥80	14261	12740	10013	78.6
80-84	6578	6130	5046	82.3
85-89	5010	4452	3485	78.3
90-94	2314	1905	1331	69.9
95-100	359	253	151	59.7
Race/Ethnicity				
American Indian	79	75	64	85.3
Asian/Pacific Islander	363	328	240	73.2
Black	8354	7817	6136	78.5
Hispanic	3389	3228	2472	76.6
White	16919	15525	13203	85.0
Unknown	264	248	200	80.6
Self Report Cohort	86039	80485	71247	88.5
Age on 9/20/2013				
<80	41497	40345	37291	92.4
≥80	44542	40140	33956	84.6
80-84	19930	18704	16641	89.0
85-89	16037	14435	12061	83.6
90-94	7446	6203	4689	75.6
95-100	1129	798	565	70.8
Race/Ethnicity				
American Indian	323	303	254	83.8
Asian/Pacific Islander	2033	1946	1640	84.3
White	82528	77148	68451	88.7
Unknown	1155	1088	902	82.9

[1] Medical Record Cohort (MRC) defined as randomized to the hormone trial, or race/ethnicity is Black or Hispanic; the Self Report Cohort are those not in the MRC.
[2] Eligibility defined as alive at the beginning of consent and willing to be contacted.

Table 1.5
Extension 2010-2015 Consent Summary by Field Center

Data as of: September 20, 2013

Field Center	DM			HT			CaD			CT			OS		
	Eligible	Consent	%	Eligible	Consent	%	Eligible	Consent	%	Eligible	Consent	%	Eligible	Consent	%
Atlanta	1015	825	81.3	415	318	76.6	690	574	83.2	1233	986	80.0	1717	1482	86.3
Bettendorf	369	319	86.4	575	494	85.9	556	485	87.2	855	737	86.2	1044	910	87.2
Birmingham	892	673	75.4	529	389	73.5	707	560	79.2	1233	932	75.6	1238	1000	80.8
Bowman	763	648	84.9	397	332	83.6	511	442	86.5	1024	864	84.4	1466	1249	85.2
Brigham	1358	1178	86.7	629	540	85.9	898	798	88.9	1811	1567	86.5	2215	2023	91.3
Buffalo	918	831	90.5	502	453	90.2	805	734	91.2	1260	1139	90.4	1561	1432	91.7
Chapel Hill	892	785	88.0	452	383	84.7	618	542	87.7	1187	1033	87.0	1485	1351	91.0
Chi-Rush	575	467	81.2	320	244	76.3	544	433	79.6	800	633	79.1	967	847	87.6
Chicago	892	772	86.5	393	337	85.8	627	546	87.1	1173	1007	85.8	1257	1113	88.5
Cincinnati	833	713	85.6	410	328	80.0	752	649	86.3	1104	928	84.1	1536	1356	88.3
Columbus	835	778	93.2	417	384	92.1	674	633	93.9	1109	1032	93.1	1581	1461	92.4
Des Moines	383	345	90.1	579	501	86.5	602	536	89.0	879	776	88.3	1031	912	88.5
Detroit	679	596	87.8	332	286	86.1	615	547	88.9	886	773	87.2	1327	1189	89.6
Gainesville	1130	906	80.2	746	575	77.1	760	622	81.8	1680	1323	78.8	2024	1664	82.2
GWU-DC	882	777	88.1	422	361	85.5	701	621	88.6	1173	1024	87.3	1601	1472	91.9
Honolulu	775	648	83.6	265	197	74.3	500	425	85.0	960	784	81.7	932	780	83.7
Houston	602	522	86.7	255	214	83.9	418	369	88.3	783	669	85.4	1323	1161	87.8
Irvine	886	800	90.3	407	357	87.7	726	655	90.2	1187	1060	89.3	1559	1396	89.5
L.A.	857	779	90.9	368	325	88.3	747	674	90.2	1125	1018	90.5	1484	1361	91.7
La Jolla	924	832	90.0	313	271	86.6	683	621	90.9	1129	1006	89.1	1737	1519	87.4
Madison	879	814	92.6	524	471	89.9	759	698	92.0	1262	1154	91.4	1321	1225	92.7
Medlantic	839	682	81.3	415	329	79.3	663	546	82.4	1097	888	80.9	1376	1192	86.6
Memphis	792	624	78.8	425	319	75.1	602	488	81.1	1038	809	77.9	1127	952	84.5
Miami	692	549	79.3	374	272	72.7	363	285	78.5	941	728	77.4	657	580	88.3

Table 1.5 (continued)
Extension 2010-2015 Consent Summary by Field Center

Data as of: September 30, 2013

Field Center	DM Eligible	DM Consent	DM %	HT Eligible	HT Consent	HT %	CaD Eligible	CaD Consent	CaD %	CT Eligible	CT Consent	CT %	OS Eligible	OS Consent	OS %
Milwaukee	918	808	88.0	545	464	85.1	825	739	89.6	1266	1103	87.1	1492	1345	90.1
Minneapolis	1047	936	89.4	620	550	88.7	912	808	88.6	1530	1363	89.1	1847	1667	90.3
Nevada	790	676	85.6	440	365	83.0	749	650	86.8	1073	906	84.4	1399	1213	86.7
Newark	962	828	86.1	367	306	83.4	678	597	88.1	1208	1033	85.5	1590	1402	88.2
New Brunswick	306	253	82.7	298	228	76.5	371	299	80.6	535	423	79.1	600	527	87.8
NY-City	939	785	83.6	516	393	76.2	678	540	79.6	1337	1082	80.9	1444	1263	87.5
Oakland	852	787	92.4	467	422	90.4	552	516	93.5	1208	1107	91.6	1367	1257	92.0
Pawtucket	1557	1316	84.5	726	591	81.4	1139	973	85.4	2031	1698	83.6	2495	2185	87.6
Pittsburgh	934	831	89.0	476	405	85.1	683	597	87.4	1274	1113	87.4	1281	1126	87.9
Portland	874	754	86.3	477	393	82.4	699	588	84.1	1215	1040	85.6	1475	1309	88.7
San Antonio	587	438	74.6	415	264	63.6	544	388	71.3	818	581	71.0	903	751	83.2
Seattle	851	774	91.0	502	442	88.0	635	574	90.4	1268	1140	89.9	984	886	90.0
Stanford	1003	896	89.3	508	449	88.4	808	732	90.6	1342	1192	88.8	1903	1676	88.1
Stonybrook	753	656	87.1	373	309	82.8	482	423	87.8	1016	872	85.8	1368	1219	89.1
Torrance	530	449	84.7	194	161	83.0	385	327	84.9	641	542	84.6	817	724	88.6
Tucson	983	862	87.7	448	363	81.0	737	631	85.6	1320	1128	85.5	1524	1306	85.7
UC Davis	1058	900	85.1	492	406	82.5	842	712	84.6	1371	1159	84.5	1287	1107	86.0
Worcester	988	877	88.8	466	392	84.1	735	654	89.0	1315	1145	87.1	1667	1475	88.5
Total	35594	30689	86.2	18794	15583	82.9	27975	24231	86.6	48697	41497	85.2	59009	52065	88.2

Table 1.6
Extension 2010-2015 Consent Summary by Regional Center

Data as of: September 20, 2013

	DM			HT			CaD			CT			OS		
Regional Center	**Eligible**	**Consent**	**%**	**Eligible**	**Consent**	**%**	**Eligible**	**Consent**	**%**	**Eligible**	**Consent**	**%**	**Eligible**	**Consent**	**%**
Boston	3903	3371	86.4	1821	1523	83.6	2772	2425	87.5	5157	4410	85.5	6377	5683	89.1
Buffalo	3878	3353	86.5	2056	1689	82.1	3014	2593	86.0	5356	4549	84.9	6563	5843	89.0
Seattle	1775	1606	90.5	815	713	87.5	1318	1195	90.7	2397	2146	89.5	2721	2405	88.4
Columbus	4053	3538	87.3	2085	1757	84.3	3422	3000	87.7	5452	4703	86.3	6833	6122	89.6
Gainesville	3557	2836	79.7	1902	1465	77.0	2390	1961	82.1	4809	3796	78.9	5574	4682	84.0
Iowa	2678	2414	90.1	2298	2016	87.7	2829	2527	89.3	4526	4030	89.0	5243	4714	89.9
Medstar	1721	1459	84.8	837	690	82.4	1364	1167	85.6	2270	1912	84.2	2977	2664	89.5
Pittsburgh	1613	1427	88.5	808	691	85.5	1298	1144	88.1	2160	1886	87.3	2608	2315	88.8
Stanford	6060	5365	88.5	2913	2513	86.3	4759	4204	88.3	8089	7118	88.0	9892	8830	89.3
Tucson	2548	2186	85.8	1153	925	80.2	1986	1706	85.9	3353	2818	84.0	3855	3299	85.6
Wake Forest	3808	3134	82.3	2106	1601	76.0	2823	2309	81.8	5128	4129	80.5	6366	5508	86.5
Total	35594	30689	86.2	18794	15583	82.9	27975	24231	86.6	48697	41497	85.2	59009	52065	88.2

Table 1.7
Response Rates to CCC Annual Mailings
Extension Study 2010-2015, Follow-up Years 1, 2 and 3

Data as of: September 20, 2013

	1st Mailing Period				2nd Mailing Period					
Study	**Form[1,2]**	**Sent Mail 1**	**Response**		**Past 2nd mailing period**	**Sent Mail 2**		**Response**		**Cumulative Response**
Year 1										
Total	33	92528	78369	84.7%	92528	14047	15.2%	5488	39.1%	91.7%
	151	92529	77907	84.2%	92529	14482	15.7%	5828	40.2%	91.6%
HT	33	15362	12548	81.7%	15362	2702	17.6%	983	36.4%	89.3%
	151	15363	12480	81.2%	15363	2775	18.1%	1037	37.4%	89.2%
DM	33	30334	25330	83.5%	30334	4952	16.3%	1852	37.4%	90.9%
	151	30334	25182	83.0%	30334	5084	16.8%	1960	38.6%	90.8%
CaD	33	23978	20062	83.7%	23978	3862	16.1%	1463	37.9%	91.1%
	151	23979	19942	83.2%	23979	3977	16.6%	1548	38.9%	90.9%
OS	33	51543	44271	85.9%	51543	7283	14.1%	2971	40.8%	92.6%
	151	51543	44004	85.4%	51543	7538	14.6%	3164	42.0%	92.5%
Year 2										
Total	33	88974	72926	82.0%	88974	14340	16.1%	5686	39.7%	89.8%
	155	88765	72651	81.9%	88765	14536	16.4%	5765	39.7%	89.8%
HT	33	14615	11513	78.8%	14615	2656	18.2%	1027	38.7%	87.3%
	155	14571	11465	78.7%	14571	2692	18.5%	1027	38.2%	87.3%
DM	33	29111	23622	81.1%	29111	4859	16.7%	1896	39.0%	89.2%
	155	29048	23538	81.0%	29048	4923	17.0%	1916	38.9%	89.2%
CaD	33	23024	18744	81.4%	23024	3801	16.5%	1480	38.9%	89.3%
	155	22969	18673	81.3%	22969	3863	16.8%	1496	38.7%	89.3%
OS	33	49714	41285	83.1%	49714	7638	15.4%	3079	40.3%	90.6%
	155	49601	41128	82.9%	49601	7747	15.6%	3138	40.5%	90.6%
Year 3										
Total	33	74147	60414	81.5%	63618	10509	16.5%	3996	38.0%	88.2%
	151	74157	59732	80.6%	63628	11149	17.5%	4393	39.4%	87.9%
	153	17171	12508	72.8%	14987	3362	22.4%	1135	33.8%	81.2%
HT	33	12111	9184	75.8%	10641	2217	20.8%	740	33.4%	83.5%
	151	12112	9094	75.1%	10642	2312	21.7%	791	34.2%	83.3%
	153	12113	9153	75.6%	10643	2165	20.3%	741	34.2%	83.1%
DM	33	24090	19443	80.7%	21127	3558	16.8%	1356	38.1%	87.6%
	151	24095	19237	79.8%	21132	3763	17.8%	1463	38.9%	87.3%
	153	5754	4073	70.8%	5022	1196	23.8%	423	35.4%	79.9%
CaD	33	19066	15269	80.1%	16744	2949	17.6%	1076	36.5%	87.2%
	151	19067	15118	79.3%	16745	3088	18.4%	1169	37.9%	87.0%
	153	8951	6739	75.3%	7868	1622	20.6%	553	34.1%	83.1%
OS	33	41638	34552	83.0%	35088	5420	15.5%	2149	39.7%	89.5%
	151	41643	34139	82.0%	35093	5794	16.5%	2398	41.4%	89.1%
	153	2997	2036	67.9%	2561	688	26.9%	221	32.1%	77.6%

[1] Form 33 = Medical History Update; Form 151 = Activities of Daily Living (ADL); Form 153 = Medication and Supplement Inventory; Form 155 = Lifestyle Questionnaire (includes ADL).
[2] Form 153 was collected on MRC participants only.

Table 1.8
Response Rates to Regional Center Follow-up and Cumulative Response
Extension Study 2010-2015 Follow-up Years 1, 2 and 3

Data as of: September 20, 2013

Study	Form[1,2]	Eligible for RC Follow-up	Respondents		Total Estimated Response Rate
Year 1					
Total	33	7574	5911	78.0%	97.1%
	151	7946	4344	54.7%	95.3%
HT	33	1597	1374	86.0%	97.0%
	151	1710	941	55.0%	94.1%
DM	33	2732	2185	80.0%	97.1%
	151	2863	1626	56.8%	95.1%
CaD	33	2090	1703	81.5%	97.2%
	151	2213	1241	56.1%	95.1%
OS	33	3774	2809	74.4%	97.2%
	151	3935	2093	53.2%	95.7%
Year 2					
Total	33	10988	8793	80.0%	96.3%
	155	11733	1639	14.0%	88.5%
HT	33	2240	1934	86.3%	96.0%
	155	2442	337	13.8%	85.5%
DM	33	3853	3135	81.4%	96.2%
	155	4130	557	13.5%	87.6%
CaD	33	2983	2473	82.9%	96.4%
	155	3216	444	13.8%	87.8%
OS	33	5608	4331	77.2%	96.3%
	155	5929	836	14.1%	89.5%
Year 3					
Total	33	1868	1388	74.3%	94.8%
	151	2019	881	43.6%	90.6%
	153	627	138	22.0%	84.7%
HT	33	459	371	80.8%	94.2%
	151	496	219	44.2%	87.6%
	153	407	82	20.2%	86.0%
DM	33	733	560	76.4%	94.7%
	151	804	359	44.7%	89.9%
	153	249	57	22.9%	82.9%
CaD	33	579	458	79.1%	95.2%
	151	626	285	45.5%	90.3%
	153	321	66	20.6%	85.4%
OS	33	848	599	70.6%	95.1%
	151	908	381	42.0%	91.5%
	153	120	30	25.0%	81.9%

[1] Form 33 = Medical History Update; Form 151 = Activities of Daily Living (ADL); Form 153 = Medication and Supplement Inventory; Form 155 = Lifestyle Questionnaire (includes ADL).
[2] Form 153 was collected on MRC participants only.

Table 1.9
Response Rates to CCC Annual Mailings, Extension Study 2010-2015 Year 1 by Cohort and Regional Center

Data as of: September 20, 2013

	1st Mailing Period				2nd Mailing Period					
Cohort	Form[1]	Sent Mail 1	Response		Past 2nd mailing period	Sent Mail 2		Response		Cumulative Response
Total	33	92528	78369	84.7%	92528	14047	15.2%	5488	39.1%	91.7%
	151	92529	77907	84.2%	92529	14482	15.7%	5828	40.2%	91.6%
Medical Record Cohort	33	21898	17459	79.7%	21898	4259	19.5%	1474	34.6%	88.0%
	151	21899	17350	79.2%	21899	4373	20.0%	1554	35.5%	87.8%
Self Report Cohort	33	70630	60910	86.2%	70630	9788	13.9%	4014	41.0%	92.9%
	151	70630	60557	85.7%	70630	10109	14.3%	4274	42.3%	92.8%
Regional Center										
Boston	33	10022	8420	84.0%	10022	1839	18.4%	670	36.4%	91.6%
	151	10022	8379	83.6%	10022	1896	18.9%	695	36.7%	91.4%
Buffalo	33	10293	8602	83.6%	10293	1633	15.9%	597	36.6%	90.3%
	151	10293	8564	83.2%	10293	1688	16.4%	623	36.9%	90.2%
Columbus	33	10776	9212	85.5%	10776	1536	14.3%	636	41.4%	92.3%
	151	10776	9152	84.9%	10776	1596	14.8%	682	42.7%	92.2%
Gainesville	33	8350	6842	81.9%	8350	1441	17.3%	516	35.8%	90.3%
	151	8350	6792	81.3%	8350	1505	18.0%	551	36.6%	90.0%
Iowa	33	8704	7575	87.0%	8704	1108	12.7%	569	51.4%	94.4%
	151	8704	7540	86.6%	8704	1124	12.9%	592	52.7%	94.3%
Medstar	33	4400	3670	83.4%	4400	727	16.5%	261	35.9%	90.1%
	151	4400	3653	83.0%	4400	757	17.2%	269	35.5%	89.9%
Pittsburgh	33	4135	3364	81.4%	4135	741	17.9%	315	42.5%	90.2%
	151	4135	3333	80.6%	4135	751	18.2%	339	45.1%	90.0%
Seattle	33	4495	3863	85.9%	4495	609	13.6%	266	43.7%	93.0%
	151	4495	3834	85.3%	4495	644	14.3%	292	45.3%	93.0%
Stanford	33	15816	13772	87.1%	15816	2027	12.8%	815	40.2%	93.3%
	151	15816	13702	86.6%	15816	2067	13.1%	874	42.3%	93.2%
Tucson	33	6034	5110	84.7%	6034	942	15.6%	331	35.1%	91.5%
	151	6034	5063	83.9%	6034	961	15.9%	368	38.3%	91.4%
Wake Forest	33	9503	7939	83.5%	9503	1444	15.2%	512	35.5%	90.0%
	151	9504	7895	83.1%	9504	1493	15.7%	543	36.4%	89.8%

[1] Form 33 = Medical History Update; Form 151 = Activities of Daily Living.

Table 1.9 (continued for year 2)
Response Rates to CCC Annual Mailings, Extension Study 2010-2015 Year 2 by Cohort and Regional Center

Data as of: September 20, 2013

	1st Mailing Period				2nd Mailing Period					
Cohort	**Form[1]**	**Sent Mail 1**	**Response**		**Past 2nd mailing period**	**Sent Mail 2**		**Response**		**Cumulative Response**
Total	33	88974	72926	82.0%	88974	14340	16.1%	5686	39.7%	89.8%
	155	88765	72651	81.9%	88765	14536	16.4%	5765	39.7%	89.8%
Medical Record Cohort	33	20814	15959	76.7%	20814	4129	19.8%	1511	36.6%	85.7%
	155	20767	15906	76.6%	20767	4195	20.2%	1523	36.3%	85.7%
Self Report Cohort	33	68160	56967	83.6%	68160	10211	15.0%	4175	40.9%	91.0%
	155	67998	56745	83.5%	67998	10341	15.2%	4242	41.0%	91.0%
Regional Center										
Boston	33	9534	7837	82.2%	9534	1523	16.0%	645	42.4%	90.0%
	155	9516	7814	82.1%	9516	1539	16.2%	640	41.6%	89.9%
Buffalo	33	9721	7900	81.3%	9721	1622	16.7%	645	39.8%	89.5%
	155	9674	7869	81.3%	9674	1624	16.8%	642	39.5%	89.8%
Columbus	33	10432	8647	82.9%	10432	1592	15.3%	629	39.5%	89.9%
	155	10419	8626	82.8%	10419	1614	15.5%	643	39.8%	90.0%
Gainesville	33	8074	6345	78.6%	8074	1499	18.6%	561	37.4%	88.0%
	155	8067	6315	78.3%	8067	1578	19.6%	580	36.8%	87.8%
Iowa	33	8463	7204	85.1%	8463	1218	14.4%	534	43.8%	92.6%
	155	8428	7156	84.9%	8428	1224	14.5%	542	44.3%	92.5%
Medstar	33	4277	3397	79.4%	4277	761	17.8%	291	38.2%	88.1%
	155	4272	3390	79.4%	4272	772	18.1%	303	39.3%	88.3%
Pittsburgh	33	3993	3124	78.2%	3993	718	18.0%	281	39.1%	86.9%
	155	3976	3117	78.4%	3976	719	18.1%	277	38.5%	87.1%
Seattle	33	4310	3583	83.1%	4310	666	15.5%	256	38.4%	90.3%
	155	4292	3564	83.0%	4292	675	15.7%	267	39.6%	90.6%
Stanford	33	15193	12816	84.4%	15193	2158	14.2%	858	39.8%	91.2%
	155	15175	12766	84.1%	15175	2184	14.4%	880	40.3%	91.3%
Tucson	33	5893	4723	80.2%	5893	1051	17.9%	394	37.5%	88.5%
	155	5877	4705	80.1%	5877	1059	18.1%	386	36.5%	88.2%
Wake Forest	33	9084	7350	80.9%	9084	1532	17.0%	592	38.6%	88.8%
	155	9069	7329	80.8%	9069	1548	17.1%	605	39.1%	88.8%

[1] Form 33 = Medical History Update; Form 155 = Lifestyle Questionnaire (includes Activities of Daily Living).

Table 1.9 (continued for year 3)
Response Rates to CCC Annual Mailings, Extension Study 2010-2015 Year 3 by Cohort and Regional Center

Data as of: September 20, 2013

	1st Mailing Period				2nd Mailing Period					
Cohort	**Form[1,2]**	**Sent Mail 1**	**Response**		**Past 2nd mailing period**	**Sent Mail 2**		**Response**		**Cumulative Response**
Total	33	74147	60414	81.5%	63618	10509	16.5%	3996	38.0%	88.2%
	151	74157	59732	80.6%	63628	11149	17.5%	4393	39.4%	87.9%
	153	17171	12508	72.8%	14987	3362	22.4%	1135	33.8%	81.2%
Medical Record	33	17169	12563	73.2%	14985	3433	22.9%	1132	33.0%	81.7%
Cohort	151	17169	12430	72.4%	14986	3580	23.9%	1211	33.8%	81.5%
	153	17171	12508	72.8%	14987	3362	22.4%	1135	33.8%	81.2%
Self Report	33	56978	47851	84.0%	48633	7076	14.6%	2864	40.5%	90.2%
Cohort	151	56988	47302	83.0%	48642	7569	15.6%	3182	42.0%	89.8%
Regional Center										
Boston	33	8682	7062	81.3%	6956	1157	16.6%	471	40.7%	88.3%
	151	8682	6997	80.6%	6956	1214	17.5%	508	41.9%	88.0%
	153	1384	1046	75.6%	1120	239	21.3%	86	36.0%	83.0%
Buffalo	33	8503	6914	81.3%	6726	1185	17.6%	461	38.9%	88.7%
	151	8505	6832	80.3%	6727	1256	18.7%	494	39.3%	88.2%
	153	2000	1400	70.0%	1633	413	25.3%	146	35.4%	79.8%
Columbus	33	8514	6981	82.0%	7452	1160	15.6%	433	37.3%	87.9%
	151	8515	6901	81.1%	7453	1243	16.7%	481	38.7%	87.5%
	153	1979	1471	74.3%	1766	346	19.6%	95	27.5%	79.8%
Gainesville	33	6702	5250	78.3%	5939	1171	19.7%	407	34.8%	86.4%
	151	6701	5174	77.2%	5939	1256	21.2%	457	36.4%	86.0%
	153	1848	1262	68.3%	1668	471	28.2%	135	28.7%	78.7%
Iowa	33	6884	5802	84.3%	6110	931	15.2%	364	39.1%	90.9%
	151	6885	5733	83.3%	6111	994	16.3%	414	41.7%	90.7%
	153	1629	1323	81.2%	1477	265	17.9%	103	38.9%	89.0%
Medstar	33	3841	3013	78.4%	3071	585	19.1%	189	32.3%	84.7%
	151	3840	2976	77.5%	3070	618	20.1%	209	33.8%	84.3%
	153	1306	859	65.8%	1083	287	26.5%	97	33.8%	74.6%
Pittsburgh	33	3288	2599	79.1%	3001	485	16.2%	193	39.8%	85.8%
	151	3288	2563	78.0%	3001	519	17.3%	211	40.7%	85.3%
	153	831	597	71.8%	734	149	20.3%	56	37.6%	80.3%
Seattle	33	3457	2911	84.2%	3085	413	13.4%	168	40.7%	89.6%
	151	3457	2871	83.1%	3085	448	14.5%	189	42.2%	89.3%
	153	751	580	77.2%	674	129	19.1%	52	40.3%	84.9%
Stanford	33	12291	10294	83.8%	10751	1507	14.0%	635	42.1%	89.9%
	151	12296	10194	82.9%	10756	1596	14.8%	699	43.8%	89.5%
	153	2553	1962	76.9%	2265	399	17.6%	164	41.1%	84.8%
Tucson	33	4744	3808	80.3%	4199	775	18.5%	272	35.1%	87.4%
	151	4745	3774	79.5%	4200	810	19.3%	294	36.3%	87.2%
	153	975	700	71.8%	876	219	25.0%	63	28.8%	80.7%
Wake Forest	33	7241	5780	79.8%	6328	1140	18.0%	403	35.4%	87.0%
	151	7243	5717	78.9%	6330	1195	18.9%	437	36.6%	86.6%
	153	1915	1308	68.3%	1691	445	26.3%	138	31.0%	77.4%

[1] Form 33 = Medical History Update; Form 151 = Activities of Daily Living; Form 153 = Medication and Supplement Inventory.
[2] Form 153 was collected on MRC participants only.

Table 1.10
Response Rates to Regional Center Follow-up and Cumulative Response
Extension Study 2010-2015, Follow-up Year 1 by Cohort and Regional Center

Data as of: September 20, 2013

Cohort	Form[1]	Eligible for RC Follow-up	Respondents		Total Estimated Response Rate
Total	33	7574	5911	78.0%	97.1%
	151	7946	4344	54.7%	95.3%
Medical Record Cohort	33	2604	2227	85.5%	96.4%
	151	2753	1633	59.3%	93.5%
Self Report Cohort	33	4970	3684	74.1%	97.4%
	151	5193	2711	52.2%	95.9%
Regional Center					
Boston	33	802	723	90.2%	98.2%
	151	842	596	70.8%	96.7%
Buffalo	33	965	910	94.3%	98.4%
	151	997	713	71.5%	96.4%
Columbus	33	812	601	74.0%	97.5%
	151	851	446	52.4%	95.9%
Gainesville	33	791	551	69.7%	95.5%
	151	826	493	59.7%	94.5%
Iowa	33	488	197	40.4%	96.3%
	151	503	123	24.5%	95.3%
Medstar	33	430	493	114.7%	97.5%
	151	441	487	110.4%	97.2%
Pittsburgh	33	417	380	91.1%	97.8%
	151	428	357	83.4%	97.1%
Seattle	33	304	241	79.3%	97.2%
	151	331	154	46.5%	95.3%
Stanford	33	1053	851	80.8%	98.0%
	151	1110	352	31.7%	94.8%
Tucson	33	502	289	57.6%	95.1%
	151	575	84	14.6%	91.6%
Wake Forest	33	1010	675	66.8%	95.8%
	151	1042	539	51.7%	94.2%

[1] Form 33 = Medical History Update; Form 151 = Activities of Daily Living.

Table 1.10 (continued for year 2)
Response Rates to Regional Center Follow-up and Cumulative Response
Extension Study 2010-2015 Follow-up, Year 2 by Cohort and Regional Center

Data as of: September 20, 2013

Cohort	Form[1]	Eligible for RC Follow-up	Respondents		Total Estimated Response Rate
Total	33	10988	8793	80.0%	96.3%
	155	11733	1639	14.0%	88.5%
Medical Record Cohort	33	3640	3169	87.1%	95.6%
	155	3954	521	13.2%	83.5%
Self Report Cohort	33	7348	5624	76.5%	96.5%
	155	7779	1118	14.4%	90.0%
Regional Center					
Boston	33	1233	929	75.3%	95.6%
	155	1333	341	25.6%	89.5%
Buffalo	33	1212	1273	105.0%	97.8%
	155	1336	558	41.8%	91.0%
Columbus	33	1195	1035	86.6%	97.7%
	155	1238	54	4.4%	88.5%
Gainesville	33	955	853	89.3%	95.3%
	155	1137	222	19.5%	87.5%
Iowa	33	747	305	40.8%	94.5%
	155	768	185	24.1%	92.9%
Medstar	33	676	597	88.3%	96.4%
	155	732	39	5.3%	84.2%
Pittsburgh	33	614	576	93.8%	97.8%
	155	641	123	19.2%	86.9%
Seattle	33	522	431	82.6%	96.9%
	155	544	5	0.9%	87.5%
Stanford	33	1717	1384	80.6%	97.4%
	155	1760	83	4.7%	89.0%
Tucson	33	718	481	67.0%	94.4%
	155	822	10	1.22%	86.2%
Wake Forest	33	1399	929	66.4%	94.6%
	155	1422	19	1.3%	85.0%

[1] Form 33 = Medical History Update; Form 155 = Lifestyle Questionnaire (includes Activities of Daily Living).

Table 1.10 (continued for year 3)
Response Rates to Regional Center Follow-up and Cumulative Response
Extension Study 2010-2015 Follow-up, Year 3 by Cohort and Regional Center

Data as of: September 20, 2013

Cohort	Form[1,2]	Eligible for RC Follow-up	Respondents		Total Estimated Response Rate
Total	33	1868	1388	74.3%	94.8%
	151	2019	881	43.6%	90.6%
	153	627	138	22.0%	84.7%
Medical Record Cohort	33	712	581	81.6%	93.8%
	151	771	359	46.6%	86.8%
	153	627	138	22.0%	84.7%
Self Report Cohort	33	1156	807	69.8%	95.2%
	151	1248	522	41.8%	91.9%
Regional Center					
Boston	33	207	132	63.8%	92.7%
	151	224	74	33.0%	88.1%
	153	40	6	15.0%	84.3%
Buffalo	33	205	208	101.5%	97.5%
	151	226	158	69.9%	93.4%
	153	72	11	15.3%	81.6%
Columbus	33	193	176	91.2%	97.4%
	151	210	89	42.4%	91.0%
	153	67	24	35.8%	88.1%
Gainesville	33	153	105	68.6%	92.2%
	151	171	69	40.4%	88.6%
	153	69	8	11.6%	81.7%
Iowa	33	163	98	60.1%	95.3%
	151	169	65	38.5%	92.9%
	153	39	0	0.0%	89.4%
Medstar	33	109	97	89.0%	95.8%
	151	125	62	49.6%	90.0%
	153	66	19	28.8%	80.9%
Pittsburgh	33	108	103	95.4%	97.3%
	151	114	89	78.1%	95.0%
	153	32	14	43.8%	88.5%
Seattle	33	80	71	88.8%	97.2%
	151	83	36	43.4%	90.1%
	153	24	3	12.5%	84.3%
Stanford	33	255	189	74.1%	96.4%
	151	273	129	47.3%	92.9%
	153	90	27	30.0%	87.5%
Tucson	33	152	59	38.8%	88.7%
	151	169	1	0.6%	82.0%
	153	40	7	17.5%	85.3%
Wake Forest	33	243	150	61.7%	92.2%
	151	255	109	42.8%	89.1%
	153	88	19	21.6%	79.2%

[1] Form 33 = Medical History Update; Form 151 = Activities of Daily Living; Form 153 = Medication and Supplement Inventory.
[2] Form 153 was collected for MRC participants only.

Table 2.1
Lost-to-Follow-up and Vital Status: HT Participants by Hysterectomy Status

Data as of: September 20, 2013
WHI Extension Study 2010-2015 Participants

	Without Uterus (N = 5,692)		With Uterus (N = 9,891)		HT Participants (N = 15,583)	
	N	%	N	%	N	%
Vital Status/Participation						
Deceased	350	6.1	523	5.3	873	5.6
Alive: Current Participation[1]	5047	88.7	8967	90.7	14014	89.9
Alive: Recent Participation[2]	149	2.6	221	2.2	370	2.4
Alive: Past/Unknown Participation[3]	2	<0.1	3	<0.1	5	<0.1
Stopped Follow-Up[4]	79	1.4	117	1.2	196	1.3
Lost to Follow-Up[5]	65	1.1	60	0.6	125	0.8

Data as of: September 20, 2013; Status as of September 30, 2010
WHI Extension Study 2005-2010 Participants

	Without Uterus (N = 7,645)		With Uterus (N = 12,788)		HT Participants (N = 20,433)	
	N	%	N	%	N	%
Vital Status/Participation						
Deceased	684	8.9	1052	8.2	1736	8.5
Alive: Current Participation[1]	6652	87.0	11282	88.2	17934	87.8
Alive: Recent Participation[2]	92	1.2	117	0.9	209	1.0
Alive: Past/Unknown Participation[3]	10	0.1	13	0.1	23	0.1
Stopped Follow-Up[4]	123	1.6	211	1.6	334	1.6
Lost to Follow-Up[5]	84	1.1	113	0.9	197	1.0

Data as of: September 20, 2013; Status as of April 8, 2005
WHI Participants

	Without Uterus (N=10,739)		With Uterus (N=16,608)		HT Participants (N=27,347)	
	N	%	N	%	N	%
Vital Status/Participation						
Deceased	752	7.0	937	5.6	1689	6.2
Alive: Current Participation[6]	9295	86.6	14903	89.7	24198	88.5
Alive: Recent Participation[7]	86	0.8	77	0.5	163	0.6
Alive: Past/Unknown Participation[8]	2	<0.1	3	<0.1	5	<0.1
Stopped Follow-Up[4]	464	4.3	518	3.1	982	3.6
Lost to Follow-Up[5]	140	1.3	170	1.0	310	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 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 2.2
Verified Outcomes (Annualized Percentages) by Age for Hormone Therapy

Data as of: September 20, 2013; Events through September 20, 2013

Outcomes	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	27347		3420		5413		12360		6154	
Mean follow-up (months)	159.3		170.0		167.7		160.3		143.7	
Cardiovascular										
CHD[1]	1894	(0.52%)	94	(0.19%)	207	(0.27%)	875	(0.53%)	718	(0.97%)
CHD death[2]	663	(0.18%)	22	(0.05%)	50	(0.07%)	269	(0.16%)	322	(0.44%)
Total MI[3]	1429	(0.39%)	76	(0.16%)	177	(0.23%)	675	(0.41%)	501	(0.68%)
Clinical MI	1398	(0.39%)	75	(0.15%)	175	(0.23%)	659	(0.40%)	489	(0.66%)
Angina[4]	1086	(0.49%)	52	(0.18%)	139	(0.31%)	526	(0.53%)	369	(0.77%)
CABG/PTCA	1930	(0.53%)	112	(0.23%)	283	(0.37%)	984	(0.60%)	551	(0.75%)
Carotid artery disease	377	(0.10%)	11	(0.02%)	53	(0.07%)	205	(0.12%)	108	(0.15%)
Congestive heart failure, WHI[4]	806	(0.36%)	41	(0.14%)	75	(0.17%)	333	(0.34%)	357	(0.75%)
Heart failure, UNC[5]	1293	(0.40%)	51	(0.12%)	109	(0.16%)	554	(0.37%)	579	(0.85%)
Stroke	1413	(0.39%)	61	(0.13%)	129	(0.17%)	652	(0.39%)	571	(0.77%)
Non-disabling stroke[6]	763	(0.21%)	44	(0.09%)	92	(0.12%)	345	(0.21%)	282	(0.38%)
Fatal/disabling stroke[6]	582	(0.16%)	14	(0.03%)	29	(0.04%)	272	(0.16%)	267	(0.36%)
Unknown status from stroke[6]	68	(0.02%)	3	(0.01%)	8	(0.01%)	35	(0.02%)	22	(0.03%)
PVD	380	(0.10%)	20	(0.04%)	49	(0.06%)	195	(0.12%)	116	(0.16%)
DVT	721	(0.20%)	52	(0.11%)	110	(0.15%)	343	(0.21%)	216	(0.29%)
Pulmonary embolism	568	(0.16%)	41	(0.08%)	86	(0.11%)	272	(0.16%)	169	(0.23%)
Coronary disease[7]	3824	(1.05%)	215	(0.44%)	481	(0.64%)	1811	(1.10%)	1317	(1.79%)
DVT/PE	1033	(0.28%)	68	(0.14%)	150	(0.20%)	508	(0.31%)	307	(0.42%)
Aortic aneurysm[8]	16	(0.02%)	0	(0.00%)	2	(0.02%)	11	(0.04%)	3	(0.02%)
Atrial fibrillation[8]	390	(0.60%)	21	(0.26%)	54	(0.41%)	217	(0.74%)	98	(0.72%)
Valvular heart disease[8]	85	(0.13%)	5	(0.06%)	3	(0.02%)	53	(0.18%)	24	(0.18%)
Total cardiovascular disease[9]	6114	(1.68%)	349	(0.72%)	770	(1.02%)	2902	(1.76%)	2093	(2.84%)
Cancer										
Breast cancer	1590	(0.44%)	177	(0.37%)	317	(0.42%)	751	(0.45%)	345	(0.47%)
Invasive breast cancer	1301	(0.36%)	136	(0.28%)	261	(0.34%)	603	(0.37%)	301	(0.41%)
Non-invasive breast cancer	310	(0.09%)	42	(0.09%)	60	(0.08%)	161	(0.10%)	47	(0.06%)
Ovarian cancer	140	(0.04%)	11	(0.02%)	28	(0.04%)	74	(0.04%)	27	(0.04%)
Endometrial cancer[10]	198	(0.05%)	27	(0.05%)	46	(0.06%)	87	(0.05%)	38	(0.05%)
Colorectal cancer	518	(0.14%)	35	(0.07%)	66	(0.09%)	256	(0.16%)	161	(0.22%)
Other cancer[11]	2358	(0.65%)	179	(0.37%)	368	(0.49%)	1154	(0.70%)	657	(0.89%)
Total cancer	4525	(1.25%)	407	(0.84%)	788	(1.04%)	2176	(1.32%)	1154	(1.57%)
Fractures										
Hip fracture	904	(0.25%)	18	(0.04%)	58	(0.08%)	365	(0.22%)	463	(0.63%)
Deaths										
Cardiovascular deaths	1347	(0.37%)	44	(0.09%)	90	(0.12%)	529	(0.32%)	684	(0.93%)
Cancer deaths	1565	(0.43%)	94	(0.19%)	202	(0.27%)	762	(0.46%)	507	(0.69%)
Other known cause	1106	(0.30%)	44	(0.09%)	102	(0.13%)	455	(0.28%)	505	(0.69%)
Unknown cause	39	(0.01%)	1	(<0.01%)	7	(0.01%)	13	(0.01%)	18	(0.02%)
Not yet adjudicated	241	(0.07%)	8	(0.02%)	26	(0.03%)	114	(0.07%)	93	(0.13%)
Total death	4298	(1.18%)	191	(0.39%)	427	(0.56%)	1873	(1.13%)	1807	(2.45%)
Death plus post-WHI deaths[12]	5509	(1.38%)	228	(0.42%)	507	(0.61%)	2332	(1.29%)	2442	(2.98%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Studies.
[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 Studies.
[4] Angina and CHF are not verified outcomes during the WHI Extension Studies 2005-2015. Reported statistics represent experience during the original program.
[5] UNC HF is not a verified outcome during the WHI Extension Study 2010-2015. Reported Statistics represent experience during the original program and the Extension Study 2005-2010.
[6] 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.
[7] "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 and angina are not collected in the WHI Extension Studies. Congestive heart failure is not collected in the WHI Extension Study 2005-2010.
[8] Aortic aneurysm, atrial fibrillation and valvular heart disease are new adjudicated outcomes during the WHI Extension Study 2010-2015.
[9] Total CVD does not include aortic aneurysm, atrial fibrillation or valvular heart disease.
[10] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[11] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.
[12] Includes deaths for non-Extension study participants after the main WHI study close-out. Annualized rates incorporate additional follow-up from the NDI search.

Table 2.3
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Hormone Therapy
Data as of: September 20, 2013; Events through September 20, 2013

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)	144.5	146.3	151.3	140.1	162.2	150.3
Cardiovascular						
CHD[1]	8 (0.51%)	24 (0.37%)	175 (0.51%)	47 (0.26%)	1613 (0.54%)	27 (0.56%)
CHD death[2]	4 (0.26%)	9 (0.14%)	82 (0.24%)	13 (0.07%)	549 (0.18%)	6 (0.12%)
Total MI[3]	6 (0.38%)	20 (0.31%)	113 (0.33%)	36 (0.20%)	1230 (0.41%)	24 (0.50%)
Clinical MI	6 (0.38%)	19 (0.30%)	112 (0.32%)	34 (0.19%)	1204 (0.40%)	23 (0.48%)
Angina[4]	7 (0.69%)	14 (0.34%)	125 (0.57%)	44 (0.37%)	884 (0.49%)	12 (0.40%)
CABG/PTCA	10 (0.64%)	22 (0.34%)	141 (0.41%)	62 (0.35%)	1666 (0.56%)	29 (0.60%)
Carotid artery disease	1 (0.06%)	2 (0.03%)	14 (0.04%)	4 (0.02%)	353 (0.12%)	3 (0.06%)
Congestive heart failure, WHI[4]	3 (0.30%)	9 (0.22%)	99 (0.45%)	29 (0.24%)	655 (0.36%)	11 (0.37%)
Heart failure, UNC[5]	6 (0.42%)	17 (0.29%)	136 (0.43%)	32 (0.19%)	1089 (0.41%)	13 (0.30%)
Stroke	8 (0.51%)	15 (0.23%)	162 (0.47%)	31 (0.17%)	1177 (0.40%)	20 (0.41%)
Non-disabling stroke[6]	4 (0.26%)	8 (0.12%)	92 (0.27%)	19 (0.11%)	632 (0.21%)	8 (0.17%)
Fatal/disabling stroke[6]	4 (0.26%)	7 (0.11%)	59 (0.17%)	8 (0.04%)	495 (0.17%)	9 (0.19%)
Unknown status from stroke[6]	0 (0.00%)	0 (0.00%)	11 (0.03%)	4 (0.02%)	50 (0.02%)	3 (0.06%)
PVD	3 (0.19%)	6 (0.09%)	41 (0.12%)	5 (0.03%)	323 (0.11%)	2 (0.04%)
DVT	4 (0.26%)	4 (0.06%)	76 (0.22%)	11 (0.06%)	622 (0.21%)	4 (0.08%)
Pulmonary embolism	4 (0.26%)	2 (0.03%)	68 (0.20%)	6 (0.03%)	481 (0.16%)	7 (0.15%)
Coronary disease[7]	17 (1.09%)	48 (0.75%)	380 (1.10%)	124 (0.69%)	3199 (1.07%)	56 (1.16%)
DVT/PE	7 (0.45%)	4 (0.06%)	112 (0.32%)	14 (0.08%)	887 (0.30%)	9 (0.19%)
Aortic aneurysm[8]	0 (0.00%)	0 (0.00%)	3 (0.05%)	1 (0.03%)	12 (0.02%)	0 (0.00%)
Atrial fibrillation[8]	0 (0.00%)	1 (0.08%)	10 (0.16%)	7 (0.20%)	367 (0.70%)	5 (0.55%)
Valvular heart disease[8]	1 (0.34%)	1 (0.08%)	5 (0.08%)	3 (0.08%)	72 (0.14%)	3 (0.33%)
Total cardiovascular disease[9]	29 (1.85%)	68 (1.06%)	630 (1.83%)	167 (0.93%)	5148 (1.73%)	72 (1.49%)
Cancer						
Breast cancer	5 (0.32%)	32 (0.50%)	137 (0.40%)	48 (0.27%)	1352 (0.45%)	16 (0.33%)
Invasive breast cancer	4 (0.26%)	24 (0.37%)	111 (0.32%)	39 (0.22%)	1111 (0.37%)	12 (0.25%)
Non-invasive breast cancer	1 (0.06%)	9 (0.14%)	27 (0.08%)	10 (0.06%)	258 (0.09%)	5 (0.10%)
Ovarian cancer	1 (0.06%)	3 (0.05%)	9 (0.03%)	1 (0.01%)	123 (0.04%)	3 (0.06%)
Endometrial cancer[10]	1 (0.07%)	2 (0.03%)	13 (0.04%)	6 (0.03%)	174 (0.06%)	2 (0.04%)
Colorectal cancer	1 (0.06%)	15 (0.23%)	44 (0.13%)	19 (0.11%)	430 (0.14%)	9 (0.19%)
Other cancer[11]	10 (0.64%)	40 (0.62%)	165 (0.48%)	74 (0.41%)	2038 (0.68%)	31 (0.64%)
Total cancer	17 (1.09%)	89 (1.38%)	345 (1.00%)	139 (0.77%)	3878 (1.30%)	57 (1.18%)
Fractures						
Hip fracture	4 (0.26%)	8 (0.12%)	21 (0.06%)	16 (0.09%)	847 (0.28%)	8 (0.17%)
Deaths						
Cardiovascular deaths	8 (0.51%)	15 (0.23%)	154 (0.45%)	23 (0.13%)	1135 (0.38%)	12 (0.25%)
Cancer deaths	7 (0.45%)	31 (0.48%)	126 (0.37%)	55 (0.31%)	1325 (0.45%)	21 (0.44%)
Other known cause	5 (0.32%)	14 (0.22%)	80 (0.23%)	23 (0.13%)	972 (0.33%)	12 (0.25%)
Unknown cause	0 (0.00%)	1 (0.02%)	4 (0.01%)	3 (0.02%)	30 (0.01%)	1 (0.02%)
Not yet adjudicated	1 (0.06%)	2 (0.03%)	14 (0.04%)	5 (0.03%)	216 (0.07%)	3 (0.06%)
Total Death	21 (1.34%)	63 (0.98%)	378 (1.10%)	109 (0.61%)	3678 (1.24%)	49 (1.02%)
Death plus post-WHI deaths[12]	25 (1.37%)	89 (1.18%)	502 (1.28%)	165 (0.74%)	4655 (1.44%)	73 (1.33%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Studies.
[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 Studies.
[4] Angina and CHF are not verified outcomes during the WHI Extension Studies 2005-2015. Reported statistics represent experience during the original program.
[5] UNC HF is not a verified outcome during the WHI Extension Study 2010-2015. Reported Statistics represent experience during the original program and the Extension Study 2005-2010.
[6] 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.
[7] "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 and angina are not collected in the WHI Extension Studies. Congestive heart failure is not collected in the WHI Extension Study 2005-2010.
[8] Aortic aneurysm, atrial fibrillation and valvular heart disease are new adjudicated outcomes during the WHI Extension Study 2010-2015.
[9] Total CVD does not include aortic aneurysm, atrial fibrillation or valvular heart disease.
[10] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[11] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.
[12] Includes deaths for non-Extension study participants after the main WHI study close-out. Annualized rates incorporate additional follow-up from the NDI search.

Table 2.4
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: September 20, 2013; Events through September 20, 2013

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	27347	3420	5413	12360	6154
Mean follow-up (months)	159.3	170.0	167.7	160.3	143.7
Hospitalizations					
Ever	18767 (5.17%)	1793 (3.70%)	3203 (4.23%)	8807 (5.33%)	4964 (6.73%)
Two or more	13071 (3.60%)	1063 (2.19%)	2012 (2.66%)	6236 (3.78%)	3760 (5.10%)
Other					
Diabetes (treated)	3948 (1.14%)	579 (1.24%)	810 (1.13%)	1847 (1.18%)	712 (1.02%)
Gallbladder disease[1,2]	2117 (1.18%)	282 (1.14%)	443 (1.18%)	988 (1.24%)	404 (1.07%)
Hysterectomy	1132 (0.50%)	128 (0.44%)	267 (0.54%)	538 (0.53%)	199 (0.46%)
Glaucoma[2]	3201 (1.55%)	286 (1.02%)	548 (1.28%)	1519 (1.64%)	848 (1.97%)
Osteoporosis[2]	6111 (2.99%)	475 (1.69%)	962 (2.25%)	2954 (3.22%)	1720 (4.09%)
Osteoarthritis[3]	7566 (3.25%)	1049 (2.74%)	1631 (2.98%)	3448 (3.38%)	1438 (3.77%)
Rheumatoid arthritis[2]	1696 (0.82%)	211 (0.76%)	341 (0.81%)	763 (0.83%)	381 (0.87%)
Intestinal polyps	6192 (1.83%)	768 (1.64%)	1303 (1.81%)	3024 (1.97%)	1097 (1.68%)
Lupus	417 (0.12%)	47 (0.10%)	86 (0.11%)	195 (0.12%)	89 (0.12%)
Kidney stones[2,3]	769 (0.37%)	94 (0.34%)	143 (0.34%)	346 (0.37%)	186 (0.41%)
Cataracts[2,3]	8648 (4.69%)	505 (1.80%)	1344 (3.19%)	4577 (5.50%)	2222 (7.20%)
Pills for hypertension	10327 (3.96%)	1292 (3.28%)	2108 (3.58%)	4735 (4.09%)	2192 (4.65%)
COPD[4]	805 (1.25%)	73 (0.89%)	173 (1.32%)	430 (1.47%)	129 (0.94%)
Macular degeneration[4]	829 (1.28%)	42 (0.51%)	133 (1.01%)	419 (1.43%)	235 (1.72%)
Alzheimer's disease[4]	664 (1.03%)	29 (0.35%)	60 (0.46%)	337 (1.15%)	238 (1.74%)
Parkinson's disease[4]	73 (0.11%)	5 (0.06%)	14 (0.11%)	39 (0.13%)	15 (0.11%)

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)	144.5	146.3	151.3	140.1	162.2	150.3
Hospitalizations						
Ever	86 (5.49%)	269 (4.19%)	1806 (5.23%)	791 (4.41%)	15565 (5.23%)	250 (5.18%)
Two or more	65 (4.15%)	157 (2.44%)	1234 (3.58%)	434 (2.42%)	11016 (3.70%)	165 (3.42%)
Other						
Diabetes (treated)	23 (1.66%)	78 (1.30%)	551 (1.81%)	305 (1.83%)	2934 (1.02%)	57 (1.28%)
Gallbladder disease[1,2]	13 (1.72%)	32 (0.89%)	187 (0.97%)	129 (1.46%)	1730 (1.19%)	26 (1.08%)
Hysterectomy	4 (0.63%)	11 (0.24%)	74 (0.51%)	54 (0.51%)	975 (0.51%)	14 (0.47%)
Glaucoma[2]	16 (1.72%)	60 (1.57%)	408 (2.06%)	190 (1.67%)	2480 (1.48%)	47 (1.73%)
Osteoporosis[2]	32 (3.40%)	141 (3.70%)	348 (1.68%)	338 (3.08%)	5159 (3.12%)	93 (3.36%)
Osteoarthritis[3]	45 (4.14%)	153 (3.31%)	721 (3.33%)	509 (3.97%)	6028 (3.18%)	110 (3.45%)
Rheumatoid arthritis[2]	15 (1.70%)	30 (0.79%)	272 (1.39%)	219 (1.96%)	1125 (0.67%)	35 (1.27%)
Intestinal polyps	31 (2.14%)	100 (1.72%)	664 (2.06%)	283 (1.65%)	5040 (1.82%)	74 (1.68%)
Lupus	3 (0.19%)	5 (0.08%)	45 (0.13%)	29 (0.16%)	331 (0.11%)	4 (0.08%)
Kidney stones[2,3]	9 (1.00%)	25 (0.65%)	82 (0.39%)	62 (0.56%)	583 (0.35%)	8 (0.28%)
Cataracts[2,3]	44 (5.02%)	143 (4.26%)	790 (4.23%)	450 (4.15%)	7108 (4.80%)	113 (4.61%)
Pills for hypertension	57 (5.07%)	181 (4.00%)	853 (4.89%)	593 (4.37%)	8519 (3.85%)	124 (3.81%)
COPD[4]	9 (3.10%)	7 (0.57%)	65 (1.02%)	25 (0.71%)	689 (1.32%)	10 (1.11%)
Macular degeneration[4]	7 (2.41%)	7 (0.57%)	53 (0.83%)	25 (0.71%)	726 (1.39%)	11 (1.22%)
Alzheimer's disease[4]	2 (0.69%)	6 (0.49%)	66 (1.04%)	25 (0.71%)	559 (1.07%)	6 (0.66%)
Parkinson's disease[4]	0 (0.00%)	0 (0.00%)	5 (0.08%)	3 (0.08%)	64 (0.12%)	1 (0.11%)

[1] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[2] Data not collected for WHI Extension Studies.
[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.
[4] Data only collected during the WHI Extension Study 2010-2015.

Table 3.1
Lost-to-Follow-up and Vital Status: DM Participants

Data as of: September 20, 2013
WHI Extension Study 2010-2015 Participants

	DM Participants (N = 30,689) N	%
Vital Status/Participation		
Deceased	1402	4.6
Alive: Current Participation[1]	28367	92.4
Alive: Recent Participation[2]	533	1.7
Alive: Past/Unknown Participation[3]	5	<0.1
Stopped Follow-Up[4]	211	0.7
Lost to Follow-Up[5]	171	0.6

Data as of: September 20, 2013; Status as of September 30, 2010
WHI Extension Study 2005-2010 Participants

	DM Participants (N = 37,858) N	%
Vital Status/Participation		
Deceased	2480	6.6
Alive: Current Participation[1]	34423	90.9
Alive: Recent Participation[2]	312	0.8
Alive: Past/Unknown Participation[3]	21	0.1
Stopped Follow-Up[4]	400	1.1
Lost to Follow-Up[5]	222	0.6

Data as of: September 20, 2013; Status as of April 8, 2005
WHI Participants

	DM Participants (N = 48,835) N	%
Vital Status/Participation		
Deceased	2465	5.0
Alive: Current Participation[6]	44104	90.3
Alive: Recent Participation[7]	229	0.5
Alive: Past/Unknown Participation[8]	5	<0.1
Stopped Follow-Up[4]	1521	3.1
Lost to Follow-Up[5]	511	1.0

[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 3.2
Verified Outcomes (Annualized Percentages) by Age for Dietary Modification

Data as of: September 20, 2013; Events through September 30, 2010

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	48835	6961	11037	22715	8122
Mean follow-up (months)	148.3	157.6	154.2	147.3	135.1
Cancer					
Breast cancer	3236 (0.54%)	412 (0.45%)	761 (0.54%)	1535 (0.55%)	528 (0.58%)
Invasive breast cancer	2620 (0.43%)	308 (0.34%)	620 (0.44%)	1253 (0.45%)	439 (0.48%)
Non-invasive breast cancer	661 (0.11%)	109 (0.12%)	151 (0.11%)	302 (0.11%)	99 (0.11%)
Ovarian cancer	279 (0.05%)	31 (0.03%)	52 (0.04%)	142 (0.05%)	54 (0.06%)
Endometrial cancer[1]	461 (0.08%)	56 (0.06%)	115 (0.08%)	223 (0.08%)	67 (0.07%)
Colorectal cancer	786 (0.13%)	52 (0.06%)	142 (0.10%)	383 (0.14%)	209 (0.23%)
Other cancer[2]	3420 (0.57%)	305 (0.33%)	620 (0.44%)	1745 (0.63%)	750 (0.82%)
Total cancer	7717 (1.28%)	815 (0.89%)	1593 (1.12%)	3791 (1.36%)	1518 (1.66%)
Cardiovascular					
CHD[3]	2342 (0.39%)	129 (0.14%)	283 (0.20%)	1127 (0.40%)	803 (0.88%)
CHD death[4]	788 (0.13%)	36 (0.04%)	62 (0.04%)	360 (0.13%)	330 (0.36%)
Total MI[5]	1783 (0.30%)	101 (0.11%)	234 (0.17%)	860 (0.31%)	588 (0.64%)
Clinical MI	1731 (0.29%)	95 (0.10%)	227 (0.16%)	834 (0.30%)	575 (0.63%)
Angina[6]	1630 (0.40%)	94 (0.15%)	231 (0.24%)	860 (0.46%)	445 (0.69%)
CABG/PTCA	2663 (0.44%)	147 (0.16%)	378 (0.27%)	1457 (0.52%)	681 (0.74%)
Carotid artery disease	439 (0.07%)	23 (0.03%)	58 (0.04%)	236 (0.08%)	122 (0.13%)
Congestive heart failure, WHI[6]	1170 (0.29%)	52 (0.08%)	120 (0.13%)	526 (0.28%)	472 (0.73%)
Stroke	1873 (0.31%)	94 (0.10%)	212 (0.15%)	896 (0.32%)	671 (0.73%)
PVD	398 (0.07%)	17 (0.02%)	52 (0.04%)	210 (0.08%)	119 (0.13%)
Coronary disease[7]	5220 (0.87%)	301 (0.33%)	710 (0.50%)	2650 (0.95%)	1559 (1.71%)
Total cardiovascular disease	7281 (1.21%)	411 (0.45%)	974 (0.69%)	3646 (1.31%)	2250 (2.46%)
Fractures					
Hip fracture	1047 (0.17%)	22 (0.02%)	74 (0.05%)	458 (0.16%)	493 (0.54%)
Deaths					
Cardiovascular deaths	1578 (0.26%)	63 (0.07%)	126 (0.09%)	675 (0.24%)	714 (0.78%)
Cancer deaths	2111 (0.35%)	138 (0.15%)	306 (0.22%)	1075 (0.39%)	592 (0.65%)
Other known cause	1264 (0.21%)	54 (0.06%)	124 (0.09%)	559 (0.20%)	527 (0.58%)
Unknown cause	42 (0.01%)	1 (<0.01%)	7 (<0.01%)	20 (0.01%)	14 (0.02%)
Not yet adjudicated	1 (<0.01%)	0 (0.00%)	1 (<0.01%)	0 (0.00%)	0 (0.00%)
Total death	4996 (0.83%)	256 (0.28%)	564 (0.40%)	2329 (0.84%)	1847 (2.02%)
Death plus post-WHI deaths[8]	6054 (0.92%)	295 (0.30%)	644 (0.42%)	2766 (0.92%)	2349 (2.33%)

[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 Studies.
[4] "CHD death" includes definite and possible CHD death.
[5] "Total MI" includes clinical MI and evolving Q-wave MI is not collected in the WHI Extension Study.
[6] Angina and CHF are not verified outcomes during the WHI Extension Study 2005-2010. Reported statistics represent experience during the original program.
[7] "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.
[8] Includes deaths for non-Extension study participants after the main WHI study close-out. Annualized rates incorporate additional follow-up from the NDI search.

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

Data as of: September 20, 2013; Events through September 30, 2010

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)	138.6	143.5	140.3	133.2	150.4	138.4
Cancer						
Breast cancer	7 (0.30%)	74 (0.56%)	279 (0.45%)	77 (0.38%)	2764 (0.55%)	35 (0.46%)
Invasive breast cancer	5 (0.21%)	56 (0.42%)	212 (0.34%)	62 (0.30%)	2256 (0.45%)	29 (0.38%)
Non-invasive breast cancer	2 (0.09%)	19 (0.14%)	71 (0.12%)	17 (0.08%)	545 (0.11%)	7 (0.09%)
Ovarian cancer	1 (0.04%)	7 (0.05%)	22 (0.04%)	9 (0.04%)	237 (0.05%)	3 (0.04%)
Endometrial cancer[1]	0 (0.00%)	5 (0.04%)	29 (0.05%)	9 (0.04%)	412 (0.08%)	6 (0.08%)
Colorectal cancer	5 (0.21%)	13 (0.10%)	91 (0.15%)	22 (0.11%)	645 (0.13%)	10 (0.13%)
Other cancer[2]	7 (0.30%)	50 (0.38%)	265 (0.43%)	70 (0.34%)	2986 (0.60%)	42 (0.55%)
Total cancer	18 (0.77%)	139 (1.05%)	644 (1.05%)	174 (0.85%)	6654 (1.34%)	88 (1.16%)
Cardiovascular						
CHD[3]	4 (0.17%)	28 (0.21%)	247 (0.40%)	41 (0.20%)	1992 (0.40%)	30 (0.39%)
CHD death[4]	0 (0.00%)	6 (0.05%)	112 (0.18%)	14 (0.07%)	642 (0.13%)	14 (0.18%)
Total MI[5]	4 (0.17%)	25 (0.19%)	166 (0.27%)	32 (0.16%)	1534 (0.31%)	22 (0.29%)
Clinical MI	4 (0.17%)	25 (0.19%)	161 (0.26%)	31 (0.15%)	1489 (0.30%)	21 (0.28%)
Angina WHI[6]	7 (0.43%)	18 (0.20%)	213 (0.50%)	50 (0.34%)	1320 (0.40%)	22 (0.42%)
CABG/PTCA	8 (0.34%)	24 (0.18%)	247 (0.40%)	62 (0.30%)	2298 (0.46%)	24 (0.32%)
Carotid artery disease	2 (0.09%)	1 (0.01%)	31 (0.05%)	4 (0.02%)	395 (0.08%)	6 (0.08%)
Congestive heart failure, WHI[6]	2 (0.12%)	10 (0.11%)	178 (0.41%)	31 (0.21%)	933 (0.28%)	16 (0.31%)
Stroke	6 (0.26%)	28 (0.21%)	250 (0.41%)	47 (0.23%)	1515 (0.30%)	27 (0.36%)
PVD	3 (0.13%)	3 (0.02%)	76 (0.12%)	6 (0.03%)	304 (0.06%)	6 (0.08%)
Coronary disease[7]	17 (0.73%)	61 (0.46%)	621 (1.01%)	126 (0.62%)	4332 (0.87%)	63 (0.83%)
Total cardiovascular disease	27 (1.16%)	91 (0.69%)	883 (1.44%)	177 (0.86%)	6012 (1.21%)	91 (1.20%)
Fractures						
Hip fracture	2 (0.09%)	11 (0.08%)	28 (0.05%)	15 (0.07%)	982 (0.20%)	9 (0.12%)
Deaths						
Cardiovascular deaths	4 (0.17%)	18 (0.14%)	226 (0.37%)	29 (0.14%)	1283 (0.26%)	18 (0.24%)
Cancer deaths	8 (0.34%)	27 (0.20%)	185 (0.30%)	53 (0.26%)	1807 (0.36%)	31 (0.41%)
Other known cause	11 (0.47%)	12 (0.09%)	128 (0.21%)	31 (0.15%)	1067 (0.21%)	15 (0.20%)
Unknown cause	0 (0.00%)	2 (0.02%)	8 (0.01%)	0 (0.00%)	32 (0.01%)	0 (0.00%)
Not yet adjudicated	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (<0.01%)	0 (0.00%)
Total death	23 (0.99%)	59 (0.45%)	547 (0.89%)	113 (0.55%)	4190 (0.84%)	64 (0.84%)
Death plus post-WHI deaths[8]	34 (1.30%)	83 (0.56%)	705 (1.01%)	147 (0.60%)	5002 (0.93%)	83 (0.97%)

[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 Studies.
[4] "CHD death" includes definite and possible CHD death.
[5] "Total MI" includes clinical MI and evolving Q-wave MI is not collected in the WHI Extension Study.
[6] Angina and CHF are not verified outcomes during the WHI Extension Study 2005-2010. Reported statistics represent experience during the original program.
[7] "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.
[8] Includes deaths for non-Extension study participants after the main WHI study close-out. Annualized rates incorporate additional follow-up from the NDI search.

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: September 20, 2013; Events through September 20, 2013

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	48835	6961	11037	22715	8122
Mean follow-up (months)	166.4	178.2	174.7	165.7	146.9
Hospitalizations					
Ever	33470 (4.94%)	3805 (3.68%)	6727 (4.19%)	16383 (5.22%)	6555 (6.59%)
Two or more	22852 (3.37%)	2217 (2.15%)	4221 (2.63%)	11497 (3.67%)	4917 (4.94%)
Other					
DVT[1]	1054 (0.16%)	77 (0.08%)	165 (0.11%)	542 (0.18%)	270 (0.29%)
Pulmonary embolism	817 (0.12%)	67 (0.07%)	145 (0.09%)	429 (0.14%)	176 (0.18%)
Diabetes (treated)	6895 (1.06%)	1055 (1.05%)	1612 (1.04%)	3233 (1.08%)	995 (1.05%)
Gallbladder disease[2, 3]	3830 (1.16%)	573 (1.07%)	902 (1.15%)	1802 (1.22%)	553 (1.09%)
Hysterectomy	2369 (0.61%)	368 (0.62%)	604 (0.62%)	1111 (0.63%)	286 (0.53%)
Glaucoma[3]	5315 (1.40%)	567 (0.95%)	1098 (1.22%)	2587 (1.50%)	1063 (1.82%)
Osteoporosis[3]	10217 (2.74%)	1128 (1.91%)	1968 (2.21%)	5020 (2.98%)	2101 (3.73%)
Osteoarthritis[4]	14554 (3.34%)	2346 (2.89%)	3553 (3.11%)	6654 (3.53%)	2001 (3.91%)
Rheumatoid arthritis[3]	2848 (0.75%)	399 (0.68%)	631 (0.71%)	1319 (0.76%)	499 (0.83%)
Intestinal polyps	12115 (1.92%)	1810 (1.81%)	2988 (1.96%)	5786 (2.01%)	1531 (1.73%)
Lupus	717 (0.11%)	103 (0.10%)	171 (0.11%)	345 (0.11%)	98 (0.10%)
Kidney stones[3, 4]	1319 (0.35%)	175 (0.30%)	281 (0.32%)	654 (0.38%)	209 (0.34%)
Cataracts[3, 4]	15480 (4.45%)	1157 (1.95%)	2858 (3.23%)	8460 (5.38%)	3005 (7.00%)
Pills for hypertension	17934 (3.75%)	2533 (3.03%)	4182 (3.43%)	8477 (3.98%)	2742 (4.59%)

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)	154.0	160.8	154.5	146.1	169.3	154.2
Hospitalizations						
Ever	128 (4.94%)	573 (3.87%)	3383 (4.99%)	991 (4.41%)	27984 (4.99%)	411 (4.85%)
Two or more	85 (3.28%)	321 (2.17%)	2290 (3.38%)	588 (2.62%)	19310 (3.44%)	258 (3.05%)
Other						
DVT[1]	3 (0.12%)	5 (0.03%)	121 (0.18%)	20 (0.09%)	892 (0.16%)	13 (0.16%)
Pulmonary embolism	4 (0.16%)	2 (0.01%)	89 (0.13%)	16 (0.07%)	696 (0.13%)	10 (0.12%)
Diabetes (treated)	34 (1.40%)	173 (1.23%)	1096 (1.81%)	323 (1.53%)	5170 (0.95%)	99 (1.23%)
Gallbladder disease[2,3]	14 (1.22%)	60 (0.77%)	304 (0.81%)	152 (1.42%)	3250 (1.21%)	50 (1.14%)
Hysterectomy	6 (0.50%)	39 (0.42%)	160 (0.53%)	71 (0.59%)	2073 (0.63%)	20 (0.41%)
Glaucoma[3]	30 (1.95%)	108 (1.30%)	762 (1.95%)	201 (1.47%)	4150 (1.33%)	64 (1.33%)
Osteoporosis[3]	43 (2.81%)	272 (3.33%)	678 (1.68%)	409 (3.10%)	8675 (2.84%)	140 (2.96%)
Osteoarthritis[4]	57 (3.60%)	341 (3.13%)	1433 (3.41%)	576 (3.65%)	11943 (3.32%)	204 (3.78%)
Rheumatoid arthritis[3]	23 (1.59%)	49 (0.59%)	505 (1.29%)	222 (1.65%)	1998 (0.64%)	51 (1.05%)
Intestinal polyps	59 (2.44%)	258 (1.90%)	1344 (2.12%)	388 (1.81%)	9909 (1.90%)	157 (2.01%)
Lupus	5 (0.20%)	11 (0.07%)	102 (0.15%)	23 (0.10%)	563 (0.10%)	13 (0.15%)
Kidney stones[3, 4]	9 (0.60%)	27 (0.33%)	137 (0.34%)	58 (0.43%)	1071 (0.34%)	17 (0.35%)
Cataracts[3, 4]	61 (4.44%)	306 (4.04%)	1509 (4.04%)	537 (4.14%)	12863 (4.53%)	204 (4.61%)
Pills for hypertension	65 (3.82%)	385 (3.83%)	1653 (4.81%)	701 (4.20%)	14911 (3.64%)	219 (3.79%)

[1] Inpatient DVT only.
[2] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[3] Data not collected for the WHI Extension Studies.
[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
Lost-to-Follow-up and Vital Status: CaD Participants

Data as of: September 20, 2013
WHI Extension Study 2010-2015 Participants

	CaD Participants (N = 24,231)	
	N	%
Vital Status/Participation		
Deceased	1111	4.6
Alive: Current Participation[1]	22335	92.2
Alive: Recent Participation[2]	436	1.8
Alive: Past/Unknown Participation[3]	5	<0.1
Stopped Follow-Up[4]	198	0.8
Lost to Follow-Up[5]	146	0.6

Data as of: September 20, 2013; Status as of September 30, 2010
WHI Extension Study 2005-2010 Participants

	CaD Participants (N = 29,862)	
	N	%
Vital Status/Participation		
Deceased	2034	6.8
Alive: Current Participation[1]	27008	90.4
Alive: Recent Participation[2]	245	0.8
Alive: Past/Unknown Participation[3]	18	0.1
Stopped Follow-Up[4]	356	1.2
Lost to Follow-Up[5]	201	0.7

Data as of: September 20, 2013; Status as of April 8, 2005
WHI Participants

	CaD Participants (N = 36,282)	
	N	%
Vital Status/Participation		
Deceased	1584	4.4
Alive: Current Participation[6]	32647	90.0
Alive: Recent Participation[7]	1094	3.0
Alive: Past/Unknown Participation[8]	26	0.1
Stopped Follow-Up[4]	668	1.8
Lost to Follow-Up[5]	263	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 4.2
Verified Outcomes (Annualized Percentages) by Age for Calcium and Vitamin D

Data as of: September 20, 2013; Events through September 30, 2010

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	36282		5153		8269		16519		6341	
Mean follow-up (months)	138.8		146.6		144.4		138.0		127.3	
Fractures										
Hip fracture	810	(0.19%)	18	(0.03%)	74	(0.07%)	325	(0.17%)	393	(0.58%)
Cancer										
Colorectal cancer	556	(0.13%)	39	(0.06%)	89	(0.09%)	270	(0.14%)	158	(0.23%)
Breast cancer	2179	(0.52%)	276	(0.44%)	522	(0.52%)	1023	(0.54%)	358	(0.53%)
Invasive breast cancer	1752	(0.42%)	207	(0.33%)	423	(0.43%)	824	(0.43%)	298	(0.44%)
Non-invasive breast cancer	457	(0.11%)	70	(0.11%)	104	(0.10%)	213	(0.11%)	70	(0.10%)
Ovarian cancer	189	(0.05%)	23	(0.04%)	44	(0.04%)	89	(0.05%)	33	(0.05%)
Endometrial cancer[1]	299	(0.07%)	39	(0.06%)	75	(0.08%)	134	(0.07%)	51	(0.08%)
Other cancer[2]	2470	(0.59%)	211	(0.34%)	432	(0.43%)	1257	(0.66%)	570	(0.85%)
Total cancer	5395	(1.29%)	567	(0.90%)	1109	(1.11%)	2616	(1.38%)	1103	(1.64%)
Cardiovascular										
CHD[3]	1789	(0.43%)	93	(0.15%)	218	(0.22%)	850	(0.45%)	628	(0.93%)
CHD death[4]	578	(0.14%)	23	(0.04%)	49	(0.05%)	236	(0.12%)	270	(0.40%)
Total MI[5]	1372	(0.33%)	75	(0.12%)	176	(0.18%)	681	(0.36%)	440	(0.65%)
Clinical MI	1323	(0.32%)	71	(0.11%)	171	(0.17%)	657	(0.35%)	424	(0.63%)
Angina[6]	1117	(0.44%)	59	(0.15%)	163	(0.27%)	581	(0.51%)	314	(0.73%)
CABG/PTCA	2031	(0.48%)	114	(0.18%)	299	(0.30%)	1084	(0.57%)	534	(0.79%)
Carotid artery disease	355	(0.08%)	16	(0.03%)	50	(0.05%)	199	(0.10%)	90	(0.13%)
Congestive heart failure, WHI[6]	806	(0.31%)	33	(0.08%)	84	(0.14%)	376	(0.33%)	313	(0.73%)
Stroke	1386	(0.33%)	72	(0.11%)	157	(0.16%)	647	(0.34%)	510	(0.76%)
PVD	330	(0.08%)	11	(0.02%)	48	(0.05%)	165	(0.09%)	106	(0.16%)
Coronary disease[7]	3877	(0.92%)	222	(0.35%)	545	(0.55%)	1926	(1.01%)	1184	(1.76%)
Total cardiovascular disease	5441	(1.30%)	308	(0.49%)	750	(0.75%)	2669	(1.41%)	1714	(2.55%)
Deaths										
Cardiovascular deaths	1152	(0.27%)	45	(0.07%)	94	(0.09%)	471	(0.25%)	542	(0.81%)
Cancer deaths	1520	(0.36%)	107	(0.17%)	223	(0.22%)	776	(0.41%)	414	(0.62%)
Other known cause	959	(0.23%)	42	(0.07%)	100	(0.10%)	420	(0.22%)	397	(0.59%)
Unknown cause	27	(0.01%)	1	(<0.01%)	7	(0.01%)	9	(<0.01%)	10	(0.01%)
Not yet adjudicated	0	(0.00%)	0	(0.00%)	0	(0.00%)	0	(0.00%)	0	(0.00%)
Total death	3658	(0.87%)	195	(0.31%)	424	(0.43%)	1676	(0.88%)	1363	(2.03%)
Death plus post-WHI deaths[8]	4273	(0.97%)	222	(0.33%)	476	(0.46%)	1912	(0.96%)	1663	(2.33%)

[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 Studies.
[6] Angina and CHF are not verified outcomes in the WHI Extension Study. Reported statistics represent experience during the original program.
[7] "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.
[8] Includes deaths for non-Extension study participants after the main WHI study close-out. Annualized rates incorporate additional follow-up from the NDI search.

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

Data as of: September 20, 2013; Events through September 30, 2010

	Race/Ethnicity					
Outcome	**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)	131.2	132.6	132.3	126.4	140.5	128.8
Fractures						
Hip fracture	3 (0.18%)	10 (0.13%)	14 (0.04%)	10 (0.06%)	771 (0.22%)	2 (0.04%)
Cancer						
Colorectal cancer	2 (0.12%)	9 (0.11%)	56 (0.15%)	15 (0.09%)	467 (0.13%)	7 (0.15%)
Breast cancer	5 (0.31%)	43 (0.54%)	172 (0.47%)	55 (0.35%)	1883 (0.53%)	21 (0.44%)
Invasive breast cancer	3 (0.18%)	31 (0.39%)	133 (0.36%)	45 (0.28%)	1521 (0.43%)	19 (0.40%)
Non-invasive breast cancer	2 (0.12%)	14 (0.18%)	42 (0.11%)	12 (0.08%)	384 (0.11%)	3 (0.06%)
Ovarian cancer	0 (0.00%)	7 (0.09%)	13 (0.04%)	6 (0.04%)	161 (0.05%)	2 (0.04%)
Endometrial cancer[1]	1 (0.06%)	4 (0.05%)	14 (0.04%)	6 (0.04%)	270 (0.08%)	4 (0.08%)
Other cancer[2]	6 (0.37%)	38 (0.48%)	163 (0.45%)	56 (0.35%)	2184 (0.62%)	23 (0.49%)
Total cancer	13 (0.80%)	96 (1.20%)	397 (1.09%)	129 (0.82%)	4705 (1.33%)	55 (1.16%)
Cardiovascular						
CHD[3]	5 (0.31%)	14 (0.18%)	160 (0.44%)	37 (0.23%)	1550 (0.44%)	23 (0.49%)
CHD death[4]	1 (0.06%)	3 (0.04%)	67 (0.18%)	11 (0.07%)	486 (0.14%)	10 (0.21%)
Total MI[5]	5 (0.31%)	13 (0.16%)	106 (0.29%)	30 (0.19%)	1199 (0.34%)	19 (0.40%)
Clinical MI	5 (0.31%)	13 (0.16%)	103 (0.28%)	29 (0.18%)	1155 (0.33%)	18 (0.38%)
Angina[6]	3 (0.29%)	11 (0.23%)	119 (0.52%)	43 (0.42%)	927 (0.43%)	14 (0.47%)
CABG/PTCA	5 (0.31%)	19 (0.24%)	153 (0.42%)	61 (0.39%)	1768 (0.50%)	25 (0.53%)
Carotid artery disease	1 (0.06%)	1 (0.01%)	21 (0.06%)	4 (0.03%)	323 (0.09%)	5 (0.11%)
Congestive heart failure, WHI[6]	2 (0.19%)	7 (0.14%)	103 (0.45%)	29 (0.28%)	656 (0.31%)	9 (0.30%)
Stroke	8 (0.49%)	23 (0.29%)	144 (0.39%)	32 (0.20%)	1157 (0.33%)	22 (0.47%)
PVD	2 (0.12%)	5 (0.06%)	47 (0.13%)	3 (0.02%)	270 (0.08%)	3 (0.06%)
Coronary disease[7]	11 (0.68%)	38 (0.48%)	382 (1.05%)	112 (0.71%)	3287 (0.93%)	47 (1.00%)
Total cardiovascular disease	19 (1.17%)	62 (0.78%)	543 (1.49%)	148 (0.94%)	4600 (1.30%)	69 (1.46%)
Deaths						
Cardiovascular deaths	3 (0.18%)	13 (0.16%)	135 (0.37%)	24 (0.15%)	962 (0.27%)	15 (0.32%)
Cancer deaths	2 (0.12%)	26 (0.33%)	114 (0.31%)	45 (0.28%)	1315 (0.37%)	18 (0.38%)
Other known cause	8 (0.49%)	9 (0.11%)	80 (0.22%)	18 (0.11%)	836 (0.24%)	8 (0.17%)
Unknown cause	0 (0.00%)	3 (0.04%)	3 (0.01%)	1 (0.01%)	20 (0.01%)	0 (0.00%)
Not yet adjudicated	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Total death	13 (0.80%)	51 (0.64%)	332 (0.91%)	88 (0.56%)	3133 (0.89%)	41 (0.87%)
Death plus post-WHI deaths[8]	19 (1.10%)	63 (0.73%)	404 (1.03%)	111 (0.62%)	3621 (0.98%)	55 (1.08%)

[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 Studies.
[6] Angina and CHF are not verified outcomes in the WHI Extension Study. Reported statistics represent experience during the original program.
[7] "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.
[8] Includes deaths for non-Extension study participants after the main WHI study close-out. Annualized rates incorporate additional follow-up from the NDI search.

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: September 20, 2013; Events through September 20, 2013

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	36282	5153	8269	16519	6341
Mean follow-up (months)	158.0	168.0	166.1	157.5	140.4
Hospitalizations					
Ever	24542 (5.14%)	2735 (3.79%)	4944 (4.32%)	11766 (5.43%)	5097 (6.87%)
Two or more	16431 (3.44%)	1527 (2.12%)	3033 (2.65%)	8127 (3.75%)	3744 (5.05%)
Other					
DVT[1]	790 (0.17%)	56 (0.08%)	128 (0.11%)	389 (0.18%)	217 (0.30%)
Pulmonary embolism	597 (0.13%)	50 (0.07%)	115 (0.10%)	309 (0.14%)	123 (0.17%)
Diabetes (treated)	4920 (1.07%)	770 (1.09%)	1132 (1.03%)	2296 (1.10%)	722 (1.02%)
Gallbladder disease[2,3]	2410 (1.12%)	355 (1.03%)	591 (1.14%)	1116 (1.18%)	348 (1.00%)
Hysterectomy	1617 (0.57%)	234 (0.56%)	437 (0.62%)	745 (0.59%)	201 (0.48%)
Glaucoma[3]	3570 (1.45%)	389 (1.01%)	751 (1.28%)	1702 (1.55%)	728 (1.83%)
Osteoporosis[3]	6835 (2.81%)	717 (1.87%)	1333 (2.28%)	3299 (3.05%)	1486 (3.83%)
Osteoarthritis[4]	10144 (3.28%)	1646 (2.92%)	2499 (3.06%)	4557 (3.45%)	1442 (3.70%)
Rheumatoid arthritis[3]	1773 (0.72%)	257 (0.68%)	405 (0.70%)	798 (0.73%)	313 (0.77%)
Intestinal polyps	8449 (1.90%)	1294 (1.85%)	2096 (1.92%)	3928 (1.96%)	1131 (1.71%)
Lupus	526 (0.11%)	72 (0.10%)	124 (0.11%)	236 (0.11%)	94 (0.13%)
Kidney stones[3,4]	818 (0.32%)	111 (0.29%)	180 (0.30%)	383 (0.34%)	144 (0.34%)
Cataracts[3,4]	10522 (4.69%)	809 (2.12%)	2040 (3.54%)	5602 (5.64%)	2071 (7.13%)
Pills for hypertension	12705 (3.69%)	1809 (3.06%)	2992 (3.38%)	5900 (3.93%)	2004 (4.32%)

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)	146.9	150.6	148.1	139.8	160.4	145.2
Hospitalizations						
Ever	92 (5.05%)	381 (4.21%)	2130 (5.21%)	774 (4.42%)	20882 (5.18%)	283 (5.32%)
Two or more	63 (3.45%)	213 (2.35%)	1405 (3.44%)	419 (2.39%)	14151 (3.51%)	180 (3.38%)
Other						
DVT[1]	6 (0.34%)	2 (0.02%)	86 (0.22%)	17 (0.10%)	671 (0.17%)	8 (0.15%)
Pulmonary embolism	4 (0.22%)	0 (0.00%)	53 (0.13%)	11 (0.06%)	521 (0.13%)	8 (0.15%)
Diabetes (treated)	23 (1.35%)	102 (1.19%)	619 (1.68%)	267 (1.62%)	3836 (0.98%)	73 (1.46%)
Gallbladder disease[2,3]	10 (1.25%)	36 (0.82%)	165 (0.79%)	120 (1.51%)	2053 (1.15%)	26 (1.04%)
Hysterectomy	4 (0.53%)	25 (0.42%)	92 (0.52%)	48 (0.49%)	1431 (0.59%)	17 (0.56%)
Glaucoma[3]	20 (2.00%)	56 (1.20%)	443 (2.06%)	171 (1.70%)	2850 (1.38%)	30 (1.07%)
Osteoporosis[3]	27 (2.70%)	148 (3.16%)	394 (1.78%)	282 (2.91%)	5907 (2.91%)	77 (2.78%)
Osteoarthritis[4]	49 (4.07%)	205 (3.03%)	855 (3.35%)	463 (3.76%)	8438 (3.25%)	134 (3.70%)
Rheumatoid arthritis[3]	17 (1.83%)	28 (0.60%)	288 (1.35%)	136 (1.38%)	1279 (0.62%)	25 (0.90%)
Intestinal polyps	41 (2.44%)	143 (1.72%)	832 (2.18%)	271 (1.62%)	7071 (1.88%)	91 (1.86%)
Lupus	5 (0.28%)	4 (0.04%)	60 (0.15%)	20 (0.12%)	430 (0.11%)	7 (0.13%)
Kidney stones[3,4]	7 (0.69%)	18 (0.37%)	73 (0.32%)	46 (0.46%)	666 (0.31%)	8 (0.27%)
Cataracts[3,4]	50 (5.35%)	168 (3.99%)	866 (4.22%)	419 (4.41%)	8893 (4.77%)	126 (4.83%)
Pills for hypertension	42 (3.60%)	231 (3.66%)	971 (4.54%)	528 (3.90%)	10806 (3.62%)	127 (3.70%)

[1] Inpatient DVT only.
[2] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[3] Data not collected for the WHI Extension Studies.
[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
Lost-to-Follow-up and Vital Status: OS Participants

Data as of: September 20, 2013
WHI Extension Study 2010-2015 Participants

	OS Participants (N = 52,065)	
	N	%
Vital Status/Participation		
Deceased	2546	4.9
Alive: Current Participation[1]	47980	92.2
Alive: Recent Participation[2]	849	1.6
Alive: Past/Unknown Participation[3]	14	<0.1
Stopped Follow-Up[4]	449	0.9
Lost to Follow-Up[5]	227	0.4

Data as of: September 20, 2013; Status as of September 30, 2010
WHI Extension Study 2005-2010 Participants

	OS Participants (N = 63,231)	
	N	%
Vital Status/Participation		
Deceased	4745	7.5
Alive: Current Participation[1]	57203	90.5
Alive: Recent Participation[2]	369	0.6
Alive: Past/Unknown Participation[3]	34	0.1
Stopped Follow-Up[4]	607	1.0
Lost to Follow-Up[5]	273	0.4

Data as of: September 20, 2013; Status as of April 8, 2005
WHI Participants

	OS Participants (N =93,676)	
	N	%
Vital Status/Participation		
Deceased	6347	7.1
Alive: Current Participation[1]	78251	87.6
Alive: Recent Participation[2]	424	0.5
Alive: Past/Unknown Participation[3]	47	0.1
Stopped Follow-Up[4]	2264	2.5
Lost to Follow-Up[5]	2001	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 5.2
Verified Outcomes (Annualized Percentages) by Age for OS Participants

Data as of: September 20, 2013; Events through September 30, 2010

Outcome	Total	Age 50-54	Age 55-59	Age 60-69	Age 70-79
Number enrolled	93676	12381	17329	41200	22766
Mean follow-up (months)	136.7	146.4	145.1	137.4	124.0
Cardiovascular					
CHD[1]	4273 (0.40%)	162 (0.11%)	366 (0.17%)	1803 (0.38%)	1942 (0.83%)
CHD death[2]	1627 (0.15%)	43 (0.03%)	98 (0.05%)	571 (0.12%)	915 (0.39%)
Clinical MI	3089 (0.29%)	125 (0.08%)	287 (0.14%)	1384 (0.29%)	1293 (0.55%)
Angina[3]	2834 (0.38%)	124 (0.12%)	318 (0.22%)	1319 (0.41%)	1073 (0.62%)
CABG/PTCA	4608 (0.43%)	199 (0.13%)	534 (0.25%)	2305 (0.49%)	1570 (0.67%)
Carotid artery disease	843 (0.08%)	42 (0.03%)	79 (0.04%)	383 (0.08%)	339 (0.14%)
Congestive heart failure, WHI[3]	2295 (0.31%)	81 (0.08%)	174 (0.12%)	882 (0.27%)	1158 (0.67%)
Stroke	3324 (0.31%)	101 (0.07%)	253 (0.12%)	1399 (0.30%)	1571 (0.67%)
PVD	840 (0.08%)	23 (0.02%)	74 (0.04%)	381 (0.08%)	362 (0.15%)
Coronary disease[4]	9178 (0.86%)	396 (0.26%)	941 (0.45%)	4093 (0.87%)	3748 (1.59%)
Total cardiovascular disease	13157 (1.23%)	540 (0.36%)	1273 (0.61%)	5772 (1.22%)	5572 (2.37%)
Cancer					
Breast cancer	6045 (0.57%)	722 (0.48%)	1087 (0.52%)	2829 (0.60%)	1407 (0.60%)
Invasive breast cancer	5020 (0.47%)	577 (0.38%)	885 (0.42%)	2346 (0.50%)	1212 (0.52%)
Non-invasive breast cancer	1089 (0.10%)	155 (0.10%)	211 (0.10%)	516 (0.11%)	207 (0.09%)
Ovarian cancer	564 (0.05%)	61 (0.04%)	107 (0.05%)	251 (0.05%)	145 (0.06%)
Endometrial cancer[5]	828 (0.08%)	77 (0.05%)	153 (0.07%)	384 (0.08%)	214 (0.09%)
Colorectal cancer	1353 (0.13%)	78 (0.05%)	144 (0.07%)	623 (0.13%)	508 (0.22%)
Other cancer[6]	6611 (0.62%)	489 (0.32%)	920 (0.44%)	3147 (0.67%)	2055 (0.87%)
Total cancer	14493 (1.36%)	1358 (0.90%)	2284 (1.09%)	6779 (1.44%)	4072 (1.73%)
Fractures					
Hip fracture	2199 (0.21%)	52 (0.03%)	131 (0.06%)	777 (0.16%)	1239 (0.53%)
Deaths					
Cardiovascular deaths	3576 (0.34%)	90 (0.06%)	219 (0.10%)	1230 (0.26%)	2037 (0.87%)
Cancer deaths	4513 (0.42%)	263 (0.17%)	518 (0.25%)	2062 (0.44%)	1670 (0.71%)
Other known cause	3007 (0.28%)	116 (0.08%)	196 (0.09%)	1150 (0.24%)	1545 (0.66%)
Unknown cause	102 (0.01%)	7 (<0.01%)	11 (0.01%)	38 (0.01%)	46 (0.02%)
Not yet adjudicated	6 (<0.01%)	0 (0.00%)	1 (<0.01%)	2 (<0.01%)	3 (<0.01%)
Total death	11204 (1.05%)	476 (0.32%)	945 (0.45%)	4482 (0.95%)	5301 (2.25%)
Death plus post-WHI deaths[7]	15163 (1.24%)	605 (0.35%)	1188 (0.50%)	5868 (1.10%)	7502 (2.73%)

[1] "CHD" includes clinical MI and CHD death.
[2] "CHD death" includes definite and possible CHD death.
[3] Angina and CHF are not verified outcomes in the WHI Extension Study 2005-2010. Reported statistics represent experience during the original program.
[4] "Coronary disease" includes clinical MI, CHD death, angina, congestive heart failure, and CABG/PTCA; angina and congestive heart failure are not collected in the WHI Extension Study.
[5] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[6] Only one report of "other cancer " is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.
[7] Includes deaths for non-Extension study participants after the main WHI study close-out. Annualized rates incorporate additional follow-up from the NDI search.

Table 5.3
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for OS Participants

Data as of: September 20, 2013; Events through September 30, 2010

	Race/Ethnicity					
Outcomes	**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)	120.0	121.7	118.2	113.4	140.4	127.9
Cardiovascular						
CHD[1]	23 (0.55%)	63 (0.23%)	374 (0.50%)	86 (0.25%)	3667 (0.40%)	60 (0.43%)
CHD death[2]	13 (0.31%)	26 (0.10%)	190 (0.25%)	31 (0.09%)	1344 (0.15%)	23 (0.16%)
Clinical MI	13 (0.31%)	44 (0.16%)	227 (0.30%)	63 (0.18%)	2699 (0.30%)	43 (0.30%)
Angina[3]	18 (0.58%)	40 (0.20%)	250 (0.44%)	80 (0.31%)	2412 (0.39%)	34 (0.34%)
CABG/PTCA	23 (0.55%)	57 (0.21%)	287 (0.38%)	123 (0.36%)	4053 (0.44%)	65 (0.46%)
Carotid artery disease	5 (0.12%)	9 (0.03%)	38 (0.05%)	16 (0.05%)	762 (0.08%)	13 (0.09%)
Congestive heart failure, WHI[3]	16 (0.52%)	22 (0.11%)	233 (0.41%)	42 (0.16%)	1948 (0.31%)	34 (0.34%)
Stroke	14 (0.33%)	75 (0.28%)	273 (0.36%)	65 (0.19%)	2840 (0.31%)	57 (0.40%)
PVD	3 (0.07%)	6 (0.02%)	88 (0.12%)	8 (0.02%)	722 (0.08%)	13 (0.09%)
Coronary disease[4]	53 (1.26%)	126 (0.47%)	787 (1.05%)	221 (0.65%)	7869 (0.86%)	122 (0.86%)
Total cardiovascular disease	67 (1.59%)	211 (0.78%)	1120 (1.49%)	300 (0.88%)	11265 (1.23%)	194 (1.37%)
Cancer						
Breast cancer	17 (0.40%)	126 (0.47%)	375 (0.50%)	137 (0.40%)	5328 (0.58%)	62 (0.44%)
Invasive breast cancer	16 (0.38%)	106 (0.39%)	303 (0.40%)	108 (0.32%)	4434 (0.49%)	53 (0.38%)
Non-invasive breast cancer	1 (0.02%)	22 (0.08%)	78 (0.10%)	31 (0.09%)	947 (0.10%)	10 (0.07%)
Ovarian cancer	1 (0.02%)	6 (0.02%)	28 (0.04%)	18 (0.05%)	508 (0.06%)	3 (0.02%)
Endometrial cancer[5]	1 (0.02%)	12 (0.04%)	28 (0.04%)	12 (0.04%)	760 (0.08%)	15 (0.11%)
Colorectal cancer	4 (0.10%)	28 (0.10%)	124 (0.16%)	29 (0.09%)	1154 (0.13%)	14 (0.10%)
Other cancer[6]	23 (0.55%)	116 (0.43%)	375 (0.50%)	115 (0.34%)	5892 (0.65%)	90 (0.64%)
Total cancer	45 (1.07%)	274 (1.01%)	881 (1.17%)	305 (0.89%)	12813 (1.40%)	175 (1.24%)
Fractures						
Hip fracture	5 (0.12%)	21 (0.08%)	47 (0.06%)	19 (0.06%)	2086 (0.23%)	21 (0.15%)
Deaths						
Cardiovascular deaths	24 (0.57%)	69 (0.25%)	364 (0.48%)	76 (0.22%)	2989 (0.33%)	54 (0.38%)
Cancer deaths	13 (0.31%)	86 (0.32%)	343 (0.46%)	95 (0.28%)	3928 (0.43%)	48 (0.34%)
Other known cause	24 (0.57%)	46 (0.17%)	240 (0.32%)	84 (0.25%)	2582 (0.28%)	31 (0.22%)
Unknown cause	0 (0.00%)	2 (0.01%)	7 (0.01%)	10 (0.03%)	79 (0.01%)	4 (0.03%)
Not yet adjudicated	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (<0.01%)	5 (<0.01%)	0 (0.00%)
Total death	61 (1.45%)	203 (0.75%)	954 (1.27%)	266 (0.78%)	9583 (1.05%)	137 (0.97%)
Death plus post-WHI deaths[7]	93 (1.77%)	317 (0.90%)	1402 (1.45%)	419 (0.90%)	12707 (1.25%)	225 (1.32%)

[1] "CHD" includes clinical MI and CHD death.
[2] "CHD death" includes definite and possible CHD death.
[3] Angina and CHF are not verified outcomes in the WHI Extension Study 2005-2010. Reported statistics represent experience during the original program.
[4] "Coronary disease" includes clinical MI, CHD death, angina, congestive heart failure, and CABG/PTCA; angina and congestive heart failure are not collected in the WHI Extension Study.
[5] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[6] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin.
[7] Includes deaths for non-Extension study participants after the main WHI study close-out. Annualized rates incorporate additional follow-up from the NDI search.

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: September 20, 2013; Events through September 20, 2013

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number enrolled	93676	12381	17329	41200	22766
Mean follow-up (months)	152.8	166.1	164.7	154.0	134.3
Hospitalizations					
Ever	60278 (5.05%)	6044 (3.53%)	9692 (4.07%)	27576 (5.21%)	16966 (6.66%)
Two or more	39491 (3.31%)	3328 (1.94%)	5866 (2.47%)	18341 (3.47%)	11956 (4.69%)
Other					
DVT[1]	1507 (0.13%)	110 (0.07%)	199 (0.09%)	717 (0.14%)	481 (0.20%)
Pulmonary embolism	1221 (0.10%)	114 (0.07%)	191 (0.08%)	578 (0.11%)	338 (0.13%)
Diabetes (treated)	9776 (0.85%)	1352 (0.81%)	1901 (0.82%)	4498 (0.88%)	2025 (0.83%)
Gallbladder disease[2,3]	5652 (0.95%)	832 (0.96%)	1141 (0.98%)	2534 (0.98%)	1145 (0.85%)
Hysterectomy	4404 (0.37%)	664 (0.39%)	991 (0.42%)	2009 (0.38%)	740 (0.29%)
Glaucoma[3]	8452 (1.26%)	843 (0.87%)	1364 (1.04%)	3886 (1.32%)	2359 (1.56%)
Osteoporosis[3]	20667 (3.20%)	2090 (2.21%)	3364 (2.62%)	9501 (3.38%)	5712 (4.01%)
Osteoarthritis[4]	23827 (3.41%)	3499 (2.82%)	4832 (3.09%)	10580 (3.58%)	4916 (4.01%)
Rheumatoid arthritis[3]	4571 (0.68%)	634 (0.67%)	877 (0.68%)	1880 (0.64%)	1180 (0.76%)
Intestinal polyps	20024 (1.85%)	2781 (1.70%)	4273 (1.92%)	9205 (1.94%)	3765 (1.71%)
Lupus	1419 (0.12%)	191 (0.11%)	272 (0.11%)	647 (0.12%)	309 (0.12%)
Kidney stones[3,4]	2314 (0.34%)	292 (0.31%)	433 (0.33%)	994 (0.34%)	595 (0.38%)
Cataracts[3,4]	27103 (4.66%)	1726 (1.81%)	4088 (3.20%)	14045 (5.47%)	7244 (7.13%)
Pills for hypertension	31036 (3.58%)	3936 (2.75%)	5872 (3.13%)	13954 (3.74%)	7274 (4.47%)

Outcomes	Race/Ethnicity: American Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number enrolled	421	2671	7635	3609	78016	1324
Mean follow-up (months)	131.7	132.8	128.3	123.2	157.6	140.9
Hospitalizations						
Ever	264 (5.71%)	1100 (3.72%)	4329 (5.31%)	1641 (4.43%)	52158 (5.09%)	786 (5.06%)
Two or more	179 (3.87%)	552 (1.87%)	2626 (3.22%)	903 (2.44%)	34720 (3.39%)	511 (3.29%)
Other						
DVT[1]	4 (0.09%)	9 (0.03%)	135 (0.17%)	25 (0.07%)	1317 (0.13%)	17 (0.11%)
Pulmonary embolism	3 (0.07%)	8 (0.03%)	92 (0.11%)	13 (0.04%)	1098 (0.11%)	7 (0.05%)
Diabetes (treated)	71 (1.75%)	277 (0.98%)	1150 (1.58%)	479 (1.38%)	7649 (0.77%)	150 (1.01%)
Gallbladder disease[2,3]	31 (1.32%)	81 (0.46%)	374 (0.77%)	230 (1.18%)	4860 (0.97%)	76 (0.94%)
Hysterectomy	11 (0.24%)	72 (0.24%)	160 (0.20%)	134 (0.36%)	3959 (0.39%)	68 (0.44%)
Glaucoma[3]	45 (1.64%)	253 (1.35%)	987 (1.97%)	308 (1.31%)	6737 (1.18%)	122 (1.32%)
Osteoporosis[3]	90 (3.29%)	625 (3.50%)	1069 (2.06%)	735 (3.21%)	17825 (3.29%)	323 (3.64%)
Osteoarthritis[4]	88 (3.45%)	697 (3.33%)	1731 (3.64%)	967 (3.98%)	20004 (3.37%)	340 (3.56%)
Rheumatoid arthritis[3]	38 (1.39%)	98 (0.52%)	661 (1.33%)	382 (1.65%)	3306 (0.58%)	86 (0.95%)
Intestinal polyps	66 (1.57%)	456 (1.73%)	1487 (1.99%)	596 (1.72%)	17173 (1.85%)	246 (1.77%)
Lupus	10 (0.22%)	25 (0.09%)	137 (0.17%)	70 (0.19%)	1158 (0.11%)	19 (0.12%)
Kidney stones[3,4]	17 (0.61%)	40 (0.21%)	263 (0.50%)	125 (0.53%)	1825 (0.32%)	44 (0.47%)
Cataracts[3,4]	102 (4.20%)	683 (4.33%)	1937 (4.26%)	894 (4.11%)	23094 (4.73%)	393 (5.02%)
Pills for hypertension	129 (4.29%)	755 (3.59%)	2024 (4.98%)	1114 (3.96%)	26567 (3.48%)	447 (4.02%)

[1] Inpatient DVT only.
[2] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[3] Data not collected for the WHI Extension Studies.
[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 6.1
Lost-to-Follow-up and Vital Status: CT Participants

Data as of: September 20, 2013
WHI Extension Study 2010-2015 Participants

	CT Participants (N = 41,497) N	%
Vital Status/Participation		
Deceased	2025	4.9
Alive: Current Participation[1]	38068	91.7
Alive: Recent Participation[2]	782	1.9
Alive: Past/Unknown Participation[3]	9	<0.1
Stopped Follow-Up[4]	364	0.9
Lost to Follow-Up[5]	249	0.6

Data as of: September 20, 2013; Status as of September 30, 2010
WHI Extension Study 2005-2010 Participants

	CT Participants (N = 52,176) N	%
Vital Status/Participation		
Deceased	3770	7.2
Alive: Current Participation[1]	46915	89.9
Alive: Recent Participation[2]	448	0.9
Alive: Past/Unknown Participation[3]	38	0.1
Stopped Follow-Up[4]	651	1.2
Lost to Follow-Up[5]	354	0.7

Data as of: September 20, 2013; Status as of April 8, 2005
WHI Participants

	CT Participants (N = 68,132) N	%
Vital Status/Participation		
Deceased	3696	5.4
Alive: Current Participation[6]	61165	89.8
Alive: Recent Participation[7]	339	0.5
Alive: Past/Unknown Participation[8]	10	<0.1
Stopped Follow-Up[4]	2194	3.2
Lost to Follow-Up[5]	728	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 15 months.
[7] Participants who last filled in a Form 33 between 15 and 24 months ago.
[8] Participants without a Form 33 within the last 24 months, who have been located (as indicated on Form 23) within the last 6 months.

Table 6.2
Verified Outcomes (Annualized Percentages) by Age for CT Participants

Data as of: September 20, 2013; Events through September 30, 2010

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	68132		9188		14661		31389		12894	
Mean follow-up (months)	146.5		155.8		152.7		145.9		134.0	
Cardiovascular										
CHD[1]	3604	(0.43%)	192	(0.16%)	410	(0.22%)	1678	(0.44%)	1324	(0.92%)
CHD death[2]	1227	(0.15%)	48	(0.04%)	90	(0.05%)	524	(0.14%)	565	(0.39%)
Total MI[3]	2727	(0.33%)	154	(0.13%)	339	(0.18%)	1283	(0.34%)	951	(0.66%)
Clinical MI	2651	(0.32%)	148	(0.12%)	331	(0.18%)	1245	(0.33%)	927	(0.64%)
Angina[4]	2414	(0.43%)	129	(0.16%)	331	(0.27%)	1215	(0.48%)	739	(0.73%)
CABG/PTCA	3947	(0.47%)	216	(0.18%)	550	(0.29%)	2082	(0.55%)	1099	(0.76%)
Carotid artery disease	693	(0.08%)	27	(0.02%)	90	(0.05%)	371	(0.10%)	205	(0.14%)
Congestive heart failure,WHI[4]	1748	(0.31%)	81	(0.10%)	172	(0.14%)	745	(0.29%)	750	(0.74%)
Stroke	2741	(0.33%)	119	(0.10%)	274	(0.15%)	1286	(0.34%)	1062	(0.74%)
PVD	647	(0.08%)	29	(0.02%)	86	(0.05%)	333	(0.09%)	199	(0.14%)
Coronary disease[5]	7813	(0.94%)	441	(0.37%)	101	(0.55%)	3806	(1.00%)	2548	(1.77%)
Total cardiovascular disease	10849	(1.30%)	585	(0.49%)	136	(0.73%)	5248	(1.37%)	3651	(2.54%)
Cancer										
Breast cancer	4220	(0.51%)	513	(0.43%)	939	(0.50%)	1997	(0.52%)	771	(0.54%)
Invasive breast cancer	3420	(0.41%)	390	(0.33%)	768	(0.41%)	1614	(0.42%)	648	(0.45%)
Non-invasive breast cancer	855	(0.10%)	129	(0.11%)	182	(0.10%)	409	(0.11%)	135	(0.09%)
Ovary cancer	371	(0.04%)	35	(0.03%)	73	(0.04%)	190	(0.05%)	73	(0.05%)
Endometrial cancer[6]	572	(0.07%)	64	(0.05%)	138	(0.07%)	274	(0.07%)	96	(0.07%)
Colorectal cancer	1114	(0.13%)	70	(0.06%)	181	(0.10%)	541	(0.14%)	322	(0.22%)
Other cancer[7]	4931	(0.59%)	405	(0.34%)	839	(0.45%)	2466	(0.65%)	1221	(0.85%)
Total cancer	10587	(1.27%)	1037	(0.87%)	206	(1.11%)	5149	(1.35%)	2339	(1.62%)
Fractures										
Hip fracture	1638	(0.20%)	32	(0.03%)	115	(0.06%)	665	(0.17%)	826	(0.57%)
Deaths										
Cardiovascular deaths	2429	(0.29%)	86	(0.07%)	176	(0.09%)	990	(0.26%)	1177	(0.82%)
Cancer deaths	3110	(0.37%)	189	(0.16%)	430	(0.23%)	1559	(0.41%)	932	(0.65%)
Other known cause	1937	(0.23%)	82	(0.07%)	183	(0.10%)	822	(0.22%)	850	(0.59%)
Unknown cause	67	(0.01%)	2	(<0.01%)	13	(0.01%)	27	(0.01%)	25	(0.02%)
Not yet adjudicated	1	(<0.01%)	0	(0.00%)	1	(<0.01%)	0	(0.00%)	0	(0.00%)
Total death	7544	(0.91%)	359	(0.30%)	803	(0.43%)	3398	(0.89%)	2984	(2.07%)
Death plus post-WHI deaths[8]	9227	(1.02%)	421	(0.32%)	927	(0.46%)	4065	(0.99%)	3814	(2.41%)

[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 2005-2010. 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.
[8] Includes deaths for non-Extension study participants after the main WHI study close-out. Annualized rates incorporate additional follow-up from the NDI search.

Table 6.3
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for CT Participants

Data as of: September 20, 2013; Events through September 30, 2010

Outcomes	Race/Ethnicity: American Indian/Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number enrolled	292	1519	6983	2875	55525	938
Mean follow-up (months)	135.1	140.5	139.2	131.5	148.5	137.3
Cardiovascular						
CHD[1]	8 (0.24%)	46 (0.26%)	349 (0.43%)	72 (0.23%)	3081 (0.45%)	48 (0.45%)
CHD death[2]	2 (0.06%)	13 (0.07%)	165 (0.20%)	22 (0.07%)	1006 (0.15%)	19 (0.18%)
Total MI[3]	7 (0.21%)	40 (0.22%)	229 (0.28%)	56 (0.18%)	2358 (0.34%)	37 (0.34%)
Clinical MI	7 (0.21%)	39 (0.22%)	224 (0.28%)	54 (0.17%)	2292 (0.33%)	35 (0.33%)
Angina[4]	12 (0.51%)	30 (0.25%)	298 (0.53%)	80 (0.36%)	1964 (0.43%)	30 (0.41%)
CABG/PTCA	13 (0.40%)	42 (0.24%)	337 (0.42%)	104 (0.33%)	3408 (0.50%)	43 (0.40%)
Carotid artery disease	3 (0.09%)	3 (0.02%)	42 (0.05%)	6 (0.02%)	630 (0.09%)	9 (0.08%)
Congestive heart failure, WHI[4]	5 (0.21%)	17 (0.14%)	244 (0.43%)	49 (0.22%)	1409 (0.31%)	24 (0.32%)
Stroke	10 (0.30%)	40 (0.22%)	341 (0.42%)	67 (0.21%)	2242 (0.33%)	41 (0.38%)
PVD	5 (0.15%)	7 (0.04%)	99 (0.12%)	8 (0.03%)	520 (0.08%)	8 (0.07%)
Coronary disease[5]	26 (0.79%)	98 (0.55%)	853 (1.05%)	210 (0.67%)	6526 (0.95%)	100 (0.93%)
Total cardiovascular disease	40 (1.22%)	141 (0.79%)	1217 (1.50%)	279 (0.89%)	9033 (1.31%)	139 (1.30%)
Cancer						
Breast cancer	10 (0.30%)	95 (0.53%)	363 (0.45%)	104 (0.33%)	3605 (0.52%)	43 (0.40%)
Invasive breast cancer	7 (0.21%)	72 (0.40%)	286 (0.35%)	86 (0.27%)	2935 (0.43%)	34 (0.32%)
Non-invasive breast cancer	3 (0.09%)	25 (0.14%)	81 (0.10%)	20 (0.06%)	716 (0.10%)	10 (0.09%)
Ovarian cancer	2 (0.06%)	10 (0.06%)	27 (0.03%)	9 (0.03%)	318 (0.05%)	5 (0.05%)
Endometrial cancer[6]	1 (0.03%)	7 (0.04%)	37 (0.05%)	13 (0.04%)	506 (0.07%)	8 (0.07%)
Colorectal cancer	6 (0.18%)	24 (0.13%)	115 (0.14%)	31 (0.10%)	921 (0.13%)	17 (0.16%)
Other cancer[7]	12 (0.37%)	79 (0.44%)	359 (0.44%)	124 (0.39%)	4299 (0.63%)	58 (0.54%)
Total cancer	29 (0.88%)	203 (1.14%)	850 (1.05%)	263 (0.83%)	9121 (1.33%)	121 (1.13%)
Fractures						
Hip fracture	5 (0.15%)	16 (0.09%)	40 (0.05%)	24 (0.08%)	1541 (0.22%)	12 (0.11%)
Deaths						
Cardiovascular deaths	9 (0.27%)	30 (0.17%)	322 (0.40%)	44 (0.14%)	1997 (0.29%)	27 (0.25%)
Cancer deaths	11 (0.33%)	50 (0.28%)	264 (0.33%)	90 (0.29%)	2654 (0.39%)	41 (0.38%)
Other known cause	13 (0.40%)	22 (0.12%)	174 (0.21%)	44 (0.14%)	1662 (0.24%)	22 (0.21%)
Unknown cause	0 (0.00%)	3 (0.02%)	10 (0.01%)	3 (0.01%)	50 (0.01%)	1 (0.01%)
Not yet adjudicated	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (<0.01%)	0 (0.00%)
Total death	33 (1.00%)	105 (0.59%)	770 (0.95%)	181 (0.57%)	6364 (0.93%)	91 (0.85%)
Death plus post-WHI deaths[8]	47 (1.26%)	141 (0.70%)	988 (1.08%)	243 (0.64%)	7681 (1.04%)	127 (1.05%)

[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 2005-2010. Reported statistics represent experience during the original program.
[5] "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 Studies.
[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.
[8] Includes deaths for non-Extension study participants after the main WHI study close-out. Annualized rates incorporate additional follow-up from the NDI search.

Table 6.4
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: September 20, 2013; Events through September 20, 2013

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	68132	9188	14661	31389	12894
Mean follow-up (months)	163.9	175.8	172.8	163.8	145.6
Hospitalizations					
Ever	46709 (5.02%)	4949 (3.68%)	8848 (4.19%)	22514 (5.25%)	10398 (6.65%)
Two or more	32014 (3.44%)	2888 (2.15%)	5539 (2.62%)	15774 (3.68%)	7813 (5.00%)
Other					
DVT[1]	1548 (0.17%)	110 (0.08%)	231 (0.11%)	764 (0.18%)	443 (0.29%)
Pulmonary embolism	1142 (0.12%)	92 (0.07%)	192 (0.09%)	587 (0.14%)	271 (0.17%)
Diabetes (treated)	9440 (1.06%)	1385 (1.06%)	2098 (1.03%)	4438 (1.08%)	1519 (1.02%)
Gallbladder disease[2,3]	5248 (1.15%)	746 (1.07%)	1195 (1.15%)	2463 (1.21%)	844 (1.05%)
Hysterectomy	3178 (0.58%)	439 (0.56%)	793 (0.60%)	1507 (0.61%)	439 (0.50%)
Glaucoma[3]	7565 (1.44%)	744 (0.96%)	1457 (1.23%)	3662 (1.54%)	1702 (1.86%)
Osteoporosis[3]	14695 (2.85%)	1450 (1.88%)	2635 (2.24%)	7142 (3.07%)	3468 (3.92%)
Osteoarthritis[4]	19760 (3.32%)	3004 (2.84%)	4629 (3.07%)	9020 (3.49%)	3107 (3.85%)
Rheumatoid arthritis[3]	4009 (0.76%)	538 (0.70%)	866 (0.74%)	1822 (0.77%)	783 (0.84%)
Intestinal polyps	16378 (1.89%)	2303 (1.77%)	3837 (1.91%)	7875 (1.99%)	2363 (1.71%)
Lupus	1030 (0.11%)	140 (0.10%)	235 (0.11%)	485 (0.11%)	170 (0.11%)
Kidney stones[3,4]	1877 (0.36%)	241 (0.31%)	379 (0.32%)	898 (0.38%)	359 (0.38%)
Cataracts[3,4]	21570 (4.54%)	1468 (1.90%)	3731 (3.20%)	11649 (5.43%)	4722 (7.09%)
Pills for hypertension	25167 (3.80%)	3369 (3.08%)	5570 (3.44%)	11779 (4.00%)	4449 (4.60%)

Outcomes	Race/Ethnicity: Am Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	292	1519	6983	2875	55525	938
Mean follow-up (months)	149.2	156.5	153.0	143.3	166.8	152.5
Hospitalizations						
Ever	188 (5.18%)	785 (3.96%)	4533 (5.09%)	1514 (4.41%)	39097 (5.06%)	592 (4.97%)
Two or more	132 (3.64%)	443 (2.24%)	3050 (3.43%)	869 (2.53%)	27142 (3.52%)	378 (3.17%)
Other						
DVT[1]	6 (0.17%)	8 (0.04%)	174 (0.20%)	29 (0.09%)	1316 (0.18%)	15 (0.13%)
Pulmonary embolism	6 (0.17%)	5 (0.03%)	114 (0.13%)	20 (0.06%)	984 (0.13%)	13 (0.11%)
Diabetes (treated)	47 (1.42%)	233 (1.25%)	1421 (1.79%)	526 (1.63%)	7081 (0.95%)	132 (1.18%)
Gallbladder disease[2,3]	22 (1.31%)	86 (0.81%)	420 (0.85%)	243 (1.45%)	4403 (1.18%)	74 (1.20%)
Hysterectomy	8 (0.50%)	49 (0.38%)	210 (0.54%)	110 (0.57%)	2770 (0.59%)	31 (0.44%)
Glaucoma[3]	40 (1.85%)	153 (1.35%)	1005 (1.96%)	338 (1.59%)	5930 (1.37%)	99 (1.47%)
Osteoporosis[3]	66 (3.04%)	389 (3.49%)	909 (1.71%)	639 (3.12%)	12483 (2.96%)	209 (3.11%)
Osteoarthritis[4]	87 (3.84%)	463 (3.18%)	1868 (3.38%)	914 (3.77%)	16144 (3.28%)	284 (3.67%)
Rheumatoid arthritis[3]	32 (1.55%)	74 (0.66%)	682 (1.33%)	357 (1.70%)	2787 (0.65%)	77 (1.13%)
Intestinal polyps	75 (2.24%)	334 (1.85%)	1753 (2.11%)	568 (1.73%)	13438 (1.88%)	210 (1.91%)
Lupus	8 (0.22%)	16 (0.08%)	136 (0.15%)	47 (0.14%)	808 (0.11%)	15 (0.13%)
Kidney stones[3,4]	15 (0.71%)	47 (0.42%)	190 (0.35%)	100 (0.48%)	1501 (0.35%)	24 (0.35%)
Cataracts[3,4]	92 (4.68%)	428 (4.21%)	2002 (4.10%)	828 (4.10%)	17927 (4.62%)	293 (4.72%)
Pills for hypertension	102 (4.23%)	533 (3.91%)	2182 (4.84%)	1083 (4.20%)	20962 (3.69%)	305 (3.78%)

[1] Inpatient DVT only.
[2] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[3] Data not collected for the WHI Extension Studies.
[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 6.5
Verified Other Cancers (Annualized Percentages): CT and OS Participants

Data as of: September 20, 2013; Events through September 20, 2013

	CT	OS
Number of participants	68132	93676
Mean follow-up time (months)	163.9	152.8
Ppts with other cancer	5346 (0.57%)	7014 (0.59%)
Accessory sinus	1 (<0.01%)	4 (<0.01%)
Adrenal gland	2 (<0.01%)	6 (<0.01%)
Anus	34 (<0.01%)	46 (<0.01%)
Appendix	15 (<0.01%)	14 (<0.01%)
Biliary tract, parts of (other/unspecified)	46 (<0.01%)	46 (<0.01%)
Bladder	319 (0.03%)	405 (0.03%)
Bones/joints/articular cartilage (limbs)	4 (<0.01%)	6 (<0.01%)
Bones/joints/articular cartilage (other)	8 (<0.01%)	5 (<0.01%)
Brain	102 (0.01%)	119 (0.01%)
Cervix	52 (0.01%)	48 (<0.01%)
Central Nervous System (excludes brain)	0 (0.00%)	2 (<0.01%)
Connective/subcutaneous/soft tissues	52 (0.01%)	59 (<0.01%)
Endocrine glands, related structures	1 (<0.01%)	1 (<0.01%)
Esophagus	48 (0.01%)	46 (<0.01%)
Eye and adnexa	40 (<0.01%)	29 (<0.01%)
Genital organs	35 (<0.01%)	53 (<0.01%)
Kidney	255 (0.03%)	283 (0.02%)
Larynx	25 (<0.01%)	21 (<0.01%)
Leukemia	306 (0.03%)	387 (0.03%)
Liver	61 (0.01%)	82 (0.01%)
Lung	1169 (0.13%)	1493 (0.13%)
Lymph nodes	2 (<0.01%)	0 (0.00%)
Lymphoma, Hodgkins	21 (<0.01%)	30 (<0.01%)
Lymphoma, Non-Hodgkins	524 (0.06%)	747 (0.06%)
Melanoma of the skin	756 (0.08%)	1014 (0.08%)
Multiple myeloma	198 (0.02%)	216 (0.02%)
Oral (mouth)	10 (<0.01%)	9 (<0.01%)
Palate	10 (<0.01%)	17 (<0.01%)
Pancreas	305 (0.03%)	378 (0.03%)
Parotid gland (Stensen's duct)	16 (<0.01%)	32 (<0.01%)
Peripheral nerves and autonomic nervous	1 (<0.01%)	1 (<0.01%)
Pyriform sinus	0 (0.00%)	2 (<0.01%)
Respiratory system, intrathoracic, other	1 (<0.01%)	1 (<0.01%)
Salivary glands, major (other/unspecified)	5 (<0.01%)	10 (<0.01%)
Stomach	94 (0.01%)	115 (0.01%)
Thyroid	178 (0.02%)	235 (0.02%)
Tongue, part of (other/unspecified)	21 (<0.01%)	29 (<0.01%)
Urinary organs (other/unspecified)	9 (<0.01%)	11 (<0.01%)
Uterus, not otherwise specified	6 (<0.01%)	2 (<0.01%)
Other/unknown site of cancer	548 (0.06%)	747 (0.06%)
Other/unknown cancers reported on death	249 (0.03%)	501 (0.04%)

Table 6.6
Self Reported Fractures (Annualized Percentages): CT and OS Participants

Data as of: September 20, 2013; Events through September 20, 2013

	CT		OS	
Number of participants	68132		93676	
Mean follow-up time (months)	163.9		152.8	
Elbow	988	(0.11%)	1334	(0.11%)
Foot	3385	(0.36%)	4238	(0.36%)
Hand	917	(0.10%)	1052	(0.09%)
Hip	2136	(0.23%)	2975	(0.25%)
Knee	1394	(0.15%)	1829	(0.15%)
Lower arm	4784	(0.51%)	6046	(0.51%)
Lower leg	3699	(0.40%)	4592	(0.38%)
Pelvis	1110	(0.12%)	1788	(0.15%)
Tailbone	401	(0.04%)	577	(0.05%)
Upper arm	2633	(0.28%)	3249	(0.27%)
Upper leg	872	(0.09%)	1202	(0.10%)
Spine	3049	(0.33%)	4449	(0.37%)
Other	6763	(0.73%)	8775	(0.74%)
Total fracture	21756	(2.34%)	28482	(2.39%)

Table 6.7
Cause of Death[1] (Annualized Percentages): CT and OS Participants

Data as of: September 20, 2013; Events through September 20, 2013

	CT		OS	
Number of participants	68132		93676	
Mean Follow-up Time (months)	179.8		176.3	
Death plus post-WHI deaths	12056	(1.18%)	19255	(1.40%)
Adjudicated death	10646	(1.04%)	16696	(1.21%)
Centrally adjudicated death	9052	(0.89%)	7713	(0.56%)
Locally adjudicated death (final)	1	(<0.01%)	5578	(0.41%)
Identified by NDI search	1593	(0.16%)	3405	(0.25%)
Not yet adjudicated	280	(0.03%)	65	(<0.01%)
Form 120 death[2]	1130	(0.11%)	2494	(0.18%)
Cardiovascular				
Atherosclerotic cardiac	1768	(0.17%)	2617	(0.19%)
Definite CHD deaths after 10/99	836	(0.08%)	1022	(0.07%)
Possible CHD deaths after 10/99	911	(0.09%)	1536	(0.11%)
Cerebrovascular	869	(0.09%)	1462	(0.11%)
Pulmonary embolism	94	(0.01%)	102	(0.01%)
Other cardiovascular	883	(0.09%)	1664	(0.12%)
Unknown cardiovascular	32	(<0.01%)	108	(0.01%)
Total cardiovascular deaths	3646	(0.36%)	5953	(0.43%)
Cancer				
Breast cancer	328	(0.03%)	872	(0.06%)
Ovarian cancer	265	(0.03%)	432	(0.03%)
Endometrial cancer	72	(0.01%)	98	(0.01%)
Colorectal cancer	348	(0.03%)	495	(0.04%)
Uterus cancer	28	(<0.01%)	54	(<0.01%)
Lung cancer	1010	(0.10%)	1336	(0.10%)
Pancreas cancer	368	(0.04%)	501	(0.04%)
Lymphoma (NHL only)	182	(0.02%)	292	(0.02%)
Leukemia	177	(0.02%)	244	(0.02%)
Brain cancer	129	(0.01%)	161	(0.01%)
Multiple myeloma	139	(0.01%)	156	(0.01%)
Other cancer	832	(0.08%)	1212	(0.09%)
Unknown cancer site	199	(0.02%)	305	(0.02%)
Total cancer deaths	4077	(0.40%)	6158	(0.45%)
Accident/injury				
Homicide	14	(<0.01%)	18	(<0.01%)
Accident	306	(0.03%)	450	(0.03%)
Suicide	24	(<0.01%)	51	(<0.01%)
Other injury	13	(<0.01%)	32	(<0.01%)
Total accidental deaths	357	(0.03%)	551	(0.04%)

[1] Includes deaths for non-Extension Study participants after the main WHI study close-out. Annualized rates incorporate additional follow-up from the NDI search.
[2] Includes SRC participants and discovered deaths among non-Extension Study 2010-2015 participants that occurred during Extension Study 2010-2015.

Table 6.7 (continued)
Cause of Death[1] (Annualized Percentages): CT and OS Participants

Data as of: September 20, 2013; Events through September 20, 2013

	CT		OS	
Other				
Alzheimer's disease	384	(0.04%)	779	(0.06%)
COPD	467	(0.05%)	684	(0.05%)
Pneumonia	319	(0.03%)	539	(0.04%)
Pulmonary fibrosis	86	(0.01%)	124	(0.01%)
Renal failure	168	(0.02%)	289	(0.02%)
Sepsis	236	(0.02%)	334	(0.02%)
Dementia, NOS	344	(0.03%)	643	(0.05%)
Amyotrophic Lateral Sclerosis	5	(<0.01%)	0	(0.00%)
Parkinson's	94	(0.01%)	165	(0.01%)
Hepatic cirrhosis	76	(0.01%)	114	(0.01%)
Other known cause	1043	(0.10%)	1931	(0.14%)
Unknown cause	383	(0.04%)	831	(0.06%)
Total other cause deaths	3605	(0.35%)	6433	(0.47%)

[1] Includes deaths for non-Extension Study participants after the main WHI study close-out. Annualized rates incorporate additional follow-up from the NDI search.

Table 7.1
Lost-to-Follow-up and Vital Status: WHI Extension Study 2010-2015 Participants by Cohort

Data as of: September 20, 2013; Events through September 20, 2013

	MRC (N = 22,315)		SRC (N = 71,247)		Total Participants (N = 93,562)	
	N	%	N	%	N	%
Vital Status/Participation						
Deceased	1133	5.1	3438	4.8	4571	4.9
Alive: Current Participation[1]	20068	89.9	65980	92.6	86048	92.0
Alive: Recent Participation[2]	591	2.6	1040	1.5	1631	1.7
Alive: Past/Unknown Participation[3]	7	<0.1	16	<0.1	23	<0.1
Stopped Follow-Up[4]	288	1.3	525	0.7	813	0.9
Lost to Follow-Up[5]	228	1.0	248	0.3	476	0.5

[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 7.2
Verified Outcomes (Annualized Percentages) by Age for MRC Participants

Data as of: September 20, 2013; Events through September 20, 2013

Outcomes	Total	Age 50-54	55-59	60-69	70-79
Number randomized	22315	3727	5292	10112	3184
Mean follow-up (months)	195.6	200.8	198.2	194.1	190.2
Cardiovascular					
CHD[1]	1019 (0.28%)	88 (0.14%)	152 (0.17%)	513 (0.31%)	266 (0.53%)
CHD death[2]	115 (0.03%)	5 (0.01%)	14 (0.02%)	45 (0.03%)	51 (0.10%)
Clinical MI	929 (0.26%)	83 (0.13%)	145 (0.17%)	478 (0.29%)	223 (0.44%)
Angina[3]	692 (0.37%)	57 (0.17%)	113 (0.25%)	374 (0.44%)	148 (0.57%)
CABG/PTCA	1478 (0.41%)	141 (0.23%)	265 (0.30%)	800 (0.49%)	272 (0.54%)
Carotid artery disease	259 (0.07%)	11 (0.02%)	36 (0.04%)	156 (0.10%)	56 (0.11%)
Congestive heart failure, WHI[3]	307 (0.16%)	34 (0.10%)	39 (0.09%)	156 (0.19%)	78 (0.30%)
Heart failure, UNC[4]	574 (0.18%)	43 (0.08%)	64 (0.09%)	298 (0.21%)	169 (0.39%)
Stroke	802 (0.22%)	63 (0.10%)	117 (0.13%)	421 (0.26%)	201 (0.40%)
PVD	265 (0.07%)	23 (0.04%)	43 (0.05%)	141 (0.09%)	58 (0.11%)
Coronary disease[5]	2391 (0.66%)	229 (0.37%)	408 (0.47%)	1230 (0.75%)	524 (1.04%)
Aortic aneurysm[6]	21 (0.04%)	0 (0.00%)	2 (0.02%)	13 (0.05%)	6 (0.09%)
Atrial fibrillation[6]	454 (0.86%)	28 (0.31%)	60 (0.47%)	253 (1.06%)	113 (1.60%)
Valvular heart disease[6]	108 (0.21%)	6 (0.07%)	7 (0.05%)	63 (0.26%)	32 (0.45%)
Total cardiovascular disease[7]	3337 (0.92%)	301 (0.48%)	558 (0.64%)	1711 (1.05%)	767 (1.52%)
Cancer					
Breast cancer	1566 (0.43%)	235 (0.38%)	391 (0.45%)	709 (0.43%)	231 (0.46%)
Invasive breast cancer	1251 (0.34%)	178 (0.29%)	310 (0.35%)	560 (0.34%)	203 (0.40%)
Non-invasive breast cancer	343 (0.09%)	60 (0.10%)	85 (0.10%)	166 (0.10%)	32 (0.06%)
Ovarian cancer	90 (0.02%)	13 (0.02%)	22 (0.03%)	44 (0.03%)	11 (0.02%)
Endometrial cancer[8]	180 (0.05%)	33 (0.05%)	49 (0.06%)	76 (0.05%)	22 (0.04%)
Colorectal cancer	356 (0.10%)	41 (0.07%)	68 (0.08%)	179 (0.11%)	68 (0.13%)
Other cancer[9]	1173 (0.32%)	146 (0.23%)	269 (0.31%)	560 (0.34%)	198 (0.39%)
Total cancer	3175 (0.87%)	445 (0.71%)	761 (0.87%)	1476 (0.90%)	493 (0.98%)
Fractures					
Hip fracture	533 (0.15%)	21 (0.03%)	38 (0.04%)	260 (0.16%)	214 (0.42%)
Deaths[10]					
Cardiovascular deaths	284 (0.08%)	11 (0.02%)	27 (0.03%)	109 (0.07%)	137 (0.27%)
Cancer deaths	263 (0.07%)	26 (0.04%)	48 (0.05%)	117 (0.07%)	72 (0.14%)
Other known cause	258 (0.07%)	9 (0.01%)	18 (0.02%)	119 (0.07%)	112 (0.22%)
Unknown cause	15 (<0.01%)	0 (0.00%)	0 (0.00%)	6 (<0.01%)	9 (0.02%)
Not yet adjudicated	313 (0.09%)	17 (0.03%)	36 (0.04%)	152 (0.09%)	108 (0.21%)
Total death	1133 (0.31%)	63 (0.10%)	129 (0.15%)	503 (0.31%)	438 (0.87%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Studies.
[2] "CHD death" includes definite and possible CHD death.
[3] Angina and CHF are not verified outcomes in the WHI Extension Studies. Reported statistics represent experience during the original program.
[4] UNC HF is not a verified outcome during the WHI Extension Study 2010-2015. Reported Statistics represent experience during the original program and the Extension Study 2005-2010.
[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 and angina are not collected in the WHI Extension Studies. Congestive heart failure is not collected in the WHI Extension Study 2005-2010.
[6] Aortic aneurysm, atrial fibrillation and valvular heart disease are new adjudicated outcomes during the WHI Extension Study 2010-2015.
[7] Total CVD does not include aortic aneurysm, atrial fibrillation or valvular heart disease.
[8] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[9] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.
[10] Deaths from Extension Study 2010-2015.

Table 7.3
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for MRC Participants

Data as of: September 20, 2013; Events through September 20, 2013

Outcomes	Race/Ethnicity: American Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	64	240	6136	2472	13203	200
Mean follow-up (months)	194.7	193.1	194.9	193.1	196.6	192.1
Cardiovascular						
CHD[1]	5 (0.48%)	8 (0.21%)	217 (0.22%)	72 (0.18%)	712 (0.33%)	5 (0.16%)
CHD death[2]	2 (0.19%)	1 (0.03%)	31 (0.03%)	4 (0.01%)	77 (0.04%)	0 (0.00%)
Clinical MI	4 (0.39%)	6 (0.16%)	197 (0.20%)	69 (0.17%)	648 (0.30%)	5 (0.16%)
Angina[3]	3 (0.55%)	2 (0.10%)	206 (0.40%)	59 (0.29%)	416 (0.37%)	6 (0.37%)
CABG/PTCA	7 (0.67%)	10 (0.26%)	329 (0.33%)	128 (0.32%)	989 (0.46%)	15 (0.47%)
Carotid artery disease	0 (0.00%)	1 (0.03%)	39 (0.04%)	9 (0.02%)	209 (0.10%)	1 (0.03%)
Congestive heart failure, WHI[3]	1 (0.18%)	1 (0.05%)	98 (0.19%)	19 (0.09%)	186 (0.16%)	2 (0.12%)
Heart failure, UNC[4]	3 (0.34%)	4 (0.12%)	156 (0.18%)	22 (0.06%)	386 (0.21%)	3 (0.11%)
Stroke	5 (0.48%)	2 (0.05%)	235 (0.24%)	45 (0.11%)	507 (0.23%)	8 (0.25%)
PVD	1 (0.10%)	1 (0.03%)	77 (0.08%)	11 (0.03%)	173 (0.08%)	2 (0.06%)
Coronary disease[5]	10 (0.96%)	18 (0.47%)	592 (0.59%)	187 (0.47%)	1561 (0.72%)	23 (0.72%)
Aortic aneurysm[6]	0 (0.00%)	0 (0.00%)	6 (0.04%)	3 (0.05%)	12 (0.04%)	0 (0.00%)
Atrial fibrillation[6]	0 (0.00%)	1 (0.18%)	58 (0.40%)	23 (0.40%)	367 (1.17%)	5 (1.07%)
Valvular heart disease[6]	1 (0.70%)	1 (0.18%)	23 (0.16%)	8 (0.14%)	72 (0.23%)	3 (0.64%)
Total cardiovascular disease[7]	14 (1.35%)	20 (0.52%)	864 (0.87%)	239 (0.60%)	2172 (1.00%)	28 (0.87%)
Cancer						
Breast cancer	5 (0.48%)	22 (0.57%)	451 (0.45%)	152 (0.38%)	925 (0.43%)	11 (0.34%)
Invasive breast cancer	4 (0.39%)	15 (0.39%)	347 (0.35%)	125 (0.31%)	751 (0.35%)	9 (0.28%)
Non-invasive breast cancer	1 (0.10%)	7 (0.18%)	116 (0.12%)	28 (0.07%)	188 (0.09%)	3 (0.09%)
Ovarian cancer	1 (0.10%)	1 (0.03%)	22 (0.02%)	10 (0.03%)	55 (0.03%)	1 (0.03%)
Endometrial cancer[8]	1 (0.10%)	2 (0.05%)	41 (0.04%)	10 (0.03%)	125 (0.06%)	1 (0.03%)
Colorectal cancer	1 (0.10%)	6 (0.16%)	90 (0.09%)	29 (0.07%)	227 (0.10%)	3 (0.09%)
Other cancer[9]	4 (0.39%)	9 (0.23%)	240 (0.24%)	88 (0.22%)	819 (0.38%)	13 (0.41%)
Total cancer	11 (1.06%)	38 (0.98%)	796 (0.80%)	276 (0.69%)	2025 (0.94%)	29 (0.91%)
Fractures						
Hip fracture	3 (0.29%)	2 (0.05%)	38 (0.04%)	24 (0.06%)	460 (0.21%)	6 (0.19%)
Deaths[10]						
Cardiovascular deaths	3 (0.29%)	1 (0.03%)	74 (0.07%)	8 (0.02%)	197 (0.09%)	1 (0.03%)
Cancer deaths	2 (0.19%)	3 (0.08%)	54 (0.05%)	27 (0.07%)	173 (0.08%)	4 (0.12%)
Other known cause	0 (0.00%)	3 (0.08%)	43 (0.04%)	14 (0.04%)	197 (0.09%)	1 (0.03%)
Unknown cause	0 (0.00%)	0 (0.00%)	3 (<0.01%)	2 (0.01%)	10 (<0.01%)	0 (0.00%)
Not yet adjudicated	1 (0.10%)	2 (0.05%)	73 (0.07%)	18 (0.05%)	216 (0.10%)	3 (0.09%)
Total Death	6 (0.58%)	9 (0.23%)	247 (0.25%)	69 (0.17%)	793 (0.37%)	9 (0.28%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Studies.
[2] "CHD death" includes definite and possible CHD death.
[3] Angina and CHF are not verified outcomes in the WHI Extension Studies. Reported statistics represent experience during the original program.
[4] UNC HF is not a verified outcome during the WHI Extension Study 2010-2015. Reported Statistics represent experience during the original program and the Extension Study 2005-2010.
[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 and angina are not collected in the WHI Extension Studies. Congestive heart failure is not collected in the WHI Extension Study 2005-2010.
[6] Aortic aneurysm, atrial fibrillation and valvular heart disease are new adjudicated outcomes during the WHI Extension Study 2010-2015.
[7] Total CVD does not include aortic aneurysm, atrial fibrillation or valvular heart disease.
[8] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[9] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.
[10] Deaths from Extension Study 2010-2015.

Table 7.4
Verified Outcomes (Annualized Percentages) by Age for MRC Participants
During the WHI Extension Study 2010-2015

Data as of: September 20, 2013; Events through September 20, 2013

Outcomes	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	22315		3727		5292		10112		3184	
Mean follow-up (months)	28.3		28.9		28.9		28.3		26.6	
Cardiovascular										
CHD[1]	276	(0.52%)	15	(0.17%)	41	(0.32%)	131	(0.55%)	89	(1.26%)
CHD death[2]	115	(0.22%)	5	(0.06%)	14	(0.11%)	45	(0.19%)	51	(0.72%)
Clinical MI	183	(0.35%)	11	(0.12%)	31	(0.24%)	95	(0.40%)	46	(0.65%)
CABG/PTCA	192	(0.36%)	22	(0.24%)	38	(0.30%)	111	(0.47%)	21	(0.30%)
Carotid artery disease	40	(0.08%)	1	(0.01%)	11	(0.09%)	22	(0.09%)	6	(0.09%)
Stroke	247	(0.47%)	17	(0.19%)	33	(0.26%)	127	(0.53%)	70	(0.99%)
PVD	54	(0.10%)	9	(0.10%)	9	(0.07%)	28	(0.12%)	8	(0.11%)
Coronary disease[3]	400	(0.76%)	33	(0.37%)	64	(0.50%)	202	(0.85%)	101	(1.43%)
Aortic aneurysm	21	(0.04%)	0	(0.00%)	2	(0.02%)	13	(0.05%)	6	(0.09%)
Atrial fibrillation	454	(0.86%)	28	(0.31%)	60	(0.47%)	253	(1.06%)	113	(1.60%)
Valvular heart disease	108	(0.21%)	6	(0.07%)	7	(0.05%)	63	(0.26%)	32	(0.45%)
Total cardiovascular disease[4]	976	(1.85%)	79	(0.88%)	164	(1.29%)	475	(1.99%)	258	(3.66%)
Cancer										
Breast cancer	221	(0.42%)	26	(0.29%)	73	(0.57%)	92	(0.39%)	30	(0.43%)
Invasive breast cancer	189	(0.36%)	22	(0.24%)	58	(0.45%)	80	(0.34%)	29	(0.41%)
Non-invasive breast cancer	32	(0.06%)	4	(0.04%)	15	(0.12%)	12	(0.05%)	1	(0.01%)
Ovarian cancer	18	(0.03%)	1	(0.01%)	4	(0.03%)	10	(0.04%)	3	(0.04%)
Endometrial cancer[5]	42	(0.08%)	12	(0.13%)	13	(0.10%)	15	(0.06%)	2	(0.03%)
Colorectal cancer	57	(0.11%)	7	(0.08%)	12	(0.09%)	28	(0.12%)	10	(0.14%)
Other cancer[6]	395	(0.75%)	46	(0.51%)	86	(0.67%)	186	(0.78%)	77	(1.09%)
Total cancer	720	(1.37%)	90	(1.00%)	186	(1.46%)	325	(1.36%)	119	(1.69%)
Fractures										
Hip fracture	131	(0.25%)	6	(0.07%)	7	(0.05%)	74	(0.31%)	44	(0.62%)
Deaths										
Cardiovascular deaths	284	(0.54%)	11	(0.12%)	27	(0.21%)	109	(0.46%)	137	(1.94%)
Cancer deaths	263	(0.50%)	26	(0.29%)	48	(0.38%)	117	(0.49%)	72	(1.02%)
Other known cause	258	(0.49%)	9	(0.10%)	18	(0.14%)	119	(0.50%)	112	(1.59%)
Unknown cause	15	(0.03%)	0	(0.00%)	0	(0.00%)	6	(0.03%)	9	(0.13%)
Not yet adjudicated	313	(0.59%)	17	(0.19%)	36	(0.28%)	152	(0.64%)	108	(1.53%)
Total death	1133	(2.15%)	63	(0.70%)	129	(1.01%)	503	(2.11%)	438	(6.21%)

[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, and CABG/PTCA.
[4] Total CVD does not include AAA, aortic aneurysm, atrial fibrillation or valvular heart disease.
[5] Only women without a prior hysterectomy are used to compute the annual rates of endometrial cancer.
[6] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.

Table 7.5
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for MRC Participants
During the WHI Extension Study 2010-2015

Data as of: September 20, 2013; Events through September 20, 2013

	Race/Ethnicity					
Outcomes	**American Indian/ Alaskan Native**	**Asian/Pacific Islander**	**Black/African American**	**Hispanic/ Latino**	**White**	**Unknown**
Number randomized	64	240	6136	2472	13203	200
Mean follow-up (months)	26.8	28.1	28.2	28.1	28.4	28.2
Cardiovascular						
CHD[1]	3 (2.10%)	3 (0.53%)	65 (0.45%)	22 (0.38%)	182 (0.58%)	1 (0.21%)
CHD death[2]	2 (1.40%)	1 (0.18%)	31 (0.21%)	4 (0.07%)	77 (0.25%)	0 (0.00%)
Clinical MI	2 (1.40%)	2 (0.36%)	41 (0.28%)	18 (0.31%)	119 (0.38%)	1 (0.21%)
CABG/PTCA	4 (2.79%)	0 (0.00%)	42 (0.29%)	14 (0.24%)	127 (0.41%)	5 (1.07%)
Carotid artery disease	0 (0.00%)	0 (0.00%)	5 (0.03%)	0 (0.00%)	35 (0.11%)	0 (0.00%)
Stroke	1 (0.70%)	1 (0.18%)	63 (0.44%)	15 (0.26%)	167 (0.53%)	0 (0.00%)
PVD	1 (0.70%)	1 (0.18%)	16 (0.11%)	4 (0.07%)	32 (0.10%)	0 (0.00%)
Coronary disease[3]	6 (4.19%)	3 (0.53%)	96 (0.67%)	29 (0.50%)	261 (0.84%)	5 (1.07%)
Aortic aneurysm	0 (0.00%)	0 (0.00%)	6 (0.04%)	3 (0.05%)	12 (0.04%)	0 (0.00%)
Atrial fibrillation	0 (0.00%)	1 (0.18%)	58 (0.40%)	23 (0.40%)	367 (1.17%)	5 (1.07%)
Valvular heart disease	1 (0.70%)	1 (0.18%)	23 (0.16%)	8 (0.14%)	72 (0.23%)	3 (0.64%)
Total cardiovascular disease[4]	8 (5.59%)	5 (0.89%)	264 (1.83%)	60 (1.04%)	633 (2.03%)	6 (1.28%)
Cancer						
Breast cancer	1 (0.70%)	3 (0.53%)	54 (0.37%)	25 (0.43%)	137 (0.44%)	1 (0.21%)
Invasive breast cancer	1 (0.70%)	2 (0.36%)	43 (0.30%)	22 (0.38%)	120 (0.38%)	1 (0.21%)
Non-invasive breast cancer	0 (0.00%)	1 (0.18%)	11 (0.08%)	3 (0.05%)	17 (0.05%)	0 (0.00%)
Ovarian cancer	0 (0.00%)	0 (0.00%)	3 (0.02%)	3 (0.05%)	11 (0.04%)	1 (0.21%)
Endometrial cancer[5]	0 (0.00%)	0 (0.00%)	13 (0.09%)	1 (0.02%)	28 (0.09%)	0 (0.00%)
Colorectal cancer	0 (0.00%)	1 (0.18%)	15 (0.10%)	8 (0.14%)	33 (0.11%)	0 (0.00%)
Other cancer[6]	3 (2.10%)	4 (0.71%)	73 (0.51%)	37 (0.64%)	275 (0.88%)	3 (0.64%)
Total cancer	4 (2.79%)	8 (1.42%)	156 (1.08%)	73 (1.26%)	474 (1.52%)	5 (1.07%)
Fractures						
Hip fracture	1 (0.70%)	0 (0.00%)	10 (0.07%)	6 (0.10%)	112 (0.36%)	2 (0.43%)
Deaths						
Cardiovascular deaths	3 (2.10%)	1 (0.18%)	74 (0.51%)	8 (0.14%)	197 (0.63%)	1 (0.21%)
Cancer deaths	2 (1.40%)	3 (0.53%)	54 (0.37%)	27 (0.47%)	173 (0.55%)	4 (0.85%)
Other known cause	0 (0.00%)	3 (0.53%)	43 (0.30%)	14 (0.24%)	197 (0.63%)	1 (0.21%)
Unknown cause	0 (0.00%)	0 (0.00%)	3 (0.02%)	2 (0.03%)	10 (0.03%)	0 (0.00%)
Not yet adjudicated	1 (0.70%)	2 (0.36%)	73 (0.51%)	18 (0.31%)	216 (0.69%)	3 (0.64%)
Total Death	6 (4.19%)	9 (1.60%)	247 (1.71%)	69 (1.19%)	793 (2.54%)	9 (1.92%)

[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, and CABG/PTCA.
[4] Total CVD does not include AAA, aortic aneurysm, atrial fibrillation or valvular heart disease.
[5] Only women without a prior hysterectomy are used to compute the annual rates of endometrial cancer.
[6] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.

Table 7.6
Verified Outcomes (Annualized Percentages) by Age for SRC Participants

Data as of: September 20, 2013; Events through September 30, 2010

Outcomes	Total	Age 50-54	Age 55-59	Age 60-69	Age 70-79
Number randomized	71247	10750	16244	33247	11006
Mean follow-up (months)	167.7	173.3	170.3	165.6	164.3
Cardiovascular					
Clinical MI	1979 (0.20%)	109 (0.07%)	273 (0.12%)	1015 (0.22%)	582 (0.39%)
Angina[1]	1748 (0.29%)	87 (0.09%)	276 (0.19%)	914 (0.33%)	471 (0.52%)
CABG/PTCA	3612 (0.36%)	172 (0.11%)	534 (0.23%)	2003 (0.44%)	903 (0.60%)
Carotid artery disease	566 (0.06%)	28 (0.02%)	73 (0.03%)	305 (0.07%)	160 (0.11%)
Congestive heart failure, WHI[1]	675 (0.11%)	31 (0.03%)	81 (0.06%)	322 (0.12%)	241 (0.27%)
Stroke	1502 (0.15%)	69 (0.04%)	174 (0.08%)	781 (0.17%)	478 (0.32%)
PVD	426 (0.04%)	19 (0.01%)	48 (0.02%)	228 (0.05%)	131 (0.09%)
Coronary disease[2]	5316 (0.53%)	284 (0.18%)	798 (0.35%)	2826 (0.62%)	1408 (0.93%)
Total cardiovascular disease	7133 (0.72%)	380 (0.24%)	1015 (0.44%)	3773 (0.82%)	1965 (1.30%)
Cancer					
Breast cancer	5330 (0.54%)	723 (0.47%)	1211 (0.53%)	2599 (0.57%)	797 (0.53%)
Invasive breast cancer	4273 (0.43%)	552 (0.36%)	970 (0.42%)	2083 (0.45%)	668 (0.44%)
Non-invasive breast cancer	1118 (0.11%)	181 (0.12%)	256 (0.11%)	543 (0.12%)	138 (0.09%)
Ovarian cancer	233 (0.02%)	42 (0.03%)	56 (0.02%)	102 (0.02%)	33 (0.02%)
Endometrial cancer[3]	750 (0.08%)	96 (0.06%)	181 (0.08%)	363 (0.08%)	110 (0.07%)
Colorectal cancer	871 (0.09%)	57 (0.04%)	124 (0.05%)	457 (0.10%)	233 (0.15%)
Other cancer[4]	3440 (0.35%)	398 (0.26%)	718 (0.31%)	1747 (0.38%)	577 (0.38%)
Total cancer	10016 (1.01%)	1246 (0.80%)	2169 (0.94%)	4945 (1.08%)	1656 (1.10%)
Fractures					
Hip fracture	1449 (0.15%)	51 (0.03%)	128 (0.06%)	661 (0.14%)	609 (0.40%)

[1] Angina and CHF are not verified outcomes in the WHI Extension Study. Reported statistics represent experience during the original program.
[2] "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.
[3] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[4] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.

Table 7.7
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for SRC Participants

Data as of: September 20, 2013; Events through September 30, 2010

Outcomes	Race/Ethnicity: American Indian/ Alaskan Native	Asian/Pacific Islander	White	Unknown
Number randomized	254	1640	68451	902
Mean follow-up (months)	167.2	165.7	167.7	165.1
Cardiovascular				
Clinical MI	5 (0.14%)	19 (0.08%)	1932 (0.20%)	23 (0.19%)
Angina[1]	10 (0.47%)	27 (0.20%)	1694 (0.29%)	17 (0.23%)
CABG/PTCA	17 (0.48%)	40 (0.18%)	3512 (0.37%)	43 (0.35%)
Carotid artery disease	2 (0.06%)	4 (0.02%)	551 (0.06%)	9 (0.07%)
Congestive heart failure, WHI[1]	1 (0.05%)	3 (0.02%)	666 (0.11%)	5 (0.07%)
Stroke	2 (0.06%)	26 (0.11%)	1450 (0.15%)	24 (0.19%)
PVD	0 (0.00%)	2 (0.01%)	417 (0.04%)	7 (0.06%)
Coronary disease[2]	21 (0.59%)	63 (0.28%)	5174 (0.54%)	58 (0.47%)
Total cardiovascular disease	24 (0.68%)	91 (0.40%)	6926 (0.72%)	92 (0.74%)
Cancer				
Breast cancer	12 (0.34%)	119 (0.53%)	5143 (0.54%)	56 (0.45%)
Invasive breast cancer	9 (0.25%)	95 (0.42%)	4124 (0.43%)	45 (0.36%)
Non-invasive breast cancer	3 (0.08%)	26 (0.11%)	1077 (0.11%)	12 (0.10%)
Ovarian cancer	0 (0.00%)	4 (0.02%)	228 (0.02%)	1 (0.01%)
Endometrial cancer[3]	1 (0.03%)	9 (0.04%)	727 (0.08%)	13 (0.11%)
Colorectal cancer	4 (0.11%)	19 (0.08%)	836 (0.09%)	12 (0.10%)
Other cancer[4]	9 (0.25%)	55 (0.24%)	3335 (0.35%)	41 (0.33%)
Total cancer	24 (0.68%)	192 (0.85%)	9682 (1.01%)	118 (0.95%)
Fractures				
Hip fracture	4 (0.11%)	12 (0.05%)	1425 (0.15%)	8 (0.06%)

[1] Angina and CHF are not verified outcomes in the WHI Extension Study. Reported statistics represent experience during the original program.
[2] "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.
[3] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[4] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.

Table 7.8
Verified Cancer and Self Reported Outcomes (Annualized Percentages) by Age for SRC Participants During the WHI Extension Study 2010-2015

Data as of: September 20, 2013; Events through September 20, 2013

Outcomes	Total	Age 50-54	55-59	60-69	70-79
Number randomized	71247	10750	16244	33247	11006
Mean follow-up (months)	28.9	29.8	29.6	28.9	27.0
Cardiovascular					
CHD[1]	981 (0.57%)	56 (0.21%)	126 (0.31%)	456 (0.57%)	343 (1.38%)
CHD death[2]	293 (0.17%)	7 (0.03%)	19 (0.05%)	117 (0.15%)	150 (0.61%)
MI, IP/OP	750 (0.44%)	56 (0.21%)	118 (0.29%)	369 (0.46%)	207 (0.83%)
MI, IP	695 (0.41%)	49 (0.18%)	108 (0.27%)	342 (0.43%)	196 (0.79%)
MI, OP	57 (0.03%)	7 (0.03%)	11 (0.03%)	28 (0.04%)	11 (0.04%)
Angina	1747 (1.02%)	153 (0.57%)	319 (0.80%)	899 (1.12%)	376 (1.52%)
CABG/PTCA, IP/OP	992 (0.58%)	94 (0.35%)	169 (0.42%)	558 (0.70%)	171 (0.69%)
CABG/PTCA, IP	922 (0.54%)	84 (0.31%)	161 (0.40%)	515 (0.64%)	162 (0.65%)
CABG/PTCA, OP	83 (0.05%)	11 (0.04%)	11 (0.03%)	49 (0.06%)	12 (0.05%)
Carotid artery disease, IP/OP	313 (0.18%)	25 (0.09%)	49 (0.12%)	180 (0.23%)	59 (0.24%)
Carotid artery disease, IP	270 (0.16%)	22 (0.08%)	44 (0.11%)	153 (0.19%)	51 (0.21%)
Carotid artery disease, OP	47 (0.03%)	3 (0.01%)	5 (0.01%)	30 (0.04%)	9 (0.04%)
Congestive heart failure, IP/OP	1287 (0.75%)	55 (0.21%)	126 (0.31%)	660 (0.83%)	446 (1.80%)
Congestive heart failure, IP	1028 (0.60%)	41 (0.15%)	96 (0.24%)	538 (0.67%)	353 (1.42%)
Congestive heart failure, OP	285 (0.17%)	14 (0.05%)	31 (0.08%)	138 (0.17%)	102 (0.41%)
Stroke, IP/OP	1249 (0.73%)	74 (0.28%)	193 (0.48%)	659 (0.82%)	323 (1.30%)
Stroke, IP	1133 (0.66%)	56 (0.21%)	166 (0.41%)	604 (0.76%)	307 (1.24%)
Stroke, OP	232 (0.14%)	23 (0.09%)	42 (0.10%)	116 (0.15%)	51 (0.21%)
PVD, IP/OP	760 (0.44%)	50 (0.19%)	104 (0.26%)	410 (0.51%)	196 (0.79%)
PVD, IP	265 (0.15%)	10 (0.04%)	26 (0.06%)	150 (0.19%)	79 (0.32%)
PVD, OP	515 (0.30%)	42 (0.16%)	79 (0.20%)	271 (0.34%)	123 (0.50%)
Coronary disease[3]	3565 (2.08%)	254 (0.95%)	517 (1.29%)	1842 (2.30%)	952 (3.84%)
Abdominal aortic aneurysm (AAA)	247 (0.14%)	18 (0.07%)	47 (0.12%)	128 (0.16%)	54 (0.22%)
Atrial fibrillation	3091 (1.80%)	231 (0.87%)	488 (1.22%)	1658 (2.07%)	714 (2.88%)
Valvular heart disease	589 (0.34%)	36 (0.13%)	88 (0.22%)	322 (0.40%)	143 (0.58%)
Cancer[4]					
Breast cancer	813 (0.47%)	140 (0.52%)	191 (0.48%)	388 (0.49%)	94 (0.38%)
Invasive breast cancer	690 (0.40%)	108 (0.40%)	155 (0.39%)	342 (0.43%)	85 (0.34%)
Non-invasive breast cancer	125 (0.07%)	32 (0.12%)	38 (0.09%)	46 (0.06%)	9 (0.04%)
Ovarian cancer	85 (0.05%)	12 (0.04%)	19 (0.05%)	41 (0.05%)	13 (0.05%)
Endometrial cancer[5]	124 (0.07%)	24 (0.09%)	38 (0.09%)	48 (0.06%)	14 (0.06%)
Colorectal cancer	185 (0.11%)	10 (0.04%)	25 (0.06%)	107 (0.13%)	43 (0.17%)
Other cancer[6]	1534 (0.89%)	167 (0.63%)	292 (0.73%)	775 (0.97%)	300 (1.21%)
Total cancer	2700 (1.57%)	350 (1.31%)	556 (1.39%)	1338 (1.67%)	456 (1.84%)
Fractures					
Hip fracture	925 (0.54%)	49 (0.18%)	97 (0.24%)	492 (0.62%)	287 (1.16%)
Deaths					
Cardiovascular deaths	755 (0.44%)	11 (0.04%)	45 (0.11%)	297 (0.37%)	402 (1.62%)
Cancer deaths	825 (0.48%)	53 (0.20%)	129 (0.32%)	409 (0.51%)	234 (0.94%)
Other known cause	855 (0.50%)	23 (0.09%)	63 (0.16%)	374 (0.47%)	395 (1.59%)
Unknown cause	1003 (0.58%)	30 (0.11%)	83 (0.21%)	425 (0.53%)	465 (1.88%)
Total death	3438 (2.00%)	117 (0.44%)	320 (0.80%)	1505 (1.88%)	1496 (6.03%)

IP = Inpatient; OP = Outpatient.

[1] "CHD" includes MI and CHD death.

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

[3] "Coronary disease" includes MI, CHD death, angina, congestive heart failure, and CABG/PTCA.

[4] All cancers are adjudicated in the WHI Extension Study 2010-2015.

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

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

Table 7.9
Verified Cancer and Self Reported Outcomes (Annualized Percentages) by Race/Ethnicity for SRC Participants During the WHI Extension Study 2010-2015

Data as of: September 20, 2013; Events through September 20, 2013

	Race/Ethnicity			
Outcomes	**American Indian/Alaskan Native**	**Asian/Pacific Islander**	**White**	**Other/Unspecified**
Number randomized	254	1640	68451	902
Mean follow-up (months)	28.8	28.7	28.9	28.6
Cardiovascular				
CHD[1]	5 (0.82%)	15 (0.38%)	950 (0.58%)	11 (0.51%)
CHD death[2]	1 (0.16%)	3 (0.08%)	285 (0.17%)	4 (0.19%)
MI, IP/OP	4 (0.66%)	13 (0.33%)	726 (0.44%)	7 (0.33%)
MI, IP	4 (0.66%)	12 (0.31%)	672 (0.41%)	7 (0.33%)
MI, OP	0 (0.00%)	1 (0.03%)	56 (0.03%)	0 (0.00%)
Angina	11 (1.80%)	21 (0.54%)	1696 (1.03%)	19 (0.88%)
CABG/PTCA, IP/OP	8 (1.31%)	11 (0.28%)	965 (0.59%)	8 (0.37%)
CABG/PTCA, IP	8 (1.31%)	9 (0.23%)	898 (0.54%)	7 (0.33%)
CABG/PTCA, OP	0 (0.00%)	2 (0.05%)	80 (0.05%)	1 (0.05%)
Carotid artery disease, IP/OP	1 (0.16%)	0 (0.00%)	305 (0.18%)	7 (0.33%)
Carotid artery disease, IP	0 (0.00%)	0 (0.00%)	264 (0.16%)	6 (0.28%)
Carotid artery disease, OP	1 (0.16%)	0 (0.00%)	45 (0.03%)	1 (0.05%)
Congestive heart failure, IP/OP	4 (0.66%)	12 (0.31%)	1259 (0.76%)	12 (0.56%)
Congestive heart failure, IP	1 (0.16%)	8 (0.20%)	1012 (0.61%)	7 (0.33%)
Congestive heart failure, OP	3 (0.49%)	4 (0.10%)	273 (0.17%)	5 (0.23%)
Stroke, IP/OP	5 (0.82%)	19 (0.48%)	1209 (0.73%)	16 (0.74%)
Stroke, IP	4 (0.66%)	14 (0.36%)	1097 (0.67%)	18 (0.84%)
Stroke, OP	0 (0.00%)	6 (0.15%)	226 (0.14%)	0 (0.00%)
PVD, IP/OP	4 (0.66%)	6 (0.15%)	734 (0.45%)	16 (0.74%)
PVD, IP	3 (0.49%)	3 (0.08%)	254 (0.15%)	5 (0.23%)
PVD, OP	1 (0.16%)	3 (0.08%)	500 (0.30%)	11 (0.51%)
Coronary disease[3]	17 (2.79%)	40 (1.02%)	3475 (2.11%)	33 (1.53%)
Abdominal aortic aneurysm (AAA)	3 (0.49%)	7 (0.18%)	233 (0.14%)	4 (0.19%)
Atrial fibrillation	10 (1.64%)	36 (0.92%)	3016 (1.83%)	29 (1.35%)
Valvular heart disease	2 (0.33%)	7 (0.18%)	574 (0.35%)	6 (0.28%)
Cancer[4]				
Breast cancer	6 (0.98%)	15 (0.38%)	782 (0.47%)	10 (0.46%)
Invasive breast cancer	3 (0.49%)	15 (0.38%)	664 (0.40%)	8 (0.37%)
Non-invasive breast cancer	3 (0.49%)	0 (0.00%)	120 (0.07%)	2 (0.09%)
Ovarian cancer	0 (0.00%)	0 (0.00%)	83 (0.05%)	2 (0.09%)
Endometrial cancer[5]	0 (0.00%)	4 (0.10%)	117 (0.07%)	3 (0.14%)
Colorectal cancer	0 (0.00%)	1 (0.03%)	182 (0.11%)	2 (0.09%)
Other cancer[6]	4 (0.66%)	19 (0.48%)	1490 (0.90%)	21 (0.98%)
Total cancer	10 (1.64%)	39 (0.99%)	2613 (1.58%)	38 (1.77%)
Fractures				
Hip fracture	0 (0.00%)	13 (0.33%)	903 (0.55%)	9 (0.42%)
Deaths				
Cardiovascular deaths	1 (0.16%)	7 (0.18%)	739 (0.45%)	8 (0.37%)
Cancer deaths	4 (0.66%)	12 (0.31%)	798 (0.48%)	11 (0.51%)
Other known cause	7 (1.15%)	10 (0.25%)	829 (0.50%)	9 (0.42%)
Unknown cause	2 (0.33%)	16 (0.41%)	966 (0.59%)	19 (0.88%)
Total death	14 (2.30%)	45 (1.15%)	3332 (2.02%)	47 (2.18%)

IP = Inpatient; OP = Outpatient.

[1] CHD" includes MI and CHD death.

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

[3] "Coronary disease" includes MI, CHD death, angina, congestive heart failure, and CABG/PTCA.

[4] All cancers are adjudicated in the WHI Extension Study 2010-2015.

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

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

Table 7.10
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes During WHI Extension Study 2010-2015 by Age and Race/Ethnicity for MRC Participants Without a Prior Event[1]

Data as of: September 20, 2013; Events through September 20, 2013

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	22315	3727	5292	10112	3184
Mean follow-up (months)	28.3	28.9	28.9	28.3	26.6
Angina	629 (1.19%)	74 (0.82%)	113 (0.89%)	337 (1.41%)	105 (1.49%)
Diabetes (treated)	849 (1.61%)	165 (1.84%)	188 (1.47%)	393 (1.65%)	103 (1.46%)
Hysterectomy	171 (0.32%)	41 (0.46%)	62 (0.49%)	59 (0.25%)	9 (0.13%)
Osteoarthritis	1180 (2.24%)	253 (2.82%)	307 (2.41%)	506 (2.12%)	114 (1.62%)
Intestinal polyps	872 (1.66%)	188 (2.09%)	283 (2.22%)	359 (1.50%)	42 (0.60%)
Lupus	50 (0.09%)	9 (0.10%)	10 (0.08%)	26 (0.11%)	5 (0.07%)
Pills for hypertension	1010 (1.92%)	216 (2.40%)	250 (1.96%)	433 (1.81%)	111 (1.57%)
COPD	1081 (2.05%)	136 (1.51%)	243 (1.91%)	543 (2.28%)	159 (2.25%)
Macular degeneration	1082 (2.06%)	83 (0.92%)	200 (1.57%)	529 (2.22%)	270 (3.83%)
Alzheimer's disease	861 (1.64%)	48 (0.53%)	97 (0.76%)	439 (1.84%)	277 (3.93%)
Parkinson's disease	105 (0.20%)	11 (0.12%)	19 (0.15%)	52 (0.22%)	23 (0.33%)

Outcomes	Race/Ethnicity: Am Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	64	240	6136	2472	13203	200
Mean follow-up (months)	26.8	28.1	28.2	28.1	28.4	28.2
Angina	3 (2.10%)	5 (0.89%)	175 (1.21%)	64 (1.11%)	376 (1.20%)	6 (1.28%)
Diabetes (treated)	6 (4.19%)	10 (1.78%)	273 (1.89%)	96 (1.66%)	457 (1.46%)	7 (1.49%)
Hysterectomy	0 (0.00%)	1 (0.18%)	35 (0.24%)	17 (0.29%)	117 (0.37%)	1 (0.21%)
Osteoarthritis	3 (2.10%)	17 (3.02%)	295 (2.04%)	153 (2.64%)	703 (2.25%)	9 (1.92%)
Intestinal polyps	2 (1.40%)	12 (2.13%)	297 (2.06%)	106 (1.83%)	449 (1.44%)	6 (1.28%)
Lupus	1 (0.70%)	1 (0.18%)	17 (0.12%)	5 (0.09%)	26 (0.08%)	0 (0.00%)
Pills for hypertension	3 (2.10%)	12 (2.13%)	178 (1.23%)	122 (2.11%)	685 (2.19%)	10 (2.13%)
COPD	9 (6.29%)	7 (1.24%)	265 (1.84%)	101 (1.75%)	689 (2.20%)	10 (2.13%)
Macular degeneration	7 (4.89%)	7 (1.24%)	212 (1.47%)	119 (2.06%)	726 (2.32%)	11 (2.34%)
Alzheimer's disease	2 (1.40%)	6 (1.07%)	208 (1.44%)	80 (1.38%)	559 (1.79%)	6 (1.28%)
Parkinson's disease	0 (0.00%)	0 (0.00%)	27 (0.19%)	13 (0.22%)	64 (0.20%)	1 (0.21%)

[1] Prior events include prevalence at baseline or an event during the original program or the WHI Extension Study 2005-2010.

Table 7.11
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes During WHI Extension Study 2010-2015 by Age and Race/Ethnicity for SRC Participants Without a Prior Event[1]

Data as of: September 20, 2013; Events through September 20, 2013

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	71247	10750	16244	33247	11006
Mean follow-up (months)	28.9	29.8	29.6	28.9	27.0
DVT, IP/OP[2]	804 (0.47%)	82 (0.31%)	122 (0.30%)	424 (0.53%)	176 (0.71%)
PE, IP/OP	445 (0.26%)	40 (0.15%)	87 (0.22%)	242 (0.30%)	76 (0.31%)
PE, IP[3]	401 (0.23%)	38 (0.14%)	77 (0.19%)	216 (0.27%)	70 (0.28%)
PE, OP	50 (0.03%)	2 (0.01%)	10 (0.02%)	31 (0.04%)	7 (0.03%)
Diabetes (treated)	2366 (1.38%)	351 (1.31%)	551 (1.37%)	1121 (1.40%)	343 (1.38%)
Hysterectomy	626 (0.36%)	128 (0.48%)	203 (0.51%)	258 (0.32%)	37 (0.15%)
Osteoarthritis	3540 (2.06%)	622 (2.33%)	911 (2.27%)	1614 (2.02%)	393 (1.59%)
Intestinal polyps	2510 (1.46%)	527 (1.97%)	742 (1.85%)	1060 (1.33%)	181 (0.73%)
Lupus	107 (0.06%)	10 (0.04%)	28 (0.07%)	53 (0.07%)	16 (0.06%)
Pills for hypertension	3630 (2.12%)	605 (2.27%)	863 (2.15%)	1720 (2.15%)	442 (1.78%)
COPD	2990 (1.74%)	287 (1.07%)	545 (1.36%)	1619 (2.02%)	539 (2.17%)
Macular degeneration	3588 (2.09%)	239 (0.89%)	558 (1.39%)	1916 (2.40%)	875 (3.53%)
Alzheimer's disease	2416 (1.41%)	85 (0.32%)	220 (0.55%)	1287 (1.61%)	824 (3.32%)
Parkinson's disease	399 (0.23%)	30 (0.11%)	59 (0.15%)	239 (0.30%)	71 (0.29%)

Outcomes	Race/Ethnicity: Am Indian/ Alaskan Native	Asian/Pacific Islander	White	Unknown
Number randomized	254	1640	68451	902
Mean follow-up (months)	28.8	28.7	28.9	28.6
DVT, IP/OP[2]	3 (0.49%)	14 (0.36%)	775 (0.47%)	12 (0.56%)
PE, IP/OP	0 (0.00%)	6 (0.15%)	435 (0.26%)	4 (0.19%)
PE, IP[3]	0 (0.00%)	5 (0.13%)	393 (0.24%)	3 (0.14%)
PE, OP	0 (0.00%)	1 (0.03%)	48 (0.03%)	1 (0.05%)
Diabetes (treated)	9 (1.48%)	68 (1.73%)	2256 (1.37%)	33 (1.53%)
Hysterectomy	0 (0.00%)	8 (0.20%)	606 (0.37%)	12 (0.56%)
Osteoarthritis	14 (2.30%)	82 (2.09%)	3396 (2.06%)	48 (2.23%)
Intestinal polyps	3 (0.49%)	59 (1.50%)	2414 (1.46%)	34 (1.58%)
Lupus	1 (0.16%)	2 (0.05%)	100 (0.06%)	4 (0.19%)
Pills for hypertension	13 (2.13%)	90 (2.29%)	3486 (2.11%)	41 (1.91%)
COPD	16 (2.62%)	33 (0.84%)	2907 (1.76%)	34 (1.58%)
Macular degeneration	10 (1.64%)	65 (1.66%)	3472 (2.11%)	41 (1.91%)
Alzheimer's disease	8 (1.31%)	40 (1.02%)	2337 (1.42%)	31 (1.44%)
Parkinson's disease	2 (0.33%)	6 (0.15%)	388 (0.24%)	3 (0.14%)

IP = Inpatient; OP = Outpatient

[1] Prior events include prevalence at baseline or an event during the original program or the WHI Extension Study 2005-2010.

[2] Both IP and OP DVT are adjudicated.

[3] Only IP PE is adjudicated.

Table 7.12
Verified Other Cancers (Annualized Percentages): MRC and SRC Participants

Data as of: September 20, 2013; Events through September 20, 2013

	MRC	SRC
Number of participants	22315	71247
Mean follow-up time (months)	195.6	196.6
Ppts with other cancer	1159 (0.32%)	4639 (0.40%)
Accessory sinus	1 (<0.01%)	3 (<0.01%)
Adrenal gland	0 (0.00%)	0 (0.00%)
Anus	8 (<0.01%)	41 (<0.01%)
Appendix	8 (<0.01%)	13 (<0.01%)
Biliary tract, parts of (other/unspecified)	3 (<0.01%)	16 (<0.01%)
Bladder	103 (0.03%)	345 (0.03%)
Bones/joints/articular cartilage (limbs)	0 (0.00%)	3 (<0.01%)
Bones/joints/articular cartilage (other)	1 (<0.01%)	6 (<0.01%)
Brain	3 (<0.01%)	27 (<0.01%)
Cervix	19 (0.01%)	37 (<0.01%)
Central Nervous System (excludes brain)	0 (0.00%)	0 (0.00%)
Connective/subcutaneous/soft tissues	8 (<0.01%)	42 (<0.01%)
Endocrine glands, related structures	0 (0.00%)	0 (0.00%)
Esophagus	11 (<0.01%)	12 (<0.01%)
Eye and adnexa	8 (<0.01%)	34 (<0.01%)
Genital organs	7 (<0.01%)	49 (<0.01%)
Kidney	74 (0.02%)	230 (0.02%)
Larynx	9 (<0.01%)	14 (<0.01%)
Leukemia	66 (0.02%)	278 (0.02%)
Liver	9 (<0.01%)	22 (<0.01%)
Lung	211 (0.06%)	669 (0.06%)
Lymph nodes	0 (0.00%)	1 (<0.01%)
Lymphoma, Hodgkins	4 (<0.01%)	16 (<0.01%)
Lymphoma, Non-Hodgkins	142 (0.04%)	582 (0.05%)
Melanoma of the skin	206 (0.06%)	1202 (0.10%)
Multiple myeloma	47 (0.01%)	117 (0.01%)
Oral (mouth)	3 (<0.01%)	11 (<0.01%)
Palate	1 (<0.01%)	14 (<0.01%)
Pancreas	35 (0.01%)	134 (0.01%)
Parotid gland (Stensen's duct)	6 (<0.01%)	26 (<0.01%)
Peripheral nerves and autonomic nervous	0 (0.00%)	1 (<0.01%)
Pyriform sinus	0 (0.00%)	1 (<0.01%)
Respiratory system, intrathoracic, other	0 (0.00%)	0 (0.00%)
Salivary glands, major (other/unspecified)	3 (<0.01%)	6 (<0.01%)
Stomach	23 (0.01%)	48 (<0.01%)
Thyroid	61 (0.02%)	258 (0.02%)
Tongue, part of (other/unspecified)	4 (<0.01%)	29 (<0.01%)
Urinary organs (other/unspecified)	4 (<0.01%)	5 (<0.01%)
Uterus, not otherwise specified	3 (<0.01%)	4 (<0.01%)
Other/unknown site of cancer	101 (0.03%)	409 (0.04%)
Other/unknown cancers reported on death	16 (<0.01%)	119 (0.01%)

Table 7.13
Self Reported Fractures (Annualized Percentages): MRC and SRC Participants

Data as of: September 20, 2013; Events through September 20, 2013

	MRC		SRC	
Number of participants	22315		71247	
Mean follow-up time (months)	195.6		196.6	
Elbow	363	(0.10%)	1346	(0.12%)
Foot	1207	(0.33%)	4586	(0.39%)
Hand	338	(0.09%)	1133	(0.10%)
Hip	593	(0.16%)	2440	(0.21%)
Knee	587	(0.16%)	1768	(0.15%)
Lower arm	1752	(0.48%)	6004	(0.51%)
Lower leg	1373	(0.38%)	4572	(0.39%)
Pelvis	341	(0.09%)	1690	(0.14%)
Tailbone	135	(0.04%)	599	(0.05%)
Upper arm	957	(0.26%)	3183	(0.27%)
Upper leg	287	(0.08%)	1196	(0.10%)
Spine	974	(0.27%)	4297	(0.37%)
Other	2442	(0.67%)	9414	(0.81%)
Total fracture	7648	(2.10%)	27689	(2.37%)

Table 7.14
Cause of Death (Annualized Percentages): MRC and SRC Participants

Data as of: September 20, 2013; Events through September 20, 2013

	MRC		SRC	
Number of participants	22315		71247	
Mean Follow-up Time (months)	195.9		196.7	
Death plus post-WHI deaths	1133	(0.31%)	3438	(0.29%)
Adjudicated death	820	(0.23%)	0	(0.00%)
Centrally adjudicated death	804	(0.22%)	0	(0.00%)
Identified by NDI search	16	(<0.01%)	0	(0.00%)
Not yet adjudicated	313	(0.09%)	0	(0.00%)
Form 120 death (SRC participants only)	0	(0.00%)	3438	(0.29%)
Cardiovascular				
Atherosclerotic cardiac	115	(0.03%)	293	(0.03%)
Definite CHD deaths after 10/99	82	(0.02%)	93	(0.01%)
Possible CHD deaths after 10/99	33	(0.01%)	123	(0.01%)
Cerebrovascular	74	(0.02%)	154	(0.01%)
Pulmonary embolism	8	(<0.01%)	8	(<0.01%)
Other cardiovascular	80	(0.02%)	291	(0.02%)
Unknown cardiovascular	7	(<0.01%)	9	(<0.01%)
Total cardiovascular deaths	284	(0.08%)	755	(0.06%)
Cancer				
Breast cancer	23	(0.01%)	86	(0.01%)
Ovarian cancer	22	(0.01%)	67	(0.01%)
Endometrial cancer	6	(<0.01%)	10	(<0.01%)
Colorectal cancer	20	(0.01%)	59	(0.01%)
Uterus cancer	4	(<0.01%)	6	(<0.01%)
Lung cancer	66	(0.02%)	147	(0.01%)
Pancreas cancer	27	(0.01%)	67	(0.01%)
Lymphoma (NHL only)	11	(<0.01%)	28	(<0.01%)
Leukemia	7	(<0.01%)	29	(<0.01%)
Brain cancer	4	(<0.01%)	14	(<0.01%)
Multiple myeloma	11	(<0.01%)	20	(<0.01%)
Other cancer	50	(0.01%)	235	(0.02%)
Unknown cancer site	12	(<0.01%)	57	(<0.01%)
Total cancer deaths	263	(0.07%)	825	(0.07%)
Accident/injury				
Homicide	2	(<0.01%)	1	(<0.01%)
Accident	20	(0.01%)	63	(0.01%)
Suicide	0	(0.00%)	1	(<0.01%)
Other injury	1	(<0.01%)	3	(<0.01%)
Total accidental deaths	23	(0.01%)	68	(0.01%)

Table 7.14 (continued)
Cause of Death (Annualized Percentages): MRC and SRC Participants

Data as of: September 20, 2013; Events through September 20, 2013

	MRC		SRC	
Other				
Alzheimer's disease	10	(<0.01%)	59	(0.01%)
COPD	37	(0.01%)	108	(0.01%)
Pneumonia	40	(0.01%)	79	(0.01%)
Pulmonary fibrosis	6	(<0.01%)	21	(<0.01%)
Renal failure	15	(<0.01%)	45	(<0.01%)
Sepsis	24	(0.01%)	38	(<0.01%)
Dementia, NOS	26	(0.01%)	37	(<0.01%)
Amyotrophic Lateral Sclerosis	5	(<0.01%)	0	(0.00%)
Parkinson's	3	(<0.01%)	4	(<0.01%)
Hepatic cirrhosis	7	(<0.01%)	5	(<0.01%)
Other known cause	62	(0.02%)	391	(0.03%)
Unknown cause	15	(<0.01%)	1003	(0.09%)
Total other cause deaths	250	(0.07%)	1790	(0.15%)

Table 8.1
Agreement of the Central Adjudications with Self-Reports for Outcomes Reported in Extension Study 2010-2015

Data as of: September 20, 2013

	Participants with a self-report[1]	Closed		Confirmed		Denied – related outcome found[2]		Denied – unrelated outcome found		Denied – no outcome found		Administrative denials	
		N	%	N	(%)[3]	N	(%)[3]	N	(%)[3]	N	(%)[3]	N	(%)[3]
Cardiovascular													
Clinical MI	184	165	90%	96	(58%)	43	(26%)	3	(2%)	23	(14%)	0	(0%)
CABG	80	74	93%	48	(65%)	21	(28%)	2	(3%)	3	(4%)	0	(0%)
PTCA	235	211	90%	138	(65%)	38	(18%)	2	(1%)	33	(16%)	0	(0%)
Carotid artery disease	77	76	99%	39	(51%)	25	(33%)	0	(0%)	12	(16%)	0	(0%)
Stroke/TIA[4]	331	305	92%	192	(63%)	39	(13%)	0	(0%)	71	(23%)	3	(1%)
PVD	91	82	90%	37	(45%)	10	(12%)	9	(11%)	26	(32%)	0	(0%)
DVT	216	183	85%	95	(52%)	7	(4%)	39	(21%)	42	(23%)	0	(0%)
Pulmonary embolism	113	96	85%	82	(85%)	3	(3%)	4	(4%)	7	(7%)	0	(0%)
Atrial fibrillation	773	696	90%	358	(51%)	95	(14%)	9	(1%)	234	(34%)	0	(0%)
Valvular heart disease	130	119	92%	86	(72%)	16	(13%)	1	(1%)	16	(13%)	0	(0%)
Cancers													
Breast cancer	1055	1001	95%	976	(98%)	1	(0%)	0	(0%)	24	(2%)	0	(0%)
Ovarian cancer	132	119	90%	71	(60%)	36	(30%)	3	(3%)	9	(8%)	0	(0%)
Endometrial cancer	197	174	88%	147	(84%)	22	(13%)	1	(1%)	4	(2%)	0	(0%)
Cervical cancer	26	23	88%	5	(22%)	15	(65%)	1	(4%)	2	(9%)	0	(0%)
Colorectal cancer	276	260	94%	213	(82%)	32	(12%)	1	(0%)	13	(5%)	1	(0%)
Bladder cancer	124	113	91%	94	(83%)	14	(12%)	1	(1%)	4	(4%)	0	(0%)
Brain cancer	45	43	96%	13	(30%)	13	(30%)	3	(7%)	14	(33%)	0	(0%)
Esophagus cancer	21	19	90%	11	(58%)	4	(21%)	0	(0%)	4	(21%)	0	(0%)
Gallbladder/bile duct cancer	22	16	73%	8	(50%)	8	(50%)	0	(0%)	0	(0%)	0	(0%)
Kidney cancer	98	89	91%	49	(55%)	26	(29%)	1	(1%)	13	(15%)	0	(0%)
Leukemia	105	99	94%	77	(78%)	9	(9%)	2	(2%)	11	(11%)	0	(0%)
Liver cancer	91	85	93%	12	(14%)	51	(60%)	3	(4%)	19	(22%)	0	(0%)
Lung cancer	384	362	94%	299	(83%)	30	(8%)	2	(1%)	31	(9%)	0	(0%)
Lymphoma/Hodgkin's	164	139	85%	106	(76%)	23	(17%)	4	(3%)	6	(4%)	0	(0%)
Melanoma	432	400	93%	266	(67%)	14	(4%)	1	(0%)	119	(30%)	0	(0%)
Multiple myeloma	64	57	89%	46	(81%)	5	(9%)	0	(0%)	6	(11%)	0	(0%)
Pancreas cancer	116	107	92%	88	(82%)	13	(12%)	0	(0%)	6	(6%)	0	(0%)
Stomach cancer	45	43	96%	15	(35%)	21	(49%)	0	(0%)	7	(16%)	0	(0%)

[1] Excludes duplicates and prior conditions.
[2] All cardiovascular outcomes are considered related, all cancers are considered related and all fractures are considered related.
[3] Percentages between parentheses are relative to "closed."
[4] Stroke and TIA have a combined self-report. Only stroke is monitored.

Table 8.1 (continued)
Agreement of the Central Adjudications with Self-Reports for Outcomes Reported in Extension Study 2010-2015

Data as of: September 20, 2013

	Participants with a self-report[1]	Closed		Confirmed		Denied – related outcome found[2]		Denied – unrelated outcome found		Denied – no outcome found		Administrative denials	
		N	%	N	(%)[3]	N	(%)[7]	N	(%)[7]	N	(%)[7]	N	(%)[7]
Thyroid cancer	66	60	91%	49	(82%)	4	(7%)	0	(0%)	7	(12%)	0	(0%)
Other genital organ cancer	50	48	96%	6	(13%)	37	(77%)	4	(8%)	1	(2%)	0	(0%)
Other cancer[5]	261	252	97%	122	(48%)	53	(21%)	8	(3%)	68	(27%)	1	(0%)
Fractures													
Hip fracture	142	125	88%	96	(77%)	0	(0%)	0	(0%)	28	(22%)	1	(1%)
Upper leg fracture[6]	101	93	92%	0	(0%)	36	(39%)	7	(8%)	49	(53%)	1	(1%)

[1] Excludes duplicates and prior conditions.
[2] All cardiovascular outcomes are considered related, all cancers are considered related and all fractures are considered related.
[3] Percentages between parentheses are relative to "closed."
5 Any cancer other than those listed above, excluding non-melanoma skin cancer.
6 Upper leg fractures are only investigated for possible occurrence of hip fracture.

Table 8.2
Source of Outcomes Identified by Central Adjudications for Outcomes Reported in Extension Study 2010-2015

Data as of: September 20, 2013

	Centrally confirmed	Reason for central investigation					
		Self-report same outcome		Self-report related outcome[1]		Self-report unrelated outcome[2]	
	N	N	%	N	%	N	%
Cardiovascular							
Clinical MI	183	97	53%	66	36%	20	11%
CABG	54	48	89%	6	11%	0	0%
PTCA	155	143	92%	12	8%	0	0%
Carotid artery disease	40	31	78%	4	10%	5	13%
Stroke	222	197	89%	2	1%	23	10%
PVD	54	37	69%	5	9%	12	22%
DVT	126	97	77%	9	7%	20	16%
Pulmonary embolism	101	80	79%	11	11%	10	10%
Atrial fibrillation	454	303	67%	78	17%	73	16%
Valvular heart disease	108	66	61%	34	31%	8	7%
Cancers							
Breast cancer	987	979	99%	6	1%	2	<1%
Ovarian cancer	74	71	96%	3	4%	0	0%
Endometrial cancer	163	147	90%	16	10%	0	0%
Cervical cancer	5	5	100%	0	0%	0	0%
Colorectal cancer	222	212	95%	7	3%	3	1%
Bladder cancer	97	93	96%	4	4%	0	0%
Brain Cancer	13	13	100%	0	0%	0	0%
Kidney cancer	52	50	96%	1	2%	1	2%
Leukemia	84	76	90%	6	7%	2	2%
Liver cancer	14	12	86%	2	14%	0	0%
Lung cancer	313	303	97%	8	3%	2	1%
Lymphoma/Hodgkin's	141	106	75%	34	24%	1	1%
Melanoma	271	266	98%	5	2%	0	0%
Multiple myeloma	53	46	87%	7	13%	0	0%
Pancreas cancer	91	88	97%	1	1%	2	2%
Thyroid cancer	49	49	100%	0	0%	0	0%
Other cancer	260	0	0%	258	99%	2	1%
Fractures							
Hip fracture	131	97	74%	33	25%	1	1%

[1] All cardiovascular outcomes are considered related, all cancers are considered related and all fractures are considered related.
[2] Includes self-report of hospitalizations.

Table 9.1
UNC Heart Failure Diagnosis Detail for HT, African American and Hispanic (HAH) Participants with a Form 135[1] by Age and Race/Ethnicity

Data as of: September 20, 2013; Events through September 30, 2010

	Total # of Cases (N = 4,458)		# Cases by Age							
			50-54 (N = 258)		55-59 (N = 442)		60-69 (N = 1,964)		70-79 (N = 1,794)	
	N	%	N	%	N	%	N	%	N	%
Heart failure diagnosis										
Definite decompensated	1577	35.4	76	29.5	148	33.5	684	34.8	669	37.3
Possible decompensated	986	22.1	61	23.6	102	23.1	434	22.1	389	21.7
Chronic stable heart failure	877	19.7	56	21.7	86	19.5	381	19.4	354	19.7
Heart failure unlikely	643	14.4	40	15.5	67	15.2	302	15.4	234	13.0
Unclassifiable	375	8.4	25	9.7	39	8.8	163	8.3	148	8.2

	# Cases by Race/Ethnicity									
	American Indian/ Alaskan Native (N = 16)		Asian/Pacific Islander (N = 33)		Black/African American (N = 1,325)		Hispanic/ Latino (N = 237)		White (N = 2,813)		Unknown (N = 34)	
	N	%	N	%	N	%	N	%	N	%	N	%
Heart failure diagnosis												
Definite decompensated	12	75.0	13	39.4	467	35.2	76	32.1	992	35.3	17	50.0
Possible decompensated	0	0.0	9	27.3	277	20.9	47	19.8	650	23.1	3	8.8
Chronic stable heart failure	3	18.8	2	6.1	297	22.4	44	18.6	524	18.6	7	20.6
Heart failure unlikely	1	6.3	7	21.2	158	11.9	43	18.1	428	15.2	6	17.6
Unclassifiable	0	0.0	2	6.1	126	9.5	27	11.4	219	7.8	1	2.9

[1] Form 135 = UNC Heart Failure adjudication. Includes multiple forms per participant. Cases sent to UNC for adjudication include all self-reported or discovered heart failure cases and a portion of self reported angina or other heart condition cases with 2 or more essential documents among HAH participants.

Table 9.2
WHI CHF vs. UNC HF[1] for HT, African American and Hispanic (HAH) Participants

Data as of: September 20, 2013; Events through April 8, 2005

	Congestive Heart Failure, WHI			
	No		Yes	
	# of Participants	%	# of Participants	%
All HAH participants				
Heart failure, UNC				
No	42571	99.2	254	20.4
Yes[2]	158	0.4	918	73.7
Unclassifiable[3]	141	0.3	64	5.1
Insufficient documentation[4]	58	0.1	10	0.8
HT participants				
Heart failure, UNC				
No	26283	99.0	77	9.6
Yes[2]	127	0.5	682	84.6
Unclassifiable[3]	94	0.4	41	5.1
Insufficient documentation[4]	37	0.1	6	0.7
MRC participants				
Heart failure, UNC				
No	21905	99.5	69	22.5
Yes[2]	32	0.1	213	69.4
Unclassifiable[3]	55	0.2	21	6.8
Insufficient documentation[4]	16	0.1	4	1.3

[1] UNC heart failure is counted as yes if the participant had any case adjudicated as heart failure. It is counted as no if all cases were adjudicated as no heart failure or the participant had no possible heart failure cases. It is counted as unclassifiable or insufficient documentation if any case was coded unclassifiable or if a possible case was not forwarded to UNC and any other case is classified as no heart failure.
[2] UNC heart failure includes definite or possible decompensated heart failure.
[3] Coded by UNC as unclassifiable.
[4] Insufficient documentation to forward the case to UNC.

Table 9.3
Number of UNC Cases Per Participant Adjudicated as Definite or Possible Decompensated HF by Cohort

Data as of: September 20, 2013; Events through September 30, 2010

	HAH participants[1]		HT participants		MRC participants	
	N	%	N	%	N	%
Total number of cases sent to UNC						
1	1649	64.1	1164	62.3	600	65.4
2	473	18.4	357	19.1	182	19.8
3	222	8.6	173	9.3	68	7.4
4	104	4.0	78	4.2	31	3.4
≥5	126	4.9	96	5.1	37	4.0
Number of HF[2] cases						
0	829	32.2	572	30.6	344	37.5
1	1266	49.2	925	49.5	443	48.3
2	288	11.2	224	12.0	81	8.8
3	116	4.5	82	4.4	32	3.5
≥4	75	2.9	65	3.5	18	2.0

[1] HT, African American and Hispanic Participants.
[2] Definite or possible decompensated heart failure.

Table 10.1
Age[1] Distribution by Race/Ethnicity for Active[2] WHI Extension Study 2010-2015 Participants

Data as of: September 20, 2013

Age at start of Extension 2010-2015 (September 30, 2010)	Total (N = 86,046)		Race/Ethnicity: American Indian/ Alaskan Native (N = 285)		Asian/Pacific Islander (N = 1,738)		Black/African American (N = 5,515)		Hispanic/ Latino (N = 2,205)		White (N = 75,307)		Unknown (N = 996)	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
<65	965	1.1	10	3.5	51	2.9	152	2.8	79	3.6	658	0.9	15	1.5
65-69	14758	17.2	71	24.9	396	22.8	1268	23.0	610	27.7	12238	16.3	175	17.6
70-79	43877	51.0	136	47.7	844	48.6	2975	53.9	1107	50.2	38336	50.9	479	48.1
80-89	24870	28.9	66	23.2	416	23.9	1051	19.1	398	18.0	22634	30.1	305	30.6
90+	1576	1.8	2	0.7	31	1.8	69	1.3	11	0.5	1441	1.9	22	2.2

[1] Age on September 30, 2010.
[2] Vital status is alive with current participation on September 20, 2013.

Table 10.2
Distribution of Aging Indicators Collected During the WHI Extension Study 2010-2015 Stratified by Age at the Beginning of the WHI Extension Study 2010-2015 for WHI Extension Study 2010-2015 Participants

Data as of: September 20, 2013

	Total (N = 93,562)		Age on September 30, 2010									
			<65 (N = 1,013)		65-69 (N = 15,266)		70-79 (N = 46,378)		80-89 (N = 28,698)		90+ (N = 2,207)	
	N	%	N	%	N	%	N	%	N	%	N	%
Never completed Form 155	12099	12.9	112	11.1	1357	8.9	4674	10.1	5226	18.2	730	33.1
Perceived Health Status												
Excellent	9764	12.3	199	22.3	2592	18.9	5214	12.8	1667	7.4	92	6.6
Very good	33916	42.7	402	45.0	6631	48.2	18301	44.8	8173	36.1	409	29.4
Good	28199	35.5	232	26.0	3767	27.4	14016	34.3	9589	42.4	595	42.8
Fair	6956	8.7	49	5.5	690	5.0	3051	7.5	2910	12.9	256	18.4
Poor	682	0.9	11	1.2	69	0.5	262	0.6	302	1.3	38	2.7
Quality of Life												
Worst, 0-3	1275	1.6	15	1.7	155	1.1	528	1.3	505	2.2	72	5.3
Halfway, 4-6	12511	15.8	95	10.7	1316	9.6	5763	14.2	4952	22.0	385	28.2
Best, 7-10	65252	82.6	778	87.6	12224	89.3	34326	84.5	17015	75.7	909	66.5
Functional Capacity, ADL Dependencies												
None[1]	70521	88.5	846	94.9	13170	95.7	37545	91.8	18237	80.2	723	51.6
Eating	430	0.5	5	0.6	28	0.2	163	0.4	195	0.9	39	2.8
Dressing	1417	1.8	9	1.0	88	0.6	517	1.3	682	3.0	121	8.7
Transferring	833	1.0	7	0.8	52	0.4	301	0.7	388	1.7	85	6.1
Bathing	2205	2.8	12	1.3	96	0.7	700	1.7	1160	5.1	237	17.1
Grocery Shopping	7616	9.6	35	3.9	423	3.1	2683	6.6	3869	17.1	606	44.2
Taking Medication	2350	3.0	6	0.7	101	0.7	708	1.7	1295	5.7	240	17.4
Performance Measures, Rand-36 Scale												
0-25	7940	10.4	36	4.1	567	4.2	3060	7.8	3807	17.7	470	37.1
25-50	12754	16.7	63	7.2	1163	8.6	5865	14.9	5307	24.7	356	28.1
51-75	19753	25.8	142	16.2	2637	19.6	10342	26.2	6339	29.5	293	23.1
76-100	36080	47.1	633	72.4	9092	67.6	20188	51.2	6018	28.0	149	11.8
Independence												
Supportive Services Availability	9233	12.7	40	5.0	652	5.2	3561	9.6	4485	21.6	495	39.4
Supportive Services Use	2620	29.3	4	10.5	58	9.2	618	18.0	1664	38.2	276	58.6
Need for nursing care	2111	2.7	9	1.0	159	1.2	863	2.2	965	4.4	115	8.6
Use of walking aid [2]	11264	14.3	38	4.3	616	4.5	3984	9.8	5888	26.5	738	55.1
Lives alone	31611	41.4	240	27.2	4017	30.0	14864	37.7	11703	54.8	787	61.9
Falls[3]												
None	38500	41.8	505	50.3	7232	47.6	20050	43.7	10054	35.9	659	31.6
One time	19923	21.6	199	19.8	3164	20.8	9893	21.5	6220	22.2	447	21.5
Two times	12342	13.4	112	11.2	1828	12.0	5990	13.0	4094	14.6	318	15.3
Three or more times	21434	23.2	188	18.7	2960	19.5	9998	21.8	7629	27.3	659	31.6

[1] No limitations or need for help reported at any follow-up visit.
[2] Cane, crutches, walker, or wheelchair.
[3] Falls data is collected on Form 33 and is summed over the Extension Study 2010-2015 time period.

Table 10.3
Distribution of Aging Indicators Collected During the WHI Extension Study 2010-2015 Stratified by Race/Ethnicity for WHI Extension Study 2010-2015 Participants

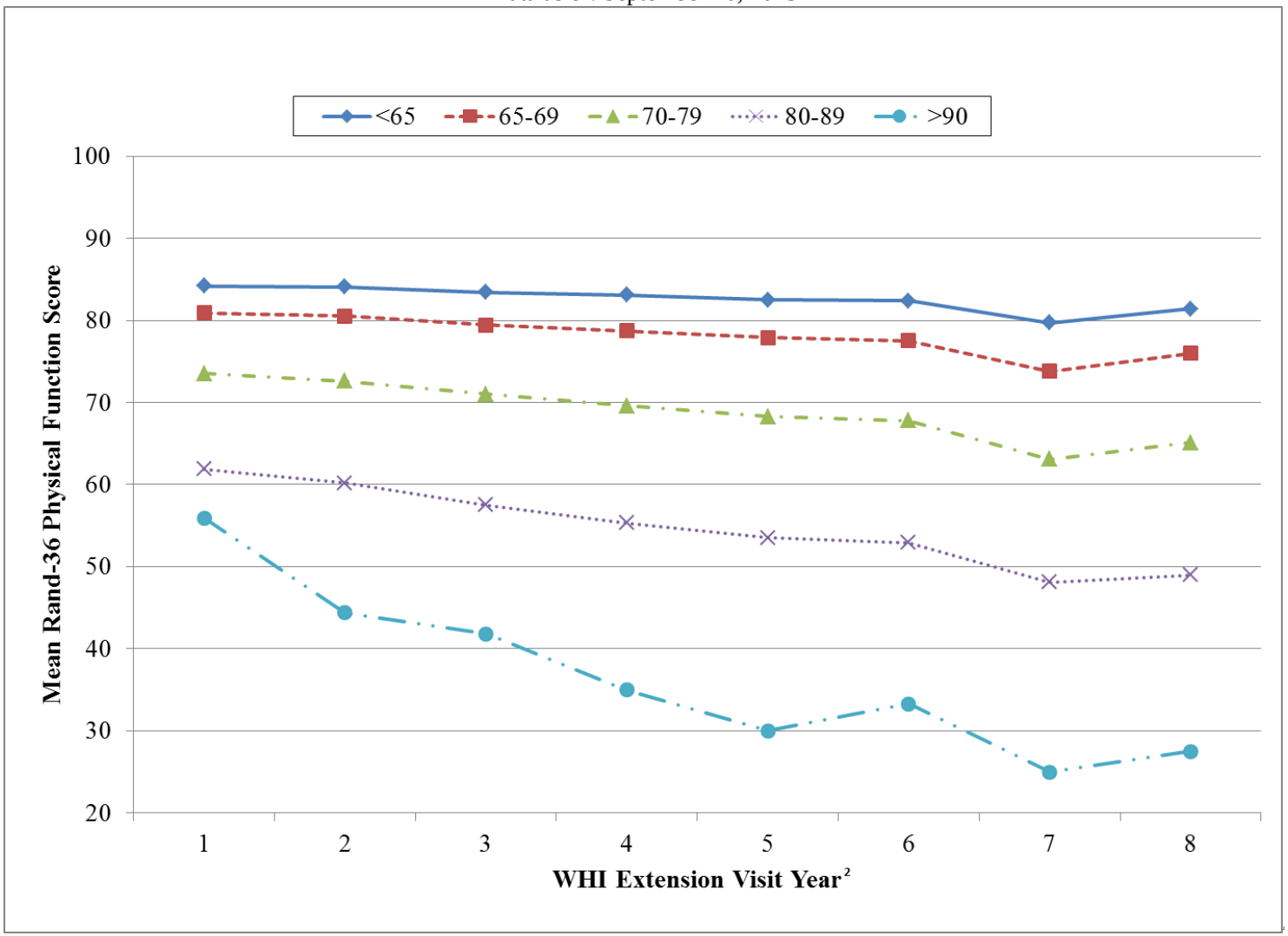
Data as of: September 20, 2013

	Race/Ethnicity											
	American Indian/ Alaskan Native (N =318)		Asian/Pacific Islander (N =1,880)		Black/African American (N =6,136)		Hispanic/ Latino (N =2,472)		White (N =81,654)		Unknown (N = 1,102)	
	N	%	N	%	N	%	N	%	N	%	N	%
Never completed Form 155	62	19.5	242	12.9	1447	23.6	481	19.5	9691	11.9	176	16.0
Perceived Health Status												
Excellent	26	10.6	141	8.8	269	5.9	212	10.9	9032	12.9	84	9.4
Very good	105	42.7	659	41.0	1495	32.8	725	37.3	30574	43.5	358	40.0
Good	79	32.1	642	40.0	2157	47.3	749	38.5	24227	34.5	345	38.5
Fair	32	13.0	153	9.5	593	13.0	237	12.2	5840	8.3	101	11.3
Poor	4	1.6	12	0.7	50	1.1	21	1.1	588	0.8	7	0.8
Quality of Life												
Worst, 0-3	7	2.8	19	1.2	52	1.2	12	0.6	1165	1.7	20	2.3
Halfway, 4-6	48	19.3	264	16.5	885	19.6	374	19.4	10778	15.4	162	18.3
Best, 7-10	194	77.9	1318	82.3	3584	79.3	1545	80.0	57908	82.9	703	79.4
Functional Capacity, ADL Dependencies												
None[1]	211	85.4	1468	91.0	3970	86.6	1735	89.0	62354	88.6	783	86.4
Eating	2	0.8	8	0.5	29	0.6	10	0.5	376	0.5	5	0.6
Dressing	5	2.0	14	0.9	82	1.8	24	1.2	1272	1.8	20	2.2
Transferring	3	1.2	10	0.6	47	1.0	21	1.1	737	1.0	15	1.7
Bathing	6	2.4	15	0.9	174	3.8	25	1.3	1954	2.8	31	3.4
Grocery Shopping	29	11.7	121	7.5	526	11.5	162	8.4	6677	9.5	101	11.2
Taking Medication	8	3.3	32	2.0	110	2.4	46	2.4	2125	3.0	29	3.2
Performance Measures, Rand-36 Scale												
0-25	33	14.1	105	6.8	526	12.2	143	7.9	7050	10.4	83	9.8
25-50	34	14.5	174	11.3	842	19.6	224	12.3	11333	16.7	147	17.3
51-75	65	27.8	402	26.0	1144	26.6	464	25.6	17469	25.8	209	24.6
76-100	102	43.6	863	55.9	1785	41.5	985	54.2	31934	47.1	411	48.4
Independence												
Supportive Services Availability	35	15.0	250	18.1	429	10.1	177	10.1	8219	12.8	123	15.1
Supportive Services Use	9	27.3	30	12.5	127	31.1	29	16.8	2392	30.1	33	27.7
Need for nursing care	4	1.6	17	1.1	91	2.0	16	0.8	1953	2.8	30	3.4
Use of walking aid[2]	41	16.8	138	8.6	904	20.1	190	9.9	9853	14.2	138	15.6
Lives alone	105	43.9	451	29.0	2099	47.7	643	34.6	27986	41.5	327	37.7
Falls[3]												
None	149	48.1	894	48.4	3260	53.9	1191	49.2	32495	40.4	511	47.1
One time	52	16.8	405	21.9	1235	20.4	486	20.1	17530	21.8	215	19.8
Two times	43	13.9	229	12.4	635	10.5	310	12.8	10999	13.7	126	11.6
Three or more times	66	21.3	320	17.3	916	15.2	436	18.0	19463	24.2	232	21.4

[1] No limitations or need for help reported at any follow-up visit.
[2] Cane, crutches, walker, or wheelchair.
[3] Falls data is collected o+n Form 33 and is summed over the Extension Study 2010-2015 time period.

Figure 10.1
Mean Rand-36 Physical Function Score Over Time by Age[1] During the WHI Extension Studies 2005-2015

Data as of: September 20, 2013



[1] Age on April 1, 2005.
[2] WHI Extension Visit Years 6, 7 and 8 data were collected during WHI Extension Study 2010-2015.

Table 11.1
Medication Inventory Response Rates

Data as of: September 17, 2012

Form	# Mailed	Total Response	% Total Response
153 (Medication and Supplement Inventory)	108296	97462	90.0
154 (Breast Health Supplement to Medication Inventory)	6584	5792	88.0

Table 11.2
Barriers to Prescription Medication

Data as of: September 17, 2012

	WHI Extension Study 2005-2010 Participants (N = 97,448)		WHI Extension Study 2010-2015 MRC Participants (N = 20,735)		WHI Extension Study 2010-2015 SRC Participants (N = 68,773)	
Description	**N**	**%**	**N**	**%**	**N**	**%**
Did not experience any barriers to taking prescription medications	66026	67.8	13727	66.2	47452	69.0
No Response to Barriers Question	18443	18.9	4254	20.5	12297	17.9
Concerned about possible side effects or complications	6934	7.1	1408	6.8	4924	7.2
Don't like taking medications	5643	5.8	1236	6.0	3824	5.6
The medication or copayment cost too much	4192	4.3	1018	4.9	2805	4.1
Health insurance would not cover the medication	3568	3.7	819	3.9	2420	3.5
Taking too many medications	1742	1.8	443	2.1	1074	1.6
Problem getting to the medical facility/physician	395	0.4	107	0.5	202	0.3
Family discouraged me from taking the medication	316	0.3	65	0.3	209	0.3
Taking the medication would be inconvenient	280	0.3	50	0.2	185	0.3
Friends discouraged me from taking the medication	210	0.2	42	0.2	146	0.2
Concerned about missing work due to taking the medication	117	0.1	33	0.2	65	0.1

Table 11.3
Top 20 Therapeutic Classes from the WHI Extension Study 2005-2010
Medication Inventory by WHI Extension Study 2010-2015 Cohort

Data as of: September 17, 2012

Therapeutic Class	WHI Extension Study 2005-2010 Participants (N = 97,448) N	%	WHI Extension Study 2010-2015 MRC Participants (N = 20,735) N	%	WHI Extension Study 2010-2015 SRC Participants (N = 68,773) N	%
Calcium Combinations	56957	58.4	10690	51.6	42614	62.0
Multiple Vitamins w/ Minerals	56642	58.1	10871	52.4	41903	60.9
Salicylates	50018	51.3	10492	50.6	35785	52.0
HMG CoA Reductase Inhibitors	38746	39.8	8432	40.7	27339	39.8
Nonsteroidal Anti-inflammatory Agents (NSAID)	29222	30.0	6182	29.8	21151	30.8
Vitamin D	27207	27.9	4690	22.6	20694	30.1
Thyroid Hormones	24165	24.8	4150	20.0	18126	26.4
Proton Pump Inhibitors	22515	23.1	4417	21.3	16238	23.6
Beta Blockers Cardio-selective	22118	22.7	4597	22.2	15545	22.6
Calcium Channel Blockers	17340	17.8	4336	20.9	11425	16.6
Bisphosphonates	17085	17.5	3246	15.7	12640	18.4
ACE Inhibitors	16593	17.0	3825	18.4	11244	16.3
Thiazides and Thiazide-like Diuretics	11978	12.3	2892	13.9	8214	11.9
Angiotensin II Receptor Antagonists	10747	11.0	2283	11.0	7608	11.1
Analgesics Other	8757	9.0	1794	8.7	6224	9.1
Selective Serotonin Reuptake Inhibitors (SSRI)	8604	8.8	1292	6.2	6357	9.2
Antacids - Calcium Salts	8509	8.7	1475	7.1	6498	9.4
H-2 Antagonists	7662	7.9	1614	7.8	5490	8.0
Loop Diuretics	7071	7.3	1735	8.4	4497	6.5
Urinary Antispasmodics	5978	6.1	1240	6.0	4231	6.2

Table 12.1
Consent Status for Long Life Study Participants

Data as of: September 20, 2013

	N	(%)
Number eligible	14081	
Phase 1: Age 72-79	9930	(70.5%)
Phase 2: Age 63-72	2651	(18.8%)
Phase 3: Age 64-98	1500	(10.7%)
Consented	9246	(65.7%[1])
Completed visit	7875	(85.2%[2])
Age at visit		
63-69	724	(9.2%)
70-79	3050	(38.7%)
80-89	3689	(46.8%)
≥90	412	(5.2%)
Race/ethnicity		
White	3910	(49.7%)
Black	2651	(33.7%)
Hispanic	1314	(16.7%)
Blood draw	7481	(95.0%[3])

[1] Percentage of eligible.
[2] Percentage of consented.
[3] Percentage of completed visit.

Table 12.2
Blood Pressure, Anthropometric and Physical Performance Measures
by Age for Long Life Study Participants

Data as of: September 20, 2013

	Total (N = 7,875)		Age at visit: 63-69 (N = 724)		70-79 (N = 3,050)		80-89 (N = 3,689)		≥90 (N = 412)	
	N	%	N	%	N	%	N	%	N	%
Systolic blood pressure, mmHg, Mean (SD)	125.9	(14.6)	122.4	(12.9)	125.5	(14.0)	126.5	(14.9)	129.1	(17.5)
≤120	2962	47.1	340	47.1	1179	38.6	1310	35.6	135	32.8
120 - 140	3796	48.3	327	45.3	1476	48.4	1806	49.0	187	45.4
>140	1106	14.1	55	7.6	395	13.0	566	15.4	90	21.8
Diastolic blood pressure, mmHg, Mean (SD)	72.6	(8.9)	73.8	(8.1)	73.4	(8.7)	71.8	(9.1)	71.5	(9.4)
<90	7608	96.8	702	97.1	2931	96.2	3575	97.1	400	97.1
≥90	254	3.2	21	2.9	117	3.8	104	2.8	12	2.9
Resting pulse in 30 seconds, Mean (SD)	34.1	(5.4)	34.5	(5.4)	34.2	(5.5)	34.0	(5.5)	34.0	(4.6)
Height, cm, Mean (SD)	159.5	(7.3)	160.9	(7.2)	160.5	(7.2)	158.9	(7.2)	156.2	(7.1)
Weight, kg, Mean (SD)	71.9	(15.9)	78.2	(17.5)	75.8	(16.7)	68.5	(13.9)	62.7	(11.8)
Waist circumference, cm, Mean (SD)	90.4	(13.9)	92.3	(13.9)	92.0	(14.5)	89.1	(13.3)	86.4	(12.8)
Body mass index, kg/m^2, Mean (SD)	28.2	(5.9)	30.1	(6.4)	29.4	(6.2)	27.2	(5.3)	25.7	(4.8)
Underweight (< 18.5)	112	1.4	11	1.5	29	1.0	59	1.6	13	3.2
Normal (18.5 - 24.9)	2378	30.6	136	19.0	741	24.5	1316	36.2	185	45.8
Overweight (25.0 - 29.9)	2799	36.0	244	34.1	1056	35.0	1357	37.3	142	35.1
Obesity I (30.0 - 34.9)	1505	19.4	187	26.2	660	21.9	615	16.9	43	10.6
Obesity II (35.0 - 39.9)	633	8.1	80	11.2	337	11.2	200	5.5	16	4.0
Extreme Obesity III (≥ 40)	348	4.5	57	8.0	196	6.5	90	2.5	5	1.2
Grip Strength										
Completed	7296	94.2	674	94.0	2859	95.3	3393	93.8	370	90.7
Attempted, unable to complete	35	0.5	1	0.1	11	0.4	17	0.5	6	1.5
Refused	15	0.2	4	0.6	3	0.1	7	0.2	1	0.2
Not attempted	397	5.1	38	5.3	128	4.3	200	5.5	31	7.6
If attempted, grip strength, kg, Mean (SD)	17.8	(7.1)	21.8	(7.0)	19.7	(7.0)	16.0	(6.4)	13.2	(5.8)
Walking pace										
Completed	7086	95.5	669	97.0	2767	96.6	3292	94.9	358	90.6
Attempted, unable to complete	20	0.3	1	0.1	7	0.2	9	0.3	3	0.8
Refused	21	0.3	5	0.7	3	0.1	10	0.3	3	0.8
Not attempted	290	3.9	15	2.2	86	3.0	158	4.6	31	7.8
If attempted, walking pace, m/sec, Mean (SD)	0.6	(0.3)	0.7	(0.3)	0.7	(0.3)	0.6	(0.3)	0.5	(0.2)
Single chair stand										
Completed	7091	92.2	691	97.6	2861	95.8	3249	90.2	290	73.6
Attempted, unable to complete	238	3.1	6	0.8	40	1.3	155	4.3	37	9.4
Refused	46	0.6	4	0.6	8	0.3	27	0.7	7	1.8
Not attempted	313	4.1	7	1.0	76	2.5	170	4.7	60	15.2
Repeated chair stand										
Completed	6803	89.7	678	96.4	2765	94.2	3090	87.0	270	68.0
Attempted, unable to complete	216	2.8	7	1.0	42	1.4	142	4.0	25	6.3
Refused	75	1.0	7	1.0	12	0.4	43	1.2	13	3.3
Not attempted	493	6.5	11	1.6	115	3.9	278	7.8	89	22.4
If attempted, repeated chair stands, #stands/sec, Mean (SD)	0.3	(0.1)	0.4	(0.1)	0.4	(0.1)	0.3	(0.1)	0.3	(0.2)
Look AHEAD SPPB score[1], Mean (SD)	1.3	(0.5)	1.6	(0.4)	1.4	(0.4)	1.2	(0.5)	0.9	(0.5)

[1] Look AHEAD (Action for Health in Diabetes) study. SPPB (Short Physical Performance Battery) score.

Table 12.3
Blood Pressure, Anthropometric and Physical Performance Measures
by Race/Ethnicity for Long Life Study Participants

Data as of: September 20, 2013

	Race/Ethnicity					
	White (N = 3,910)		Black (N = 2,651)		Hispanic (N = 1,314)	
	N	%	N	%	N	%
Systolic blood pressure, mmHg, Mean (SD)	125.8	(14.8)	127.0	(14.6)	123.7	(13.6)
≤120	1461	37.4	919	34.7	582	37.7
120 - 140	1892	48.5	1323	50.0	581	44.2
>140	552	14.1	404	15.3	150	11.4
Diastolic blood pressure, mmHg, Mean (SD)	71.8	(9.1)	74.0	(8.9)	72.2	(8.2)
<90	3790	97.1	2536	95.8	1282	97.8
≥90	114	2.9	111	4.2	29	2.2
Resting pulse in 30 seconds	34.0	5.3	34.3	5.4	34.2	5.9
Height, cm, Mean (SD)	159.3	(26.3)	161.2	(11.3)	156.8	(27.6)
Weight, kg, Mean (SD)	69.1	(14.5)	77.9	(17.2)	68.4	(14.1)
Waist circumference, cm	89.5	13.9	92.2	14.1	89.4	13.4
Body mass index, kg/m^2, Mean (SD)	27.3	(5.5)	29.8	(6.2)	27.9	(5.6)
Underweight (< 18.5)	74	1.9	26	1.0	12	0.9
Normal (18.5 - 24.9)	1380	35.8	558	21.3	440	33.8
Overweight (25.0 - 29.9)	1406	36.4	922	35.3	471	36.2
Obesity I (30.0 - 34.9)	651	16.9	613	23.5	241	18.5
Obesity II (35.0 - 39.9)	228	5.9	316	12.1	89	6.8
Extreme Obesity III (≥ 40)	120	3.1	179	6.8	49	3.8
Grip Strength						
Completed	3603	93.6	2495	96.0	1198	92.5
Attempted, unable to complete	21	0.5	11	0.4	3	0.2
Refused	5	0.1	8	0.3	2	0.2
Not attempted	221	5.7	84	3.2	92	7.1
If attempted, grip strength, kg, Mean (SD)	16.3	(6.7)	20.0	(7.3)	18.0	(6.4)
Walking pace						
Completed	3536	95.6	2348	94.8	1202	96.9
Attempted, unable to complete	9	0.2	10	0.4	1	0.1
Refused	9	0.2	9	0.4	3	0.2
Not attempted	146	3.9	110	4.4	34	2.7
If attempted, walking pace, m/sec, Mean (SD)	0.6	(0.3)	0.6	(0.3)	0.7	(0.3)
Single chair stand						
Completed	3449	90.3	2386	92.7	1256	97.1
Attempted, unable to complete	157	4.1	71	2.8	10	0.8
Refused	23	0.6	17	0.7	6	0.5
Not attempted	191	5.0	100	3.9	22	1.7
Repeated chair stand						
Completed	3292	87.3	2285	90.0	1226	95.9
Attempted, unable to complete	135	3.6	71	2.8	10	0.8
Refused	43	1.1	24	0.9	8	0.6
Not attempted	300	8.0	158	6.2	35	2.7
If attempted, repeated chair stands, #stands/sec, Mean (SD)	0.3	(0.1)	0.3	(0.1)	0.4	(0.1)
Look AHEAD SPPB score[1], Mean (SD)	1.2	(0.5)	1.3	(0.5)	1.5	(0.5)

[1] Look AHEAD (Action for Health in Diabetes) study. SPPB (Short Physical Performance Battery) score.

Table 12.4
CBC and Biomarker Results by Age for Long Life Study Participants

Data as of: September 20, 2013

	Total (N = 7,875)			Age at visit: 63-69 (N = 724)			70-79 (N = 3,050)			80-89 (N = 3,689)			≥90 (N = 412)		
	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD
CBC															
Hemoglobin, g/dL	7399	13.1	1.2	684	13.1	1.1	2867	13.1	1.2	3465	13.1	1.3	383	13.0	1.3
Hematocrit, %	7399	39.8	3.5	684	39.9	3.1	2867	39.7	3.4	3465	39.9	3.5	383	39.7	3.6
Red Blood Cell Count, 10^6/ul	7399	4.4	0.4	684	4.5	0.4	2867	4.5	0.4	3465	4.4	0.4	383	4.3	0.4
Platelet Count, 10^3/ul[1]	7399	227.6	61.6	684	242.7	60.0	2867	232.9	62.6	3465	222.2	60.2	383	213.3	61.2
White Blood Cell Count, 10^3/ul[1]	7398	6.0	1.8	684	5.8	1.7	2867	5.8	1.8	3464	6.1	1.7	383	6.3	1.9
Neutrophil Count, 10^3/ul[1]	7398	3.3	1.3	684	3.1	1.3	2867	3.2	1.3	3464	3.5	1.3	383	3.6	1.4
Neutrophil, %	7398	56.9	10.1	684	54.8	9.6	2867	55.6	10.1	3464	58.1	9.8	383	58.9	10.3
Basophil Count, 10^3/ul	7398	0.04	0.03	684	0.03	0.03	2867	0.04	0.02	3464	0.04	0.03	383	0.04	0.02
Basophil, %	7398	0.6	0.4	684	0.6	0.3	2867	0.6	0.4	3464	0.6	0.5	383	0.6	0.4
Eosinophil Count, 10^3/ul	7398	0.2	0.1	684	0.2	0.1	2867	0.2	0.1	3464	0.2	0.1	383	0.2	0.1
Eosinophil, %	7398	3.2	2.1	684	3.0	1.9	2867	3.2	2.1	3464	3.3	2.1	383	3.3	2.3
Monocyte Count, 10^3/ul[1]	7397	0.5	0.2	684	0.5	0.2	2867	0.5	0.2	3463	0.6	0.2	383	0.6	0.2
Monocyte, %	7397	9.5	2.7	684	8.8	2.2	2867	9.2	2.5	3463	9.8	2.8	383	10.3	3.3
Immature Granulocyte Count, 10^3/ul	7398	0.1	0.2	684	0.1	0.2	2867	0.1	0.2	3464	0.1	0.2	383	0.1	0.2
Immature Granulocyte Fraction, %	7398	0.2	0.3	684	0.2	0.3	2867	0.2	0.3	3464	0.2	0.3	383	0.2	0.3
Lymphocyte Count, 10^3/ul[1]	7398	1.7	0.6	684	1.8	0.6	2867	1.7	0.6	3464	1.6	0.6	383	1.6	0.7
Lymphocyte, %[1]	7398	28.4	9.2	684	31.7	9.2	2867	30.0	9.1	3464	26.8	8.9	383	25.5	8.6
Reticulocyte Count,10^3/ul[1]	7399	51.2	15.8	684	53.8	16.5	2867	52.5	16.1	3465	50.1	15.4	383	46.6	14.3
Reticulocyte, %[1]	7399	1.2	0.4	684	1.2	0.4	2867	1.2	0.4	3465	1.1	0.4	383	1.1	0.3
Mean Corpuscular Hemoglobin, pg	7399	29.7	2.1	684	29.1	2.1	2867	29.4	2.2	3465	30.0	2.0	383	30.3	1.8
Mean Corpuscular Hemoglobin Concentration, g/dL	7399	32.9	1.1	684	32.8	1.1	2867	32.9	1.2	3465	32.9	1.1	383	32.7	1.1
Mean Corpuscular Volume, fL	7399	90.4	5.9	684	88.7	6.0	2867	89.3	6.1	3465	91.3	5.5	383	92.6	5.3
Mean Platelet Volume, fL	7274	11.5	0.9	668	11.6	0.9	2810	11.5	0.9	3417	11.5	0.9	379	11.6	0.9
Platelet Distribution Width, fL	7274	14.6	2.4	668	14.6	2.3	2810	14.6	2.4	3417	14.6	2.4	379	14.8	2.4
Red Cell Distribution Width - CV, %[1]	7397	14.1	1.2	684	14.0	1.2	2866	14.1	1.3	3464	14.1	1.2	383	14.1	1.1
Red Cell Distribution Width - SD, fL[1]	7396	45.3	4.0	684	44.3	3.7	2865	44.9	3.8	3464	45.7	4.0	383	46.6	4.2

[1] Geometric mean and SD.

Table 12.4 (continued)
CBC and Biomarker Results by Age for Long Life Study Participants

Data as of: September 20, 2013

	Total (N = 7,875)			Age at visit: 63-69 (N = 724)			70-79 (N = 3,050)			80-89 (N = 3,689)			≥90 (N = 412)		
	N	**Mean**	**SD**	**N**	**Mean**	**SD**	**N**	**Mean**	**SD**	**N**	**Mean**	**SD**	**N**	**Mean**	**SD**
Inflammatory, lipids and other biomarkers															
C-reactive protein (high sensitivity), mg/L[1]	7324	1.9	2.1	678	2.3	2.5	2829	2.1	2.3	3438	1.8	1.9	379	1.5	1.5
Creatinine, mg/dL[1]	7325	0.9	0.2	678	0.8	0.2	2829	0.8	0.2	3439	0.9	0.2	379	0.9	0.2
Insulin, pmol/L[1]	7185	67.6	53.3	668	75.2	58.9	2772	71.8	54.5	3373	64.0	51.3	372	58.4	48.2
Glucose, mg/dL[1]	7317	96.5	22.8	678	95.8	22.3	2827	97.3	23.9	3433	96.3	22.2	379	94.7	20.7
HDL cholesterol, mg/dL	7325	60.5	15.1	678	60.1	16.0	2829	60.2	15.0	3439	60.5	14.8	379	62.5	16.2
LDL cholesterol, mg/dL	7306	114.8	34.8	675	118.8	35.7	2822	116.7	35.6	3430	112.6	34.1	379	113.7	32.2
Total Cholesterol, mg/dL	7325	196.9	39.9	678	200.6	40.9	2829	198.3	40.8	3439	195.0	39.0	379	197.4	37.3
Triglyceride, mg/dL[1]	7325	98.0	44.4	678	97.0	45.0	2829	96.5	44.0	3439	99.5	44.7	379	96.3	42.2

[1] Geometric mean and SD.

Table 12.5
CBC and Biomarker Results by Race/Ethnicity for Long Life Study Participants

Data as of: September 20, 2013

	Race/Ethnicity								
	White (N = 3,910)			Black (N = 2,651)			Hispanic (N = 1,314)		
	N	Mean	SD	N	Mean	SD	N	Mean	SD
CBC									
Hemoglobin, g/dL	3721	13.3	1.2	2408	12.7	1.2	1270	13.2	1.1
Hematocrit, %	3721	40.4	3.4	2408	38.9	3.4	1270	39.8	3.2
Red Blood Cell Count, 10^6/ul	3721	4.4	0.4	2408	4.4	0.5	1270	4.4	0.4
Platelet Count, 10^3/ul[1]	3721	224.4	61.3	2408	231.2	62.7	1270	230.7	60.2
White Blood Cell Count, 10^3/ul	3720	6.2	1.7	2408	5.6	1.8	1270	6.0	1.6
Neutrophil Count, 10^3/ul[1]	3721	3.6	1.3	2407	2.9	1.3	1270	3.4	1.2
Neutrophil, %	3721	58.9	9.4	2407	53.3	10.6	1270	57.7	9.0
Basophil Count, 10^3/ul	3720	0.04	0.03	2408	0.03	0.03	1270	0.04	0.02
Basophil, %	3720	0.6	0.4	2408	0.6	0.5	1270	0.6	0.3
Eosinophil Count, 10^3/ul	3721	0.2	0.1	2407	0.2	0.1	1270	0.2	0.1
Eosinophil, %	3721	3.3	2.1	2407	3.2	2.2	1270	3.1	2.0
Monocyte Count, 10^3/ul[1]	3720	0.6	0.2	2407	0.5	0.2	1270	0.5	0.2
Monocyte, %	3720	9.8	2.8	2407	9.4	2.6	1270	8.8	2.1
Immature Granulocyte Count, 10^3/ul	3721	0.1	0.2	2407	0.1	0.2	1270	0.1	0.1
Immature Granulocyte Fraction, %	3721	0.2	0.3	2407	0.2	0.3	1270	0.1	0.2
Lymphocyte Count, 10^3/ul[1]	3721	1.6	0.6	2407	1.8	0.6	1270	1.7	0.6
Lymphocyte, %[1]	3721	26.1	8.4	2407	32.1	9.7	1270	28.7	8.3
Reticulocyte Count,10^3/ul[1]	3721	49.9	15.5	2408	52.8	16.2	1270	52.0	15.6
Reticulocyte, %[1]	3721	1.1	0.3	2408	1.2	0.4	1270	1.2	0.3
Mean Corpuscular Hemoglobin, pg	3721	30.3	1.8	2408	28.7	2.3	1270	30.0	1.9
Mean Corpuscular Hemoglobin Concentration, g/dL	3721	33.0	1.1	2408	32.6	1.2	1270	33.2	1.1
Mean Corpuscular Volume, fL	3721	91.8	5.0	2408	88.1	6.8	1270	90.3	5.1
Mean Platelet Volume, fL	3682	11.4	0.9	2343	11.7	0.9	1249	11.5	0.9
Platelet Distribution Width, fL	3682	14.5	2.4	2343	14.8	2.4	1249	14.7	2.4
Red Cell Distribution Width - CV, %[1]	3720	13.9	1.2	2407	14.4	1.4	1270	13.9	1.1
Red Cell Distribution Width - SD, fL[1]	3720	45.6	3.9	2406	45.2	4.2	1270	44.6	3.6

[1] Geometric mean and SD.

Table 12.5 (continued)
CBC and Biomarker Results by Race/Ethnicity for Long Life Study Participants

Data as of: September 20, 2013

	Race/Ethnicity								
	White (N = 3,910)			Black (N = 2,651)			Hispanic (N = 1,314)		
	N	Mean	SD	N	Mean	SD	N	Mean	SD
Inflammatory, lipids and other biomarkers									
C-reactive protein (high sensitivity), mg/L[1]	3690	1.7	1.8	2377	2.3	2.6	1257	1.9	1.9
Creatinine, mg/dL[1]	3691	0.9	0.2	2377	0.9	0.3	1257	0.8	0.2
Insulin, pmol/L[1]	3622	61.4	48.1	2325	76.7	59.6	1238	70.5	55.7
Glucose, mg/dL[1]	3687	95.6	21.2	2374	97.3	25.3	1256	97.9	22.4
HDL cholesterol, mg/dL	3691	60.1	15.0	2377	62.3	15.4	1257	58.1	14.3
LDL cholesterol, mg/dL	3682	114.2	34.2	2374	115.4	35.9	1250	115.2	34.4
Total Cholesterol, mg/dL	3691	197.0	39.3	2377	196.2	40.7	1257	197.8	39.9
Triglyceride, mg/dL[1]	3691	103.6	46.0	2377	84.2	35.8	1257	110.8	50.3

[1] Geometric mean and SD.

Table 13.1
Extension Study 2010-2015 Form 33 – Medical History Update Processing

Data as of August 31, 2013

	Form 33 -- Due 5-1-12 thru 4-30-13													Cases to Forward to CCC[7]	
	Self-Report and Screening Outcomes Qxs 2-16										Outcomes Qxs 17-46				
	Total		CCC Mailings[2] Not Collected		Ppts Due for RC Collection[3]				Incomplete Qx 2-16		Incomplete[5] Qx 17-end			Incomplete Form 33[6]	
	# Due	% Collected	#	%	#	% of Due	Not Collected #	Not Collected %	#	% of Collected	# Required[4]	#	% of Collected	# Forms	# Cases	# Not Processed CCC
Boston	9,881	94.5	1,276	12.9	752	7.6	22	2.9	0		582	0		0	1,112	26
Buffalo	10,183	99.4	1,339	13.1	1,329	13.1	54	4.1	0		942	0		0	1,711	0
Columbus	10,661	98.4	1,173	11.0	1,096	10.3	94	8.6	0		926	0		0	1,617	21
Gainesville	8,336	94.1	1,144	13.7	720	8.6	68	9.4	2	0.0	698	2	0.3	2	1,043	30
Iowa	8,478	97.1	673	7.9	439	5.2	12	2.7	0		682	0		0	1,054	44
Medstar	4,584	95.5	766	16.7	599	13.1	38	6.3	0		506	0		0	684	0
Pittsburgh	4,124	98.4	573	13.9	547	13.3	40	7.3	2	0.0	418	4	1.0	4	787	0
Seattle/LaJolla	4,376	98.8	503	11.5	469	10.7	18	3.8	0		366	0		0	593	3
Stanford	15,568	97.1	1,514	9.7	1,105	7.1	39	3.5	6	0.0	1,024	2	0.2	6	1,806	1
Tucson	6,036	94.6	735	12.2	432	7.2	24	5.6	0		382	4	1.0	4	648	2
Wakeforest	9,436	93.9	1,362	14.4	823	8.7	32	3.9	2	0.0	696	2	0.3	2	1,009	11
All RCs	91,663	96.5	11,058	12.1	8,311	9.1	441	5.3	12	0.0	7,222	14	0.2	18	12,064	138

[1] Includes Form 33, ver 11, with mailings starting Nov 2010; excludes absolutely no contact and deceased participants
[2] CCC prepares the 1st mailing 2 months before the due date, waits 3 months, and prepares for a 2nd mailing to non-responders. Because the lag time for this report is 4 months, participants may still respond to the 2nd mailing before they appear in the 'Ppts Due for RC Collection' column.
[3] Includes participants who have not returned forms 2 months after the second mailing, have a 'no mail' status, or have an invalid address.
[4] Required based on responses to Qx 8-16 for MRC and to Qx 9-Cancer for SRC
[5] Includes Form 33s with incomplete/missing data in Qxs 17-end and forms with responses needing data entry at RC (e.g., dates, provider names and addresses)
[6] Maximum of incomplete form 33, Qx 2-16 or Qx 17-end
[7] Outcomes cases closed with a code '9-forward to CCC'; not limited to Form 33, ver. 11 (ES 1 cases)

Table 13.2
Extension Study 2010-2015 Outcomes Processing Workload

Data as of August 31, 2013

	Outcomes Cases[1]	Closed Cases[2]				Open Cases[3]								
		Total Closed		Sent to CCC[4]		Total Open		No MRs Requested[5]		No MRs Received[6]		Some MRs Received[7]		Open > 12 Mos
	Total #	#	%	#	% of Closed	#	%	#	% of Open	#	% of Open	#	% of Open	#
Boston	1,459	1,376	94.3	1,112	80.8	83	5.7	5	6.0	52	62.7	26	31.3	1
Buffalo	2,069	1,959	94.7	1,711	87.3	110	5.3	35	31.8	45	40.9	30	27.3	0
Columbus	1,844	1,743	94.5	1,617	92.8	101	5.5	14	13.9	84	83.2	3	3.0	0
Gainesville	1,273	1,143	89.8	1,043	91.3	130	10.2	42	32.3	69	53.1	19	14.6	19
Iowa	1,373	1,222	89.0	1,054	86.3	151	11.0	24	15.9	85	56.3	42	27.8	0
Medstar	836	815	97.5	684	83.9	21	2.5	5	23.8	12	57.1	4	19.0	0
Pittsburgh	956	927	97.0	787	84.9	29	3.0	18	62.1	9	31.0	2	6.9	2
Seattle/LaJolla	748	720	96.3	593	82.4	28	3.7	0	0.0	14	50.0	14	50.0	0
Stanford	2,240	2,106	94.0	1,806	85.8	134	6.0	42	31.3	13	9.7	79	59.0	2
Tucson	810	765	94.4	648	84.7	45	5.6	1	2.2	20	44.4	24	53.3	1
Wakeforest	1,270	1,166	91.8	1,009	86.5	104	8.2	18	17.3	41	39.4	45	43.3	0
All RCs	14,878	13,942	93.7	12,064	86.5	936	6.3	204	21.8	444	47.4	288	30.8	25

[1] Outcomes cases in process at the Regional Center since Oct. 1, 2010.
[2] Closed cases includes all cases closed since Oct. 1, 2010 (date ES 2015 started for the RCs)
[3] Open cases includes all open cases for ES 2015 participants (not restricted to ES 2 cases)
[4] Cases to be adjudicated; other closed cases do not require adjudication or cannot be processed (no ROI or no records received)
[5] Request for MR documents not yet done; RC needs to obtain signed ROI before requesting records.
[6] MR documents have been requested but none received
[7] Some but not all MR documents received or case not yet reviewed and closed

Table 13.3
Extension Study 2010–2015 Workload for Form 33 and Outcomes

Data as of August 31, 2013

	Form 33 Workload			Outcomes Workload			Combined Form 33 and Outcomes Workload	MRC Deaths[3]			# Open Cases with Deaths[3,4]
	Missing and Incomplete Forms[1]	Ave # Collected/Mo last 12 Mo	Est Months to Catch Up	Open Cases[2]	Avg # Cases Closed/Mo last 12 Mo	Est Months to Catch Up		Cum	Open		
	# Forms	# Forms	# Months	# Cases	# Cases	# Months	# Months	#	#	%	#
Boston	22	61	0.4	83	42	2.0	2.3	100	16	16.0	30
Buffalo	54	106	0.5	110	60	1.8	2.3	149	21	14.1	25
Columbus	94	84	1.1	101	56	1.8	2.9	138	24	17.4	41
Gainesville	70	54	1.3	130	33	3.9	5.2	123	40	32.5	36
Iowa	12	36	0.3	151	40	3.8	4.1	109	33	30.3	39
Medstar	38	47	0.8	21	27	0.8	1.6	51	2	3.9	3
Pittsburgh	44	42	1.0	29	30	1.0	2.0	50	5	10.0	9
Seattle/LaJolla	18	38	0.5	28	21	1.3	1.8	51	5	9.8	7
Stanford	45	89	0.5	134	60	2.2	2.7	152	11	7.2	19
Tucson	28	34	0.8	45	23	2.0	2.8	74	13	17.6	13
Wakeforest	34	66	0.5	104	37	2.8	3.4	107	30	28.0	24
All RCs	459	656	0.7	936	429	2.2	2.9	1,104	200	18.1	246

[1] From Table 1
[2] From Table 2
[3] MRC deaths since Oct. 1, 2010. RCs do not follow-up on SRC deaths.
[4] A death may have more than one open case (i.e., the number of open cases may be larger than the number of open deaths).

Table 13.4
Extension Study 2010-2015 Closure Codes for Closed Outcomes Cases

Data as of August 31, 2013

	Closed Cases[1]	**Send to CCC** (Code 9)		**Adjudication Not Needed** (Code 10)		**Duplicate** (Code 11)		**No Doc in 12 Months** (Code 12)		**No ROI** (Code 13)		**Administrative** (Code 14)	
	#	#	%	#	%	#	%	#	%	#	%	#	%
Boston	1,376	1,112	80.8	121	8.8	121	8.8	4	0.3	18	1.3	0	
Buffalo	1,959	1,711	87.3	154	7.9	46	2.3	12	0.6	36	1.8	0	
Columbus	1,743	1,617	92.8	36	2.1	60	3.4	4	0.2	26	1.5	0	
Gainesville	1,143	1,043	91.3	50	4.4	24	2.1	9	0.8	17	1.5	0	
Iowa	1,222	1,054	86.3	91	7.4	55	4.5	5	0.4	17	1.4	0	
Medstar	815	684	83.9	72	8.8	23	2.8	22	2.7	14	1.7	0	
Pittsburgh	927	787	84.9	27	2.9	80	8.6	4	0.4	29	3.1	0	
Seattle/LaJolla	720	593	82.4	56	7.8	63	8.8	6	0.8	2	0.3	0	
Stanford	2,106	1,806	85.8	177	8.4	99	4.7	5	0.2	19	0.9	0	
Tucson	765	648	84.7	45	5.9	47	6.1	7	0.9	18	2.4	0	
Wakeforest	1,166	1,009	86.5	66	5.7	55	4.7	6	0.5	30	2.6	0	
All RCs	13,942	12,064	86.5	895	6.4	673	4.8	84	0.6	226	1.6	0	

[1] Closed cases includes all cases closed since Oct. 1, 2010 (date ES 2015 started for the RCs)

Table 13.5
Extension Study 2010-2015 Participant Follow-up Status[1]

Data as of August 31, 2013

	# Participants	Full		Partial/Custom		Proxy		Lost		No Follow-up		Absolutely No Contact		Deceased	
		#	%	#	%	#	%	#	%	#	%	#	%	#	%
Boston	10,093	9,241	91.6	226	2.2	85	0.8	20	0.2	18	0.2	54	0.5	449	4.4
Buffalo	10,392	8,779	84.5	771	7.4	208	2.0	5	0.0	47	0.5	24	0.2	558	5.4
Columbus	10,825	9,475	87.5	601	5.6	91	0.8	14	0.1	14	0.1	104	1.0	526	4.9
Gainesville	8,478	7,148	84.3	744	8.8	33	0.4	52	0.6	54	0.6	61	0.7	386	4.6
Iowa	8,744	7,712	88.2	430	4.9	65	0.7	47	0.5	12	0.1	90	1.0	388	4.4
Medstar	4,576	3,980	87.0	352	7.7	15	0.3	35	0.8	13	0.3	25	0.5	156	3.4
Pittsburgh	4,201	3,581	85.2	314	7.5	71	1.7	12	0.3	0		13	0.3	210	5.0
Seattle/LaJolla	4,551	3,997	87.8	153	3.4	91	2.0	1	0.0	22	0.5	23	0.5	264	5.8
Stanford	15,948	13,934	87.4	919	5.8	156	1.0	45	0.3	2	0.0	109	0.7	783	4.9
Tucson	6,117	5,309	86.8	334	5.5	45	0.7	106	1.7	6	0.1	39	0.6	278	4.5
Wakeforest	9,637	8,543	88.6	393	4.1	62	0.6	128	1.3	27	0.3	32	0.3	452	4.7
All RCs	93,562	81,699	87.3	5,237	5.6	922	1.0	465	0.5	215	0.2	574	0.6	4,450	4.8

[1] Follow-up Status from Form 9-WHI ES Participation Status; Lost calculated by WHIX; Deceased from Form 120-Initial Notification of Death (all versions)

Table 13.6
Extension Study 2010-2015 Form Collection

Data as of August 31, 2013

	Form 151 - Activities of Daily Living 10-1-12 thru 4-30-13				Form 153 – Medications Inventory 10-1-12 thru 4-30-13			
	Total Collected		Not Collected		Total Collected		Not Collected	
	# Due[1]	% Collected[2]	#	%	# Due[1]	% Collected	#	%
Boston	5,118	91.1	455	8.9	887	78.7	189	21.3
Buffalo	5,197	96.0	210	4.0	1,306	76.0	314	24.0
Columbus	2,295	93.8	142	6.2	510	81.2	96	18.8
Gainesville	5,602	94.0	338	6.0	1,391	79.9	279	20.1
Iowa	4,466	89.0	490	11.0	1,350	76.4	318	23.6
Medstar	4,771	95.3	222	4.7	1,187	88.9	132	11.1
Pittsburgh	2,413	89.6	251	10.4	903	68.7	283	31.3
Seattle/LaJolla	2,415	96.5	85	3.5	602	78.2	131	21.8
Stanford	8,032	93.3	541	6.7	1,810	83.6	296	16.4
Tucson	3,141	89.7	325	10.3	699	79.4	144	20.6
Wakeforest	5,096	90.8	467	9.2	1,383	72.4	382	27.6
All RCs	48,546	92.7	3,526	7.3	12,028	78.7	2,564	21.3

[1] Excludes absolutely no contact and deceased participants
[2] Form 153 send to MRC participants only

Note: CCC mailings begin 2 months before form is due; the window for forms due and forms collected is the same in this report.

Table 13.7
Extension Study 2010-2015 CCC Data Entry Volume
March 1, 2013 to Aug. 31, 2013

Form	Forms					Sheets Scanned[3]	Forms with Comments[4]	
	Total[1]	Key-Entered[2]		Scanned				
	#	#	%	#	%	#	#	%
Return Mail Processing								
33 - Medical History Update (16 pages)	43,896	388	0.9	43,508	99.1	348,064	6,437	14.7
115 - Extension 2 Consent Status (1 page)	1	1	100	0		0		
120 – Initial Report Of Death (1 page)	294	294	100	0		0		
151 - Activities Of Daily Life (2 pages)	43,495	207	0.5	43,288	99.5	43,288	288	0.7
153 – Current Medications and Supplements	1,286	1,286	100	0		0		
155 - Lifestyle Questionnaire (16 pages)	144	0	0	144	100	1152	2	1.4
Totals	89,116	2,176	2.4	86,940	97.6	392,504	6,727	7.5
Outcomes Data Entry								
121-Report of Cardiovascular Outcomes (7 pages)[5]	478	956	100					
123 – Report of Fracture Outcome (1 page)[5]	17	34	100					
124 – Report of Death (Final) (3 pages)[5]	176	352	100					
126 – Report of Venous Thromboembolic Disease (2 pages)[5]	69	138	100					
130 – Report of Cancer Outcome (4 pages)[5]	1,755	3,510	100					
132 – Report of Stroke Outcome (3 pages)[5]	104	208	100					
Totals	2,599	5,198	100					

[1] Total number of Form 33 also represents number of mailing packets returned to the CCC. CCC mailing staff open and pull forms, review the forms for hand written comments from participants, and set those forms aside for review by Data Operations staff, burst the Form 33 and Form 155, ensuring the staples and extraneous perforation debris is removed from the sheets so that the forms will scan properly.
[2] Scannable forms are key-entered if the form is damaged, ripped, or otherwise not able to be scanned.
[3] For scannable forms, one sheet is scanned for every 2 pages of a form; for example, 8 sheets are scanned for a 16-page form. .
[4] Data Operations staff review each comment written by participant; if the comment is about the participant health, contact information, or other information which the RC staff need to read, the Data Ops staff marks the FC bubble on the first page of the form; this triggers the form to be listed on a RC report indicating RC staff need to review the scanned image of the form available for them to view in WHIX.
[5] Outcomes forms are double-data entered for validation.

Table 13.8
Extension Study 2010-2015 Outcomes Cases Received from RCs

Data as of 9-16-13

Committees	Total # Cases in WHIX	Cases at RCs Not Yet Sent to CCC				Cases at CCC					
						Referred From					
		< 14 Days	14-29 Days	≥ 30 Days	Total (not sent)	Rec'd from RCs	Form 125 Review	Other Committee	Cases from RCs and Referrals	QA Cases	# Cases to Adjudicate
ES 2010-2015 (ES2)[1]											
Cancers[2]	4,605	57	27	8	92	4,493	15	5	4,513	297	4,810
CVD[3]	2,726	36	37	3	76	2,366	174	110	2,650	378	3,028
Heart Failure	625	8	4		12	485	95	33	613		613
Fatal Events	973	9	10	11	30	937		6	943	132	1,075
Stroke	747		7	2	9	652	58	28	730		730
Fracture	292	3	4		7	280	3	2	285		285
Extension Total	**9,968**	**113**	**89**	**24**	**226**	**9,213**	**345**	**184**	**9,734**	**826**	**10,560**
Form 125-Hospital	3,641	55	34	5	94	3,547			3,547		3,547
Retrospective Cases5											
HF (UNC)[6]	4,464					4,464			4,464		4,464
Stroke[7]	3,380					3,377			3,380		3,380

[1] Includes cases identified starting with Extension Study 2010 (Sept 1, 2010)
[2] Includes Primary and Other Cancers. If Other Cancer is coded to a primary site, it is counted as a Primary Cancer
[3] Includes additional Extension 2010 cases of aortic aneurysum, heart valve, and atrial fibrulation (A Fib)
[4] Data QA independent of outcome type
[5] Retrospective cases identified during Extension Study 2005 and scheduled to be adjudicated during Extension Study 2010
[6] **Still under development - Estimated HF cases to be forwarded to UNC
[7] **Still under development - DM and OS strokes

Table 13.9
Extension Study 2010-2015 Status of Outcomes Adjudication

Data as of 9-16-13

	# Cases at CCC			Status of Open Case Packets					
	Total	**# Closed**	**# Open**	**To Forward to Adj**	**Wait for Return from Adj**	**Adj Follow-up**	**Queries**	**Full Committee Review**	**Data Enter and Close**
ES 2010-2015 (ES2)[1]									
Cancer[2]	4,810	4,631	179	54	53		35		37
CVD[3]	3,028	2,741	287	79	138		2		68
Heart Failure	613	265	348	348					0
Fatal Events	1,075	832	243	93	54		1		95
Stroke	730	667	63	23	34			6	0
Fracture	285	258	27	6	19				2
Extension Total	**10,560**	**9,394**	**1,417**	**603**	**298**	**0**	**38**	**6**	**202**
Form 125-Hospitalization	3,547	3,495	52	35	4				0
Retrospective Cases[5]									
HF (UNC)[6]	4,464	4,460	1		1				
Stroke[7]	3,380	889	2,491	2,465					9

[1] Includes cases identified starting with Extension Study 2010 (Sept 1, 2010)
[2] Includes Primary and Other Cancers. If Other Cancer is coded to a primary site, it is counted as a Primary Cancer
[3] Includes additional Extension 2010 cases of aortic aneurysum, heart valve, and atrial fibrulation (A Fib)
[4] Data QA independent of outcome type
[5] Retrospective cases identified during Extension Study 2005 and scheduled to be adjudicated during Extension Study 2010
[6] **Still under development - Estimated HF cases to be forwarded to UNC
[7] **Still under development - DM and OS strokes

Table 14.1
CT Outcomes Cases with Remaining Blood Sample by Estimated Volume (in ml)
After Accounting for Approved Ancillary Studies: Baseline and AV1

					Volume of Designated Blood Components (mL)** as of 10/2013																	
Visit	Outcome As of 9/13	Total*** Ppts	No Draw*	Blood Type	0*		>0 - <.5		.5 - <1		1 - <1.5		1.5 - <2		2 - <2.5		2.5 - <3		3 - <3.5		3.5 - <4		4+	
					Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%
Base-line	Breast Cancer	4666	21	Serum	21	0%	1	0%	6	0%	41	1%	32	1%	111	2%	170	4%	640	14%	431	9%	3213	69%
				Citrate	41	1%	1	0%	9	0%	48	1%	31	1%	270	6%	41	1%	4100	88%	7	0	118	3%
				EDTA	72	2%	1	0	2	0%	28	1%	22	0%	317	7%	101	2%	3995	86%	12	0	116	2%
	Breast Cancer Invasive	3811	15	Serum	15	0%			5	0%	37	1%	30	1%	100	3%	150	4%	567	15%	342	9%	2565	67%
				Citrate	33	1%			6	0%	42	1%	27	1%	219	6%	35	1%	3341	88%	7	0	101	3%
				EDTA	59	2%	1	0	2	0%	19	0%	19	0%	260	7%	86	2%	3257	85%	9	0	99	3%
	Colorectal Cancer	1230	4	Serum	4	0%			2	0%	19	2%	11	1%	54	4%	74	6%	287	23%	162	13%	617	50%
				Citrate	11	1%	2	0%	4	0%	14	1%	8	1%	79	6%	26	2%	1064	87%	1	0	21	2%
				EDTA	22	2%			1	0%	11	1%	5	0%	101	8%	43	3%	1020	83%	6	0	21	2%
	Endometrial Cancer	647	5	Serum	5	1%	1	0%	1	0	7	1%	4	1%	7	1%	15	2%	62	10%	47	7%	498	77%
				Citrate	7	1%			2	0%	6	1%	7	1%	37	6%	2	0%	575	89%			11	2%
				EDTA	8	1%					5	1%	5	1%	46	7%	8	1%	563	87%	2	0	10	2%
	Ovarian Cancer	407	1	Serum	1	0%			2	0%	5	1%	2	0%	12	3%	7	2%	43	11%	53	13%	282	69%
				Citrate	6	1%			1	0%	7	2%	4	0.01	26	6%			352	86%	1	0	10	2%
				EDTA	2	0%					8	2%	3	1%	33	8%	6	1%	343	84%	2	0	10	2%
	CHD	3874	22	Serum	22	1%	4	0%	25	1%	69	2%	97	3%	170	4%	224	6%	433	11%	476	12%	2354	61%
				Citrate	36	1%	16	0%	36	1%	183	5%	107	3%	330	9%	80	2%	2967	77%	8	0	111	3%
				EDTA	67	2%	14	0%	27	1%	129	3%	225	6%	392	10%	319	8%	2568	66%	27	1%	106	3%
	Clinical MI	2806	17	Serum	17	1%	3	0%	17	1%	48	2%	80	3%	131	5%	168	6%	304	11%	349	12%	1689	60%
				Citrate	27	1%	14	0%	28	1%	143	5%	82	3%	238	8%	56	2%	2131	76%	6	0	81	3%
				EDTA	53	2%	11	0%	21	1%	103	4%	168	6%	289	10%	226	8%	1845	66%	10	0%	80	3%
	DVT/PE	1048	3	Serum	3	0%	1	0%	5	0%	16	2%	20	2%	62	6%	112	11%	257	25%	183	17%	389	37%
				Citrate	12	1%	5	0%	24	2%	105	10%	112	11%	76	7%	13	1%	663	63%	2	0%	36	3%
				EDTA	12	1%	4	0%	3	0%	36	3%	28	3%	264	25%	47	4%	611	58%	6	0.01	37	4%
	Stroke	2953	19	Serum	19	1%	4	0%	11	0%	39	1%	52	2%	132	4%	249	8%	393	13%	264	9%	1790	61%
				Citrate	44	1%	13	0%	29	1%	219	7%	99	3%	280	9%	123	4%	2077	70%	7	0%	62	2%
				EDTA	47	2%	4	0%	2	0%	54	2%	58	2%	427	14%	111	4%	2174	74%	15	0.01	61	2%
	Hip Fracture	1762	10	Serum	10	1%	1	0%	4	0%	18	1%	19	1%	47	3%	84	5%	220	12%	250	14%	1109	63%
				Citrate	20	1%	4	0%	8	0%	38	2%	34	2%	93	5%	24	1%	1491	85%	6	0	44	2%
				EDTA	23	1%	1	0%	5	0%	15	1%	27	2%	146	8%	43	2%	1448	82%	10	0.01	44	2%

*Participants with no draw included in 0 volume column

** Includes sample reserved for future WHI use (1 mL each serum, citrate and EDTA)

Represents conservative estimate of 1 ml in each vial collected, with 4 serum, 3 citrate and 3 EDTA vials collected at Baseline for CT/OS , at AV1 for CT, and at AV3 for OS.

***Total # of participants whose first occurrence of outcome occurred after blood draw.

Table 14.1 (continued)
CT Outcomes Cases with Remaining Blood Sample by Estimated Volume (in ml)
After Accounting for Approved Ancillary Studies: Baseline and AV1

					Volume of Designated Blood Components (mL)** as of 10/2013																			
Visit	Outcome As of 9/13	Total*** Ppts	No Draw*	Blood Type	0*		>0 - <.5		.5 - <1		1 - <1.5		1.5 - <2		2 - <2.5		2.5 - <3		3 - <3.5		3.5 - <4		4+	
					Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%
AV1	Breast Cancer	4465	244	Serum	244	5%			2	0%	24	1%	11	0%	50	1%	75	2%	393	9%	421	9%	3245	73%
				Citrate	256	6%			4	0%	49	1%	12	0%	270	6%	32	1%	3835	86%			7	0%
				EDTA	296	7%					23	1%	15	0%	294	7%	24	1%	3805	85%	1	0	7	0%
	Breast Cancer Invasive	3653	214	Serum	214	6%			2	0%	21	1%	11	0%	43	1%	69	2%	332	9%	396	11%	2565	70%
				Citrate	222	6%			2	0%	41	1%	10	0%	222	6%	24	1%	3125	86%			7	0%
				EDTA	253	7%					19	1%	12	0%	244	7%	18	0%	3099	85%	1	0	7	0%
	Colorectal Cancer	1151	72	Serum	72	6%			1	0	10	1%	5	0%	17	1%	13	1%	176	15%	46	4%	811	70%
				Citrate	76	7%	1	0%	3	0%	13	1%	7	1%	82	7%	14	1%	954	83%			1	0%
				EDTA	86	7%			1	0%	8	1%	3	0%	89	8%	7	1%	956	83%			1	0%
	Endometrial Cancer	607	28	Serum	28	5%					5	1%			9	1%	3	0%	53	9%	18	3%	491	81%
				Citrate	34	6%					9	1%	3	0%	34	6%	2	0%	524	86%			1	0
				EDTA	32	5%			1	0	1	0%	2	0%	45	7%	2	0%	523	86%			1	0
	Ovarian Cancer	387	19	Serum	19	5%					4	1%			2	1%	1	0%	44	11%	27	7%	290	75%
				Citrate	20	5%	1	0%	1	0%	3	1%	3	1%	32	8%	2	1%	325	84%				
				EDTA	24	6%			1	0	1	0%	3	1%	35	9%	3	1%	320	83%				
	CHD	3657	267	Serum	267	7%			2	0%	26	1%	7	0%	44	1%	43	1%	334	9%	213	6%	2721	74%
				Citrate	299	8%	12	0%	15	0%	122	3%	72	2%	313	9%	48	1%	2774	76%			2	0%
				EDTA	318	9%	4	0%	12	0%	53	1%	123	3%	355	10%	84	2%	2694	74%	12	0	2	0%
	Clinical MI	2625	170	Serum	170	6%			2	0%	18	1%	6	0%	32	1%	33	1%	247	9%	145	6%	1972	75%
				Citrate	198	8%	10	0%	12	0%	95	4%	56	2%	222	8%	36	1%	1994	76%			2	0%
				EDTA	212	8%	4	0%	7	0%	44	2%	98	4%	257	10%	65	2%	1927	73%	9	0	2	0%
	DVT/PE	962	44	Serum	44	5%					2	0%	1	0%	9	1%	15	2%	113	12%	95	10%	683	71%
				Citrate	56	6%	4	0%	14	1%	61	6%	72	7%	86	9%	14	1%	654	68%			1	0%
				EDTA	55	6%	1	0%			26	3%	8	1%	197	20%	11	1%	663	69%			1	0%
	Stroke	2811	173	Serum	173	6%	2	0%	1	0%	17	1%	4	0%	27	1%	53	2%	263	9%	179	6%	2092	74%
				Citrate	192	7%	9	0%	25	1%	157	6%	65	2%	296	11%	102	4%	1964	70%			1	0%
				EDTA	210	7%			3	0%	36	1%	27	1%	362	13%	21	1%	2147	76%	4	0	1	0%
	Hip Fracture	1712	90	Serum	90	5%	1	0%			10	1%	6	0%	22	1%	24	1%	172	10%	114	7%	1273	74%
				Citrate	103	6%	3	0%	3	0%	38	2%	23	1%	96	6%	22	1%	1423	83%			1	0%
				EDTA	111	6%	1	0	4	0%	15	1%	9	1%	128	7%	14	1%	1427	83%	2	0	1	0%

*Participants with no draw included in 0 volume column

** Includes sample reserved for future WHI use (1 mL each serum, citrate and EDTA)

Represents conservative estimate of 1 ml in each vial collected, with 4 serum, 3 citrate and 3 EDTA vials collected at Baseline for CT/OS , at AV1 for CT, and at AV3 for OS.

***Total # of participants whose first occurrence of outcome occurred after blood draw.

Table 14.2
OS Outcomes Cases with Remaining Blood Sample by Estimated Volume (in ml)
After Accounting for Approved Ancillary Studies: Baseline and AV3

					Volume of Designated Blood Components (mL)** as of 10/2013																	
	Outcome As of 9/13	Total*** Ppts	No Draw*	Blood Type	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					Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%
Base-line	Breast Cancer	6610	19	Serum	19	0%	4	0%	7	0%	36	1%	32	0%	212	3%	275	4%	662	10%	638	10%	4725	71%
				Citrate	71	1%	2	0%	4	0%	45	1%	50	1%	305	5%	610	9%	5285	80%	107	0.02	131	2%
				EDTA	136	2%	2	0%	7	0%	63	1%	97	1%	435	7%	736	11%	4749	72%	252	4%	133	2%
	Breast Cancer Invasive	5507	17	Serum	17	0%	4	0%	5	0%	30	1%	26	0%	189	3%	259	5%	595	11%	567	10%	3815	69%
				Citrate	63	1%	2	0%	4	0%	38	1%	43	1%	254	5%	542	10%	4357	79%	93	0.02	111	2%
				EDTA	114	2%	2	0%	7	0%	54	1%	86	2%	360	7%	645	12%	3881	70%	245	4%	113	2%
	Colorectal Cancer	1479	5	Serum	5	0%	2	0%	2	0%	16	1%	27	2%	96	6%	126	9%	293	20%	203	14%	709	48%
				Citrate	15	1%			6	0%	23	2%	33	2%	166	11%	297	20%	848	57%	50	0.03	41	3%
				EDTA	36	2%	4	0%	11	1%	67	5%	96	6%	515	35%	300	20%	403	27%	9	0.01	38	3%
	Endometrial Cancer	920	9	Serum	9	1%	5	1%	14	2%	35	4%	44	5%	148	16%	118	13%	167	18%	130	14%	250	27%
				Citrate	12	1%					6	1%	12	1%	57	6%	111	12%	692	75%	11	0.01	19	2%
				EDTA	22	2%					14	2%	20	2%	56	6%	83	9%	685	74%	21	0.02	19	2%
	Ovarian Cancer	630	1	Serum	1	0%	2	0%	4	1%	18	3%	19	3%	78	12%	67	11%	130	21%	108	17%	203	32%
				Citrate	4	1%					4	1%	2	0%	26	4%	36	6%	541	86%	5	0.01	12	2%
				EDTA	8	1%	1	0%	1	0%	5	1%	13	2%	39	6%	78	12%	454	72%	19	0.03	12	2%
	CHD	4469	19	Serum	19	0%	5	0%	18	0%	56	1%	60	1%	293	7%	172	4%	335	7%	514	12%	2997	67%
				Citrate	68	2%	10	0%	39	1%	149	3%	149	3%	512	11%	708	16%	2693	60%	26	1%	115	3%
				EDTA	108	2%	6	0%	26	1%	150	3%	255	6%	723	16%	861	19%	2048	46%	177	4%	115	3%
	Clinical MI	3117	13	Serum	13	0%	4	0%	13	0%	42	1%	44	1%	227	7%	124	4%	245	8%	388	12%	2017	65%
				Citrate	50	2%	7	0%	36	1%	116	4%	117	4%	409	13%	514	16%	1770	57%	21	1%	77	2%
				EDTA	81	3%	5	0%	23	1%	111	4%	199	6%	547	18%	639	21%	1314	42%	119	4%	79	3%
	Stroke	3355	6	Serum	6	0%	6	0%	9	0%	32	1%	38	1%	129	4%	92	3%	283	8%	498	15%	2262	67%
				Citrate	38	1%	7	0%	18	1%	109	3%	218	6%	498	15%	402	12%	1971	59%	17	0.01	77	2%
				EDTA	63	2%	15	0%	53	2%	301	9%	383	11%	461	14%	514	15%	1355	40%	130	4%	80	2%
	Hip Fracture	2206	7	Serum	7	0%	5	0%	20	1%	57	3%	85	4%	145	7%	181	8%	244	11%	241	11%	1221	55%
				Citrate	25	1%			2	0%	15	1%	24	1%	133	6%	170	8%	1770	80%	26	0.01	41	2%
				EDTA	49	2%			2	0%	37	2%	47	2%	189	9%	238	11%	1562	71%	43	0.02	39	2%

*Participants with no draw included in 0 volume column

**Includes sample reserved for future WHI use (1 mL each serum, citrate and EDTA)

Represents conservative estimate of 1 ml in each vial collected, with 4 serum, 3 citrate and 3 EDTA vials collected at Baseline for CT/OS , at AV1 for CT, and at AV3 for OS.

***Total # of participants whose first occurrence of outcome occurred after blood draw.

Table 14.2 (continued)
OS Outcomes Cases with Remaining Blood Sample by Estimated Volume (in ml)
After Accounting for Approved Ancillary Studies: Baseline and AV3

					Volume of Designated Blood Components (mL)** as of 10/2013																	
Visit	Outcome As of 9/13	Total*** Ppts	No Draw*	Blood Type	0*		>0 - <.5		.5 - <1		1 - <1.5		1.5 - <2		2 - <2.5		2.5 - <3		3 - <3.5		3.5 - <4		4+	
					Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%
AV3	Breast Cancer	5002	607	Serum	607	12%					12	0%			30	1%	4	0%	65	1%	38	1%	4246	85%
				Citrate	643	13%					24	0%			56	1%	4	0%	4274	85%			1	0%
				EDTA	685	14%	1	0%	1	0%	26	1%	7	0%	107	2%	227	5%	3876	77%	70	0.01	4	0%
	Breast Cancer Invasive	4165	521	Serum	521	13%					11	0%			27	1%	4	0%	53	1%	32	1%	3517	84%
				Citrate	547	13%					20	0%			49	1%	3	0%	3545	85%			1	0%
				EDTA	581	14%	1	0%	1	0%	24	1%	6	0%	88	2%	215	5%	3177	76%	68	0.02	4	0%
	Colorectal Cancer	1145	176	Serum	176	15%			1	0%	2	0%	4	0%	4	0%	4	0%	21	2%	88	8%	845	74%
				Citrate	180	16%					3	0%			19	2%	10	1%	933	81%				
				EDTA	192	17%					11	1%	1	0%	34	3%	77	7%	827	72%	3	0		
	Endometrial Cancer	707	94	Serum	94	13%									5	1%			14	2%	7	1%	587	83%
				Citrate	99	14%					3	0%			10	1%			594	84%			1	0
				EDTA	104	15%					2	0%	1	0%	12	2%	15	2%	567	80%	4	0.01	1	0
	Ovarian Cancer	493	79	Serum	79	16%									2	0%			14	3%	26	5%	372	75%
				Citrate	81	16%					3	1%			3	1%			406	82%				
				EDTA	81	16%					1	0%	2	0%	7	1%	27	5%	368	75%	7	0.01		
	CHD	3695	648	Serum	648	18%					9	0%	1	0%	23	1%	5	0%	68	2%	70	2%	2871	78%
				Citrate	677	18%					10	0%			103	3%	7	0%	2897	78%			1	0%
				EDTA	707	19%	1	0%			30	1%	26	1%	322	9%	333	9%	2270	61%	6	0	1	0%
	Clinical MI	2475	369	Serum	369	15%					3	0%	1	0%	17	1%	5	0%	46	2%	46	2%	1988	80%
				Citrate	387	16%					6	0%			80	3%	6	0%	1996	81%				
				EDTA	406	16%	1	0%			24	1%	22	1%	249	10%	267	11%	1504	61%	3	0		
	Stroke	2765	468	Serum	468	17%					7	0%			25	1%	2	0%	38	1%	28	1%	2197	79%
				Citrate	490	18%					14	1%			45	2%	3	0%	2212	80%			1	0
				EDTA	526	19%					15	1%	1	0%	78	3%	74	3%	2060	75%	10	0	1	0
	Hip Fracture	1913	295	Serum	295	15%					1	0%			9	0%			23	1%	19	1%	1566	82%
				Citrate	312	16%					6	0%			20	1%	17	1%	1556	81%			1	0%
				EDTA	326	17%	1	0%			9	0%	2	0%	40	2%	42	2%	1487	78%	4	0	1	0%

*Participants with no draw included in 0 volume column

** Includes sample reserved for future WHI use (1 mL each serum, citrate and EDTA)

Represents conservative estimate of 1 ml in each vial collected, with 4 serum, 3 citrate and 3 EDTA vials collected at Baseline for CT/OS , at AV1 for CT, and at AV3 for OS.

***Total # of participants whose first occurrence of outcome occurred after blood draw.

Table 14.3
CT and OS Outcomes Cases with DNA* Available
Data as of 10/2013

		No DNA Available[1]		< 25 ug Extracted, no Buffy Coat Available for Extraction[2]		< 25 ug Extracted, with Buffy Coat Available for Extraction[3]		> 25 ug Extracted[4]	
Outcome As of 9/13	**Ppts**	**#**	**%**	**#**	**%**	**#**	**%**	**#**	**%**
CT									
Breast Cancer	4666	70	1.50%	46	1.00%	753	16.10%	3797	81.40%
Breast Cancer Invasive	3811	52	1.40%	42	1.10%	407	10.70%	3310	86.90%
CHD	3874	78	2.00%	60	1.50%	434	11.20%	3302	85.20%
Clinical MI	2806	52	1.90%	47	1.70%	248	8.80%	2459	87.60%
Colorectal Cancer	1230	18	1.50%	20	1.60%	154	12.50%	1038	84.40%
Endometrial Cancer	647	12	1.90%	6	0.90%	103	15.90%	526	81.30%
Hip Fracture	1762	41	2.30%	49	2.80%	125	7.10%	1547	87.80%
Ovarian Cancer	407	5	1.20%	3	0.70%	62	15.20%	337	82.80%
Stroke	2953	46	1.60%	90	3.00%	270	9.10%	2547	86.30%
OS									
Breast Cancer	6610	62	0.90%	19	0.30%	1182	17.90%	5347	80.90%
Breast Cancer Invasive	5507	56	1.00%	17	0.30%	695	12.60%	4739	86.10%
CHD	4469	59	1.30%	29	0.60%	237	5.30%	4144	92.70%
Clinical MI	3117	33	1.10%	21	0.70%	89	2.90%	2974	95.40%
Colorectal Cancer	1479	21	1.40%	8	0.50%	118	8.00%	1332	90.10%
Endometrial Cancer	920	9	1.00%	1	0.10%	132	14.30%	778	84.60%
Hip Fracture	2206	24	1.10%	16	0.70%	193	8.70%	1973	89.40%
Ovarian Cancer	630	7	1.10%	4	0.60%	127	20.20%	492	78.10%
Stroke	3355	44	1.30%	22	0.70%	279	8.30%	3010	89.70%

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

Table 14.4
Number of Funded Core, BAA, and Ancillary Studies
Using Blood Sample
by Outcome[1] and Specimen Type

	Serum/Plasma Only	Both Serum/Plasma and DNA	DNA Only	GWAS[2]	Urine	RBCs	Total[3]
Cancer							
Bladder Cancer			2	1			2
Breast Cancer	11	1	10	4	2		24
Colon Cancer	1		1	1			2
Colorectal Cancer	7	4	5	1		1	16
Endometrial Cancer	3		2				5
Gastric/Esophageal Cancer		1		1			1
Glioma			1	1			1
Kidney Cancer		1	1	1		1	2
Lung Cancer	2	3	1				6
Lymphoma, Non Hodgkins		1	2	1			3
Melanoma	1		2				3
Multiple Myeloma		1					1
Pancreatic Cancer	1	2	2	1		1	5
Ovarian Cancer	5		1				6
Cardiovascular							
CHD	15	5	4	2		1	23
Hypertension		1					1
Stroke	10	2	7	2		1	19
VTE	2	1	2	1			5
Fracture							
Elbow, Lower Humerus	1						1
Hip Fracture	4	2	2	1		1	8
Spine	2						2
Overall Fracture	1						1
Other							
Cognitive decline	1		1			1	2
Eye Disease	1		1				2
Frailty-disability	1	1					2
Sarcopenia		1					1
Type 2 Diabetes	1	1	4	1			6

[1] Several studies include more than one outcome
[2] GWAS counted in number of DNA studies
[3] Several studies may use more than one specimen type

Table 15.1
Approved Core Studies[1]

Ref #	Title	Status	Study Population	Blood	Analytes/Data	Used in Approved Publications
W1	CT core analytes on 6% subsample; quarterly core analytes on QC pools A and B	Complete	CT Controls:3800 *B, Y1, Y3, Y6 on 6% Blood Subsample	Y	Citrate 1ml: FVII Ag; FVII Conc; Fibrinogen EDTA 1ml: Cholesterol; HDL2; HDL3; HDLC; LDLC; Lp(a); Trig Serum 1ml: Carotene, alpha; Carotene, beta; Cryptoxan, beta; Glucose; Insulin; Lutein+Zeax; Lycopene; Retinol; Tocopherol, alpha; Tocopherol, gamma	204, 210, 222, 240, 273, 345, 347, 350, 447, 448, 449, 520, 521, 524, 866
W2	OS-measurement precision study (OS-MPS)	Complete	OS Controls:800 *B, 3 month	Y	Citrate 1ml: FVII Ag; FVII Conc; Fibrinogen EDTA 1ml: Cholesterol; HDL2; HDL3; HDLC; LDLC; Lp(a); Trig Serum 1ml: Carotene, alpha; Carotene, beta; Cryptoxan, beta; Glucose; Insulin; Lutein+Zeax; Lycopene; Retinol; Tocopherol, alpha; Tocopherol, gamma	442, 524
W4	National validation and quality control assurance of vitamin D absorption from CaD tablets for WHI	Complete	CaD Controls:448 *Y3	Y	Serum 1ml: Vit D 25-OH	
W5	Correlates of endogenous sex hormone concentrations in WHI	Complete	DM Controls:300 *150 DM Intervention + 150 DM controls at B and Y1	Y	Serum 3ml: Albumin; Androstenedione; DHEA; DHEAS; DHT; Estradiol (E2); Estradiol, bioavail; Estradiol, bioavail (%); Estrone (E1); Estrone sulfate; Progesterone; Prolactin; SHBG; Testosterone	20, 280, 1218

Table 15.1 (continued)
Approved and Proposed Core Studies[1]

Ref #	Title	Status	Study Population	Blood	Analytes/Data	Used in Approved Publications
W6	HT CVD Biomarkers: study of CHD, Stroke and VTE - Phase I	Complete	HRT CHD:402 Stroke:272 VTE:223 Controls:877 *B, Y1	Y	Citrate 1ml: ATIII; CRP; D-dimers; F1+2; FIX Conc; FVIII Activity; Fibrinogen; PAI-1 Ag; PAP; Protein C; Protein S Free; Protein S Total; Prothrombin Ag; TAFI; vWF DNA 3ug: ESR1; ESR2; GP3A-P1A; GPIba; ITGA2807CT DNA 3ug: FV Leiden; FV-HR2; FXIII val34leu; MTHFR; PAI-1; PRO2; PROT EDTA .25ml: NMR Lipids EDTA 1ml: Cholesterol; E-Selectin; HDL2; HDL3; HDLC; Homocysteine; IL-6; LDLC; Lipo-particles; Lp(a); Trig Serum 1ml: MMP-9	204, 210, 222, 273, 345, 347, 350, 380, 429, 445, 462, 526, 589, 854, 866, 972, 2048
W7	Genome-wide scan on breast cancer, CHD, and stroke	Complete	General Population Breast Cancer:2145 CHD:2119 Stroke:2215 Controls:6479	Y	DNA 2ug: Pooled GWAS	1104, 1653

Table 15.1 (continued)
Approved and Proposed Core Studies[1]

Ref #	Title	Status	Study Population	Blood	Analytes/Data	Used in Approved Publications
W8	Nutritional biomarkers study (NBS)	Complete	DM	Y	EDTA 1ml: NBS-24hr Urine 1.85ml: 24 hr Urine Volume; PABA; PABA24; PABACMP; PABACMPH; PABARCVR; PABARCVRH; Paba mg/24hr (hplc); Paba mg/L (hplc); Urine N g/L; Urine N g/day; 24 hr urine volume, nitrogen g/day, nitrogen g/L, sodium, potasium; Paba mg/L (colorimetric and HPLC); Paba mg/24 hr (colorimetric); Paba completeness (colorimetric and HPLC); Paba recovery (colorimetric and HPLC); NBS-24hr Urine 4ml: BUN; Urinary potassium NBS-Spot Urine 4ml: % Fat; DE-SU3; DE-SU4; DE-SU5; DE-SU6; DSRATIO; EE3/5; EE4/6; Fat-free mass; Fluid; H2CONST; LOT; Nd; No; O18-SU3; O18-SU4; O18-SU5; O18-SU6; O18CONST; RCO2-3/5; RCO2-4/6; TEE-CONRQ; TEE-INTVRQ; TEE-USRQ; Total Body Water; r-H2O; NBS Spot Urine 4 ml: %Fat; DE-SU3; DE-SU4; DE-SU5; DE-SU6; EE3/5; EE4/6; Fat-free mass; Fluid; H2CONST; Internal check DSRatio; LOT; Nd; No; O18-SU3; O18-SU4; O18-SU5; O18-SU6; O18CONST; RCO2-3/5; RCO2-4/6; TEE-CONRQ RQ Control group (38.1/44.7/17.2 %E from F/C/P); TEE-INTVRQ Intervention (29.8/52.7/17.5 %E from F/C/P); TEE-USRQ RQ assumed general US (34/47/18 %E F/C/P); Total Body Water; r-H2O Serum .2ml: Carotene, alpha; Carotene, beta; Cholesterol; Folate; Tocopherol, alpha; Tocopherol, gamma; Alpha-carotene, alpha-tocopherol, beta-carotene, folate, gamma-tocopherol, total cholesterol	464, 624, 646, 708, 831, 941, 945, 1903, 2022, 2106

Table 15.1 (continued)
Approved and Proposed Core Studies[1]

Ref #	Title	Status	Study Population	Blood	Analytes/Data	Used in Approved Publications
W9	Biological markers of the effect of HT on risk of fractures in the Women's Health Initiative clinical trial	Analysis	HRT Fracture - Hip:750 Controls:750 *Fill in with non-spine fractures to make 750	Y	Serum .65ml: Estradiol (E2); Estradiol, bioavail (FE2+AE2); Estradiol, free; SHBG Serum .25ml:	433, 1218, 1579
W10	Biological markers of the effect of HT on risk of breast cancer in the Women's Health Initiative clinical trial	Complete	HRT Breast Cancer:755 Controls:755 *498 E+P and 260 E-Alone cases through Sept 2005; B, Y1	Y	Serum .95ml: Estradiol (E2); Estradiol, bioavail (FE2+AE2); Estradiol, free; Estrone (E1); Estrone sulfate; Progesterone; SHBG; Testosterone; Testosterone, bioavail; Testosterone, free; (progesterone and testosterone at baseline only)	1033, 1218, 1742, 2028
W11	CVD biomarkers - Phase II: strokes after Feb. 2001	Complete	HRT Stroke:316 Controls:316 *108 new E+P cases up to July 2002, 174 E alone cases up to March 2005 (316 total as of 4-8-05); B, Y1	Y	Citrate .35ml: TFPI activity; TFPI, free; TFPI, total Citrate .65ml: APC-ETP; LT_APC; NAPCSR DNA 1ug: ESR1; ESR2; GP3A-P1A; GPIba; ITGA2807CT; Serum .25ml: Glucose; Insulin	435, 462, 1114
W14	CVD biomarkers - Phase I: additional asays	Analysis	HRT CHD:390 Stroke:270 VTE:220 Controls:880 *B, Y1	Y	Citrate .95ml: Citrate .35ml: TFPI activity; TFPI, free; TFPI, total Citrate .65ml: APC-ETP; LT_APC; NAPCSR Serum .25ml: Glucose; Insulin;	866, 972, 1114
W15	CaD Vitamin D levels in CaD participants with colorectal cancer or fractures	Complete	CaD Colorectal Cancer:334 Fracture - Hip:360 Fracture - Elbow, Lower humerous:853 Fracture - Spine Only:283 Controls:1830 *Y1; B only if Y1 not available	Y	Serum .2ml: Vit D 25-OH	450, 451, 581, 861, 876, 878, 910, 1121

Table 15.1 (continued)
Approved and Proposed Core Studies[1]

Ref #	Title	Status	Study Population	Blood	Analytes/Data	Used in Approved Publications
W18	HT Hormone Pretest	Analysis	HRT Controls:240 *120 active + 120 placebo; B, Y1	Y	Serum .95ml: Estradiol (E2); Estradiol, bioavail (FE2+AE2); Estradiol, free; Estrone (E1); Progesterone; SHBG; Testosterone; Testosterone, bioavail; Testosterone, free; (progesterone and testosterone only on E+P samples)	795, 1218
W19	WHI HT Proteomic Pilot Study	Complete	HRT Controls:200 *100 active, 100 control; B, AV1	Y	Serum .1ml: Proteomics Serum .3ml: Phase II proteins	843, 921
W20	WHI-EDRN pilot study for the identification of circulating biomarkers for colon cancer in pre-clinical specimens	Complete	OS Colorectal Cancer:100 Controls:120 *Colon cancer cases 6-18 mo after Year 3	Y	EDTA .2ml: Proteomics; Calibration for Wayne State lab. EDTA .55ml: Proteomics	
W22	Vitamin D levels in 6% blood subsample of CaD	Complete	CaD *600 ppts from CaD trial at AV1 and AV3	Y	Serum .2ml: 25-OH Vitamin D3	
W24	CaD vitamin D and breast cancer	Analysis	CaD Breast Cancer:1081 Controls:1081 *Use controls from W15 when possible	Y	Serum .2ml: Vit D 25-OH	470, 861, 876, 878, 910, 1121
W25	WHI coronary artery calcification study in E-alone (WHI-CACS)	Complete	HRT *1150 E-Alone ppts aged 50-59	N		503, 506, 570, 591, 806, 816, 912, 955
W26	Food grouping in WHI by FHCRC nutrition shared resource group	Complete	DM	N		

Table 15.1 (continued)
Approved and Proposed Core Studies[1]

Ref #	Title	Status	Study Population	Blood	Analytes/Data	Used in Approved Publications
W27	Nutrition and physical activity assessment study (AS218) lab work	Funded	OS *450 ppts	Y	EDTA 1.8ml: NPAAS-24hr Urine 1.8ml 4ml: 24 hr urine volume, unirary nitrogen g/day, urinary nitrogen g/L NPAAS-24hr Urine 1.8ml 4ml NPAAS-24hr Urine 1.8ml 1ml NPAAS-Spot Urine 4ml: % Fat; BMI; DSRATIO; Fat-free mass; Fluid; Isotope Approval; Nd; No; RCO2-3/5; RCO2-4/6; RQ; TEE; TEE mj/day; Total Body Water; r-H2O; %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 1ml	1178, 1385, 1532, 1903
W28	Medicare claims data linkage	Complete	General Population	N		
W30	Dietary assessment study	Complete	DM *160 ppts for 4DFR analyses, repeat 24 hr recalls, and repeat FFQs	N		35
W31	4DFR on DM ovarian cancers	Complete	DM Ovarian Cancer:160 *For DM Other Cancer paper	N		469
W33	4DFR and DM breast cancer	Complete	DM Breast Cancer:1800 *For DM Breast Cancer paper	N		448

Table 15.1 (continued)
Approved and Proposed Core Studies[1]

Ref #	Title	Status	Study Population	Blood	Analytes/Data	Used in Approved Publications
W34	Extension of WHI stroke genome-wide association study (W-7)	Complete	General Population Stroke:2096 Controls:2096	Y	DNA 2ug: SNPs 5.4K	
W35	Full CMS data on all CT and OS participants aged 65 or over	Complete	General Population	N		889, 1217, 1371, 1372, 1373, 1394, 1409, 1608, 1623, 1640, 1658, 1659, 1660, 1702, 1730, 1747, 1762, 1765, 1766, 1767, 1839, 1840, 1916, 1917, 1929
W39	27-hydroxycholesterol in CVD biomarkers (W-6)	Complete	HRT CHD:359 Controls:820 *CHD cases from W6-HT CVD Biomarkers	Y	Serum .55ml: Chol, 27-OH	1300
W40	Validation of E-alone proteins in W19-HT proteomics	Complete	HRT Controls:100 *100 E-Alone ppts in active treatment arm	Y	Serum .4ml: AHSG; CLL16; CP; FIX; FX; ICAM-1; IGF-I; IGFBP-1; IGFBP-2; IGFBP-3; IGFBP-4; IGFBP-6; KNG1; MCAM; MMP-2; NOV; Protein Z; Proteomics; SHBG; TFF3; VTN; VitD Binding	843
W41	Medications inventory on WHI Extension participants	Complete	General Population	N		
W42	SEER code WHI and ES non-primary cancers	Complete	General Population	N		
W43	Gene sequencing of selected genes in breast cancer and stroke SNP studies (W7 and W34)	Complete	HRT E+P Breast Cancer:60 Controls:60 *60 active treatment. 60 placebo	Y	DNA 0ug: Gene seq; Use samples from W7 and W34.	
W44	Biological validation of E+P effects on the serum proteome and comparison of E+P and E-Alone effects (see W19 and W40)	Complete	HRT Controls:50 *50 E+P ppts at baseline,AV1	Y	Serum .55ml: ACE; AGTASE; ANG; Apo D; Apo F; B2M; CAPPT; CCL18; CP; CSF1; FX; ICAM-1; IGF-I; IGFBP-1; IGFBP-2; IGFBP-4; KNG1; LCN2; LGALS3BP; LYVE1; MCAM; MCSF1; MMP-2; NOV; PARCq; RNASE4; TFF3; THBS1; TNC; VTN; XLKD1	921

Table 15.1 (continued)
Approved and Proposed Core Studies[1]

Ref #	Title	Status	Study Population	Blood	Analytes/Data	Used in Approved Publications
W45	Proteomic Colon Cancer Study	Complete	OS Colon cancer:100 Controls:100	Y	Citrate .15ml: ADAMTS13; APP; CEA; ENO1; IGFBP-1; IGFBP-2; IGFBP-6; LGALS3BP; LRG1; LTF; MAPRE1; MMP-2; NID1; PKM2; PPBP; PPIA; SPARC	
W47	Breast Tumor Tissue Pilot	Complete	General Population	N		
W51	Transfer of AS62-WHISE blood samples to WHI repository	Complete	General Population	N		
W52	SHARe data clean-up	Complete	General Population	N		
W54	CVD Biomarkers for 2010-2015 (SHARe cohort only)	Complete	General Population Controls:12008 *SHARe ppts (12,008)	Y	Serum 25ml: hsCRP; Cholesterol; Glucose; HDL; Insulin; LDL; Trig; creatinine	1872
W57	Proposal to Extend CVD Biomarker Study using HT Proteomics Study	Complete	General Population CHD:356 Stroke:348 Controls: 704 *B+Yr 1	Y	Citrate .15ml: B2M Citrate .15ml: IGFBP-4	1065
W58	CVD Biomarkers on non-SHARe participants	Complete	General Population *AS39-WHIMS (6061) + M13-GARNET (3015) + subset of HT EA aged 65 and over (279) and under 65 (899)	Y	Serum SST.25ml: hsCRP; Cholesterol; Glucose; HDL; Insulin; LDL; Trig; creatinine	2024
W59	Collaborative telomere studies pilot study	Complete	General Population	Y	DNA .0625ug: Leukocyte Telomere	
W61	DNA Extraction of Medical Records Cohort Participants	Complete	General Population Controls:12000 *~12,000 Med Records Cohort ppts who need to be extracted.	Y		
W63	GWAS on the 80+ Year Old Women	Funded	General Population	Y	GWAS – Illumina Omni Express + Exome	1902, 1919, 1920, 1921, 1925, 1926, 1927, 1932, 1943, 2018, 2024, 2035, 2036, 2037, 2085, 2093

Table 15.1 (continued)
Approved and Proposed Core Studies[1]

Ref #	Title	Status	Study Population	Blood	Analytes/Data	Used in Approved Publications
W64	Long Life Study (LLS)	Funded	General Population **7,875 63+ year old MRC ppts with GWAS and Baseline Biomarkers	N	Serum .25ml: hsCRP; Cholesterol; Glucose; HDL; Insulin; LDL; Trig; creatinine SCCA: Draw Requirements=Home Visit: Whole blood 2ml EDTA within ~30 hours of draw: MCH; MCV; PLT; BASO; MONO; NEUT; Hemoglobin; PDW; NEUT%; IG; HCT; BASO%; RET; EOS%; RDW-CV; MPV; RBC; EOS; WBC; LYMPH; IG%; RET%; MCHC; RDW-SD; MONO%; LYMPH%.	
W66	LLS Phase III GWAS and Biomarkers	Funded	General Population *The last 1500 women to became eligible for the Long Life Study. At the time they became eligible, they did not have GWAS and Baseline Biomarkers. This study was funded to generate those data.	Y	Serum .25ml: hsCRP; Cholesterol; Glucose; HDL; Insulin; LDL; Trig; creatinine GWAS – Illumina Omni Express + Exome	
AS286[2]	Objective physical activity and cardiovascular health in women aged 80 and older (OPACH)	Funded	CT *6500 E+P women, 2500 E - alone women, 1000 SHARe participants	N		2246
M3[2]	NCI Cancer Genetic Markers of Susceptibility (CGEMS) Initiative: Replication Phase	Complete	OS Breast Cancer:2956 Controls:2956 *Caucasians only.	Y	DNA 4ug: SNPs 30K	874, 906, 907, 908, 1104, 1109, 1814
M4[2]	Whole genome scan for pancreatic cancer risk in the pancreatic cancer cohort consortium (PANSCAN)	Analysis	General Population Pancreatic Cancer:283 Controls:283	Y	DNA 4ug: GWAS	875, 930, 931, 932, 933, 934, 936, 1075, 1085, 1201, 1266, 1276, 1530, 1588, 1663, 1808, 1955, 2039, 2040, 2154, 2189, 2195

Table 15.1 (continued)
Approved and Proposed Core Studies[1]

Ref #	Title	Status	Study Population	Blood	Analytes/Data	Used in Approved Publications
M5[2]	SHARe: SNP Health Association Resource GWAS	Analysis	General Population Controls:12500 *Blacks, Hispanics who signed Supplemental Consent	Y	DNA 2ug: GWAS	981, 982, 983, 984, 985, 986, 987, 988, 989, 990, 991, 993, 994, 995, 996, 998, 999, 1001, 1002, 1003, 1006, 1007, 1008, 1010, 1013, 1015, 1016, 1018, 1019, 1020, 1022, 1024, 1050, 1089, 1092, 1105, 1108, 1112, 1119, 1122, 1145, 1157, 1160, 1167, 1174, 1176, 1180, 1199, 1204, 1219, 1256, 1258, 1268, 1286, 1299, 1313, 1314, 1316, 1356, 1370, 1401, 1416, 1423, 1453, 1459, 1469, 1486, 1505, 1520, 1552, 1559, 1633, 1678, 1728, 1740, 1753, 1778, 1784, 1856, 1872, 1881, 1893, 1925, 1926, 1927, 1954, 2024, 2025, 2035, 2036, 2037, 2069, 2071, 2205

Table 15.1 (continued)
Approved and Proposed Core Studies[1]

Ref #	Title	Status	Study Population	Blood	Analytes/Data	Used in Approved Publications
M6[2]	PAGE: Population Architecture of Genes and Environment (formally Epidemiologic investigation of putative causal genetic variants: The Women's Health Initiative)	Funded	General Population Colorectal Cancer:1436 Endometrial Cancer:1103 CHD:4274 Type 2 Diabetes:4000 Stroke:3455 Ovarian Cancer:703 Lung Cancer:1751 Melanoma - Skin:1102 Lymphoma, Non Hodgkins:843 Breast Cancer - Invasive:1961 Controls:80000 *~20,000 ppts (cases & controls) every year for 4 years (new set of outcomes each year); Yr 01 Outcomes: CVD, Stroke, T2D	Y	DNA 1ug: Metabochip DNA 2ug: SNPs 96 DNA 2ug: SNPs 384; year 2 DNA 2ug: SNPs 384 ekg DNA 2ug: AIMS	1072, 1073, 1170, 1171, 1172, 1192, 1193, 1194, 1221, 1235, 1236, 1237, 1238, 1239, 1240, 1241, 1242, 1243, 1244, 1245, 1246, 1247, 1248, 1249, 1250, 1345, 1346, 1347, 1348, 1349, 1350, 1351, 1352, 1353, 1380, 1423, 1439, 1440, 1441, 1491, 1589, 1590, 1606, 1610, 1642, 1645, 1648, 1674, 1689, 1759, 1788, 1807, 1832, 1862, 1871, 1879, 1885, 1922, 1923, 1982, 2003, 2004, 2005, 2006, 2007, 2008, 2009, 2010, 2015, 2051, 2133, 2135, 2141, 2151, 2175, 2180, 2233
M13[2]	HT CVD/Diabetes GWAS of treatment response in randomized clinical trials	Funded	General Population CHD:615 Type 2 Diabetes:1184 Stroke:438 VTE:373 Controls:2610	Y	DNA 2ug: Illumina 1M Omni DNA 2ug: Phase II Validation	1122, 1219, 1342, 1362, 1483, 1559, 1630, 1649, 1651, 1675, 1777, 1778, 1890, 1894, 1919, 1920, 1921, 1995, 2018, 2024, 2035, 2036, 2037, 2085, 2093, 2109, 2177

Table 15.1 (continued)
Approved and Proposed Core Studies[1]

Ref #	Title	Status	Study Population	Blood	Analytes/Data	Used in Approved Publications
M24[2]	WHISP - WHI Sequencing Project	Funded	General Population *Phase I: BMI/T2D, Early MI. Phase II: Stroke, Blood Pressure, Deeply Phenotyped Reference Group (DPR)	Y	DNA 5ug: DNA 5ug: Exomic Sequencing; large-scale genetic sequencing DNA 5ug:	1458, 1501, 1543, 1544, 1545, 1546, 1547, 1548, 1549, 1550, 1551, 1682, 1709, 1736, 1802, 1818, 1819, 1820, 1821, 1822, 1823, 1824, 1825, 1826, 1829, 1848, 1863, 1875, 1918, 1919, 1920, 1921, 1924, 1938, 1954, 1958, 1996, 2011, 2016, 2020, 2021, 2027, 2031, 2035, 2036, 2037, 2042, 2050, 2085, 2103, 2109, 2160, 2161, 2176, 2191, 2213, 2236

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

Table 15.2
Broad Agency Announcement Activities

BAA	Title	PI	Institution	Approved Publications
1	Ancestry Association Analyses of WHI Traits	Dr. Michael Seldin	University of California, Davis	964, 1158, 1185, 1253, 1315, 1500, 1599, 1741, 1783
2	High-Dimensional Genotype in Relation to Breast Cancer and WHI Clinical Trial Interventions	Dr. Ross Prentice	Fred Hutchinson Cancer Research Center	846, 1045, 1055, 1070, 1104
3	Genome-wide Association Study to Identify Genetic Components of Hip Fracture	Dr. Rebecca Jackson	Ohio State University Research Foundation	1510, 1845
4	Proteomics and the Health Effects of Postmenopausal Hormone Therapy	Dr. Ross Prentice	Fred Hutchinson Cancer Research Center	1064, 1065
5	Identification and Validation of Circulating Biomarkers for the Early Detection of Breast Cancer in Pre-Clinical Specimens	Dr. Christopher Li	Fred Hutchinson Cancer Research Center	1127, 1448, 1782, 1813
6	Interaction Effects of Genes in the Inflammatory Pathway and Dietary, Supplement, and Medication Exposures on General Cancer Risk	Dr. Jianfeng Xu	Wake Forest University	1068, 1069
7	Endogenous Estradiol and the Effects of Estrogen Therapy on Major Outcomes of WHI	Dr. Steve Cummings	California Pacific Medical Center	1033, 1123, 1140, 1141, 1218, 1329
8	Predictive Value of Nutrient Biomarkers for CHD Death	Dr. Alice Lichtenstein	Tufts University	1151, 2145
9	Biochemical Antecedents of Fracture in Minority Women	Dr. Jane Cauley	University of Pittsburgh	841, 863, 945, 1158, 1218, 1422, 1858
10	Adipokines and Risk of Obesity-Related Diseases	Dr. Gloria Ho	Albert Einstein College of Medicine	893, 894, 922, 1025, 1029, 1061, 1083, 1411, 1507, 1517, 1700
11	Physical Activity, Obesity, Inflammation and CHD in a Multi-Ethnic Cohort of Women	Dr. I-Min Lee	Brigham and Women’s Hospital	895, 1700
12	Hormone Therapy, Estrogen Metabolism and Risk of Breast Cancer or Hip Fracture in the WHI Hormone Trial	Dr. Lewis Kuller	University of Pittsburgh	916, 917, 1742
13	Markers of B-cell stimulation as potential predictors of Non-Hodgkins lymphoma	Dr. Anne DeRoos	Fred Hutchinson Cancer Research Center	1283, 1374, 1817

Table 15.2 (continued)
Broad Agency Announcement Activities

BAA	Title	PI	Institution	Approved Publications
14	Inflammation and thrombosis gene pathways and cardiovascular disease	Dr. Alex Reiner	Fred Hutchinson Cancer Research Center	1186, 1215, 1216, 1251, 1252, 1508, 1533, 1626, 1778, 1794, 1795, 1919, 1920, 1921, 1992, 2093, 2109, 2111, 2121, 2176, 2182
15	Discovery and confirmation of cancer specific serum protein markers for ovarian cancer early detection	Dr. Martin McIntosh	Fred Hutchinson Cancer Research Center	1433
16	Identifying biomarkers for pancreatic cancer	Dr. Sunil Hingorani	Fred Hutchinson Cancer Research Center	
17	Proteomics based discovery of blood based biomarkers and risk factors for lung cancer among women smokers and never smokers	Dr. Sam Hanash	Fred Hutchinson Cancer Research Center	1357
18	Follow-up studies of genetically determined risk factors	Dr. Rebecca Jackson	Ohio State University	1554
19	Omega-3 fatty acid biomarkers and cognitive decline in WHIMS	Dr. William Harris	Sanford Research/University of South Dakota	1058, 1259, 1260, 1558, 1746, 1780, 1816, 2017
20	Evaluation of specific markers of rheumatoid arthritis, Inflammation, thrombogenesis and risk of cardiovascular disease and total mortality	Dr. Larry Mooreland	University of Pittsburgh	1078, 1701, 1732, 1838, 1859, 2132
21	Understanding the role of sex hormones in colorectal cancer	Dr. Marc Gunter	Albert Einstein College of Medicine	1173, 1218, 1338
22	Predictive modeling for CVD in a multiethnic cohort in women	Dr. Nancy Cook	Brigham and Women’s Hospital and Harvard Medical School	1272, 1318, 1319, 1496, 1555, 1745
23	Integrative genomics for risk of CHD and related phenotypes in the Women's Health Initiative	Dr. Phil Tsao, Dr. Tim Assimes, Dr. Devin Absher, Dr. Steve Horvath	Stanford University School of Medicine	
24	Metabolomics of CHD in the WHI	Dr. Kathryn Rexrode	Brigham and Women’s Hospital and Harvard Medical School	

Table 15.2 (continued)
Broad Agency Announcement Activities

BAA	Title	PI	Institution	Approved Publications
25	Telomeres dynamics, cardiovascular risk and longevity in older women	Dr. Alex Reiner	Fred Hutchinson cancer Research Institute	

Table 15.3
Summary of Ancillary Studies

Data as of September 2013

Current Status	Number of Studies	Led by WHI Investigator	
		Yes	No
Dropped	212	76	136
Seeking approval	31	9	22
Approved	49	17	32
Funded	82	43	39
Data analysis in progress	63	35	28
Complete	70	39	31
Total	**507**	**219**	**288**

Table 15.4
All Approved Ancillary Studies
(From Oct. 1, 2012)

Anc #	Title	PI	WHI PI	Status	Study Dates	Case Controls	Blood study	Ms #(s)
388	Immune response biomarkers in inflammation-related digestive cancers	Ho - Albert Einstein College of Medicine	N	Approved	12/01/13-05/31/16	General population Pancreatic Cancer:600 Colorectal Cancer:600 Controls:900	Y	
389	A pooled investigation of multiple myeloma risk in relation to circulating adiponectin levels	Hofmann - NCI	N	Approved	09/01/13-08/31/14	General population Multiple Myeloma:200 Controls:400 *Participants will be the cases and controls from AS207	Y	
391	Defining and timing of sudden arrhythmic death in WHI	Eaton - Memorial Hospital of Rhode Island	Y	Funded	11/01/12-09/30/13	General population	N	
397	Assessment of fibromyalgia and polysomatic distress in the WHI: Pilot study	Walitt - MedStar Research Institute	Y	Analysis	11/01/12-09/30/13	General population	N	2201, 2202
398	Enhanced dietary assessment to evaluate post-trial cancer outcomes in the WHI Dietary Modification Trial.	Tinker - Fred Hutchinson Cancer Research Center	Y	Analysis	01/01/13-08/31/13	DM Breast Cancer:796 Ovarian Cancer:70 *4DFRs	N	
400	Methylation profiling of early stage lung tumors in short and long-term survivors	Cote - Wayne State University	N	Funded	11/01/12-09/30/13	General population	N	
402	Biomarkers and risk of ALS	Ascherio - Harvard School of Public Health	N	Approved	01/01/13-12/31/18	OS	Y	
403	Systemic and breast-cancer specific autoimmunity in the WHI	Parks - National Institute of Environmental Health Sciences	N	Analysis	11/01/12-09/30/13	General population	Y	
405	Pharmacogenomics of risk factors for cardiac arrhythmias in global populations	Avery - University of North Carolina at Chapel Hill	N	Funded	11/01/12-09/30/13	General population	N	2064, 2068, 2122

Table 15.4 (continued)
All Approved Ancillary Studies
(From Oct. 1, 2012)

Anc #	Title	PI	WHI PI	Status	Study Dates	Case Controls	Blood study	Ms #(s)
407	A feasibility study to assess the accuracy of self-reported glaucoma outcomes and participant interest in participating in ancillary glaucoma studies	Vajaranant - University of Illinois at Chicago	N	Funded	11/01/12-09/30/13	General population 200 Ppts@3 clinics	N	
408	Validating the chronic condition warehouse (CCW) Alzheimer's disease and related disorders of senile dementia identification algorithm in WHI-linked CMS data	Bensink - Fred Hutchinson Cancer Research Center	N	Funded	11/01/12-09/30/13	General population	N	
411	Novel predictors of excess mortality in women with rheumatoid arthritis	Mackey - University of Pittsburgh	Y	Funded	11/01/12-09/30/13	General population Controls:162 *162 BAA20 with anti-CCP+ RA participants who died during follow-up	Y	
412	Mindfulness meditation and cognitive function: A pilot feasibility study	Danhauer - Wake Forest School of Medicine	N	Approved	11/01/12-09/30/13	General population	N	
413	Feasibility of sleep apnea assessment in WHI participants: Prelude to an ancillary study of sleep, CVD and cognitive impairment	Stone - Research Institute, California Pacific Medical Center	N	Funded	11/01/12-09/30/13	General population	N	
414	Social networks and health among women in the WHI: A new area of inquiry	Cene - University of North Carolina at Chapel Hill	N	Funded	11/01/12-09/30/13	General population	N	
415	Assessing DNA methylation relationships in blood and tumor tissue	Malone - Fred Hutchinson Cancer Research Center	N	Analysis	11/01/12-09/30/13	General population Breast Cancer - Invasive:60 *60 participants from W47 BTTP with tumor specimen available	Y	

Table 15.4 (continued)
All Approved Ancillary Studies
(From Oct. 1, 2012)

Anc #	Title	PI	WHI PI	Status	Study Dates	Case Controls	Blood study	Ms #(s)
416	Biomarkers of human age and longevity	Reis - University of Arkansas for Medical Sciences and VA Medical Center	N	Funded	10/01/12-09/30/13	General population Controls:300 *100 women with plasma from baseline and Long Life Study; 100 short-lived and 100 long-lived women	Y	
417	Dietary metabolite profiling of nutrition and physical assessment	Raftery - University of Washington	N	Analysis	01/01/13-08/31/13	General population Controls:50 *50 NPAAS-FS	Y	
418	A prospective study of circulating androgen levels and melanoma risk among women	Han - Brigham and Women's Hospital	N	Approved	01/01/13-12/31/17	OS	Y	
419	Sex steroids, genetic variants and risk of ER- triple-negative breast cancer	Rohan - Albert Einstein College of Medicine	Y	Approved	04/01/14-03/31/18	General population Breast Cancer:827 Controls:827 *ER- breast cancer cases	Y	
421	LPL Pathway and Risk of Coronary Heart Disease	Reiner - Fred Hutchinson Cancer Research Center	Y	Funded	01/01/14-12/31/17	General population CHD:3057 CABG:2334 PTCA:4109 Controls:9500 *For AIM #2: Cases: 62 AA SHARe participants with the rare His504 variant + 62 controls	Y	
422	Measuring cardiovascular biomarkers in WHI Native Americans	Kooperberg - Fred Hutchinson Cancer Research Center	Y	Analysis	04/01/13-08/31/13	General population Controls:594 *PAGE Native Americans - 594 (same as pull M6-350)	Y	

Table 15.4 (continued)
All Approved Ancillary Studies
(From Oct. 1, 2012)

Anc #	Title	PI	WHI PI	Status	Study Dates	Case Controls	Blood study	Ms #(s)
423	Validating multiple stable isotope measures of diet within the NPAAS Feeding Study (AS272)	O'Brien - University of Alaska Fairbanks	N	Approved	12/01/13-11/30/15	General population	Y	
424	Role of circulating adiponectin and high-molecular weight adiponectin and risk of renal cell carcinoma	Liao - NIH/NCI	N	Approved	04/01/13-04/30/14	General population Cancer of Kidney:481 Controls:481	Y	
425	A Pilot Study of Urinary Bisphenol-A in the Womens Health Initiative	Luo - Indiana University	Y	Funded	11/01/12-09/30/13	General population	Y	
426	Micro RNA and risk of CHD in women	Mukamal - Beth Israel Deaconess Medical Center	N	Approved	12/01/14-11/30/18	OS HD:2000 Controls:2000 *2000 CVD cases and controls used in BA22	Y	
427	(Pilot study II) Trial of a cocoa supplement and multivitamin for CVD and cancer prevention among WHI participants	Manson - Brigham and Women's/Harvard University	Y	Funded	01/01/13-05/31/13	General population 577 Ppts@11 clinics	N	
429	The relationship between neighborhood walkability and health behaviors, body weight, health outcomes, and mortality risk in the WHI cohort	Seguin - Cornell University	N	Approved	04/01/13-04/30/14	General population	N	
430	Environmental endocrine disrupting chemicals and risk of diabetes in white and black postmenopausal women	Liu - Brown University	Y	Approved	04/01/14-03/31/19	General population	Y	
431	Role of brown and white adipose tissue in renal cell carcinoma	Lipworth - Vanderbilt University	N	Approved	04/01/14-03/31/18	General population	Y	
432	Calcium excretion and osteoporosis. For the WHI	Carbone - University of Tennessee Health Science Center	N	Approved	12/01/13-12/01/18	General population Fracture (general):2800 Controls:2800	Y	

Table 15.4 (continued)
All Approved Ancillary Studies
(From Oct. 1, 2012)

Anc #	Title	PI	WHI PI	Status	Study Dates	Case Controls	Blood study	Ms #(s)
434	Prospective study of biomarkers for diet-microbial interaction and colon cancer	Kato - Wayne State University	N	Approved	07/01/14-06/30/19	OS Colon cancer:1130	Y	
436	PQA5 objective physical activity, cancer outcomes and molecular mechanisms	Marshall – University of California – San Diego	N	Approved	04/01/13-03/31/18	General population Controls:2230 *2230 OPACH participants	Y	
437	Alterations in systemic metabolism and pancreatic cancer risk: a translational approach to define novel prevention and screening strategies	Wolpin - Dana-Farber Cancer Institute	N	Approved	04/01/14-03/31/19	OS	Y	
439	Nutrition and physical activity interest survey	Neuhouser - Fred Hutchinson Cancer Research Center	Y	Funded	05/24/13-08/31/13	General population 500 Ppts@11 clinics	N	
447	Parkinson’s Disease Etiology and Clinical Epidemiology (PEACE) Consortium	Jain - University of Pittsburgh	N	Approved	04/01/14-03/31/19	General population	N	
449	Validity of self-reported medication use compared with pharmacy records among a cohort of postmenopausal women	Drieling - Fred Hutchinson Cancer Research Center	N	Approved	08/01/13-04/30/14	General population	N	
450	Physical activity to improve cardiovascular health in women: a pragmatic trial (WHISH)	LaCroix - Fred Hutchinson Cancer Research Center	Y	Approved	04/01/14-03/31/19	General population	N	

Table 15.5a
Recruitment to Core and Ancillary Studies Requiring Separate Consents by Field Centers[1]

Data as of September 2013

Clinic	9 Oral Bone Loss	15 The Relationship Between Osteopenia and Periodontitis	34 Ethnic Differences in Hip Bone Geometry by DXA and QCT	36 HRT and Changes in Mammographic Density	39 The Effects of HRT on the Development and Progression of Dementia (WHIMS)	62 Prevention of Age-Related Maculopathy in the WHI HRT CT: WHI-SE	65 Benign Breast Disease	68 Coronary Artery Calcification Detected with Ultrafast CT as an Indication of CAD in OS	84 Estrogen, Vitamin E and Cognitive Change in Women	98 Bone Mineral Density as a Predictor for Periodontitis	100 Genetic, Biochemical and Behav. Determinants of Obesity	103 Effects of HRT on Cognitive Aging: WHI Study of Cognitive Aging (WHISCA)	105 Carotenoids in Age-Related Eye Disease Study	117 Risk Factors for Dry Eye Syndrome in Postmenopausal Women
Atlanta					99									
Birmingham	450			91	175									
Bowman				36	65		11				548			
Brigham				45	202	372								
Buffalo		1468			157	231	21			969				
Chapel Hill				64	252							172		
Chicago-Rush					158							100		
Chicago					31				546					
Cincinnati					165		8							
Columbus				43	290	282	19					198		217
Detroit			311		131	176								
Gainesville					234							169		
GWU-DC				57	183			442						
Honolulu					97		9							
Houston					118	131					249			
Iowa City				102	395	507	13					236	631	
Irvine					198	191								
LA					237							159		
La Jolla					137	323								
Madison				35	166	260							693	
Medlantic					179	129		293						
Memphis				105	157	290								
Miami					47									
Milwaukee				42	259							198		
Minneapolis					210							134		
Nevada				35	232	170						113		
Newark					329	269								
New York					279	141						128		
Oakland					186									
Pawtucket					338									
Pittsburgh				52	160	168	14							
Portland					199								683	
San Antonio					118									
Seattle							2							
Stanford					282							179		
Stonybrook					252	136						127		
Torrance					61									
Tucson				94	245									
UC Davis				56	218	304	4					135		
Worcester					287	350						218		
Total	**450**	**1468**	**311**	**857**	**7528**	**4430**	**101**	**735**	**546**	**969**	**797**	**2266**	**2007**	**217**

Table 15.5a (continued)
Recruitment to Core and Ancillary Studies Requiring Separate Consents by Field Centers[1]

Data as of September 2013

Clinic	130 Randomized Controlled Trial of Fat Reduction, Calcium/ Vit D Supplementation, HRT, and Risk of Proliferative Forms of Benign Breast Disease	153 Longitudinal Changes in Hip Geometry and Skeletal Muscle	178 Mammographic Density and Invasive Breast Cancer	197 Validity of self-reported diabetes mellitus in the WHI	216 Decision-making About Cancer Screening Among Older Women	218 WHI Nutrition and Physical Activity Assessment Study (NPAAS)	219 Diet and Eye Health in the WHI: End of Trial Study	233 WHIMS Extension	262 Memory Study of Younger Women (WHIMS-Y)	272 WHI Nutrition and Physical Activity Assessment Study (NPAAS)	W25 WHI Coronary Artery Calcification Study in E-Alone	W30 Dietary Assessment Study	W47 Breast Tumor Tissue Pilot
Atlanta	118		21					70	36		74	8	3
Birmingham	66		3	180					60		59	6	4
Bowman	67		24	161					36			11	7
Brigham	156		38						27		38	9	9
Buffalo	76		42						36		41	10	17
Chapel Hill	119		25			40		147	35		32		7
Chicago-Rush	56								33				4
Chicago	94					70		1	23		22	6	2
Cincinnati	121		25					117	24		47		6
Columbus	105		36					135	24		21		10
Detroit	85		9					63	35				5
Gainesville	137		49					157	50				4
GWU-DC	88		27					111	36		22		6
Honolulu	109							58	0				7
Houston	101		13						34				5
Iowa City	124		76					173	64		60	9	9
Irvine	79							93	40				9
LA	75		16					102	27		16		10
La Jolla	73								20		24	10	15
Madison	128		26			40	400	97	50		36		19
Medlantic	84		12					115	36		48		5
Memphis	87		14			40		76	23		54	10	4
Miami	71		6						0		49		3
Milwaukee	87							126	29		42		9
Minneapolis	147		51	224				125	41		54	7	17
Nevada	87		21						43				18
Newark	149								45		25	8	14
New York	66		21			40		165	28		26		6
Oakland	82		35			70		115	54		39		10
Pawtucket	149		34					216	50		43	9	14
Pittsburgh	97		20					108	39		66	8	5
Portland	78		27	173				130	22		47		7
San Antonio	69								32		58		5
Seattle	97					70			67	154		8	8
Stanford	96		42					194	45		28		10
Stonybrook	120				1300			153	22				8
Torrance	34								18				7
Tucson	101	47	9			40		108	29			9	11
UC Davis	106		22					119	33		46	6	8
Worcester	117		49			40			27		24		13
Total	**3901**	**47**	**793**	**738**	**1300**	**450**	**400**	**3074**	**1373**	**154**	**1141**	**134**	**340**

[1] Table 15a lists all ancillary studies (AS) requiring signed consent forms, with funding for the AS starting before Extension Study 2 (before Oct. 2010), regardless of whether or not the AS is still recruiting . If enrollment for an AS extends past Oct 2010, (e.g., 262-WHIIMS-Y, 272-NPAAS, W47-Breast Tumor Tissue), the AS is also shown in Table 15b under the Regional Center responsible for Field Center. The number of participants represents total recruitment to date (i.e., is the same in both Tables 15a and 15b).

Table 15.5b
Recruitment to Core and Ancillary Studies Requiring Separate Consents by Regional Centers[1]

Data as of September 2013

Regional Clinic	117[2] Risk Factors for Dry Eye Syndrome in Postmenopausal Women	197[2] Validity of self-reported diabetes mellitus in the Women's Health Initiative	262[2] Women's Health Initiative memory study of younger women (WHIMS-Y)	272[2] WHI Nutrition and Physical Activity Assessment Study (NPAAS) (Competitive Renewal)	286 Objective physical activity and cardiovascular health in women aged 80 and older (OPACH)	352 PILOT for Trial of vitamin D, alpha-linolenic acid, and resveratrol for CVD and cancer prevention among high-risk WHI participants	370 WHI cancer survivor cohort (LILAC)	384 Methylation profiling of early stage lung tumors in short and long-term survivors (Pilot to AS370)	407 A feasibility study to assess the accuracy of self-reported glaucoma outcomes and participant interest in participating in ancillary glaucoma studies	427 Study of a cocoa supplement and multivitamin for CVD and cancer prevention among WHI participants (Pilot Study II)	439 Nutrition and physical activity interest survey	W47[2] Breast Tumor Tissue Pilot	W64 Long Life Study
Midwest													
Columbus	217		133		1061	108	9	14	31	77	49	31	1152
Iowa		224	155		656	65	6	12	142	61	27	45	718
Pittsburgh			74		412	43	4	7	27	34	19	10	461
Northeast													
Boston			104		570	78	7	15		63	27	36	613
Buffalo			131		1036	100	12	21		59	57	45	1116
Medstar			72		661	58	1	9		27	40	11	720
Southeast													
Gainesville		180	146		871	107	4	12		41	48	14	934
Wake Forest		161	160		1039	78	7	12		57	75	28	1119
West													
CCC			87	154	416	28	4	6		22	27	23	436
Stanford		173	239		1401	131	13	21		101	89	61	1476
Tucson			72		435	39	4	7		57	42	36	469
TOTAL	**217**	**738**	**1373**	**154**	**8558**	**835**	**71**	**136**	**200**	**577**	**500**	**340**	**9214**

[1] Table 15a lists all ancillary studies (AS) requiring signed consent forms, with funding for the AS starting before Extension Study 2 (before Oct. 2010), regardless of whether or not the AS was still recruiting . If enrollment for an AS extends past Oct 2010, (e.g., 262-WHIIMS-Y, 272-NPAAS, W47-Breast Tumor Tissue), the AS is also shown in Table 15b under the Regional Center responsible for Field Center. The numbers of participants represents total recruitment to date (i.e., is the same in both Tables 15a and 15b).

[2] Ancillary studies that are found in both Tables 15a and 15b are 117, 197, 262, 272, and W47.

Table 15.6
Participant Enrollment in WHI Ancillary Studies
Requiring Separate Consents

Data as of September 2013

CT+OS

	Ppts	%
CT+OS	161,808	
Not Enrolled in Ancillary Studies	131,181	81.1
Enrolled in Ancillary Studies	30,627	18.9

Number of Studies	Ppts	%	Enrollments
1	17,688	10.9	17,688
2	7,745	4.8	15,490
3	2,784	1.7	8,352
4	1,315	0.8	5,260
5	766	0.5	3,830
6	272	0.2	1,632
7	50	0.0	350
8	5	0.0	40
9	2	0.0	18
Total	**30,627**	**18.9**	**52,660**

Extension 1

	Ppts	%
Consented to Extension 1	115,407	
Not Enrolled in Ancillary Studies	88,999	77.1
Enrolled in Ancillary Studies	26,408	22.9

Number of Studies	Ppts	%	Enrollments
1	14,180	12.2	14,180
2	7,148	6.2	14,296
3	2,678	2.3	8,034
4	1,308	1.1	5,232
5	765	0.7	3,825
6	272	0.2	1,632
7	50	0.0	350
8	5	0.0	40
9	2	0.0	18
Total	**26,408**	**22.9**	**47,607**

Extension 2

	Ppts	%
Consented to Extension 2	93,562	
Not Enrolled in Ancillary Studies	71,070	76.0
Enrolled in Ancillary Studies	22,492	24.0

Number of Studies	Ppts	%	Enrollments
1	11,698	12.5	11,698
2	6,288	6.7	12,576
3	2,239	2.4	6,717
4	1,186	1.3	4,744
5	753	0.8	3,765
6	271	0.3	1,626
7	50	0.1	350
8	5	0.0	40
9	2	0.0	18
Total	**22,492**	**24.0**	**41,534**

Table 15.7
Funded BAA and Ancillary Studies PI List
(As of Sept. 2013)

Last Name	First Name	PI Institution	WHI Investigator	Anc PI for	WHI PI for	CCC PI for
Anderson	Garnet	Fred Hutchinson Cancer Research Center	Yes	97, 370, 384	97, 282, 297, 337, 370, 384, 415, M11, W47, W64,	97, 121, 129, 140, 150, 282, 297, 370, 384, BA6, BA11, BA15, BA21, M11, M8, M9, W47
Assimes	Tim	Stanford University School of Medicine	Yes	332	BA23	
Avery	Christy	University of North Carolina at Chapel Hill	No	405		
Barnhart	Janice	Albert Einstein College of Medicine	No	127		
Bassford	Tamsen	University of Arizona	Former		113, 153, 175, 191, 199	
Beasley	Jeannette	Fred Hutchinson Cancer Research Center	No	340		
Bensink	Mark	Fred Hutchinson Cancer Research Center	No	408		
Beresford	Shirley	University of Washington	Yes		272, 327	
Berndt	Sonja	National Institute of Health - NCI	No	301		
Bhatti	Parveen	Fred Hutchinson Cancer Research Center	No	311		
Bird	Cloe	Rand Corp	No	220		
Bowen	Deborah	Fred Hutchinson Cancer Research Center	Former		5	39
Bray	Paul	Thomas Jefferson University	Former	137		
Brennan	Paul	International Agency for Research on Cancer (IARC)	No	294		
Brinton	Louise	National Institute of Health - NCI	No	297		
Burke	Greg	Wake Forest University School of Medicine	Former		56, 139	
Burrows	Beth	Fred Hutchinson Cancer Research Center	Yes	50		
Caan	Bette	Kaiser Foundation Research Institute - Oakland	Yes	M20, W48	243, M20	
Carty	Cara	Fred Hutchinson Cancer Research Center	Yes			M16
Cauley	Jane	University of Pittsburgh	Yes	161, 181, BA9		
Cene	Crystal	University of North Carolina at Chapel Hill	No	414		
Chanock	Stephen	National Institute of Health	No	M3, M8		
Chen	Jiu-Chiuan	Univ. of Southern California Keck School of Medicine	No	226, 252		
Chen	Zhao	University of Arizona	Yes	82, 153, 191, 199, M2		
Chlebowski	Rowan	UCLA Medical Center	Yes	76, 99	76, 99, 108	

Table 15.7 (continued)
Funded BAA and Ancillary Studies PI List

Last Name	First Name	PI Institution	WHI Investigator	Anc PI for	WHI PI for	CCC PI for
Cochrane	Barbara	Fred Hutchinson Cancer Research Center	Yes			110, 133, 134, 146, 167, 192, 196, 214, 242, 250, 262
Colditz	Graham	Washington University Saint Louis	No	207		
Cook	Nancy	Brigham and Women's/ Harvard University	No	BA22		
Cote	Michele	Wayne State University	No	400		
Coy	Christine	UC-Irvine	No	118		
Criqui	Michael	Univ. of California, San Diego	Former	93		
Cummings	Steve	UC-San Francisco	Former	90, 167, BA7		
Curb	David	Pacific Health Research and Education Institute	Former		25, 95, 122	
DeRoos	Anneclaire	University of Washington	No	BA13		
Donovan	Geoffrey	USDA Forest Service, PNW Research Station	No	386		
Dorn	Joan	University of Buffalo	No	141		
Driscoll	Ira	University of Wisconsin - Milwaukee	No	250		
Dunn	Julie	Tufts University	Former	84		
Eaton	Charles	Memorial Hospital of RI	Yes	391	251, 391	
Edlefsen	Kerstin	University of Washington	Yes	337		
Fouad	Mona	University of Alabama at Birmingham	Yes	78, 102		
Franceschini	Nora	University of North Carolina at Chapel Hill	No	376		
Fuchs	Charles	Dana-Farber Cancer Institute	No	146, 214		
Glanz	Karen	University of Hawaii System	No	122		
Going	Scott	University of Arizona	Yes	14		
Green	Pamela	Fred Hutchinson Cancer Research Center	No	5		
Grimm	Richard	Berman Center for Clinical Research	Former		50	
Gunter	Marc	Albert Einstein College of Medicine	No	BA21		
Haan	Mary	UC-San Francisco	Former	62	407	
Haines	Pam	University of North Carolina	No	63		
Hakim	Iman	University of Arizona	No	113		
Han	Jiali	Brigham and Women's Hospital	No	242		
Hanash	Sam	MD Anderson Cancer Center	Yes	BA17, W45		
Harris	William S.	Sanford Health	No	BA19		
Hays	Jennifer	Univ. of Oklahoma - Tulsa	Yes	100, 163	100, 137, 163,	
He	Ka	Indiana University	No	187		

Table 15.7 (continued)
Funded BAA and Ancillary Studies PI List

Last Name	First Name	PI Institution	WHI Investigator	Anc PI for	WHI PI for	CCC PI for
Heiss	Gerardo	UNC School of Medicine	Yes		36, 63, 70, 140, 165, 178, 226, 236, 252, 264, 376	
Hendrix	Susan	Wayne State University Medical School	Former		34	
Hingorani	Sunil	Fred Hutchinson Cancer Research Center	No	BA16		
Ho	Gloria	Albert Einstein College of Medicine	No	152, 208, 266, BA10		
Howard	Barbara	MedStar Research Institute	Yes		217, 397, 403,	
Hsia	Judith	George Washington University	Yes	68	68	
Hubble	Allan	Univ. of California - Irvine	Yes		118	
Hulka	Barbara	University of North Carolina	Former	36		
Hunt	Julie	Fred Hutchinson Cancer Research Center	Yes			220, 223, 226, 252, 425
Hunter	David	Harvard	No	M18		
Jackson	Rebecca	Ohio State University	Yes	271, BA3, BA18, M24	117, 223, 271, 301, BA3, M24, W22	
Jeffcoat	Marjorie	Penn Dental School	No	9		
Jiao	Li	Baylor College of Medicine	Yes	292		
Kaufman	Joel	University of Washington	No	150		
Kerwin	Diana	Northwestern University	No	235		
Kipnis	Victor	National Institute of Health	No	289, M12		
Klein	Liviu	University of California San Francisco	No	196		
Kleinstein	Robert	University of Alabama at Birmingham	No	31		
Kooperberg	Charles	Fred Hutchinson Cancer Research Center	Yes	349, 422, M6	349, 421, 422, M6, M13, M26,	90, 126, BA10, BA12, BA18, BA19, BA20, M4
Kotchen	Jane	Medical College of Wisconsin	Yes		235	
Kripke	Daniel	Univ. of California, San Diego	No	11		
Kuller	Lew	University of Pittsburgh	Yes	BA12	13, 121, 134, 161, 181, 189, 411, M9	
LaCroix	Andrea	Fred Hutchinson Cancer Research Center	Yes	179, 286, W64	179, 286, 290, 321, 340, 416, BA25, M4	83, 137, 153, 165, 179, 181, 191, 199, 286, 290, 340, 416, BA3, BA7, BA9, BA13, BA14, BA22, M2
LaMonte	Michael	University of Buffalo	No	287		
Lane	Dorothy	Stony Brook Univ. - New York	Yes		216	
Langer	Robert	Univ. of California - San Diego	Former	47	11, 24, 47, 73, 93, 124	

Table 15.7 (continued)
Funded BAA and Ancillary Studies PI List

Lasser	Norm	University of Medicine and Dentistry of New Jersey	Former		17	
Lee	I-Minn	Brigham and Women's/ Harvard University	No	BA11		
Lewis	Beth	University of Alabama at Birmingham	Yes		9, 111	

Last Name	First Name	PI Institution	WHI Investigator	Anc PI for	WHI PI for	CCC PI for
Li	Rongling	University of Tennessee Health Science Center	No	BA5		
Lichtenstein	Alice	Tufts University	No	BA8		
Lin	Henry	Harbor-UCLA	No	108		
Liu	Simin	Brown University	Yes	132, 238, 254		
Lorenz	Carol	University of North Carolina	No	165		
Lund	Bernedine	Fred Hutchinson Cancer Research Center	Yes			206, 352, 427, W54, W61
Luo	Juhua	Indiana University	Yes	425		
Mackey	Rachel	University of Pittsburgh,	Yes	189, 411		
Malone	Kathy	Fred Hutchinson Cancer Research Center	No	415		
Mann	Sue	Fred Hutchinson Cancer Research Center	Yes			224, M26
Manson	JoAnn	Brigham and Women's/ Harvard University	Yes	352, 427, W25	83, 110, 132, 133, 146, 192, 207, 214, 242, 325, 352, 427, BA11, BA24	
Mares	Julie	University of Wisconsin	Former	105, 219, 257, M1		
Margolis	Karen	Health Partners Minnesota	Yes	197	197, 220, 425	
Masaki	Kamal	Pacific Health Research and Education Institute	Former	25		
Mayo	Charlotte	University of Alabama at Birmingham	No	33		
McGlynn	Katherine	National Institute of Health - NCI	No	296		
McIntosh	Martin	Fred Hutchinson Cancer Research Center	Yes	BA15		
McTiernan	Anne	Fred Hutchinson Cancer Research Center	Yes			36, 178
Melnikow	Joy	University of California - Davis	No	104		
Messina	Catherine	Stony Brook University Medical Center	Yes	216		
Michael	Yvonne	Drexel University	Yes	171		
Millen	Amy	University of Buffalo	Yes	304		
Modugno	Francesmary	Carnegie Mellon University	No	121, 134,		
Moon	Tom	University of Arizona	Former		14	
Moreland	Larry W.	University of Pittsburgh	No	BA20		
Mouton	Charles	Howard University	Former	17		

Table 15.7 (continued)
Funded BAA and Ancillary Studies PI List

Last Name	First Name	PI Institution	WHI Investigator	Anc PI for	WHI PI for	CCC PI for
Namie	Joylin	Univ. of California - San Diego	No	124		
Nathan	Lauren	UCLA Medical Center	Former		238, 254	
Nelson	Dorothy	Wayne State University School of Medicine	No	34		
Neuhouser	Marian	Fred Hutchinson Cancer Research Center	Yes	327, 439		130, 195, 207, 236, 275, BA8
Newcomb	Polly	Fred Hutchinson Cancer Research Center	No	290		
Nicholas	J. Skye	University of Arizona	No	175		
Nichols	Kelley	University of Houston	No	117		
Nygaard	Ingrid	University of Utah Health Sciences	No	135		
Ober	Beth	University of California - Davis	No	61		
Oberman	Albert	University of Alabama at Birmingham	Former		31, 33, 60, 78, 102	
Ockene	Judith	University of Massachusetts Medical Center	Yes		75, 275	
Parks	Christine	National Institute of Environmental Health Sciences	No	403		
Paskett	Electra	Ohio State University	Yes	139, 223		
Patterson	Ruth	UCSD Moores Cancer Center	Former		177	65, 108
Peters	Ulrike	Fred Hutchinson Cancer Research Center	No	206, 224, M26		
Pisano	Etta	University of North Carolina - School of Medicine	No	178		
Pleuss	Joan	Wake Forest University	Former	56		
Polk	M.J.	University of Texas - San Antonio	No	86		
Prentice	Ross	Fred Hutchinson Cancer Research Center	Yes	218, 272, 343, 377, BA2, BA4	195, 206, 218, 224, 289, 294, 316, 343, 377, 417, M3, M12, M18, W31, W33, W45, W57	84, 263, 294, 316, BA1, BA2, BA4, BA5, BA16, BA17, W22, W44, W58
Purdue	Mark	National Institute of Health - NCI	No	M9		
Raftery	Dan	University of Washington	No	417		
Rajkovic	Aleksandar	Baylor College of Medicine	Yes		M8	
Ramsey	Scott	FHCRC	No		408	
Reding	Kerryn	University of Washington/ Fred Hutchinson Cancer Research Center	No	321		
Reiner	Alexander	Fred Hutchinson Cancer Research Center	Yes	421, BA14, BA25, M13		337
Reis	Robert	University of Arkansas for Medical Sciences and VA Med. Center	No	416		

Table 15.7 (continued)
Funded BAA and Ancillary Studies PI List

Last Name	First Name	PI Institution	WHI Investigator	Anc PI for	WHI PI for	CCC PI for
Rexrode	Kathryn	Brigham and Women's Hospital	Yes	110, BA24		
Ridker	Paul	Partners Health Care	No	83		
Ritenbaugh	Cheryl	University of Arizona	Former	57, 73	57, 82, 160, 171	
Robbins	John	University of California - Davis	Yes		61, 62, 104, BA1	
Rodriguez	Beatriz	University of Hawaii System	Yes	95		
Rohan	Tom	Albert Einstein College of Medicine	Yes	65, 130, 284		
Rosal	Milagros	University of Massachusetts Medical School	Yes	75		
Sangi-Haghpeykar	Haleh	Baylor College of Medicine	Yes		292	
Sarto	Gloria	University of Wisconsin	Yes		105, 219, 257, M1	
Schenken	Robert	University of Texas - San Antonio	Former		86	
Schneider	Diane	Univ. of California - San Diego	No	24		
Seldin	Michael	University of California - Davis	No	BA1		
Sesso	Howard	Brigham and Women's Hospital	Yes	133		
Sheps	David	University of Florida Department of Medicine	Former	70		
Shikany	James	University of Alabama at Birmingham	Former	60, 111		
Shumaker	Sally	Wake Forest School of Medicine	Yes	39, 103, 183, 233, 244, 262	39, 103, 183, 233, 244, 250, 262, 373, 413, 414	
Siega-Riz	Anna Maria	University of North Carolina	No	236		
Simon	Michael	Wayne State University Medical School	Yes		400	
Smith-Warner	Stephanie	Harvard School of Public Health	No	383		
Smoller	Sylvia	Albert Einstein College of Medicine	Yes	40, 48	40, 48, 127, 129, 130, 152, 208, 266, 284, BA10	
Song	Yiqing	Brigham and Women's Hospital	No	325		
Stefanick	Marcia	Stanford University	Yes		332, 346	
Stolzenberg-Solomon	Rachael	National Institute of Health - NCI	No	M4		
Stone	Katie	Research Institute, California Pacific Medical Center	No	413		
Strickler	Howard	Albert Einstein College of Medicine	No	129		
Sturgeon	Susan	University of Massachusetts	No	275		
Subar	Amy	National Institute of Health	No	177		

Table 15.7 (continued)
Funded BAA and Ancillary Studies PI List

Last Name	First Name	PI Institution	WHI Investigator	Anc PI for	WHI PI for	CCC PI for
Sun	Jielin	Wake Forest University	No	263		
Tang	Jean	Stanford University	Yes	346		
Taylor	Phil	National Institute of Health	No	M11		
Thomson	Cynthia	University of Arizona	Yes		383	
Tindle	Hilary	University of Pittsburgh	Yes	373		
Tinker	Lesley	Fred Hutchinson Cancer Research Center	Yes	398	439	105, 111, 132, 152, 187, 189, 208, 218, 219, 238, 251, 254, 257, 264, 266, 271, 284, 292, 296, 301, 311, 315, 321, 325, 332, 346, 376, 383, 391, 398, 403, 411, BA23, BA24, M1, M12
Trevisan	Maurizio	State Univ. of NY - Buffalo	Yes		15, 74, 98, 141	
Tsao	Phil	Stanford University School of Medicine	No	BA23		
Ulrich	Cornelia	Fred Hutchinson Cancer Research Center	No	195		
Urban	Nicole	Fred Hutchinson Cancer Research Center	Yes	282		
Vajaranant	Thasarat	Univ. of Illinois at Chicago	No	407		
Valanis	Barbara	Kaiser Permanente Center for Health Research, Portland	Former	160		
Van Horn	Linda	Northwestern University	Yes		84, 187, 196, 315	
Vitolins	Mara	Wake Forest University	Yes		263	
Vogt	Molly	University of Pittsburgh	No	13		
Wactawski-Wende	Jean	University of Buffalo	Yes	15, 98, 303, M25	287, 296, 303, 304, M25	
Walitt	Brian	MedStar Research Institute	Yes	217, 397		
Wallace	Robert	University of Iowa	Yes		135, 308	
Wang	CYes	Fred Hutchinson Cancer Research Center	Former			9
Wassertheil-Smoller	Sylvia	Albert Einstein College of Medicine	Yes	126, M16	126, M16	
Wellenius	Greg	Brown University	No	251		
Whitsel	Eric	University of North Carolina	Yes	140, 264, 315	386, 405	
Wilson	Robin	Penn State Univ College of Medicine	No	308		
Wodarski	Lois	State Univ. of NY - Buffalo	No	74		
Xu	Jianfeng	Wake Forest University School of Medicine	No	BA6		
Zhang	Shumin	Brigham and Women's Hospital	Yes	192		

Table 16.1
WHI Manuscript Stages
(Through September 2013)

Stage #	Definition	Number
12*	Published	754
11	In press / accepted by journal	8
10	Submitted to journal	35
9	Final manuscript approved by P&P Committee	179
8	Final manuscript submitted to P&P Committee	29
7	Draft manuscript	24
6	Analysis completed	24
5	Analysis in progress	68
4	Analysis proposed	7
3	Manuscript proposal and writing group approved	537
2	Approved/Writing group nominations open	59
Total		**1692**

*Only Stage 12 papers are included in Table 16.2

Table 16.2
Publications since October 2012

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
402	Subclinical hypothyroidism and risk for incident myocardial infarction among postmenopausal women	LeGrys, Funk, Lorenz, Giri, Jackson, Manson, Schectman, Edwards, Heiss, Hartmann	12	OS	J Clin Endocrinol Metab. 2013 Mar 28. [Epub ahead of print]	AS165
422	Breast cancer in postmenopausal women after non-melanomatous skin cancer: the Women's Health Initiative observational study	Pressler, Rosenberg, Derman, Greenland, Khandekar, Rodabough, McTiernan, Simon	12	OS	Breast Cancer Res Treat. 2013 Jun 13. [Epub ahead of print]	
530	B vitamin intakes and incidence of colorectal cancer: Results from the Women's Health Initiative Observational Study cohort	Zschaebitz, Cheng, Neuhouser, Zheng, Ray, Miller, Song, Bailey, Maneval Jr, Beresford, Lane, Shikany, Ulrich	12	OS	Am J Clin Nutr. 2013 Feb;97(2):332-43. doi: 10.3945/ajcn.112.034736. Epub 2012 Dec 19	AS195
555	Common genetic variants in Peroxisome Proliferator-Activated Receptor-γ (PPARG) and Type 2 Diabetes risk among Women's Health Initiative postmenopausal women	Chan, Niu, Ma, You, Song, Sobel, Hsu, Balasubramanian, Qiao, Tinker, Liu	12	OS	J Clin Endocrinol Metab. 2013 Mar;98(3):E600-4. doi: 10.1210/jc.2012-3644. Epub 2013 Feb 5	AS132
703	The relationship between urban sprawl and coronary heart disease in women	Griffin, Eibner, Bird, Jewell, Margolis, Shih, Slaughter, Whitsel, Allison, Escarce	12	Gen	Health Place. 2012 Dec 7;20C:51-61. doi: 10.1016/j.healthplace.2012.11.003. [Epub ahead of print]	AS220
830	The association of whole grain and fiber consumption with incident type 2 diabetes: The Women's Health Initiative Observational Study	Parker, Liu, Van Horn, Tinker, Shikany, Eaton, Margolis	12	OS	Ann Epidemiol 2013; 23(6):321-7.	
864	Does neighborhood walkability moderate the effects of intrapersonal characteristics on amount of walking in post-menopausal women?	Perry, Herting, Berke, Nguyen, Moudon, Beresford, Ockene, Manson, LaCroix	12	Gen	Health Place. 2013 Jan 23;21C:39-45. [Epub ahead of print]	
872	Improvement in stroke risk prediction: role of C-reactive protein and lipoprotein-associated phospholipase A(2) in the Women's Health Initiative	Wassertheil-Smoller, McGinn, Allison, Cai, Curb, Eaton, Hendrix, Kaplan, Ko, Martin, Xue	12	OS	Int J Stroke. 2012 Oct 23. [Epub ahead of print]	AS126
889	Effects of postmenopausal hormone therapy on incident atrial fibrillation: The Women's Health Initiative Randomized Controlled Trials	Perez, Wang, Larson, Virnig, Cochrane, Curb, Klein, Manson, Martin, Robinson, Wassertheil-Smoller, Stefanick	12	CT	Circ Arrhythm Electrophysiol. 2012 Nov 20. [Epub ahead of print]	W35
890	Risk factors for atrial fibrillation and their population burden in postmenopausal women: the Women's Health Initiative Observational Study	Perez, Wang, Larson, Soliman, Limacher, Rodriguez, Klein, Manson, Martin, Prineas, Connelly, Hlatky, Wassertheil-Smoller, Stefanick	12	OS	Heart. 2013 Jun 11. [Epub ahead of print]	

Table 16.2 (continued)
Publications since October 2012

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
902	Age at menopause, reproductive history, and venous thromboembolism risk among postmenopausal women: the Women's Health Initiative hormone therapy clinical trials	Canonico, Plu-Bureau, O'Sullivan, Stefanick, Cochrane, Scarabin, Manson	12	CT	Menopause. 2013 Jun 10. [Epub ahead of print]	
934	Diabetes and risk of pancreatic cancer: A pooled analysis from the Pancreatic Cancer Cohort Consortium	Elena, Steplowski, Yu, Hartge, Tobias, Kooperberg, Chanock, Stolzenberg-Solomon, Arslan, Bueno-de-Mesquita, Helzlsouer, Jacobs, Petersen, Zheng, Albanes	12	Gen	Cancer Causes Control. 2013 Jan;24(1):13-25. Epub 2012 Oct 31	M4
972	Coronary heart disease events in the Women's Health Initiative hormone trials: effect modification by metabolic syndrome: A nested case-control study within the Women's Health Initiative randomized clinical trials	Wild, Wu, Curb, Martin, Phillips, Stefanick, Trevisan, Manson	12	CT	Menopause. 2012 Oct 25. [Epub ahead of print]	W14, W6
1001	Gene-environment interactions and obesity traits among postmenopausal African-American and Hispanic women in the Women's Health Initiative SHARe Study	Velez Edwards, Naj, Monda, North, Neuhouser, Magvanjav, Kusimo, Vitolins, Manson, O'Sullivan, Rampersaud, Edwards	12	Gen	Hum Genet. 2012 Nov 29. [Epub ahead of print]	M5
1019	Association of DXA-derived bone mineral density and fat mass with African ancestry	Ochs-Balcom, Preus, Wactawski-Wende, Nie, Johnson, Zakharia, Tang, Carlson, Carty, Chen, Hoffmann, Hutter, Jackson, Kaplan, Li, Liu, et al.	12	Gen	J Clin Endocrinol Metab. 2013 Feb 22. [Epub ahead of print]	M5
1112	African American race but not genome-wide ancestry is negatively associated with atrial fibrillation among postmenopausal women in the Women's Health Initiative	Perez, Hoffmann, Tang, Thornton, Larson, Stefanick, Kooperberg, Reiner, Caan, Irribarren, Risch	12	Gen	Am Heart J. 2013 Sep;166(3):566-572.e1. doi: 10.1016/j.ahj.2013.05.024. Epub 2013 Aug 7.	M5
1121	Calcium and Vitamin D supplementation and cognitive impairment in the Women's Health Initiative	Rossom, Espeland, Manson, Dysken, Johnson, Lane, LeBlanc, Lederle, Masaki, Margolis	12	CT	J Am Geriatr Soc. 2012 Dec;60(12):2197-205. doi: 10.1111/jgs.12032. Epub 2012 Nov 23	AS103, AS39, W15, W24
1132	Effects of menopausal hormone therapy on ductal carcinoma in situ of the breast	Luo, Cochrane, Wactawski-Wende, Hunt, Ockene, Margolis	12	Gen	Breast Cancer Res Treat. 2013 Jan 12. [Epub ahead of print]	
1146	Low fat diet and skin cancer risk: the Women's Health Initiative Randomized Controlled Dietary Modification Trial.	Gamba, Stefanick, Shikany, Larson, Linos, Sims, Marshall, Van Horn, Zeitouni, Tang	12	CT	Cancer Epidemiol Biomarkers Prev. 2013 May 22. [Epub ahead of print]	

Table 16.2 (continued)
Publications since October 2012

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
1153	Calcium, magnesium, and potassium intake and mortality in women with heart failure: the Women's Health Initiative	Levitan, Shikany, Ahmed, Snetselaar, Martin, Curb, Lewis	12	OS	Br J Nutr. 2013 Jul;110(1):179-85. Epub 2012 Nov 19.	
1157	The impact of ancestry and common genetic variants on QT interval in African Americans	Smith, Avery, Evans, Nalls, Meng, Smith, Palmer, Tanaka, Mehra, Butler, Young, Buxbaum, Kerr, Berenson, Schnabel	12	Gen	Circ Cardiovasc Genet. 2012 Dec 1;5(6):647-655. Epub 2012 Nov 19	AS264, M5
1160	Common genetic variation near the connexin-43 gene is associated with resting heart rate in African Americans: A genome-wide association study of 13,372 participants	Deo, Whitsel, Avery, Smith, Evans, Keller, Butler, Buxbaum, Quibrera, Smith, Tanaka, Akylbekova, Alonso, Arking, Benjamin	12	Gen	Heart Rhythm. 2012 Nov 24. pii: S1547-5271(12)01342-2. doi: 10.1016/j.hrthm.2012.11.014. [Epub ahead of print]	AS264, M5
1164	Pre-diagnosis biomarkers of insulin-like growth factor-1, insulin, and interleukin-6 dysregulation and multiple myeloma risk in the Multiple Myeloma Cohort Consortium.	Birmann, Neuhouser, Rosner, Albanes, Buring, Giles, Lan, Lee, Purdue, Rothman, Severi, Yuan, Anderson, Pollak, Yuan, Landgren, et al.	12	Gen	Blood. 2012 Dec 13;120(25):4929-37. Epub 2012 Oct 16	AS207
1166	Diabetes, metformin use, and colorectal cancer survival in postmenopausal women	Cossor, McKnight, Chlebowski, Gunter, Johnson, Martell, McTiernan, Simon, Rohan, Wallace, Paulus	12	Gen	Cancer Epidemiol. 2013 Jun 14. pii: S1877-7821(13)00075-1. [Epub ahead of print]	
1179	Relations of depressive symptoms and antidepressant use to body mass index and selected biomarkers for diabetes and cardiovascular disease	Ma, Balasubramanian, Pagoto, Schneider, Beck, Culver, Hebert, Smoller, Phillips, Goveas, Olendzki, Sepavich, Ockene, Uebelacker, Zorn, Liu, et al.	12	Gen	Am J Public Health. 2013 Aug;103(8):e34-43. doi: 10.2105/AJPH.2013.301394. Epub 2013 Jun 13	
1181	Biomarkers of inflammation are associated with colorectal cancer risk in women but are not suitable as early detection markers	Toriola, Cheng, Neuhouser, Wener, Zheng, Brown, Miller, Song, Beresford, Gunter, Caudill, Ulrich	12	OS	Int J Cancer. 2012 Nov 15. [Epub ahead of print]	AS195
1183	Walking speed, physical activity, and breast cancer in postmenopausal women	Kwan, Chlebowski, McTiernan, Rodabough, LaMonte, Martin, Bell, Lane, Kaplan, Irwin	12	Gen	Eur J Cancer Prev. 2013 May 10. [Epub ahead of print]	
1197	Risk factors for sudden cardiac death in post-menopausal women	Bertoia, Allison, Manson, Freiberg, Kuller, Solomon, Limacher, Johnson, Curb, Wassertheil-Smoller, Eaton	12	Gen	J Am Coll Cardiol. 2012 Nov 8. pii: S0735-1097(12)04938-8. [Epub ahead of print]	
1199	Novel loci associated with PR interval in a genome-wide association study of 10 African American cohorts	Butler, Yin, Evans, Nalls, Smith, Tanaka, Li, Buxbaum, Whitsel, Alonso, Arking, Benjamin, Berenson, Bis, Chen	12	Gen	Circ Cardiovasc Genet. 2012 Dec 1;5(6):639-46. Epub 2012 Nov 8	AS264, M5

Table 16.2 (continued)
Publications since October 2012

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
1202	Racial/ethnic differences in use and duration of adjuvant hormonal therapy for breast cancer in the Women's Health Initiative	Livaudais, LaCroix, Chlebowski, Li, Habel, Simon, Thompson, Erwin, Hubbell, Yasmeen, Coronado	12	Gen	Cancer Epidemiol Biomarkers Prev. 2013 Mar;22(3):365-73. doi: 10.1158/1055-9965.EPI-12-1225. Epub 2012 Dec 28	
1203	Vitamin D intake and lung cancer risk in the Women's Health Initiative	Cheng, LaCroix, Beresford, McCarroll, Thornquist, Zheng, Chlebowski, Ho, Neuhouser	12	Gen	Am J Clin Nutr. 2013 Aug 21. [Epub ahead of print]	
1215	Loci influencing blood pressure identified using a cardiovascular gene-centric array	Ganesh, Tragante, Martin, Eaton, Reiner, Keating, Duggan, Franceschini	12	Gen	Hum Mol Genet. 2013 Apr 15;22(8):1663-78. doi: 10.1093/hmg/dds555. Epub 2013 Jan 8	BAA14
1226	Homocysteine, cysteine and risk of incident colorectal cancer in the Women's Health Initiative observational cohort	Miller, Beresford, Neuhouser, Cheng, Song, Brown, Zheng, Rodriguez, Green, Ulrich	12	OS	Am J Clin Nutr. 2013 Apr;97(4):827-34. doi: 10.3945/ajcn.112.049932. Epub 2013 Feb 20	AS195
1231	Frequency of private spiritual activity and cardiovascular risk in postmenopausal women: the Women's Health Initiative	Salmoirago-Blotcher, Fitchett, Hovey, Schnall, Andrews, Thomson, Crawford, O'Sullivan, Post, Chlebowski, Ockene	12	OS	Ann Epidemiol. 2013 May;23(5):239-45.	
1233	Social support and physical activity as moderators of life stress in predicting baseline depression and change in depression over time in the Women's Health Initiative	Uebelacker, Eaton, Weisberg, Sands, Williams, Calhoun, Manson, Denburg, Taylor	12	OS	Soc Psychiatry Psychiatr Epidemiol. 2013 May 5. [Epub ahead of print]	
1263	Changes in physical activity and body composition in postmenopausal women over time	Sims, Kubo, Desai, Bea, Beasley, Manson, Allison, Seguin, Chen, Michael, Sullivan, Beresford, Stefanick	12	Gen	Med Sci Sports Exerc. 2013 Feb 22. [Epub ahead of print]	
1264	Self-reported snoring and cardiovascular disease among postmenopausal women (from the Women's Health Initiative)	Sands, Loucks, Lu, Carskadon, Sharkey, Stefanick, Ockene, Shah, Hairston, Robinson, Limacher, Hale, Eaton	12	Gen	Am J Cardiol. 2012 Dec 4. pii: S0002-9149(12)02325-9. 2012.10.039. [Epub ahead of print]	
1275	Laxative use and incident falls, fractures and change in bone mineral density in postmenopausal women: results from the Women's Health Initiative	Haring, Pettinger, Bea, Wactawski-Wende, Carnahan, Ockene, Wyler von Ballmoos, Wallace, Wassertheil-Smoller	12	Gen	BMC Geriatr. 2013 May 1;13(1):38. [Epub ahead of print]	
1283	Investigation of Epstein-Barr virus as a potential cause of B-cell non-Hodgkin lymphoma in a prospective cohort	De Roos, Martinez-Maza, Jerome, Mirick, Kopecky, Madeleine, Magpantay, Edlefsen, LaCroix	12	OS	Cancer Epidemiol Biomarkers Prev. 2013 Jul 24. [Epub ahead of print]	BAA13
1305	Statins, angiotensin-converting enzyme inhibitors and physical performance in older women	Gray, Aragaki, LaMonte, Cochrane, Kooperberg, Robinson, Woods, LaCroix	12	CT	J Am Geriatr Soc. 2012 Dec;60(12):2206-14. Epub 2012 Nov 23	

Table 16.2 (continued)
Publications since October 2012

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
1325	Proteomic profiling of the autoimmune response to breast cancer antigens uncovers a suppressive effect of hormone therapy	Chao, Ladd, Hanash	12	OS	Proteomics Clin Appl. 2013 Feb 12. [Epub ahead of print]	
1333	Prestroke factors associated with poststroke mortality and recovery in older women in the Women's Health Initiative	Bell, LaCroix, Masaki, Hade, Manini, Mysiw, Curb, Wassertheil-Smoller	12	Gen	J Am Geriatr Soc. 2013 Jul 19. [Epub ahead of print]	
1336	Women's Health Initiative clinical trials: interaction of calcium and vitamin D with hormone therapy	Robbins, Aragaki, Manson, Carbone, Jackson, Lewis, Johnson, Sarto, Stefanick, Wactawski-Wende	12	CT	Menopause. 2013 Jun 24. [Epub ahead of print]	
1337	Geriatric syndromes and incident disability in older women: Results from the Women's Health Initiative Observational Study	Rosso, Eaton, Wallace, Gold, Stefanick, Ockene, Curb, Michael	12	CT	J Am Geriatr Soc. 2013 Mar;61(3):371-9. Epub 2013 Mar 1	
1341	Aspirin is associated with lower melanoma risk among postmenopausal Caucasian women: the Women's Health Initiative	Gamba, Swetter, Stefanick, Kubo, Desai, Spaunhurst, Sinha, Asgari, Sturgeon, Tang	12	OS	Cancer. 2013 Mar 11. [Epub ahead of print]	
1343	Body mass index, physical activity, and survival after endometrial cancer: Results from the Women's Health Initiative	Arem, Chlebowski, Stefanick, Anderson, Wactawski-Wende, Sims, Gunter, Irwin	12	Gen	Gynecol Oncol. 2012 Nov 2. pii: S0090-8258(12)00856-6. [Epub ahead of print]	
1354	Demographic and health factors associated with enrollment in posttrial studies: the Women's Health Initiative Hormone therapy trials	Espeland, Pettinger, Falkner, Shumaker, Limacher, Thomas, Weaver, Stefanick, McQuellon, Hunt, Johnson	12	CT	Clin Trials. 2013 Mar 12. [Epub ahead of print]	
1361	Change in physical activity after a diabetes diagnosis: Opportunity for intervention	Schneider, Andrews, Hovey, Seguin, Manini, LaMonte, Margolis, Waring, Ning, Sims, Ma, Ockene, Stefanick, Pagoto	12	OS	Med Sci Sports Exerc. 2013 Jul 15. [Epub ahead of print]	
1365	Menstrual and reproductive factors, exogenous hormone use, and risk of thyroid carcinoma in postmenopausal women	Kabat, Kim, Wactawski-Wende, Lane, Wassertheil-Smoller, Rohan	12	Gen	Cancer Causes Control. 2012 Dec;23(12):2031-40. doi: 10.1007/s10552-012-0084-x. Epub 2012 Oct 23	
1366	Neighborhood environment and physical activity among older women: Findings from the San Diego cohort of the Women's Health Initiative	Kerr, Norman, Millstein, Adams, Morgan, Langer, Allison	12	Gen	J Phys Act Health. 2013 Aug 19. [Epub ahead of print]	
1368	Racial/ethnic disparities in association between dietary quality and incident diabetes in postmenopausal women in the United States: the Women's Health Initiative 1993–2005	Qiao, Ma, Olendzki, Hebert, Balasubramanian, Rosal, Schneider, Liu, Sims, Hingle, Song, Sepavich, Shikany, Persuitte, Ockene, Tinker, et al.	12	Gen	hn Health. 2013 May 22. [Epub ahead of print]	

Table 16.2 (continued)
Publications since October 2012

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
1382	Oral bisphosphonate use and colorectal cancer incidence in the Women's Health Initiative	Passarelli, Newcomb, LaCroix, Lane, Ho, Chlebowski	12	Gen	J Bone Miner Res. 2013 Mar 20. [Epub ahead of print]	
1385	Physical activity assessment: biomarkers and self-report of activity-related energy expenditure in the Women's Health Initiative	Neuhouser, Di, Tinker, Thomson, Sternfeld, Mossavar-Rahmani, Stefanick, Sims, Curb, LaMonte, Seguin, Johnson, Prentice	12	OS	Am J Epidemiol. 2013 Mar 15;177(6):576-85. doi: 10.1093/aje/kws269. Epub 2013 Feb 22	AS218, W27
1392	Self-perceived physical health predicts cardiovascular disease incidence and death among postmenopausal women	Saquib, Brunner, Kubo, Tindle, Kroenke, Desai, Daviglus, Allen, Martin, Robinson, Stefanick	12	CT	BMC Public Health. 2013 May 14;13(1):468. [Epub ahead of print]	
1408	A prospective study of plasma adiponectin and pancreatic cancer risk in 5 US Cohorts	Bao, Giovannucci, Kraft, Stampfer, Ogino, Ma, Buring, Sesso, Lee, Gaziano, Rifai, Pollak, Cochrane, Kaklamani, Lin, Manson, et al.	12	OS	J Natl Cancer Inst. 2013 Jan 16;105(2):95-103. doi: 10.1093/jnci/djs474. Epub 2012 Dec 14	AS214
1410	Estrogen plus progestin and breast cancer incidence and mortality in the Women's Health Initiative Observational Study	Chlebowski, Manson, Anderson, Cauley, Aragaki, Stefanick, Lane, Johnson, Wactawski-Wende, Chen, Qi, Yasmeen, Newcomb, Prentice	12	OS	J Natl Cancer Inst. 2013 Apr 17;105(8):526-35. doi: 10.1093/jnci/djt043. Epub 2013 Mar 29	
1434	50-year trends in smoking-related mortality in the United States	Thun, Carter, Feskanich, Freedman, Prentice, Lopez, Hartge, Gapstur	12	Gen	N Engl J Med. 2013 Jan 24;368(4):351-64. doi: 10.1056/NEJMsa1211127	
1438	Prospective analysis of association between statin use and breast cancer risk in the Women's Health Initiative	Simon, Rosenberg, Abdul-Hussein, Cote, Bock, Petrucelli, Cauley, Martin, Jay, Wactawski-Wende, Thomas, Peters, Park, Manson, Luo, Lane, et al.	12	Gen	Cancer Epidemiol Biomarkers Prev. 2013 Aug 23. [Epub ahead of print].	
1440	Genetic variation and reproductive timing: African American women from the Population Architecture Using Genomics and Epidemiology (PAGE) Study	Spencer, Malinowski, Carty, Franceschini, Fernández-Rhodes, Young, Cheng, Ritchie, Haiman, Wilkens, Wu, Matise, Carlson, Brennan, Park, Rajkovic, et al.	12	Gen	PLoS ONE 8(2): e55258. 2013 Feb.	M6
1470	Recreational physical activity, body mass index and survival in women with colorectal cancer	Kuiper, Phipps, Neuhouser, Chlebowski, Thomson, Irwin, Lane, Wactawski-Wende, Hou, Jackson, Kampman, Newcomb	12	Gen	Cancer Causes Control. 2012 Dec;23(12):1939-48. Epub 2012 Oct 2	
1477	Sleep duration and incidence of colorectal cancer in postmenopausal women	Jiao, Duan, Sangi-Haghpeykar, Hale, White, El-Serag	12	OS	Br J Cancer. 2013 Jan 3. doi: 10.1038/bjc.2012.561. [Epub ahead of print]	

Table 16.2 (continued)
Publications since October 2012

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
1509	The relationship of sedentary behavior and physical activity to incident cardiovascular disease: Results from the Women's Health Initiative	Chomistek, Manson, Stefanick, Lu, Going, Sands, Garcia, Allison, Sims, LaMonte, Johnson, Eaton	12	OS	J Am Coll Cardiol. 2013 Apr 10. pii: S0735-1097(13)01404-6. doi: 10.1016/j.jacc.2013.03.031. [Epub ahead of print]	
1519	Fibrinogen may mediate the association between long sleep duration and coronary heart disease	Hale, Parente, Dowd, Sands, Berger, Song, Martin, Allison	12	OS	J Sleep Res. 2012 Dec 6. doi: 10.1111/jsr.12020. [Epub ahead of print]	
1532	Factors relating to eating style, social desirability, body image and eating meals at home increase the precision of calibration equations correcting self-report measures of diet using recovery biomarkers: findings from the Women's Health Initiative	Mossavar-Rahmani, Tinker, Huang, Neuhouser, McCann, Seguin, Vitolins, Curb, Prentice	12	OS	Nutr J. 2013 May 16;12(1):63. [Epub ahead of print]	AS218, W27
1552	Genome-wide characterization of shared and distinct genetic components that influence blood lipid levels in ethnically diverse human populations	Coram, Duan, Hoffmann, Thornton, Knowles, Ochs-Balcom, Donlon, Martin, Eaton, Robinson, Risch, Zhu, Kooperberg, Li, Reiner, Tang, et al.	12	Gen	Am J Hum Genet. 2013 May 29. pii: S0002-9297(13)00212-7. [Epub ahead of print]	M5
1554	OPG and sRANKL serum levels and incident hip fracture in postmenopausal Caucasian women in the Women's Health Initiative Observational Study	LaCroix, Jackson, Aragaki, Kooperberg, Cauley, Chen, LeBoff, Duggan, Wactawski-Wende	12	OS	Bone. 2013 Jun 2. pii: S8756-3282(13)00208-1. [Epub ahead of print]	BAA18
1557	Genome-wide association study of serum selenium concentrations	Gong, Hsu, Harrison, King, Sturup, Song, Duggan, Liu, Hutter, Chanock, Eaton, Marshall, Peters	12	Gen	Nutrients. 2013 May 21;5(5):1706-18. doi: 10.3390/nu5051706.	AS206, AS224
1560	Sleep disturbance and incidence of thyroid cancer in post-menopausal women The Women's Health Initiative	Luo, Sands, Wactawski-Wende, Song, Margolis	12		Am J Epidemiol. 2013 Jan 1;177(1):42-9. doi: 10.1093/aje/kws193. Epub 2012 Dec 5	
1574	Genetic determinants of macular pigments in women of the Carotenoids in Age-Related Eye Disease Study	Meyers, Johnson, Bernstein, Iyengar, Engelman, Karki, Liu, Igo, Truitt, Klein, Snodderly, Blodi, Gehrs, Sarto, Wallace, Robinson, et al.	12	OS	Invest Ophthalmol Vis Sci. 2013 Feb 12. [Epub ahead of print]	AS257
1584	Menstrual and reproductive factors and exogenous hormone use and risk of transitional cell bladder cancer in postmenopausal women	Kabat, Kim, Luo, Hou, Cetnar, Wactawski-Wende, Rohan	12	Gen	Eur J Cancer Prev. 2013 Feb 25. [Epub ahead of print]	
1599	Relationship between hysterectomy and admixture in African American women	Qi, Nassir, Kosoy, Garcia, Waetjen, Ochs-Balcom, Gass, Robbins, Seldin	12	Gen	Am J Obstet Gynecol. 2013 Jan 17. pii: S0002-9378(13)00074-4. doi: 10.1016/j.ajog.2013.01.027. [Epub ahead of print]	BAA1

Table 16.2 (continued)
Publications since October 2012

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
1613	Long-term effects on cognitive function of postmenopausal hormone therapy prescribed to women aged 50-55 years	Espeland, Shumaker, Leng, Manson, Brown, LeBlanc, Vaughan, Robinson, Rapp, Goveas, Lane, Wactawski-Wende, Stefanick, Li, Resnick	12	CT	JAMA Intern Med. 2013 Jun 24:1-8. [Epub ahead of print]	AS262
1615	Genetic predictors of vitamin D concentration in the Carotenoids of Age-Related Eye Disease Study (CAREDS)	Meyers, Johnson, Bernstein, Iyengar, Engelman, Karki, Liu, Igo, Truitt, Klein, Snodderly, Blodi, Gehrs, Sarto, Wallace, Robinson, et al.	12	OS	Invest Ophthalmol Vis Sci. 2013 Feb 12. [Epub ahead of print]	AS257
1644	Different patterns of bundle branch blocks and the risk of incident heart failure in the Women's Health Initiative (WHI) study.	Zhang, Rautaharju, Soliman, Manson, Martin, Perez, Vitolins, Prineas	12	CT	Circ Heart Fail. 2013 May 31. [Epub ahead of print]	
1691	Genome-wide search for gene-gene interactions in colorectal cancer	Jiao, Hsu, Berndt, Bezieau, Brenner, Caan, Carlson, Casey, Chan, Chang-Claude, Chanock, Conti, Curtis, Duggan, Gallinger	12	Gen	PLoS One. 2012;7(12):e52535. Epub 2012 Dec 26.	AS224
1695	A pooled analysis of smoking and colorectal cancer: timing of exposure and interactions with environmental factors.	Gong, Hutter, Baron, Berndt, Caan, Campbell	12	Gen	Cancer Epidemiol Biomarkers Prev. 2012 Nov;21(11):1974-85. Epub 2012 Sep 20	AS224
1701	Predictive value of autoantibody testing for validating self-reported diagnoses of rheumatoid arthritis in the Women's Health Initiative	Walitt, Mackey, Kuller, Deane, Robinson, Holers, Chang, Moreland	12	Gen	Am J Epidemiol. 2013 Mar 13. [Epub ahead of print]	BAA20
1707	Health risks and benefits of calcium and vitamin D supplementation: Women's Health Initiative clinical trial and cohort study	Prentice, Pettinger, Jackson, Wactawski-Wende, LaCroix, Anderson, Chlebowski, Manson, Van Horn, Vitolins, Datta, LeBlanc, Cauley, Rossouw	12	Gen	Osteoporos Int. 2013 Feb;24(2):567-80. doi: 10.1007/s00198-012-2224-2. Epub 2012 Dec 4	
1709	Imputation of exome sequence variants into population-based samples and blood-cell-trait-associated loci in African Americans: NHLBI GO Exome Sequencing Project.	Auer, Johnsen, Johnson, Logsdon, Lange, Nalls, Zhang, Franceschini, Fox, Lange, Rich, O'Donnell, Jackson, Wallace, Chen, Graubert, et al.	12	Gen	Am J Hum Genet. 2012 Nov 2;91(5):794-808. doi: 10.1016/j.ajhg.2012.08.031. Epub 2012 Oct 25	M24
1710	Body fat and breast cancer risk in postmenopausal women: a longitudinal study	Rohan, Heo, Choi, Datta, Freudenheim, Kamensky, Ochs-Balcom, Qi, Thomson, Vitolins, Wassertheil-Smoller, Kabat	12	Gen	J Cancer Epidemiol. 2013;2013:754815. Epub 2013 Apr 7.	
1711	Body fat and risk of colorectal cancer among postmenopausal women	Kabat, Heo, Wactawski-Wende, Messina, Thomson, Wassertheil-Smoller, Rohan	12	Gen	Accepted, Cancer Causes Control Mar 2013	

Table 16.2 (continued)
Publications since October 2012

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
1726	Common single-nucleotide polymorphisms in the estrogen receptor β promoter are associated with colorectal cancer survival in postmenopausal women	Passarelli, Potter, Makar, Phipps, Coghill, Wernli, White, Chan, Hutter, Peters, Newcomb	12	Gen	Cancer Res. 2013 Jan 15;73(2):767-775. Epub 2012 Nov 13	AS224
1751	Estrogen alone and joint symptoms in the Women's Health Initiative randomized trial	Chlebowski, Cirillo, Eaton, Stefanick, Pettinger, Carbone, Johnson, Simon, Woods, Wactawski-Wende	12	CT	Menopause. 2013 Mar 18. [Epub ahead of print]	
1758	Using the whole cohort in the analysis of case-control data	Breslow, Pettinger, Kooperberg, Rossouw	12	CT	Stat Biosci. 2013 Jan 24. [Epub ahead of print]	
1791	Calcium plus vitamin D supplementation and joint symptoms in postmenopausal women in the Women's Health Initiative randomized trial	Chlebowski, Pettinger, Johnson, Wallace, Womack, Stefanick, Wactawski-Wende, Carbone, Lu, Eaton, Walitt, Kooperberg	12	CT	J Acad Nutr Diet. 2013 Aug 14. pii: S2212-2672(13)00685-0. [Epub ahead of print]	
1806	Identification of genetic susceptibility loci for colorectal tumors in a genome-wide meta-analysis	Peters, Jiao, Schumacher, Hutter, Aragaki, Baron, Berndt, Bezieau, Brenner, Butterbach, Caan, Carlson, Casey, Chan, Chang-Claude	12	OS	Gastroenterology. 2012 Dec 22. [Epub ahead of print]	AS224
1808	Genome-wide association study of survival in patients with pancreatic adenocarcinoma	Wu, Kraft, Stolzenberg-Solomon, Steplowski, Brotzman, Xu, Mudgal, Amundadottir, Arslan, Bueno-de-Mesquita, Gross, Helzlsouer, Jacobs, Kooperberg, Petersen	12	Gen	Gut. 2012 Nov 24. [Epub ahead of print]	M4
1813	Autoantibody signatures involving glycolysis and splicesome proteins precede a diagnosis of breast cancer among postmenopausal women	Ladd, Chao, Johnson, Qiu, Chin, Israel, Mao, Wu, Amon, McIntosh, Li, Disis, Pitteri	12	OS	Cancer Res. 2013 Mar 1;73(5):1502-13. Epub 2012 Dec 26	BAA5
1830	Vitamin D and breast cancer incidence and outcome	Chlebowski	12	N/A	Anticancer Agents Med Chem. 2012 Oct 12. [Epub ahead of print]	
1849	Associations between smoking and tooth loss according to the reason for tooth loss: the Buffalo OsteoPerio Study	Mai, Wactawski-Wende, Hovey, LaMonte, Chen, Tezal, Genco	12	OS	J Am Dent Assoc. 2013 Mar;144(3):252-65.	AS15
1873	Serum fatty acids and incidence of ischemic stroke among postmenopausal women	Yaemsiri, Sen, Tinker, Evans, Robinson, Rosamond, Wassertheil-Smoller, He	12	OS	Stroke. 2013 Jul 30. [Epub ahead of print]	AS187
1875	Analysis of 6,515 exomes reveals a very recent origin of most human protein-coding variants	Fu, O'Connor, Jun, Kang, Abecasis, Leal, Gabriel, Altshuler, Shendure, Nickerson, Bamshad, Akey	12	Gen	Nature. 2013 Jan 10;493(7431):216-20. doi: 10.1038/nature11690. Epub 2012 Nov 28	M24

Table 16.2 (continued)
Publications since October 2012

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
1887	The rationale, design, and baseline characteristics of the Women's Health Initiative Memory Study of Younger Women (WHIMS-Y)	Vaughan, Espeland, Snively, Shumaker, Rapp, Shupe, Robinson, Sarto, Resnick	12	CT	Brain Res. 2013 Apr 8. pii: S0006-8993(13)00487-3. [Epub ahead of print]	AS262
1893	A meta-analysis identifies new loci associated with body mass index in individuals of African ancestry	Monda, Chen, Taylor, Lange, Demerath, Palmas, Wojczynski, Ellis, Vitolins, Liu, Papanicolaou, Irvin, Xue, Griffin, Nalls	12	Gen	Nat Genet. 2013 Apr 14. [Epub ahead of print]	M5
1915	Lessons learned from the Women's Health Initiative trials of menopausal hormone therapy	Rossouw, Manson, Kaunitz, Anderson	12	N/A	Obstet Gynecol. 2013 Jan;121(1):172-6.	
1922	Replication of genetic loci for ages at menarche and menopause in the multi-ethnic Population Architecture using Genomics and Epidemiology (PAGE) study	Carty, Spencer, Setiawan, Fernández-Rhodes, Malinowski, Buyske, Young, Jorgensen, Cheng, Carlson, Brown-Gentry, Goodloe, Park, Parikh	12	Gen	Hum Reprod. 2013 March 18. [E-pub ahead of print]	M6
1923	Post-Genome-Wide Association Study challenges for lipid traits: describing age as a modifier of gene-lipid associations in the Population Architecture Using Genomics and Epidemiology (PAGE) Study	Dumitrescu, Carty	12	Gen	Ann Hum Genet. 2013 Jun 28. [Epub ahead of print]	M6
1931	No association between germline variation in catechol-O-methyltransferase and colorectal cancer survival in postmenopausal women	Passarelli, Newcomb, Peters, Burnett-Hartman, Phipps, David, Hsu, Harrison, Hutter, Duggan, White, Chan, Peters	12	Gen	Menopause. 2013 Jul 22. [Epub ahead of print]	AS224
1936	Adult stature and risk of cancer at different anatomic sites in a cohort of postmenopausal women	Kabat, Anderson, Heo, Hosgood, Kamensky, Bea, Hou, Lane, Wactawski-Wende, Manson, Rohan	12	Gen	Cancer Epidemiol Biomarkers Prev. 2013 Jul 25. [Epub ahead of print]	
1942	Performance of multiplex cytokine assays in serum and saliva among community-dwelling postmenopausal women	Browne, Kantarci, LaMonte, Andrews, Hovey, Falkner, Cekici, Stephens, Genco, Scannapieco, Van Dyke, Wactawski-Wende	12	OS	PLoS One. 2013;8(4):e59498. doi: 10.1371/journal.pone.0059498. Epub 2013 Apr 5.	AS303
2025	Generalization of adiposity genetic loci to US Hispanic women	Graff, Fernández-Rhodes, Liu, Carlson, Wassertheil-Smoller, Neuhouser, Reiner, Kooperberg, Rampersaud, Manson, Kuller, Howard, Ochs-Balcom, Johnson, Vitolins, Sucheston, et al.	12	Gen	Nutr Diabetes. 2013 Aug 26;3:e85.	M5
2098	Smoking cessation, weight change and Coronary Heart Disease among postmenopausal women with and without diabetes	Luo, Rossouw, Margolis	12		JAMA. 2013 Jul 3;310(1):94-6.	

Table 16.2 (continued)
Publications since October 2012

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
2124	Calcium supplements and cardiovascular risk in the Women's Health Initiative: response to Bolland et al.	Prentice, Jackson, Rossouw	12		Osteoporos Int. 2013 Apr 6. [Epub ahead of print]	
2186	Conduct of the Women's Health Initiative randomised trial evaluating estrogen plus progestin: implications for breast cancer findings	Chlebowski, Nikolaenko, Anderson	12		J Fam Plann Reprod Health Care. 2013 Jul;39(3):226-8. doi: 10.1136/jfprhc-2013-100642.	
2197	Smoking and diabetes: does the increased risk ever go away?	Luo, Rossouw, Tong, Giovino, Lee, Chen, Ockene, Qi, Margolis	12		Am J Epidemiol. 2013 Jun 30. [Epub ahead of print]	
2199	The Women's Health Initiative: Hormone therapy and calcium/vitamin D supplementation trials	Cauley	12		Curr Osteoporos Rep. 2013 Jul 11. [Epub ahead of print]	

Appendix A

Women's Health Initiative

Memory Suite of Studies

2013 Annual Progress Report

Report Date: October 28, 2013

Meeting Date: November 26, 2013

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

Table of Contents

Section 1.

Introduction

Introduction

This report has been prepared to support the Observational Study Monitoring Board in its review of the Women's Health Initiative Memory Program (WHIMS). The current major initiatives in this Program are listed below. Those with an asterisk are closed in terms of data collection – however, analyses and papers continue to be generated.

- Women's Health Initiative Memory Study (WHIMS) ECHO
- WHIMS Supplemental Case Ascertainment Protocol (SCAP)
- Women's Health Initiative Memory Study of Cerebral Magnetic Resonance Imaging (WHIMS-MRI 1 & 2)*
- Women's Health Initiative Memory Study of Younger Women (WHIMS-Y)
- Women's Health Initiative Study of Cognitive Aging (WHISCA) Extension*

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

Materials are drawn from study databases and records in October 2013 to provide an up-to-date accounting. Live study databases were accessed at time points spanning several weeks so that minor discrepancies may exist across exhibits.

We organized this report into sections to describe each of the initiatives listed above. The WHIMS ECHO is continuing surveillance of the original WHIMS cohort to identify incident cases of probable dementia (PD), mild cognitive impairment (MCI), and global cognitive functioning. We describe the cohort and provide data on the post-trial incidence of study endpoints according to women's original treatment assignments. The SCAP is reaching out to proxies of deceased women and women with a WHI status of proxy follow-up to assess the participant's status at time of death or follow-up cessation. The WHISCA Extension has completed analyses of candidate genes from DNA samples in WHISCA participants. The WHIMS-MRI study has ended its second phase.

WHIMS Coordinating Center
October 28, 2013

Section 2.

Overview of Suite of Studies

The Women's Health Initiative Memory Study (WHIMS)

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

The Women's Health Initiative Memory Study - Epidemiology of Cognitive Health Outcomes (WHIMS-ECHO)

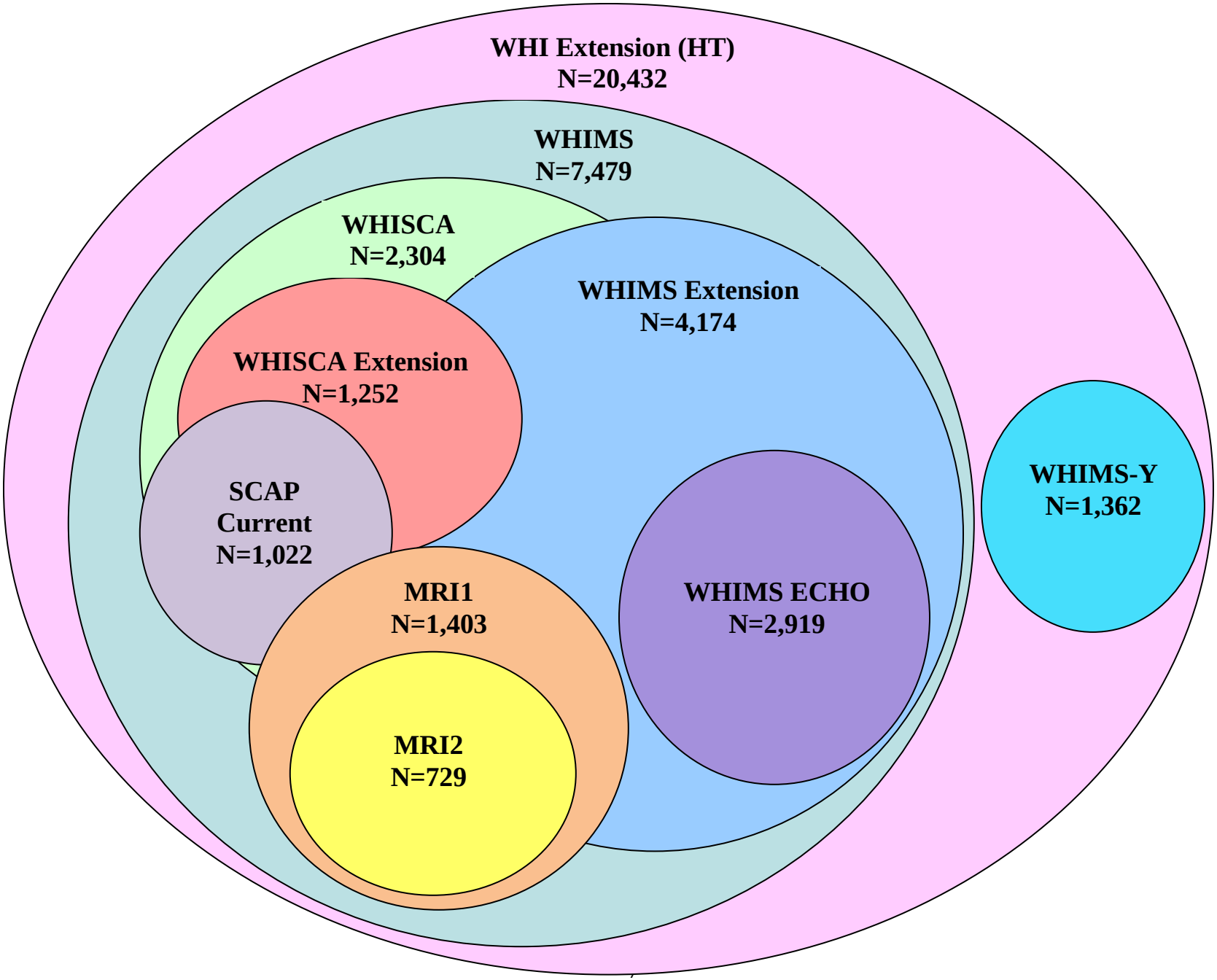
The Women's Health Initiative Memory Study of Younger Women (WHIMS-Y)

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

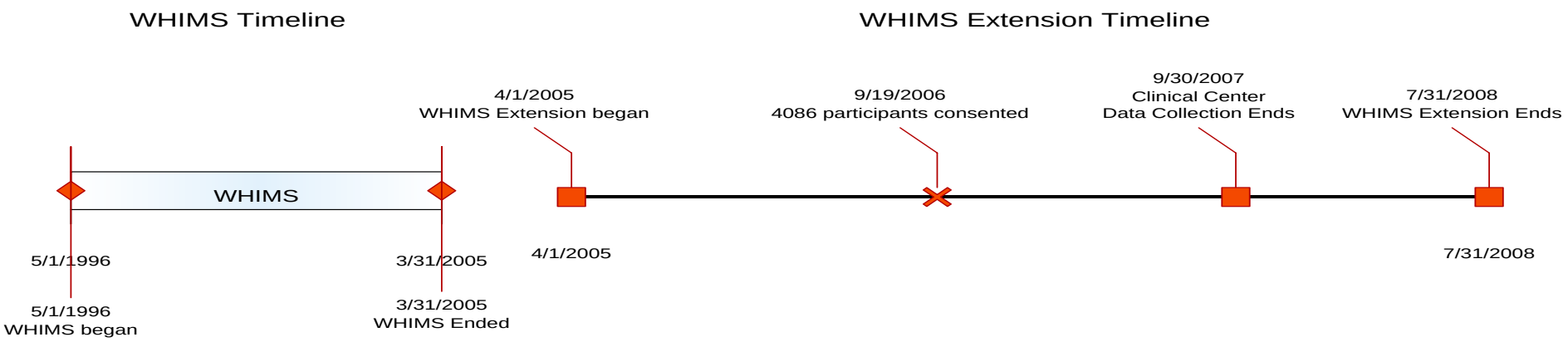
The Women's Health Initiative Study of Cognitive Aging (WHISCA) Extension

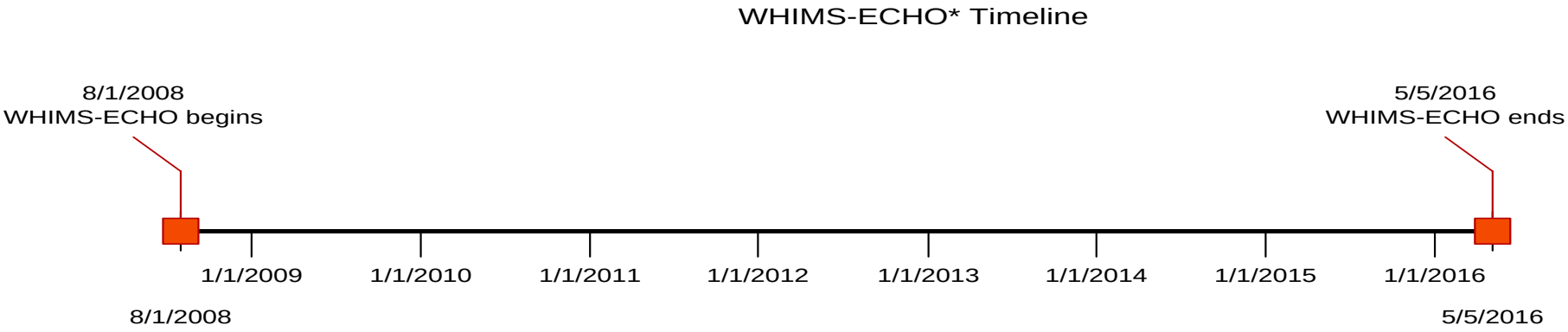
The Women's Health Initiative Memory Study of Cerebral Magnetic Resonance Imaging (WHIMS-MRI-1+2)

2.1 Relationships Among Study Cohorts



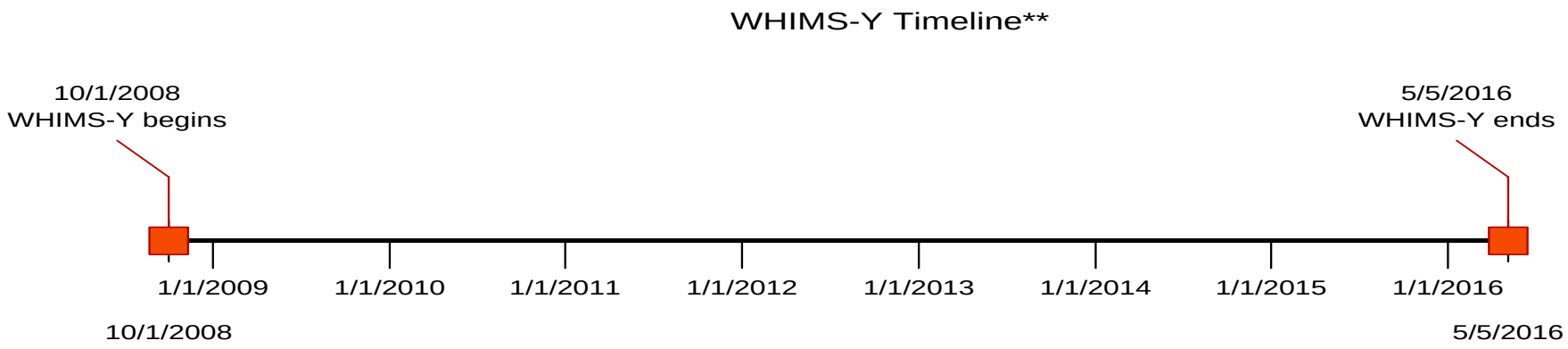
2.2 Timelines for the WHIMS, WHIMS Extension, WHIMS-ECHO, WHIMS-MRI, WHIMS-MRI2, WHISCA, WHISCA Extension, and WHIMS-Y Studies



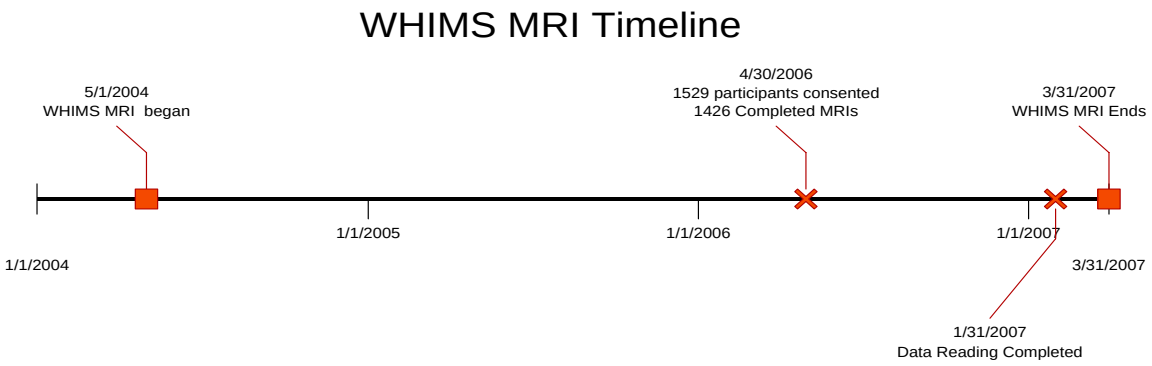


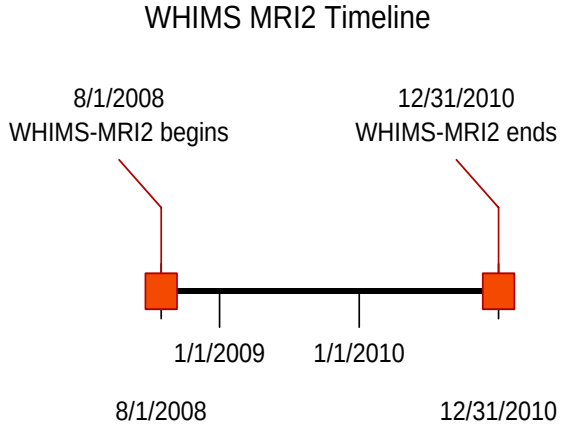
**Funding for WHIMS-ECHO: 8/1/2008-5/5/2011 – NHLBI
5/5/2011-5/6/2016 – NIA

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

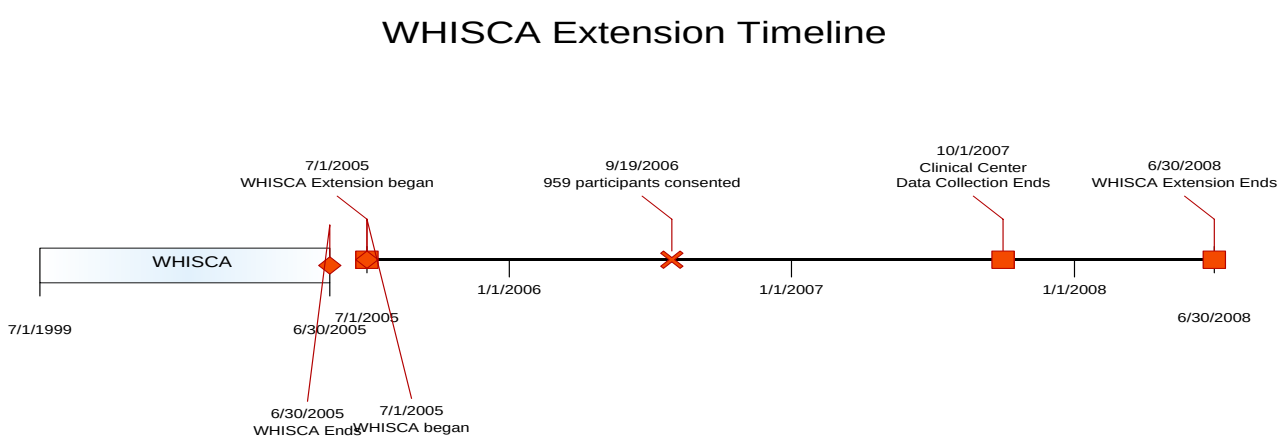


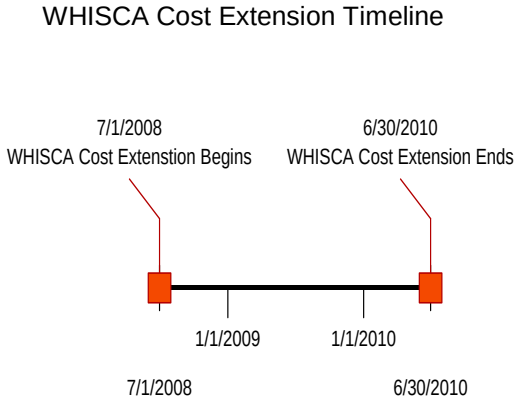
**Funding for WHIMS-Y: 10/1/2008-5/5/2011 – NHLBI
5/6/2011-5/6/2016 – NIA





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





2.3 Studies Objectives

2.3.1 Women's Health Initiative Memory Study (WHIMS)

The overall objective of the Women's Health Initiative Memory study was to determine the incidence of dementia syndromes, through cognitive functioning screening, neuropsychiatric and neuropsychological evaluations, in approximately 7,479 women who were 65 years of age and older at baseline, and participants in the HT trials of the WHI. Annual assessments of cognitive function allowed for tracking the rate of progression of cognitive decline. Collected data were sent to an adjudication panel comprised of clinicians with expertise in dementia for final classification: No dementia, mild cognitive impairment (MCI) or probable dementia. On July 9, 2002, the National Heart, Lung, Blood Institute (NHLBI) of the National Institutes of Health (NIH) stopped early the Women's Health Initiative (WHI) combined estrogen and progesterone versus placebo HT trial and the estrogen-alone (E-alone) WHI hormone trial was stopped early on February 29, 2004. Analyses have been ongoing, with a number of papers published from trial and follow-up data. (See publications list at the end of the report.)

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

Corresponding to an extension for WHI, a concomitant extension for safety monitoring in the WHIMS E-alone and the E+P trials (WHIMS Extension) was funded in March 2004 by the NHLBI. The goal of the WHIMS Extension was to provide post-trial follow-up and surveillance of participants from the completed E+P and E-alone trials to determine whether an increased risk of dementia was sustained following study drug termination. By continuing the ascertainment of PD, MCI, and global cognitive functioning, we increased the power in the surveillance component. The WHIMS Epidemiology of Cognitive Health Outcomes (WHIMS-ECHO) continues the follow-up of this cohort with telephone-based assessments rather than the previous face-to face assessments (see Section 3). In May, 2011 the WHIMS-ECHO Extension was funded by NIA for an additional five years.

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

WHISCA was an ancillary study to the WHI Memory Study and enrolled 2,304 women from 14 of the WHIMS clinical sites, aged 66 to 84 years, who did not meet criteria for dementia at enrollment into WHISCA. WHISCA investigated the effects of hormone therapy on rates of change over time in memory, other aspects of cognition (language, attention, spatial ability, motor function, and mood). Extensions to WHISCA provided follow-up cognitive testing off-study medication on 1,252 women until June 2010. The mean age at the end of the extension was 79.9 years and the oldest participant was 93 years old. The WHISCA extension has completed analyses of candidate genes from DNA samples in WHISCA participants.

2.3.4 The WHIMS Cerebral Magnetic Resonance Imaging (WHIMS-MRI-1 & 2)

WHIMS-MRI-1 was a cross-sectional sub-study of 1,403 women who were enrolled in the WHIMS E+P and E-Alone studies. Thirteen of the 14 participating MRI sites were also WHISCA sites. The primary goal was to assess the impact of hormone therapy on subclinical neuropathological changes (regional and total ischemic lesion volumes and brain volumes) to further our understanding of the processes by which hormone therapy may increase participants' risk for stroke and adverse cognitive findings. WHIMS-MRI2 continued collecting a second scan on women who had been enrolled in WHIMS-MRI-1, an average of 3-5 years after their initial scan through June 30, 2011 (see Section 6).

Section 3.

WHIMS ECHO

3.1 WHIMS ECHO Protocol Summary

The Women's Health Initiative Memory Study - Epidemiology of Cognitive Health Outcomes (WHIMS-ECHO) Extension was funded by NIA in May 2011 and will continue annual telephone-based cognitive assessments in the WHIMS Extension cohort through May 2016. This extended follow-up will increase the total cases of probable dementia and cognitive impairment, thereby enhancing the epidemiologic value of the program by providing statistical power necessary to:

- characterize the trajectories of cognitive functioning,
- identify subtypes of cognitive deficit/impairment and cognitive resilience,
- identify predictors related to cognitive health and decline, and
- identify the longitudinal relationship between changes in cognition and other health outcomes (e.g., CVD, cancer, functional status and disability)

To increase efficiency, lower participant burden, and reduce costs, centralized, validated annual telephone assessments are administered to all participants. If a woman scores below a predetermined cut-point on the modified Telephone Interview for Cognitive Status (TICSm), a standardized cognitive screening test, her friend or family member is also interviewed using the Dementia Questionnaire (DQ), a validated structured interview to determine the level of cognitive and behavioral impairment required for a diagnosis of MCI or dementia. Together, all assessments are used to centrally adjudicate participants as ND, MCI and PD. The WHIMS-ECHO Coordinating Center (CoC) includes expert clinicians, investigators and experienced and certified cognitive examiners from the WHIMS program. A national Steering Committee of WHIMS investigators and topic area experts guides the conduct of the study.

> The WHIMS-ECHO telephone-based cognitive battery (TICSm, East Boston Memory Test, Oral Trail Making Test, Category Fluency-Animals, Digit Span Test, CVLT) and questionnaires (Geriatric Depression Scale-Short Form, WHI Insomnia Scale) were validated in a separate study. One hundred and ten women were recruited from the Piedmont region of North Carolina and randomly assigned, with equal probabilities, to receive two administrations of a the same neurocognitive battery and questionnaires spaced six months apart in one of the four following orders: telephone/telephone; telephone/face-to-face; face-to-face/telephone; or face-to-face/face-to-face. All tests were administered by a trained and certified cognitive examiner. There were no statistically significant differences in scores on any of the cognitive tests or questionnaires between randomly assigned modes of administration at baseline indicating equivalence across modes[1].

3.2 WHIMS ECHO Progress Report

Data collection for Year 1 began 09/11/2009 and continues at approximately one year intervals. Currently, 10 cognitive interviewers are certified to administer the cognitive telephone assessment. There are a total of 4,175 women drawn from 38 of the former WHI Field Centers who were eligible to participate in WHIMS ECHO. To date, 3,204 (77%) women have agreed to

CoC contact, and 907 declined to release contact information. Of those, 2,919 participants enrolled in the WHIMS ECHO (Table 3.1).

3.3 Enrollment: Overall and by Clinical Site

Table 3-1 WHIMS-ECHO Recruitment Process

	Targeted for enrollment	Agreed to initial contact by WHIMS CoC		Deceased before contacted		Never Reached		Declined to participate		Agreed to participate	
Field Center	**Number**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
All Field Centers	***4175***	***3204***	***76.7***	***73***	***1.7***	***58***	***1.9***	***154***	***4.9***	***2919***	***93.2***
11=Davenport	**24**	**20**	**83.3**	**0**	**0.0**	**1**	**5.0**	**1**	**5.0**	**18**	**90.0**
12=Birmingham	**96**	**68**	**70.8**	**0**	**0.0**	**3**	**4.4**	**1**	**1.5**	**64**	**94.1**
13=Greensboro	**21**	**18**	**85.7**	**0**	**0.0**	**0**	**0.0**	**2**	**11.1**	**16**	**88.9**
14=Boston	**101**	**92**	**91.1**	**0**	**0.0**	**1**	**1.1**	**0**	**0.0**	**91**	**98.9**
15=Buffalo	**117**	**91**	**77.8**	**3**	**2.6**	**0**	**0.0**	**7**	**8.0**	**81**	**92.0**
16=Chicago	**5**	**3**	**60.0**	**0**	**0.0**	**0**	**0.0**	**0**	**0.0**	**3**	**100.0**
19=Atlanta	**70**	**58**	**82.9**	**3**	**4.3**	**1**	**1.8**	**5**	**9.1**	**49**	**89.1**
20=Chicago-Evanston	**13**	**6**	**46.2**	**0**	**0.0**	**0**	**0.0**	**0**	**0.0**	**6**	**100.0**
21=Iowa City	**21**	**18**	**85.7**	**1**	**4.8**	**0**	**0.0**	**1**	**5.9**	**16**	**94.1**
23=Pawtucket	**109**	**89**	**81.7**	**5**	**4.6**	**4**	**4.8**	**6**	**7.1**	**74**	**88.1**
24=Memphis	**45**	**34**	**75.6**	**1**	**2.2**	**0**	**0.0**	**0**	**0.0**	**33**	**97.1**
25=Minneapolis	**126**	**96**	**76.2**	**2**	**1.6**	**0**	**0.0**	**3**	**3.2**	**91**	**96.8**
26=Newark	**74**	**57**	**77.0**	**1**	**1.4**	**1**	**1.8**	**3**	**5.4**	**52**	**92.9**
27=Phoenix	**49**	**39**	**79.6**	**2**	**4.1**	**2**	**5.4**	**1**	**2.7**	**34**	**91.9**
28=Pittsburgh	**108**	**93**	**86.1**	**4**	**3.7**	**2**	**2.2**	**2**	**2.2**	**85**	**95.5**
29=Tucson	**57**	**44**	**77.2**	**2**	**3.5**	**0**	**0.0**	**3**	**7.1**	**39**	**92.9**
30=Davis	**120**	**83**	**69.2**	**1**	**0.8**	**2**	**2.4**	**5**	**6.0**	**75**	**91.5**
42=Stanford	**193**	**146**	**75.6**	**3**	**1.6**	**1**	**0.7**	**6**	**4.2**	**136**	**95.1**
43=Milwaukee	**148**	**98**	**66.2**	**0**	**0.0**	**2**	**2.0**	**1**	**1.0**	**95**	**96.9**
44=George Wash.	**116**	**94**	**81.0**	**2**	**1.7**	**1**	**1.1**	**3**	**3.3**	**88**	**95.7**
45=Honolulu	**58**	**40**	**69.0**	**2**	**3.4**	**1**	**2.6**	**6**	**15.8**	**31**	**81.6**
46=Gainesville	**101**	**68**	**67.3**	**2**	**2.0**	**3**	**4.5**	**2**	**3.0**	**61**	**92.4**
47=Houston	**59**	**53**	**89.8**	**0**	**0.0**	**1**	**1.9**	**4**	**7.5**	**48**	**90.6**
48=Worcester	**197**	**144**	**73.1**	**6**	**3.0**	**1**	**0.7**	**7**	**5.1**	**130**	**94.2**
49=New York	**165**	**114**	**69.1**	**2**	**1.2**	**5**	**4.5**	**9**	**8.0**	**98**	**87.5**
50=Columbus	**139**	**111**	**79.9**	**1**	**0.7**	**1**	**0.9**	**2**	**1.8**	**107**	**97.3**
51=Medlantic	**114**	**89**	**78.1**	**1**	**0.9**	**3**	**3.4**	**6**	**6.8**	**79**	**89.8**
53=Oakland	**116**	**92**	**79.3**	**4**	**3.4**	**2**	**2.3**	**2**	**2.3**	**84**	**95.5**
54=Jacksonville	**62**	**46**	**74.2**	**1**	**1.6**	**2**	**4.4**	**2**	**4.4**	**41**	**91.1**
55=Torrance	**24**	**20**	**83.3**	**0**	**0.0**	**0**	**0.0**	**2**	**10.0**	**18**	**90.0**

56=Madison	**98**	**87**	**88.8**	**1**	**1.0**	**0**	**0.0**	**3**	**3.5**	**83**	**96.5**
57=Stony Brook	**153**	**118**	**77.1**	**1**	**0.7**	**0**	**0.0**	**5**	**4.3**	**112**	**95.7**
58=Chapel Hill	**147**	**126**	**85.7**	**2**	**1.4**	**1**	**0.8**	**14**	**11.3**	**109**	**87.9**
59/60=Chicago-Rush	**71**	**49**	**69.0**	**1**	**1.4**	**0**	**0.0**	**0**	**0.0**	**48**	**98.0**
61=Cincinnati	**118**	**94**	**79.7**	**4**	**3.4**	**4**	**4.4**	**7**	**7.8**	**79**	**86.7**
62=Detroit	**63**	**57**	**90.5**	**2**	**3.2**	**2**	**3.6**	**2**	**3.6**	**51**	**92.7**
63=Irvine	**87**	**61**	**70.1**	**1**	**1.1**	**0**	**0.0**	**1**	**1.7**	**59**	**98.3**
65=Nevada	**112**	**96**	**85.7**	**2**	**1.8**	**3**	**3.2**	**4**	**4.3**	**87**	**92.6**
66=Portland	**130**	**83**	**63.8**	**1**	**0.8**	**1**	**1.2**	**2**	**2.4**	**79**	**96.3**
67=San Antonio	**38**	**30**	**78.9**	**1**	**2.6**	**2**	**6.9**	**1**	**3.4**	**26**	**89.7**
68=Los Angeles	**102**	**62**	**60.8**	**1**	**1.0**	**1**	**1.6**	**1**	**1.6**	**59**	**96.7**
69=Fall River	**96**	**76**	**79.2**	**3**	**3.1**	**2**	**2.7**	**2**	**2.7**	**69**	**94.5**
70=Pauline	**28**	**15**	**53.6**	**0**	**0.0**	**1**	**6.7**	**1**	**6.7**	**13**	**86.7**
71=Bowman Gray	**13**	**10**	**76.9**	**0**	**0.0**	**0**	**0.0**	**0**	**0.0**	**10**	**100.0**
72=New Brunswick	**126**	**101**	**80.2**	**2**	**1.6**	**1**	**1.0**	**8**	**8.1**	**90**	**90.9**
73=Des Moines	**145**	**115**	**79.3**	**2**	**1.4**	**0**	**0.0**	**11**	**9.7**	**102**	**89.5**

3.4 Overall Status of Last Call Attempts by Year

Table 3-2 reflects the overall status of last call attempts by study year.

Table 3-2 WHIMS ECHO Overall Status of Last Call Attempt by Year												
	Year 1		Year 2		Year 3		Year 4		Year 5		Year 6	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Agreed to participate	2663		238		18		0		0		0	
---- Cumulative number	2663	100.0	2901	100.0	2919	100.0	2919	100.0	2919	100.0	2919	100.0
Lost to follow-up												
---- Deceased	0		63		85		96		43		8	
---- Withdrew	0		6		87		142		105		75	
---- Attempts to locate exhausted	0		0		0		0		0		0	
Due for telephone contact	2663	100.0	2832	97.6	2678	91.7	2440	83.6	2292	78.5	2209	75.7
Completed test battery	2615	98.2	2469	87.2	2258	84.3	1993	81.7	1395	61.2	49	2.3
Failed after 8 attempts	2	0.1	105	3.7	167	6.2	160	6.6	122	5.4	0	0.0
Declined	2	0.1	88	3.1	169	6.3	179	7.3	163	7.2	6	0.3
Phone disconnected	0	0.0	66	2.3	43	1.6	72	3.0	89	3.9	7	0.3
Unable to locate	0	0.0	10	0.4	8	0.3	4	0.2	3	0.1	0	0.0
Recontact	2	0.1	29	1.0	0	0.0	0	0.0	0	0.0	0	0.0
Hearing impaired	26	1.0	40	1.4	21	0.8	14	0.6	13	0.6	0	0.0

Table 3-2 WHIMS ECHO Overall Status of Last Call Attempt by Year												
	Year 1		Year 2		Year 3		Year 4		Year 5		Year 6	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Discontinued	15	0.6	22	0.8	11	0.4	11	0.5	19	0.8	1	0.0
No answer	1	0.0	0	0.0	0	0.0	1	0.0	4	0.2	2	0.1
Left message	0	0.0	1	0.0	1	0.0	0	0.0	10	0.4	6	0.3
Scheduled	0	0.0	1	0.0	0	0.0	3	0.1	72	3.2	26	1.2
Busy	0	0.0	1	0.0	0	0.0	0	0.0	0	0.0	0	0.0
No message	0	0.0	0	0.0	0	0.0	1	0.0	25	1.1	12	0.6
Other	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Not attempted	0	0.0	0	0.0	0	0.0	2	0.1	364	16.0	2057	95.0

Deceased status determined by WHI or ECHO status change, or during telephone contact.

3.5 Characteristics of Enrollees

Table 3-3 WHIMS-ECHO Characteristics of Enrollees (N=2919)

Characteristic	N (%)
WHI Treatment Assignment	
E-Alone Placebo	543 (19)
E-Alone	530 (18)
E+P	892 (31)
E+P Placebo	954 (33)
Age at WHI Enrollment	
64-69	1529 (52)
70-74	1028 (35)
75+	362 (12)
Age as of October 1, 2013	
80-84	1142 (39)
85-89	1249 (43)
90+	528 (18)
Baseline WHIMS 3MS	
Less than 90	99 (3)
90-94	434 (15)
95-100	2328 (81)
Race/Ethnicity	
American Indian/Alaskan native	6 (0)
Asian/Pacific Islander	42 (1)
Black/African American	188 (6)
Hispanic/Latino	46 (2)
White	2593 (89)
Other	44 (2)

3.6 WHIMS ECHO Adjudication

The WHIMS-ECHO adjudication process provides quality assurance measures in determining the final study classification of ND, MCI or PD for study participants who score below the cut-point (≤30) on the TICSm and who complete the WHIMS-ECHO neurocognitive test battery. In a supplemental telephone interview the Dementia Questionnaire (DQ) is administered to the proxies of those participants who score below the TICSm cut-point. The DQ is used initially to make an algorithm-derived pre-classification (ND, MCI or PD) and subsequently by the Adjudication Committee to inform final study classification. The DQ assesses cognitive and behavioral changes specific to dementia observed by a person who is knowledgeable about the participant's cognitive health. By comparing DQ results with cognitive test scores, adjudicators are able to make classifications required by the study. In rare instances where the DQ is not available, cases still proceed through the adjudication process. Should adjudicators be unable to classify a case, they are permitted to designate the case as 'unable to classify'.

Pre-classification is used to control the number of cases sent to adjudication. It is based on an algorithm designed to maximize sensitivity and specificity by using responses on items from two

sections of the DQ: (a) observed cognitive impairment and (b) impairment of daily functions by cognitive impairment. If (a) and (b) are present, the case is pre-classified as PD; whereas if (a) is present but not (b), then the case is pre-classified as possible MCI; and, if neither (a) nor (b) is present then the case is pre-classified as possible ND. Note when DQ data are not available, the case automatically goes forward to adjudication with all other data (listed below) provided to the adjudicators; PD or MCI cases derived from these women are tracked separately in the analyses.

The adjudicators are clinical experts with experience diagnosing MCI and dementia. They conduct a thorough review of the following data for each participant who scores below the TICSm cut-point:

- WHIMS-ECHO cognitive battery (TICS-m, East Boston Memory Test, Digit Span Test, Oral Trail Making Test, Category Fluency-Animals, Geriatric Depression Scale-Short Form, WHI Insomnia Rating Scale);
- Dementia Questionnaire;
- All previously collected WHIMS data.

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

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

From WHIMS ECHO currently, 2,018 women were eligible for the DQ based on their TICSm scores which were below the study cut-point. Of these, 1,852 progressed to administration of the DQ.

Table 3-4 Dementia Questionnaire Progressions in WHIMS-ECHO

	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	TOTAL
TICS Administrations	**2624**	**2468**	**2262**	**2001**	**1389**	**10744**
DQ Progressions	**446 (17.0%)**	**472 (19.1%)**	**427 (18.9%)**	**390 (19.5%)**	**277 (19.9%)**	**2018 (18.8%)**
Withdrawals	**41 (9.2%)**	**42 (8.9%)**	**18 (4.2%)**	**18 (4.6%)**	**3 (1.1%)**	**122 (6.0%)**
Missing Proxy information	**10 (2.2%)**	**13 (2.8%)**	**10 (2.3%)**	**7 (1.8%)**	**4 (1.4%)**	**44 (2.2%)**
Total Eligible DQ Progressions	**395 (88.6%)**	**417 (88.3%)**	**399 (93.4%)**	**365 (93.6%)**	**270 (97.5%)**	**1852 (91.8%)**

Table 3-5 Dementia Questionnaire Administration in WHIMS-ECHO						
Outcome	**Visit 1**	**Visit 2**	**Visit 3**	**Visit 4**	**Visit 5**	**TOTAL**
DQ's completed^^	**240 (60.8%)**	**201 (48.2%)**	**250 (62.7%)**	**220 (60.3%)**	**116 (43.0%)**	**1028 (55.5%)**
DQ's in process	**0 (0.0%)**	**0 (0.0%)**	**0 (0.0%)**	**3 (0.8%)**	**33 (12.2%)**	**40 (2.2%)**
Phone Disconnected/Unable to locate/Hearing Impaired	**23 (5.8%)**	**26 (6.2%)**	**27 (6.8%)**	**19 (5.2%)**	**11 (4.1%)**	**106 (5.7%)**
Proxy Refused DQ	**42 (10.6%)**	**41 (9.8%)**	**26 (6.5%)**	**11 (3.0%)**	**6 (2.2%)**	**126 (6.8%)**
PD	**14 (3.5%)**	**45 (10.8%)**	**36 (9.0%)**	**55 (15.1%)**	**58 (21.5%)**	**209 (11.3%)**
4th attempt	**64 (16.2%)**	**56 (13.4%)**	**57 (14.3%)**	**57 (15.6%)**	**46 (17.0%)**	**280 (15.1%)**
Permanently Missing	**12 (3.0%)**	**48 (11.5%)**	**3 (0.8%)**	**0 (0.0%)**	**0 (0.0%)**	**63 (3.4%)**
TOTAL	**395**	**417**	**399**	**365**	**270**	**1852**

There are 28 (1.5%) eligible adjudication cases in process. 735 (40.5%) adjudication complete and 1054 (58.0%) were not selected to further adjudication based on algorithm.

Table 3-6 Cases Eligible to be Reviewed by Adjudication Committee						
	N (%)					
^	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Total**
Adjudication in process	**0 (0.0%)**	**0 (0.0%)**	**0 (0.0%)**	**2 (0.6%)**	**25 (16.7%)**	**28 (1.5%)**
Adjudication complete	**157 (35.0%)**	**133 (27.8%)**	**210 (52.1%)**	**174 (51.8%)**	**61 (40.7%)**	**735 (40.5%)**
- - - - ND	**30 (19.1%)**	**35 (26.3%)**	**50 (23.8%)**	**49 (28.2%)**	**11 (18.0%)**	**175 (23.8%)**
- - - - MCI	**73 (46.5%)**	**48 (36.1%)**	**85 (40.5%)**	**73 (42.0%)**	**33 (54.1%)**	**312 (42.4%)**
- - - - PD	**54 (34.4%)**	**46 (34.6%)**	**75 (35.7%)**	**52 (29.9%)**	**17 (27.9%)**	**244 (33.2%)**
- - - - UTC-CI	**0 (0.0%)**	**3 (2.3%)**	**0 (0.0%)**	**0 (0.0%)**	**0 (0.0%)**	**3 (0.4%)**
- - - - UTC-FI	**0 (0.0%)**	**1 (0.8%)**	**0 (0.0%)**	**0 (0.0%)**	**0 (0.0%)**	**1 (0.1%)**
Not Adjudicated (ND)	**85 (18.9%)**	**70 (14.6%)**	**40 (9.9%)**	**43 (12.8%)**	**18 (12.0%)**	**256 (14.1%)**
Not Adjudicated (UTC-CI)	**84 (18.7%)**	**147 (30.8%)**	**85 (21.1%)**	**61 (18.2%)**	**32 (21.3%)**	**409 (22.5%)**
Not Adjudicated (UTC-No CI+No DQ)	**123 (27.4%)**	**128 (26.8%)**	**68 (16.9%)**	**56 (16.7%)**	**14 (9.3%)**	**389 (21.4%)**
TOTAL	**449**	**478**	**403**	**336**	**150**	**1817**

Section 4.

Supplemental Case Ascertainment Protocol (SCAP)

4.1. SCAP Protocol Summary

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

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

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

4.2 SCAP DQ Call Tracking Report

Overall, the WHIMS field centers have 1,022 participants who have either the status of proxy or deceased, who are SCAP-eligible. Of the 1,022 SCAP-eligible, 758 proxies have been contacted by the WHIMS CoC.

Table 4-1 shows the current progress as outlined.

Call Outcome	N	%
Attempts at DQ completion ended		
-----Call Completed	**405**	**53.43**
-----Declined	**44**	**5.80**
-----Phone Disconnected	**49**	**6.46**
-----Unable to locate	**9**	**1.19**
-----Hearing Impaired	**0**	**0.00**
-----Discontinued	**0**	**0.00**
-----Deceased	**0**	**0.00**
-----No Proxy provided	**9**	**0.92**
-----No Answer - 4th and final attempt	**128**	**16.89**
DQ completion possible		
-----Other		
-----Left a Message	**104**	**13.72**
-----Scheduled	**0**	**0.00**
-----Re-Contact		
-----Busy	**1**	**0.13**
-----No Message	**2**	**0.26**
-----No Answer - 1st attempt	**4**	**0.53**
-----No Answer - 2nd attempt	**1**	**0.13**
-----No Answer - 3rd attempt	**2**	**0.26**

4.3 SCAP Adjudication

With SCAP adjudication,

- Each participant is classified as either "ND", "MCI" or "PD" based on evaluation and scoring of the telephone administered DQ and all prior data collected by WHIMS, the WHIMS extensions and WHIMS ECHO.

- A computerized scoring algorithm based on the DQ is used to make a pre-adjudication classification. Final adjudication based on the pre-classification is completed as follows:
    - 100% of "PD" pre-classifications,
    - 100% of "MCI" pre-classifications
    - 10% of "ND" pre-classifications which are systematically sampled by selecting every 10^{th} case for adjudication.

SCAP adjudication follows the same process as that outlined for WHIMS participants who progress through the system.

These activities have yielded 411 cases of SCAP protocols for adjudication. Of those, 159 (17.2%) have been adjudicated and 72 (7.8%) are under review. There are 180 (19.4%) protocols that were not adjudicated (ND or MCI).

Additionally, 515 cases where attempts to complete the DQ have ceased due to proxy declined, phone disconnected, 4^{th} attempt, or unable to locate were classified as Probable No Dementia (PND) without full adjudication by a single adjudicator.

The overall classification of SCAP protocols (Adjudicated + Not Adjudicated) includes 861 cases. Of those, 260 (30.2%) were classified as ND, 480 (55.7%) as PND, 20 (2.3%) were MCI 59 (6.9%) were PD and 42 (4.9%) were CC.

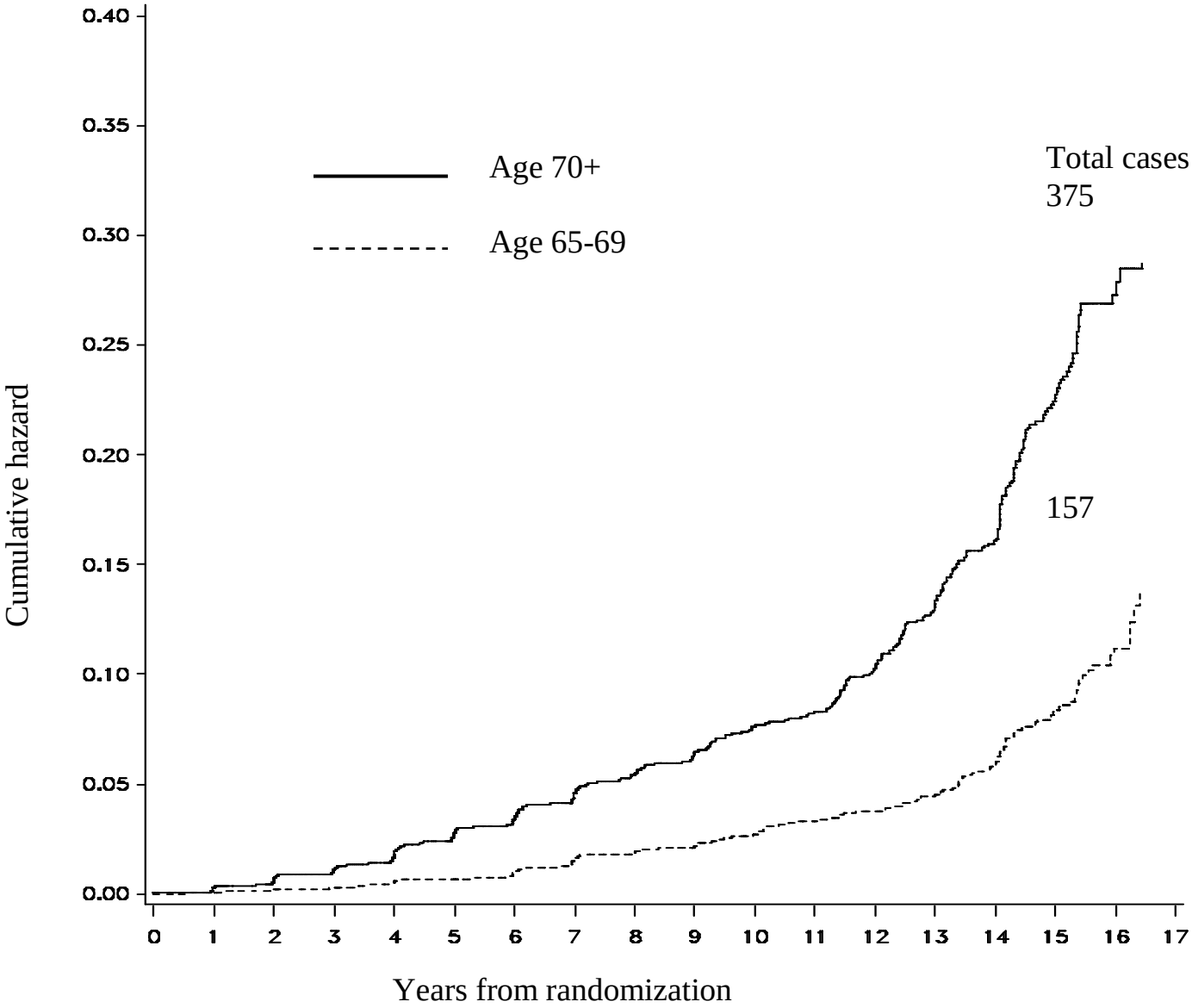
Table 4-2 SCAP Protocols		
	Subtotal	
	N	%
SCAP Phase 2 Protocols	926	
- - - - Adjudicated Protocols	159	17.2
- - - - Protocols Under Review by Adjudicators	72	7.8
- - - - Protocols Not Adjudicated (ND or MCI)	180	19.4
- - - - Protocols Classified Without Full Adjudication (PND)	480	51.8
- - - - Protocols Classified Without Full Adjudication (CC)	35	3.8

Table 4-3 Overall Classification of SCAP Protocols		
	Subtotal	
	N	%
Overall Classification of Protocols	861	
----ND	260	30.2
----PND	480	55.7
----MCI	20	2.3
----PD	59	6.9
----CC	42	4.9

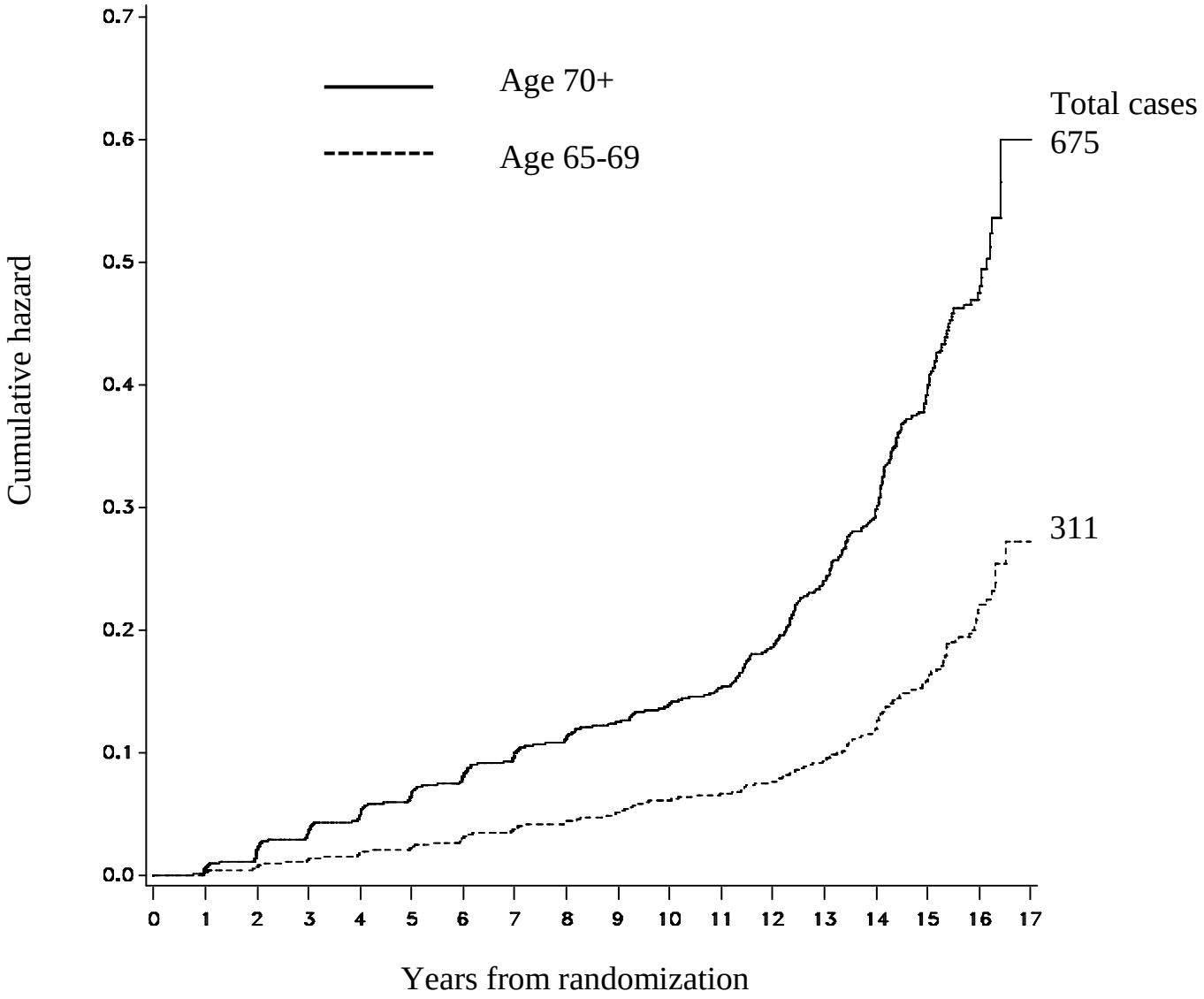
Section 5.

WHIMS Cohort

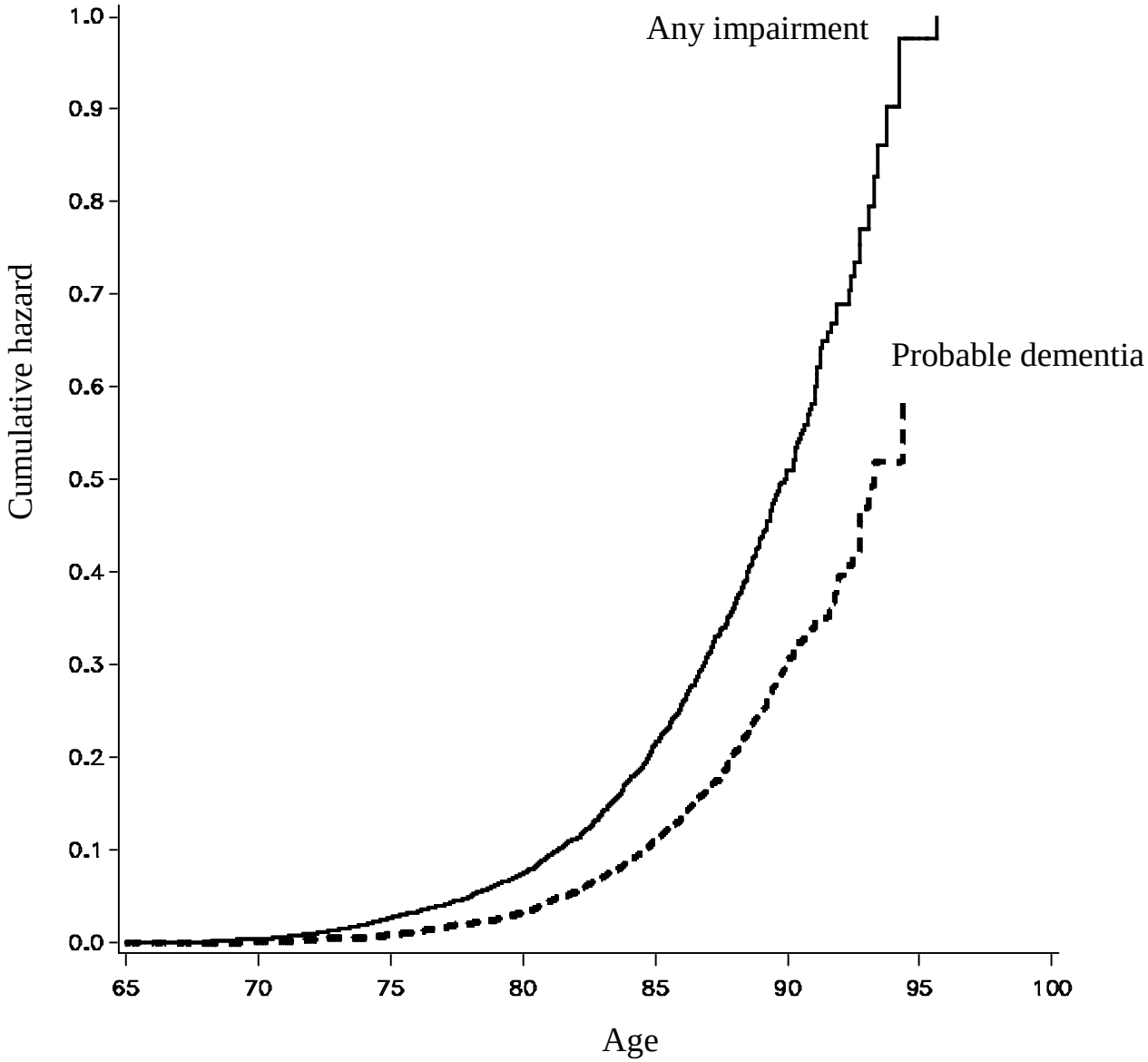
5.1 Incidence of Probable Dementia by Age at Enrollment



5.2 Incidence of Any Impairment (Probable Dementia or Mild Cognitive Impairment) by Age at Enrollment



5.3 Incidence of Probable Dementia and Any Impairment by Age at Ascertainment



Section 6.

WHIMS-MRI2

6.1 WHIMS-MRI Summary

Between April, 2005 and January, 2006, 1,426 women underwent magnetic resonance imaging (MRI) across 14 Women's Health Initiative (WHI) field centers. The effort yielded N=1,403 scans that met central reading center quality control standards.

WHIMS MRI-1 found that CEE+MPA and CEE-Alone were not associated with increased ischemic brain lesions, relative to placebo, on brain MRI conducted 8 years following randomization to CEE-based HT. However, both CEE+MPA and CEE-Alone were associated with lower mean total and regional brain volumes.

6.2 WHIMS-MRI2 Progress Report

6.2.1 WHIMS-MRI2 Enrollment

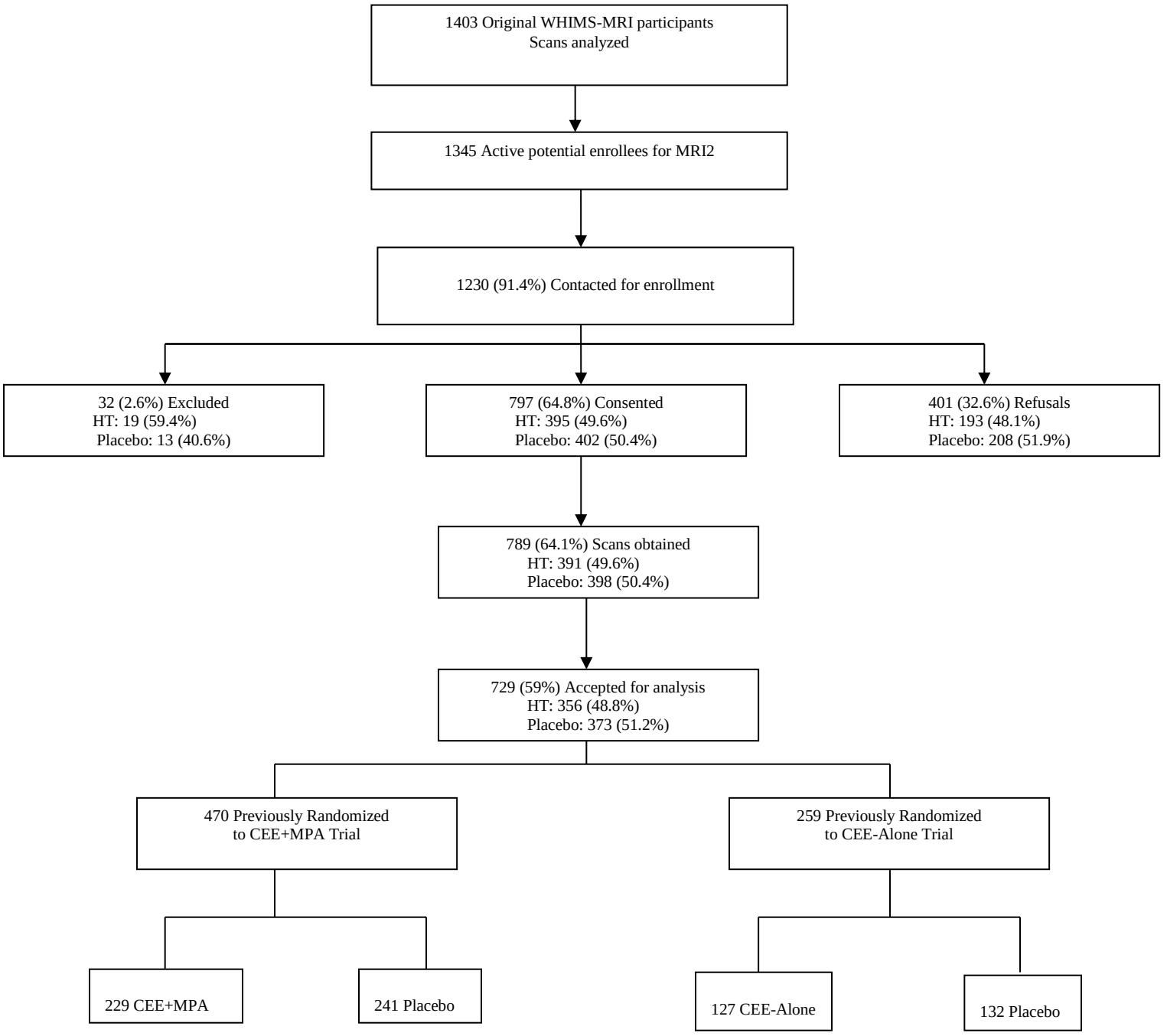
Approximately 4.7 years following the initial WHIMS MRI study, the WHIMS-MRI-2 study was initiated to collect a second MRI brain scan to assess incident neuropathology and the annual rates of change in brain volumes and lesions.

Of 1403 women who participated in the initial WHIMS MRI study, 1,345 remained active in WHIMS and were potential enrollees, and 1230 (91.4%) were contacted by field center staff. Of these 32 (2.6%) were ineligible due to absolute contraindications, 401 (32.6%) refused, and 797 (64.8%) provided informed consent. Subsequently, 789 (64.1%) received MRI brain scans of which 729 (59%) were accepted for analysis (Figure 6.1).

6.2.2 WHIMS-MRI2 Primary Outcome Summary

The WHIMS MRI2 study reported that **c**onjugated equine estrogen-based postmenopausal hormone therapy, previously assigned at WHI baseline, did not affect rates of decline in brain volumes or increases in brain lesion volumes during the 4.7 years between the initial and follow up WHIMS MRI studies. Smaller frontal lobe volumes were observed as persistent group differences among women assigned to active HT compared to placebo. Women with history of cardiovascular disease treated with active HT, compared to placebo, had higher rates of accumulation in white matter lesion volume and total brain lesion volume. Further study may elucidate mechanisms that explain these findings.

Figure 6.1: WHIMS-MRI2 Consort Diagram



6.2.2 WHIMS-MRIQCC Activities

Under the supervision of Dr. R Nick Bryan, the WHIMS MRI Quality Control Center (MRIQCC) at the University of Pennsylvania conducted a number of tasks in the overall management, quality control and data analysis of the MRI component of the WHIMS-MRI project. Those tasks included receiving the MR image data via a dicom image transfer from fourteen participating network MRI field centers, reviewing the MRI data for protocol compliance and quality control, review of ACR QC phantom data for scanner performance, planning and implementation of image analysis methodology and, quantitative image analysis.

The MRIQCC worked extensively with the WHIMS CoC and the 14 MRI facilities in preparation for the study and trained study staff on image transmission and test scan performance for site approval. Site approval involved data collection of a volunteer test scan from each site for evaluation of MRI protocol compliance and technical issues prior to analysis. In addition, a phantom test scan was acquired for scanner performance and QC. Results of the test scans were sent via an email notification for site acceptance/approval to the sites prior to recruitment of participants into the trial. The MRIQCC monitored the QC scans and participant scans for MRI protocol compliance and ACR standards. The participant scans were also reviewed for incidental findings. For safety purposes, incidental findings on MRI images were graded as follows:

- LEVEL 1 – Normal MRI Brain Scan
- LEVEL 2 – Age Related and Incidental Findings
  (MRI Abnormalities limited to age related white matter disease, leukoaraiosis, atrophy, etc. and/or other incidental findings, such as sinus disease)
- LEVEL 3 – Non-Urgent Findings of Clinical Disease
  (Findings include remote stroke, small meningioma, or other processes of potential clinical significance).
- LEVEL 4 – Urgent Disease-Related Findings
  (Findings include acute or subacute infarct, acute or chronic subdural or epidural hematoma, subarachnoid hemorrhage, arteriovenous malformation, obstructive hydrocephalus, brain tumor, brain abscess, or other lesion causing mass effect).

Of 787 scans reviewed by the QA center for safety, 15 (2%) were Level 1, 679 (86%) were Level 2, 90 (11%) were Level 3, and 3 (<1%) were Level 4. As urgent findings were encountered, the WHIMS-MRI Safety Committee was notified via e-mail and follow-up procedures were employed to ensure that the Principal Investigator, participant, and participant's primary care physician were informed of the result within 72 hours.

Data collection ended December 31, 2010. The Coordinating Center worked with each site to resolve data and close-out issues. A 6-month cost extension allowed the University of Pennsylvania MRIQCC to complete central reading of the MRI scans and to apply final QC procedures to the MRI scans prior to transferring data to the WHIMS MRI2 CoC for analysis and archiving. The WHIMS MRI2 CoC completed analyses in September 2011.

Dissemination of the primary and secondary findings through presentations at national meetings and journal articles are underway.

6.2.3 WHIMS MRI2 Publications

Journal Articles Published

Espeland MA, Bryan RN, Goveas JS, Robinson J, Siddiqui MS, Liu S, Hogan PE, Casanova R, Coker LH, Yaffe K, Masaki K, Rossom R, Resnick SM for the WHIMS-MRI2 Study Group. Influence of type 2 diabetes mellitus on brain volumes and changes in brain volumes: Results from the Women's Health Initiative Magnetic Resonance Imaging Studies. Diabetes Care, 2013;36(1):90-97.

Coker LH, Espeland MA, Hogan PE, Resnick SM, Bryan RN, Robinson JG, Goveas JS, Davatzikos C, Kuller LH, Williamson JD, Bushnell CD, Shumaker SA for the WHIMS MRI Study Group. Change in Brain and Lesion Volumes Following CEE Therapies: The WHIMS MRI Studies. Neurology, In Press.

James V. Pottala, Kristine Yaffe, Jennifer Robinson, Mark A. Espeland, Robert Wallace, Sally Shumaker, and William S. Harris. RBC EPA+DHA is associated with total brain and hippocampal volumes over 8 years: Findings from the Women's Health Initiative Memory Study. Neurology, In Press.

Abstracts Published

Coker LH, Hogan P, Espeland MA, Resnick SM, Bryan RN, Goveas J, Bushnell, Davatzikos C, Kuller LH, Robinson J, Williamson JD, Shumaker SA. Rates of Changes in Brain Volumes and Ischemic Lesion Volumes Following Exposure to Conjugated Equine Estrogen Therapies: Results From the WHIMS Magnetic Resonance Imaging Studies. Alzheimers and Dementia: The Journal of the Alzheimer's Association 2012;8(4)P168.

WHI P&P Approved Manuscript Topics

Coker LH, Rates of Changes in Brain Volumes and Ischemic Lesion Volumes Following Exposure to Conjugated Equine Estrogen Therapies: Results From the WHIMS Magnetic Resonance Imaging Studies.

Goveas J, Espeland M, Hogan P, Rapp S, Resnick S. Depression and longitudinal MRI change in subclinical cerebrovascular disease and regional brain volumes: the WHIMS MRI Study.

Goveas J, Espeland M, Hogan P, Rapp S, Resnick S. Antidepressant exposure and cross-sectional and longitudinal changes in brain volumes and ischemic lesion load in women: the WHIMS MRI2 Study.

Erickson K, Smith C, Goveas J, Hogan P, Snively B, Rapp S, Effect of physical activity on brain volume in WHIMS-MRI

Smith J Carson, Erickson K, Smith C, Hogan P, Snively B, Goveas J, Rapp S, Association between physical activity andregional brain volume and white matter lesions in the WHIMS-MRI cohort.

Presentations

Coker LH. Rates of Changes in Brain Volumes and Ischemic Lesion Volumes Following Exposure to Conjugated Equine Estrogen Therapies: Results From the WHIMS Magnetic Resonance Imaging Studies. WHI Annual Meeting, Washington, DC, May 2012.

Coker LH. Rates of Changes in Brain Volumes and Ischemic Lesion Volumes Following Exposure to Conjugated Equine Estrogen Therapies: Results From the WHIMS Magnetic Resonance Imaging Studies. Alzheimers Associations International Conference (AAIC) annual meeting, Vancouver, July 2012.

Section 7.

WHIMS-Y

7.1 WHIMS-Y Protocol Summary

The Women's Health Initiative Memory Study of Younger Women (WHIMS-Y) assesses the long-term impact of random assignment to postmenopausal HT among women enrolled in the WHI HT trials who were 50-54 years of age at study enrollment. An annual telephone-based assessment identical to the WHIMS-ECHO study provides detailed global and specific neuro-cognitive data, thus enhancing our ability to ascertain subtler cognitive changes over time. It also serves to identify women with PD and MCI.

7.2 WHIMS-Y Progress Report and Overall Enrollment

Across all Field Centers, 1,732 WHIMS-Y eligible participants agreed to contact by the WHIMS CoC (Table 7-1). Of those participants who have agreed to contact, 1,362 provided written consent for participation with 370 participants declining consent.

Table 7-1 WHIMS-Y Recruitment Process

	Agreed to initial contact by WHIMS CoC	Declined to participate		Agreed to participate	
Field Center	**Number**	**Number**	**Percent**	**Number**	**Percent**
All Field Centers	***1732***	***370***	***21.4***	***1362***	***78.6***
10=La Jolla/Seattle CoC	**24**	**3**	**12.5**	**21**	**87.5**
11/21=Bettendorf/Iowa City	**49**	**9**	**18.4**	**40**	**81.6**
12=Birmingham	**72**	**18**	**25.0**	**54**	**75.0**
13/71=Greensboro/Bowman Gray	**47**	**11**	**23.4**	**36**	**76.6**
14=Boston	**33**	**6**	**18.2**	**27**	**81.8**
15=Buffalo	**49**	**13**	**26.5**	**36**	**73.5**
16=Chicago	**31**	**8**	**25.8**	**23**	**74.2**
18=Seattle	**69**	**3**	**4.3**	**66**	**95.7**
19=Atlanta	**57**	**21**	**36.8**	**36**	**63.2**
23/69=Pawtucket/Fall River	**65**	**15**	**23.1**	**50**	**76.9**
24/70=Memphis/Pauline	**42**	**19**	**45.2**	**23**	**54.8**
25=Minneapolis	**49**	**8**	**16.3**	**41**	**83.7**
26=Newark	**37**	**4**	**10.8**	**33**	**89.2**
27/29=Phoenix/Tucson	**34**	**5**	**14.7**	**29**	**85.3**
28=Pittsburgh	**56**	**17**	**30.4**	**39**	**69.6**
30=Davis	**40**	**7**	**17.5**	**33**	**82.5**
42=Stanford	**53**	**8**	**15.1**	**45**	**84.9**
43=Milwaukee	**34**	**5**	**14.7**	**29**	**85.3**

Table 7-1 WHIMS-Y Recruitment Process					
	Agreed to initial contact by WHIMS CoC	Declined to participate		Agreed to participate	
Field Center	Number	Number	Percent	Number	Percent
44=George Wash.	50	14	28.0	36	72.0
46/54=Gainesville/Jacksonville	58	8	13.8	50	86.2
47=Houston	42	8	19.0	34	81.0
48=Worcester	38	11	28.9	27	71.1
49=New York	40	12	30.0	28	70.0
50=Columbus	28	4	14.3	24	85.7
51=Medlantic	47	11	23.4	36	76.6
53=Oakland	63	8	12.7	55	87.3
55=Torrance	29	11	37.9	18	62.1
56=Madison	62	12	19.4	50	80.6
57=Stony Brook	29	7	24.1	22	75.9
58=Chapel Hill	42	7	16.7	35	83.3
59/60=Chicago-Rush	42	10	23.8	32	76.2
61=Cincinnati	27	5	18.5	22	81.5
62=Detroit	45	10	22.2	35	77.8
63=Irvine	50	10	20.0	40	80.0
65=Nevada	59	16	27.1	43	72.9
66=Portland	30	9	30.0	21	70.0
67=San Antonio	42	10	23.8	32	76.2
68=Los Angeles	32	5	15.6	27	84.4
72=New Brunswick	12	2	16.7	10	83.3
73=Des Moines	24	0	0	24	100.0

7.3 WHIMS-Y Call Completion Rates

Table 7-2 WHIMS-Y Overall Status of Last Call Attempts by Year

	Year 1		Year 2		Year 3		Year 4		Year 5	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Agreed to participate	1362		0		0		0		0	
---- Cumulative number	1362	100.0	1362	100.0	1362	100.0	1362	100.0	1362	100.0
Lost to follow-up										
---- Deceased	1		5		10		7		2	
---- Withdrew	2		5		31		26		29	
---- Attempts to locate exhausted	0		0		0		0		0	
Due for telephone contact	1359	99.7	1349	99.0	1308	96.0	1275	93.6	1244	91.3
Completed test battery	1267	93.2	1175	87.1	1051	80.4	822	64.5	56	4.5
Failed after 8 attempts	65	4.8	113	8.4	190	14.5	157	12.3	8	0.6
Declined	4	0.3	45	3.3	52	4.0	56	4.4	4	0.3
Phone disconnected	18	1.3	11	0.8	13	1.0	18	1.4	3	0.2
Unable to locate	4	0.3	3	0.2	0	0.0	0	0.0	0	0.0
Recontact	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Hearing impaired	1	0.1	1	0.1	2	0.2	1	0.1	0	0.0
Discontinued	0	0.0	1	0.1	0	0.0	0	0.0	0	0.0
No answer	0	0.0	0	0.0	0	0.0	2	0.2	2	0.2
Left message	0	0.0	0	0.0	0	0.0	7	0.5	3	0.2
Scheduled	0	0.0	0	0.0	0	0.0	9	0.7	7	0.6
Busy	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
No message	0	0.0	0	0.0	0	0.0	13	1.0	9	0.7
Other	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Not attempted	0	0.0	0	0.0	0	0.0	190	14.9	1152	92.6

7.4 WHIMS-Y Characteristics of Enrollees (N=1362)

Table 7-3 Characteristics of Enrollees	
Characteristic	N (%)
WHI Treatment Assignment	
E-Alone	271 (20)
E-Alone Placebo	255 (19)
E+P	446 (33)
E+P Placebo	390 (29)
Age at WHI Enrollment	
50-54	1362 (100)
Age as of October 1, 2013	
65-69	501 (37)
70-74	861 (63)
Race/Ethnicity	
American Indian/Alaskan native	5 (0)
Asian/Pacific Islander	16 (1)
Black/African American	169 (12)
Hispanic/Latino	60 (4)
White	1093 (80)
Other	16 (1)

7.5 WHIMS-Y Adjudication

The WHIMS-Y adjudication process is identical to the one utilized in WHIMS-ECHO. Currently, 211 WHIMS-Y women were eligible for the DQ based on their TICSm scores which were below the study cut-points. Of these, 198 progressed to administration of the DQ.

Table 7-4 Dementia Questionnaire Progressions in WHIMS-Y

	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	TOTAL
TICS Administrations	**1265**	**1174**	**1051**	**800**	**44**	**4334**
DQ Progressions	**61 (4.8%)**	**78 (6.6%)**	**44 (4.2%)**	**1 (2.3%)**	**0**	**211 (4.9%)**
Missing Proxy information	**5 (8.2%)**	**5 (6.4%)**	**1 (2.3%)**	**2 (7.4%)**	**0**	**13 (6.2%)**
Total Eligible DQ Progressions	**56 (91.8%)**	**73 (93.6%)**	**43 (97.7%)**	**1 (100%)**	**0**	**198 (93.8%)**

Table 7-5 Dementia Questionnaire Administration in WHIMS-Y						
	Visit 1	**Visit 2**	**Visit 3**	**Visit 4**	**Visit 5**	**TOTAL**
DQ's ready and completed for adjudication^^	**30 (53.6%)**	**38 (52.1%)**	**25 (58.1%)**	**11 (44.0%)**	**1 (100.0%)**	**105 (53.0%)**
DQ's in process	**0 (0.0%)**	**4 (5.5%)**	**1 (2.3%)**	**3 (12.0%)**	**0 (0.0%)**	**8 (4.0%)**
Phone Disconnected/Unable to locate/Hearing Impaired	**3 (5.4%)**	**3 (4.1%)**	**1 (2.3%)**	**1 (4.0%)**	**0 (0.0%)**	**8 (4.0%)**
Proxy Refused DQ	**8 (14.3%)**	**8 (11.0%)**	**3 (7.0%)**	**0 (0.0%)**	**0 (0.0%)**	**19 (9.6%)**
4th attempt	**15 (26.8%)**	**20 (27.4%)**	**13 (30.2%)**	**10 (40.0%)**	**0 (0.0%)**	**58 (29.4%)**
TOTAL	**56**	**73**	**43**	**25**	**1**	**198**

There are 6 (5.7%) eligible adjudication cases in process. 37 (35.2%) adjudication complete and 62 (59.0%) were not selected to further adjudication based on algorithm.

Table 7-6 Cases Eligible to be Reviewed by Adjudication Committee						
	N (%)					
^	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Total**
Adjudication in process	**0 (0.0%)**	**0 (0.0%)**	**0 (0.0%)**	**5 (45.5%)**	**1 (100%)**	**6 (5.7%)**
Adjudication complete	**12 (40.0%)**	**14 (36.8%)**	**11 (44.0%)**	**0 (0.0%)**	**0 (0.0%)**	**37 (35.2%)**
- - - - ND	**7 (58.3%)**	**7 (50.0%)**	**2 (18.2%)**	**0 (0.0%)**	**0 (0.0%)**	**16 (43.2%)**
- - - - MCI	**5 (41.7%)**	**5 (35.7%)**	**6 (54.5%)**	**0 (0.0%)**	**0 (0.0%)**	**16 (43.2%)**
- - - - PD	**0 (0.0%)**	**2 (14.3%)**	**3 (27.3%)**	**0 (0.0%)**	**0 (0.0%)**	**5 (13.5%)**
Not Adjudicated (ND)	**18 (60.0%)**	**24 (63.2%)**	**14 (56.0%)**	**6 (54.5%)**	**0 (0.0%)**	**62 (59.0%)**
TOTAL	**30**	**38**	**25**	**11**	**1**	**105**

Section 8.

Statistical Support

8.1 Progress Report

The statisticians are organized to collaborate on writing groups from manuscripts based on WHIMS data. Listed are the 40 WHIMS writing groups that have been approved by the WHI Publications Committee and are currently active.

September 2013

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

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

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

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

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

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

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

Ms980: The Utility of Variability in Domain-Specific Cognitive Function in Predicting Incident Dementia: Evidence from the WHISCA
Chair: Mark Espeland
Biostatistical Collaborators: Mark Espeland and Sarah Gaussoin

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

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

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

Ms1115: Obesity & Brain Volume in Postmenopausal Women: WHIMS-MRI
Chair: Ira Driscoll
Biostatistical Collaborator: Sarah Gaussoin

Ms 1260: Omega-3 Fatty Acid Biomarkers, Global Cognitive Function and Cognitive Impairment
Chair: Jennifer Robinson
Biostatistical Collaborator: Eric Amman

Ms 1267: Influence of the Social Environment on Neurological Health in Aging
Chair: N. Denburg
Biostatistical Collaborator: Mark Espeland

Ms 1295: Coronary Heart Disease and the Risk for Mild Cognitive Impairment and Dementia in Postmenopausal Women
Chair: Bernhard Haring
Biostatistical Collaborator: Iris Leng

Ms 1307: Social Disparities in Disturbed Sleep: Neighborhood and Psychosocial Determinants
Chair: JC Chen
Biostatistical Collaborator: Mark Espeland

Ms 1308: Neuropsychological Mechanisms of Social Disparities in Sleep Disturbance
Chair: JC Chen
Biostatistical Collaborator: Mark Espeland

Ms 1309: Neural Impacts of Disparities in Sleep Disturbance Associated with Neighborhood Charaterstics
Chair: JC Chen
Biostatistical Collaborator: Mark Espeland

Ms 1498 Interactions between physical activity and APOE status on regional brain volume and white matter lesions in the WHIMS-MRI cohort
Chair: Carson Smith
Biostatistical Collaborator: Patricia Hogan

Ms 1499 Prediction of cognitive decline over 6 years from change in physical activity and genetic risk for Alzheimer's disease in the WHI study.
Chair: Carson Smith
Biostatistical Collaborator: Mark Espeland

Ms 1525: Antidepressant Exposure & Cross-Sectional & Longitudinal Changes in Brain Volumes & Ischmic Lesion Load in Women: The WHIMS-MRI2 Study
Chair: Joe Goveas
Biostatistical Collaborator: Patricia Hogan

Ms 1526: Depression & Longitudinal MRI Changes in Subclinical Cerebrovascular Disease & Regional Brain Volumes: The WHIMS-MRI2 Study
Chair: Joe Goveas
Biostatistical Collaborator: Patricia Hogan

Ms 1556: A Candidate Gene Study of Genetic Risk for Dementia and MCI in Older, Postmenopausal Women: Results from the WHIMS
Chair: Ira Driscoll
Biostatistical Collaborator: Beverly Snively

Ms 1631: Effect of Physical Activity on Brain Volume in WHIMS-MRI
Chair: Kirk I. Erickson
Biostatistical Collaborator: Beverly Snively

Ms 1632: Effect of Physical Activity on Cognitive and Dementia Status In WHIMS-Y
Chair: Kirk I. Erickson
Biostatistical Collaborator: Mark Espeland

Ms 1714: A Candidate Gene Study of Global and Regional Brain Atrophy In Older, Post-Menopausal Women: Results from the Women's Health Initiative Memory Study (WHIMS)
Chair: Ira Driscoll
Biostatistical Collaborator: Mark Espeland, Beverly Snively

Ms 1715: A Candidate Gene Study of Cognitive Impairment In Older, Post-Menopausal Women: Results from the Women's Health Initiative Memory Study (WHIMS)
Chair: Ira Driscoll
Biostatistical Collaborator: Mark Espeland, Beverly Snively

Ms 1746: Omega-3 Fatty Acids and Domain-Specific Cognitive Aging: Secondary Analyses of Data from WHISCA
Chair: Jane Persons
Biostatistical Collaborator: Mark Espeland

Ms 1748: Prevalence and Predictors of Driving Among Cognitively Impaired Older Adults: The WHI Memory Study
Chair: Kaycee Sink
Biostatistical Collaborator: Mark Espeland, Patricia Hogan

Ms 1781: Activity Engagement, Cognition and MRI
Chair: Leslie Vaughan
Biostatistical Collaborator: Leslie Vaughan/Patricia Hogan

Ms 1816: Red Blood Cell Fatty Acid Patterns and Risk for Incident Age-Related Macular Degeneration in WHIMS
Chair: Mark Espeland
Biostatistical Collaborator: Mark Espeland

Ms 1851: Effects of Physical and Verbal Abuse on Cognitive Function in Postmenopausal Women
Chair: B Cannell
Biostatistical Collaborator: Mark Espeland

Ms 1911: Projecting the Incidence Distribution for Cognitive Impairment and Dementia in a Clinical Cohort Trial
Chair: Mark Espeland
Biostatistical Collaborator: Mark Espeland

Ms 1914: Environmental Determinants of Brain Volume and Ischemia in Older Women: Role of Diesel Exhaust Particulate Matter
Chair: JC Chen
Biostatistical Collaborator: Mark Espeland

Ms 2043: Long-Term Effects of Depression on Cognitive Function in Women Aged 50-54 Years: The WHIMS-Y Study
Chair: Joseph Goveas
Biostatistical Collaborator: Mark Espeland

Ms 2085: Genetic variants of TREM2, Inflammation, Cognitive Function and Total and Regional Brain Volumes in the WHIMS
Chair: Susan Resnick
Biostatistical Collaborator: Beverly Snively

Ms 2146: Comparing the Strength and Costs of Bi-Directional Associations Between Cognitive Decline, Falls and Fractures
Chair: R. Shih
Biostatistical Collaborator: Mark Espeland

Ms 2153: Relationship That Caffeine Intake Has With the Risk of Cognitive Impairment and Global Cognitive Function: Results from the Women's Health Initiative Memory Study
Chair: Ira Driscol
Biostatistical Collaborator: Mark Espeland, Beverly Snively

Ms 2183: Trajectories of Cognitive Function Prior to and Following Stroke: Pooled Analyses From Three Cohorts
Chair: Leslie Vaughan
Biostatistical Collaborator: Mark Espeland

Ms 2219: 80+ Series: Correlates of Optimal Cognitive Aging in 80+ Women
Chair: Joseph Goveas
Biostatistical Collaborator: Mark Espeland, Patricia Hogan

Section 9.

Publications Activities

9.1 WHIMS SUITE OF STUDIES BIBLIOGRAPHY

Rapp SR, Espeland ME, Manson JE, Resnick SM, Bryan NR, Smoller S, Coker LH, Phillips LS, Stefanick ML, and Sarto GE for the Women's Health Initiative Memory Study. Educational attainment, MRI changes and cognitive function in older postmenopausal women from the Women's Health Initiative Memory Study, International J Psychiatry in Medicine, 2014 46(2), 119-141, 2014. In Press.

Coker LH, Espeland MA, Hogan PE, Resnick SM, Bryan RN, Robinson JG, Goveas JS, Davatzikos C, Kuller LH, Williamson JD, Bushnell CD, Shumaker SA. Change in Brain and Lesion Volumes Following CEE Therapies: The WHIMS MRI Studies. Neurology. In Press.

Pottala JV, Yaffe K, Robinson J, Espeland MA, Wallace R, Shumaker SA, Harris WS. RBC EPA+DHA Is Associated With Total Brain and Hippocampal Volumes Over 8 Years: Findings From the Women's Health Initiative Memory Study. Neurology 2013.

Goveas J S, Espeland MA, Hogan PE, Tindle HA, Shih RA, Kotchen JM, Robinson JG, Barnes DE, Resnick SM Depressive symptoms and longitudinal changes in cognition: Women's Health Initiative Study of Cognitive Aging. Journal of Geriatric Psychiatry and Neurology. 2013.

Espeland MA, Shumaker SA, Leng I, Manson JE, Brown CM, Leblanc ES, Vaughan L, Robinson J, Rapp SR, Goveas JS, Lane D, Wactawski-Wende J, Stefanick ML, Li W, Resnick SM; for the WHIMSY Group. Long-Term Effects on Cognitive Function of Postmenopausal Hormone Therapy Prescribed to Women Aged 50 to 55 Years. JAMA Intern Med. 2013 Jun 24: 1-8. [Epub ahead of print]. PubMed PMID: 23797469.

Vaughan L, Espeland MA, Snively B, Shumaker SA, Rapp SR, Shupe J, Robinson JG, Sarto GE, Resnick SM; Women's Health Initiative Memory Study of Younger Women (WHIMS-Y) Study Group. The rationale, design, and baseline characteristics of the Women's Health Initiative Memory Study of Younger Women (WHIMS-Y). Brain Res. 2013 Jun 13; 1514:3-11. Epub 2013 Apr 8. PubMed PMID: 23578696.

Rossom RC, Espeland ME, Manson JE, Dysken MW, Johnson KC, Lane DC, Leblanc ES, Lederle FA, Masaki KH, Margolis KL. Response to Annweiler and Beauchet. J Am Geriatr Soc. 2013 June;61 (6): 1050-1. PubMed PMID: 23772745.

Espeland MA, Pettinger M, Falkner KL, Shumaker SA, Limacher M, Thomas F, Weaver KE, Stefanick ML, McQuellon C, Hunt JR, Johnson KC. Demographic and health factors associated with enrollment in post-trial studies: the Women's Health Initiative Hormone Therapy Trial. Clin Trials. Volume 10 Issue 3 June 2013 pp. 459-468. Epub 2013 Mar 12. PubMed PMID:23480899.

Espeland MA, Bryan N, Goveas JS, Robinson J, Siddiqui MS, Li S, Hogan PE, Casanova R, Coker LH, Yaffee K, Masaki K, Rossom R, Resnick SM. Influence of Type 2 Diabetes on Brain Volumes and Changes in Brain Volumes: Results from the WHIMS-MRI. Diabetes Care. 2013; 36:90-97. PubMed PMID: 22933440; PubMed Central PMCID: PMC3526228.

Rossom RC, Espeland ME, Manson JE, Dysken MW, Johnson KC, Lane DC, LeBlanc ES, Lederle FA, Masaki KH, Margolis KL. Calcium and Vitamin D supplementation and Cognitive Impairment in the Women's Health Initative. J Am Geriatric Soc. Dec 2012; 60(12) 2197-205. Pub Med PMID: 23176129; PubMed Central PMCID: PMC3521077.

Pottala JV, Espeland MA, Polreis J, Robinson J, Harris WS. Correcting the Effects of -20˚C Storage and Aliquot Size on Erythrocyte Fatty Acid Content in the Women's Health Initiative. Lipids. 2012 Sept; 47(9):835-46. Epub 2012 July 11. PubMed PMID: 22782370.

Goveas JS, Hogan PE, Kotchen JM, Smoller JW, Denburg NL, Manson JE, Tummala A, Mysiw WJ, Ockene JK, Woods NF, Espeland MA, Wassertheil-Smoller S. Depressive symptoms, antidepressant use, and future cognitive health in postmenopausal women: the Women's Health Initiative Memory Study. Int Psychogeriatr. 2012 Feb 3:1-13. PubMed PMID: 22301077.

Haan M, Espeland MA, Klein BE, Casanova R, Gaussoin SA, Jackson RD, Millen AE, Resnick SM, Rossouw JE, Shumaker SA, Wallace R, Yaffe K; Women's Health Initiative Memory Study and the Women's Health Initiative Sight Exam. Cognitive function and retinal and ischemic brain changes: the Women's Health Initiative. Neurology. 2012 Mar 27;78(13):942-9. Epub 2012 Mar 14. PubMed PMID: 22422889; PubMed Central PMCID: PMC3310310.

Gaussoin SA, Espeland ME, Absher J, Howard BV, Jones BM, Rapp SR. Ascertaining dementia-related outcomes for deceased or proxy-dependent participants: An overview of the Women's Health Initiative Memory Study supplemental case ascertainment protocol. International Journal of Geriatric Psychiatry, 2012;27:205-14. Epub 2011 Mar 18. PMID: 21416508.

Rapp SR, Legault C, Espeland ME, Resnick S, Hogan P, Coker L, Dailey M, Shumaker SA. Validation of a cognitive assessment battery administered by telephone. J Amer Geriatrics Society, 2012;60:1616-1623. PMID: 22985137.

Shih RA, Ghosh-Dastidar B, Margolis KL, Slaughter ME, Jewell A, Bird CE, Eibner C, Denburg NL, Ockene J, Messina CR, Espeland MA. Neighborhood socioeconomic status and cognitive function in women. Am J Public Health. 2011 Sep; 101 (9);1721-8. PubMed PMID:21778482; PubMed Central PMCID: PMC3154213.

Espeland MA, Miller ME, Goveas JS, Hogan PE, Coker LH, Williamson J, Naughton M, Resnick For The Whisca Study Group SM. Domain-Specific Cognitive Function and Fine Motor Speed over Time in Women 65 Years and Older with Type 2 Diabetes Mellitus: Results from the Women's Health Initiative Study of Cognitive Aging. J Womens Health (Larchmt). 2011 Aug 5; PubMed PMID:21819251; PubMed Central PMCID: PMC3186442.

Driscoll I, Espeland MA, Wassertheil-Smoller S, Gaussoin SA, Ding J, Granek IA, Ockene JK, Phillips LS, Yaffe K, Resnick SM. Weight Change and Cognitive Function: Findings

From the Women's Health Initiative Study of Cognitive Aging. Obesity (Silver Spring). 2011 Aug; 19 (8) :1595-600. PubMed PMID:21394095; PubMed Central PMCID: PMC3175491.

Goveas JS, Espeland MA, Hogan P, Dotson V, Tarima S, Coker LH, Ockene J, Brunner R, Woods NF, Wassertheil-Smoller S, Kotchen JM, Resnick S. Depressive symptoms, brain volumes and subclinical cerebrovascular disease in postmenopausal women: the Women's Health Initiative MRI Study. J Affect Disord. 2011 Jul; 132 (1-2) :275-84. PubMed PMID:21349587; PubMed Central PMCID: PMC3109161.

Casanova R, Espeland MA, Goveas JS, Davatzikos C, Gaussoin SA, Maldjian JA, Brunner RL, Kuller LH, Johnson KC, Mysiw WJ, Wagner B, Resnick SM, Women's Health Initiative Memory Study. Application of machine learning methods to describe the effects of conjugated equine estrogens therapy on region-specific brain volumes. Magn Reson Imaging. 2011 May; 29 (4) :546-53. PubMed PMID:21292420; PubMed Central PMCID: PMC3079024.

Goveas JS, Espeland MA, Woods NF, Wassertheil-Smoller S, Kotchen JM. Depressive symptoms and incidence of mild cognitive impairment and probable dementia in elderly women: the Women's Health Initiative Memory Study. J Am Geriatr Soc. 2011 Jan; 59 (1) :57-66. PubMed PMID:21226676.

Kerwin DR, Gaussoin SA, Chlebowski RT, Kuller LH, Vitolins M, Coker LH, Kotchen JM, Nicklas BJ, Wassertheil-Smoller S, Hoffmann RG, Espeland MA, Women's Health Initiative Memory Study. Interaction between body mass index and central adiposity and risk of incident cognitive impairment and dementia: results from the Women's Health Initiative Memory Study. J Am Geriatr Soc. 2011 Jan; 59 (1) :107-12. PubMed PMID:21226681.

Kerwin DR, Zhang Y, Kotchen JM, Espeland MA, Van Horn L, McTigue KM, Robinson JG, Powell L, Kooperberg C, Coker LH, Hoffmann R. The cross-sectional relationship between body mass index, waist-hip ratio, and cognitive performance in postmenopausal women enrolled in the Women's Health Initiative. J Am Geriatr Soc. 2010 Aug; 58 (8) :1427-32. PubMed PMID:20646100; PubMed Central PMCID: PMC2955186.

Rapp SR, Legault C, Henderson VW, Brunner RL, Masaki K, Jones B, Absher J, Thal L. Subtypes of mild cognitive impairment in older postmenopausal women: the Women's Health Initiative Memory Study. Alzheimer Dis Assoc Disord. 2010 Jul-Sep; 24 (3) :248-55. PubMed PMID:20473134; PubMed Central PMCID: PMC2929315.

Espeland MA, Brunner RL, Hogan PE, Rapp SR, Coker LH, Legault C, Granek I, Resnick SM, Women's Health Initiative Study of Cognitive Aging Study Group. Long-term effects of conjugated equine estrogen therapies on domain-specific cognitive function: results from the Women's Health Initiative study of cognitive aging extension. J Am Geriatr Soc. 2010 Jul; 58 (7) :1263-71. PubMed PMID:20649689; PubMed Central PMCID: PMC2917208.

Kuller LH, Margolis KL, Gaussoin SA, Bryan NR, Kerwin D, Limacher M, Wassertheil-Smoller S, Williamson J, Robinson JG, Women's Health Initiative Memory Study Research

Group. Relationship of hypertension, blood pressure, and blood pressure control with white matter abnormalities in the Women's Health Initiative Memory Study (WHIMS)-MRI trial. J Clin Hypertens (Greenwich). 2010 Mar; 12 (3) :203-12. PubMed PMID:20433539; PubMed Central PMCID: PMC2864933.

Atkinson HH, Rapp SR, Williamson JD, Lovato J, Absher JR, Gass M, Henderson VW, Johnson KC, Kostis JB, Sink KM, Mouton CP, Ockene JK, Stefanick ML, Lane DS, Espeland MA. The relationship between cognitive function and physical performance in older women: results from the women's health initiative memory study. J Gerontol A Biol Sci Med Sci. 2010 Mar; 65 (3) :300-6. PubMed PMID:19789197; PubMed Central PMCID: PMC2822281.

Espeland MA, Shumaker SA, Limacher M, Rapp SR, Bevers TB, Barad DH, Coker LH, Gaussoin SA, Stefanick ML, Lane DS, Maki PM, Resnick SM. Relative effects of tamoxifen, raloxifene, and conjugated equine estrogens on cognition. J Womens Health (Larchmt). 2010 Mar; 19 (3) :371-9. PubMed PMID:20136553; PubMed Central PMCID: PMC2867626.

Coker LH, Espeland MA, Rapp SR, Legault C, Resnick SM, Hogan P, Gaussoin S, Dailey M, Shumaker SA. Postmenopausal hormone therapy and cognitive outcomes: the Women's Health Initiative Memory Study (WHIMS). J Steroid Biochem Mol Biol. 2010 Feb 28; 118 (4-5) :304-10. PubMed PMID:19932751.

Colenda CC, Legault C, Rapp SR, DeBon MW, Hogan P, Wallace R, Hershey L, Ockene J, Whitmer R, Phillips LS, Sarto GE. Psychiatric disorders and cognitive dysfunction among older, postmenopausal women: results from the Women's Health Initiative Memory Study. Am J Geriatr Psychiatry. 2010 Feb; 18 (2) :177-86. PubMed PMID:20104074; PubMed Central PMCID: PMC2939041.

Tooze JA, Gaussoin SA, Resnick SM, Fischbein NJ, Robinson JG, Bryan RN, An Y, Espeland MA, Women's Health Initiative Memory Study. A uniform approach to modeling risk factor relationships for ischemic lesion prevalence and extent: the Women's Health Initiative Magnetic Resonance Imaging study. Neuroepidemiology. 2010; 34 (1) :55-62. PubMed PMID:19940514; PubMed Central PMCID: PMC2818378.

Espeland MA, Tindle HA, Bushnell CA, Jaramillo SA, Kuller LH, Margolis KL, Mysiw WJ, Maldjian JA, Melhem ER, Resnick SM, Women's Health Initiative Memory Study. Brain volumes, cognitive impairment, and conjugated equine estrogens. J Gerontol A Biol Sci Med Sci. 2009 Dec; 64 (12) :1243-50. PubMed PMID:19729392; PubMed Central PMCID: PMC2773813.

Resnick SM, Espeland MA, An Y, Maki PM, Coker LH, Jackson R, Stefanick ML, Wallace R, Rapp SR, Women's Health Initiative Study of Cognitive Aging Investigators. Effects of conjugated equine estrogens on cognition and affect in postmenopausal women with prior hysterectomy. J Clin Endocrinol Metab. 2009 Nov; 94 (11) :4152-61. PubMed PMID:19850684; PubMed Central PMCID: PMC2775644.

Voytko ML. Women's cognitive health special edition. Age (Dordr). 2009 Sep; 31 (3):189-90. PubMed PMID:19277900; PubMed Central PMCID: PMC2734242.

Resnick SM, Espeland MA, Jaramillo SA, Hirsch C, Stefanick ML, Murray AM, Ockene J, Davatzikos C. Postmenopausal hormone therapy and regional brain volumes: the WHIMS-MRI Study. Neurology. 2009 Jan 13; 72 (2) :135-42. PubMed PMID:19139364; PubMed Central PMCID: PMC2677493.

Coker LH, Hogan PE, Bryan NR, Kuller LH, Margolis KL, Bettermann K, Wallace RB, Lao Z, Freeman R, Stefanick ML, Shumaker SA. Postmenopausal hormone therapy and subclinical cerebrovascular disease: the WHIMS-MRI Study. Neurology. 2009 Jan 13; 72 (2) :125-34. PubMed PMID:19139363; PubMed Central PMCID: PMC2677498.

Espeland ME, Shumaker SA, Hogan PE, and Resnick SM. Women's Health Initiative Memory Study (WHIMS) Program: Emerging findings. In: Hogervorst E, Henderson VW, Gibbs RB, Brinton RD, eds. Estrogens and Cognition: Perspectives and opportunities in the wake of the Women's Health Initiative Memory Study . Women's Health Initiative: Memory Study (WHIMS) program: Emerging Findings New York, NY: Cambridge University Press, 2009:1-10.

Bandelow S, Espeland MA, Henderson VW, Resnick SM, Wallace RB, Coker LH, Hogervorst E. Identifying risk factors for cognitive change in the Women's Health Initiative: A neural networks approach. In: Hogervorst E, Henderson VW, Gibbs RB, Brinton RD, eds. Hormones, Cognition and Dementia: State of the Art and Emergent Therapeutic Strategies. New York, NY: Cambridge University, 2009:11-24.

Chen JC, Brunner RL, Ren H, Wassertheil-Smoller S, Larson JC, Levine DW, Allison M, Naughton MJ, Stefanick ML. Sleep duration and risk of ischemic stroke in postmenopausal women. Stroke. 2008 Dec; 39 (12) :3185-92. PubMed PMID:18635832; PubMed Central PMCID: PMC2587518.

Johnson KC, Margolis KL, Espeland MA, Colenda CC, Fillit H, Manson JE, Masaki KH, Mouton CP, Prineas R, Robinson JG, Wassertheil-Smoller S, Women's Health Initiative Memory Study and Women's Health Initiative Investigators. A prospective study of the effect of hypertension and baseline blood pressure on cognitive decline and dementia in postmenopausal women: the Women's Health Initiative Memory Study. J Am Geriatr Soc. 2008 Aug; 56 (8) :1449-58. PubMed PMID:18637980.

Jaramillo SA, Felton D, Andrews L, Desiderio L, Hallarn RK, Jackson SD, Coker LH, Robinson JG, Ockene JK, Espeland MA, Women's Health Initiative Memory Study Research

Group. Enrollment in a brain magnetic resonance study: results from the Women's Health Initiative Memory Study Magnetic Resonance Imaging Study (WHIMS-MRI). Acad Radiol. 2007 May; 14 (5) :603-12. PubMed PMID:17434074; PubMed Central PMCID: PMC1934046.

Dunn JE, Weintraub S, Stoddard AM, Banks S. Serum alpha-tocopherol, concurrent and past vitamin E intake, and mild cognitive impairment. Neurology. 2007 Feb 27; 68 (9) :670-6. PubMed PMID:17325274.

Resnick SM, Maki PM, Rapp SR, Espeland MA, Brunner R, Coker LH, Granek IA, Hogan P, Ockene JK, Shumaker SA, Women's Health Initiative Study of Cognitive Aging Investigators. Effects of combination estrogen plus progestin hormone treatment on cognition and affect. J Clin Endocrinol Metab. 2006 May; 91 (5) :1802-10. PubMed PMID:16522699.

Espeland MA, Rapp SR, Robertson J, Granek I, Murphy C, Albert M, Bassford T, Women's Health Initiative Memory Study. Benchmarks for designing two-stage studies using modified mini-mental state examinations: experience from the Women's Health Initiative Memory Study. Clin Trials. 2006; 3 (2) :99-106. PubMed PMID:16773952.

Espeland MA, Coker LH, Wallace R, Rapp SR, Resnick SM, Limacher M, Powell LH, Messina CR, Women's Health Initiative Study of Cognitive Aging. Association between alcohol intake and domain-specific cognitive function in older women. Neuroepidemiology. 2006; 27 (1) :1-12. PubMed PMID:16717476.

Espeland MA, Gu L, Masaki KH, Langer RD, Coker LH, Stefanick ML, Ockene J, Rapp SR. Association between reported alcohol intake and cognition: results from the Women's Health Initiative Memory Study. Am J Epidemiol. 2005 Feb 1; 161 (3) :228-38. PubMed PMID:15671255.

Espeland MA, Rapp SR, Shumaker SA, Brunner R, Manson JE, Sherwin BB, Hsia J, Margolis KL, Hogan PE, Wallace R, Dailey M, Freeman R, Hays J, Women's Health Initiative Memory Study. Conjugated equine estrogens and global cognitive function in postmenopausal women: Women's Health Initiative Memory Study. JAMA. 2004 Jun 23; 291 (24) :2959-68. PubMed PMID:15213207.

Shumaker SA, Legault C, Kuller L, Rapp SR, Thal L, Lane DS, Fillit H, Stefanick ML, Hendrix SL, Lewis CE, Masaki K, Coker LH, Women's Health Initiative Memory Study. Conjugated equine estrogens and incidence of probable dementia and mild cognitive impairment in postmenopausal women: Women's Health Initiative Memory Study. JAMA. 2004 Jun 23; 291 (24) :2947-58. PubMed PMID:15213206.

Klein KP, Rapp SR. Women's cognitive health: postmenopausal dementia and the women's health initiative memory study. Womens Health Issues. 2004 May-Jun; 14 (3) :71-4. PubMed PMID:15193634.

Resnick SM, Coker LH, Maki PM, Rapp SR, Espeland MA, Shumaker SA. 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. Clin Trials. 2004; 1 (5) :440-50. PubMed PMID:16279282.

Rapp SR, Espeland MA, Shumaker SA, Henderson VW, Brunner RL, Manson JE, Gass ML, Stefanick ML, Lane DS, Hays J, Johnson KC, Coker LH, Dailey M, Bowen D, WHIMS Investigators. Effect of estrogen plus progestin on global cognitive function in postmenopausal women: the Women's Health Initiative Memory Study: a randomized controlled trial. JAMA. 2003 May 28; 289 (20) :2663-72. PubMed PMID:12771113.

Shumaker SA, Legault C, Rapp SR, Thal L, Wallace RB, Ockene JK, Hendrix SL, Jones BN 3rd, Assaf AR, Jackson RD, Kotchen JM, Wassertheil-Smoller S, Wactawski-Wende J, WHIMS Investigators. 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. JAMA. 2003 May 28; 289 (20) :2651-62. PubMed PMID:12771112.

Rapp SR, Espeland MA, Hogan P, Jones BN, Dugan E, WHIMS investigators. Baseline experience with Modified Mini Mental State Exam: The Women's Health Initiative Memory Study (WHIMS). Aging Ment Health. 2003 May; 7 (3) :217-23. PubMed PMID:12775404.

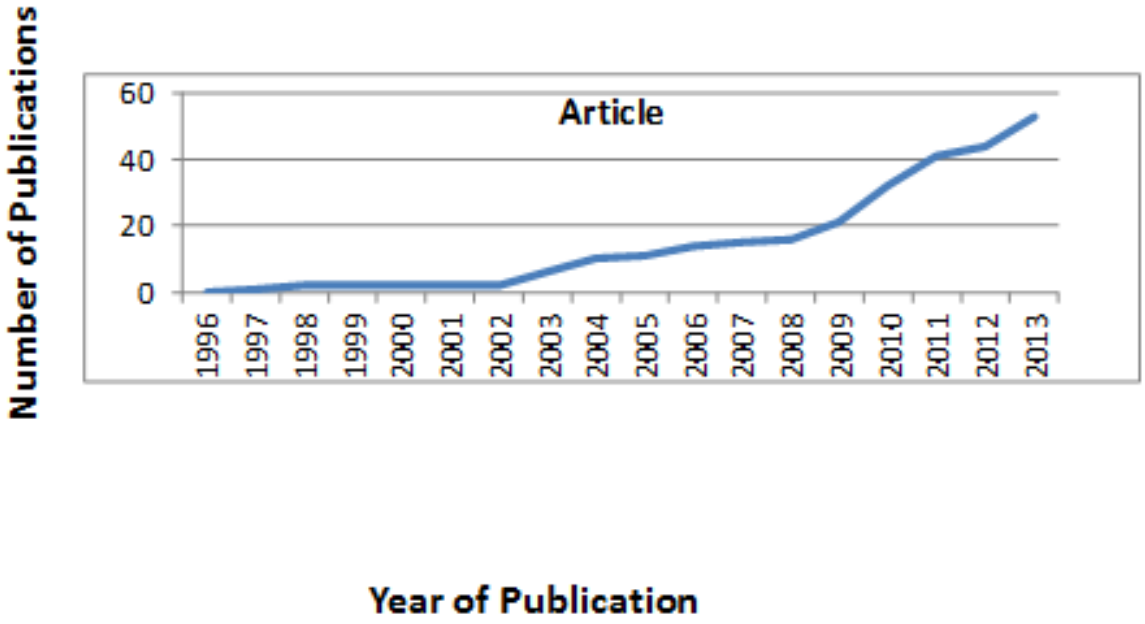
Kirschstein R. Menopausal hormone therapy: summary of a scientific workshop. Ann Intern Med. 2003 Feb 18; 138 (4) :361-4. PubMed PMID:12585848.

Shumaker SA, Reboussin BA, Espeland MA, Rapp SR, McBee WL, Dailey M, Bowen D, Terrell T, Jones BN. The Women's Health Initiative Memory Study (WHIMS): a trial of the effect of estrogen therapy in preventing and slowing the progression of dementia. Control Clin Trials. 1998 Dec; 19 (6) :604-21. PubMed PMID:9875839.

McBee WL, Dailey ME, Dugan E, Shumaker SA. Hormone replacement therapy and other potential treatments for dementias. Endocrinol Metab Clin North Am. 1997 Jun; 26 (2) :329-45. PubMed PMID:9193887.

WHI Cognition Program Publications

October, 2013



Most Highly Cited WHI Cognition Articles

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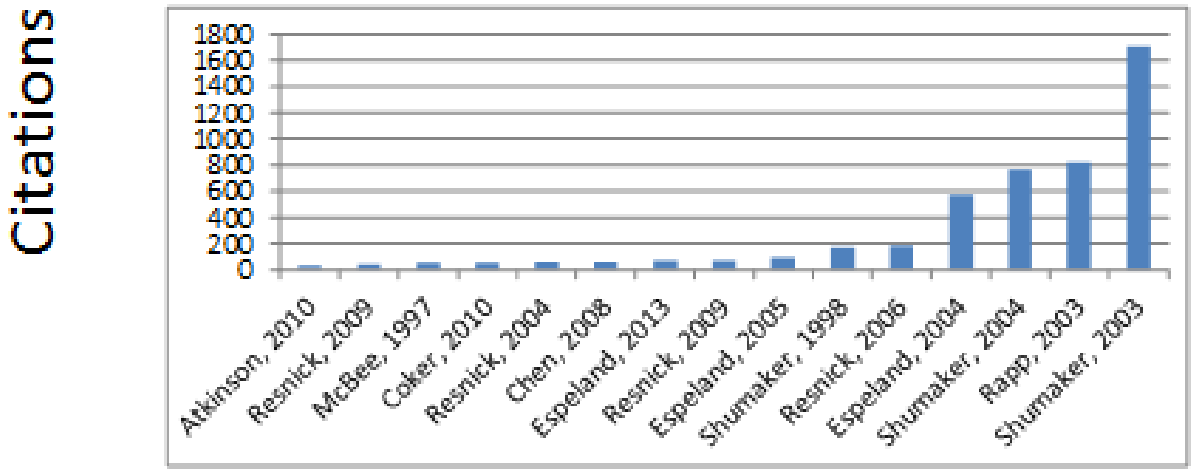
4,738 total citations



Section 10.

Ancillary Studies

Table 10-1 Funded Ancillary Studies from the WHIMS

AS #	Title	PIs	WHI Investigator	Status	Study Dates	Study Populations*	Blood Study	Ms #(s)
262	Women's Health Initiative memory study of younger women (WHIMS-Y)	Anc: Shumaker WHI: Shumaker	Yes	Funded	10/01/08-06/30/11	HT	N	
252	Environmental determinants of cognitive aging in WHIMS	Anc: Chen WHI: Heiss	No	Approved	07/01/08-06/30/13	HT	N	
BA19	Omega-3 fatty acid biomarkers and cognitive decline in WHIMS	Anc: Harris WHI: Robinson	No	Funded	01/09-01/11	HT	Y	
250	Genetic contributions to cognitive decline in normal and pathological aging in older post-menopausal women and modification by hormone therapy	Anc: Driscoll WHI: Shumaker	No	Funded	03/01/09-12/31/09	HT Controls:7479 *All 7479 WHIMS ppts	Y	
244	Women's Health Initiative memory study epidemiology of cognitive health (WHIMS-ECHO)	Anc: Shumaker WHI: Vitolins	Yes	Funded	10/01/07-12/31/10	HT	N	
235	Pilot study to explore assoc between task performance on fMRI w/ cog functioning and vascular, genetic & inflam. risk factors in WHISCA ppt characterized by differing body weight & waist-hip ratios	Anc: Kerwin WHI: Kotchen	Yes	Analysis	11/01/06-06/30/09	CT	N	
233	WHIMS (AS39) extension	Anc: Shumaker WHI: Shumaker	Yes	Analysis	12/13/03-06/30/08	HT 3074 Ppts@32 clinics	N	
183	Effects of hormone therapy on subclinical neurological pathology: WHIMS-MRI (1 & 2)	Anc: Shumaker WHI: Shumaker	Yes	Analysis (1) Funded (2)	07/01/04-06/30/08 (1) 11/30/07-12/31/10 (2)	HT E+P	N	542, 625, 626, 680, 683, 696, 727, 794, 883, 909, 937, 979, 1047 (1)
103	Effects of hormone replacement therapy on cognitive aging: Women's Health Initiative study of cognitive aging (WHISCA)	Anc: Shumaker WHI: Shumaker	Yes	Analysis	04/01/99-06/30/10	HT 2266 Ppts@15 clinics	N	216, 237, 325, 579, 598, 695, 899, 914, 980, 1038

39	The effects of HRT on the development and progression of dementia (WHIMS)	Anc: Shumaker WHI: Shumaker	Yes	Complete	06/01/96- 05/31/05	HT 7528 Ppts@48 clinics	N	60, 138, 173, 225, 226, 274, 276, 332, 336, 356,360, 370, 390, 397, 399, 421, 427, 546, 558, 595, 597, 612, 639, 665, 670, 683, 727, 750, 881, 883,938

*Number of Field Centers includes number of satellite sites.

Table 10-2 Proposed Ancillary Studies from the WHIMS

Investigators, Institutions	Proposal Title	Data Source	Relevant SIG
Laura H Coker, Peggye Dilworth-Anderson, Stephen Rapp, Sally Shumaker (Wake Forest University Health Sciences [WFUHS]; UNC-Greensboro)	Characteristics of caregivers and outcomes of care recipients	Caregiver Questionnaire (new); WHI participant (care recipient) data from the OS, HT WHIMS and WHISCA trial databases.	Psychosocial & behavioral Health (PBH)
Elizabeth Dugan (UMass-Boston); Sally Shumaker (WFUHS)	Women's mobility and driving	New questionnaire (10-15 minutes) to capture driving status, accidents, safety, behavior and needs; cognition status from WHIMS/WHISCA; US Census.	ACFS, PBE
Mark Espeland, Laura H Coker (WFUHS)	Structural magnetic resonance imaging of the WHIMSY cohort	New structural MRIs (N=616); treatment, risk factors, cognition and potential confounders from WHI, WHIMS, and WHIMSY databases.	ACFS
Mary Haan (University of California, San Francisco); Mark Espeland (WFUHS)	Associations between changes in retinopathy and brain MRI	New eye exams; brain MR outcomes, treatment, risk factors, cognition and potential confounders from WHI, WHIMS, WHIMS-MRI databases	ACFS
Christine Bell (University of Hawaii)**, Stephen Rapp** (WFUHS)	Advanced Care Planning	Supplemental mail-out items on Form 156	ACFS, PBH
J. C. Chen (University of Southern California) **Mark Espeland** (WFUHS) **Eric A Whitsel** (UNC-CH) **R-01 Submitted 10/10**	Social disparity in disturbed sleep: neighborhood and brain-behavior interaction	WHIMS, WHI, Neighborhood socio-economic status data	ACFS, PBE
Regina A Shih (RAND Corp), **Karen Margolis** (Univ Minnesota; Health Partners Research Fdn) **Mark Espeland** (WFUHS)] **R-01 Submitted 10/10**	Neighborhood Characteristics, Cognitive Declines, and Brain Structure in Older Women	WHIMS, WHI, Neighborhood socio-economic status data	ACFS, PBE
Diana Kerwin	The Relationship Between the FTO Obesity Gene & Regional Volume Measurement & Ventricular Size in Women of the WHIMS MRI Study	WHIMS-MRI	
Katie Stone (Research Institute, California Pacific Medical Center), **Sally Shumaker** (WFUHS)	Feasibility of Sleep Apnea Assessment in WHI Participants: Prelude to an Ancillary Study of Sleep, Cardiovascular Disease and Cognitive Impairment	WHIMS, Testing feasibility of a device that measures sleep apnea in WHIMS women (n=56); administering a 1-2 page mail-in questionnaire	ACFS

Key: Scientific Interest Groups: Aging, Cognition, and Functional Status (ACFS); the Physical and Built Environment (PBE); and Psychosocial and Behavioral Health (PBH).

Section 11.

Recent Scientific Findings

11.1 Published Papers

Recent scientific findings from papers appearing in the past year:

- The Women's Health Initiative Memory Study-Younger (WHIMS-Y) was designed to assess the effect of prior random assignment to hormone therapy (HT) (conjugated equine estrogen (CEE) alone or CEE plus medroxyprogesterone acetate (MPA)) on global cognitive function in younger middle-aged women relative to placebo. WHIMS-Y was an ancillary study to the Women's Health Initiative (WHI) HT trial and enrolled 1361 women who were aged 50-55 years and postmenopausal at WHI enrollment. WHIMS-Y examines whether an average of 5.4 years of HT during early menopause has longer term protective effects on global cognitive function and if these effects vary by regimen, time between menopause and study initiation, and prior use of HT. WHIMS-Y provides an unprecedented chance to examine the hypothesis that HT may have protective effects on cognition in younger postmenopausal women aged 50-55 years. Vaughan AL, Espeland MA, Snively B, et al. The rationale, design, and baseline characteristics of the Women's Health Initiative Memory Study of Younger Women. Brain Res 2013;1514-3-11. PMID: 23578696.

- Global cognitive function scores from women who had been assigned to CEE-based therapies were similar to those from women assigned to placebo: mean (95% CI) intervention effect of 0.02 (-0.08 to 0.12) standard deviation units (P=.66). Similarly, no overall differences were found for any individual cognitive domain (all P>0.15). Pre-specified subgroup analyses found some evidence that CEE-based therapies may have adversely affected verbal fluency among women who had prior hysterectomy or prior use of hormone therapy: mean treatment effects of -0.17 (-0.33 to -0.02) and -0.25 (-0.42 to -0.08), respectively; however, this may be a chance finding. CEE-based therapies produced no overall sustained benefit or risk to cognitive function when administered to postmenopausal women aged 50 to 55 years. Espeland MA, Shumaker SA, Leng I, et al. Long term effects on cognitive function of postmenopausal hormone therapy prescribed to women aged 50-54 years. JAMA Intern Med 2013;4:1-8 PMID: 23797469.

- Associations that markers of sociodemography, health, lifestyle, and on-trial experiences had with re-enrollment and contrasted the characteristics of successive posttrial cohorts with those of the original enrollees were examined. The posttrial enrollment campaigns re-enrolled 81.1% and 82.5% of available women, respectively. Women who re-enrolled tended to have better health characteristics than those not re-enrolled. Compared to women of comparable age in the original cohort, women retained for the second posttrial follow-up less often had a history of cardiovascular disease (odds ratio (OR) = 0.36), hypertension (OR = 0.57), diabetes (OR = 0.59), or measured cognitive deficit (OR = 0.40). These women more often had graduated from high school (OR = 1.72) and had participated in other WHI trials (OR = 1.76). Posttrial enrollment in follow-up studies can be successful; however, the characteristics of the resulting cohort may differ substantially from the originally assembled group of trial participants. Collection during the original trial of potential predictors of differential re-enrollment may strengthen interpretation of findings. Espeland MA, Pettinger M, Falkner KL, et al. Demographic and health factors associated with enrollment in posttrial studies. Clin Trials 2013;10:463-472. PMID 23480899

- Two thousand thirty-four women were randomized to receive 1,000 mg of calcium carbonate combined with 400 IU of vitamin D(3) (treatment) and 2,109 to placebo. Mean age of participants was 71. During a mean follow-up of 7.8 years, 39 participants in the treatment group and 37 in the placebo group developed incident dementia (hazard ratio (HR) = 1.11, 95% confidence interval (CI) = 0.71-1.74, P = .64). Likewise, 98 treatment participants and 108 placebo participants developed incident MCI (HR = 0.95, 95% CI = 0.72-1.25, P = .72). There were no significant differences in incident dementia or MCI or in global or domain-specific cognitive function between groups. There was no association between treatment assignment and incident cognitive impairment. Rossom RC, Espeland MA, Manson JE, et al. Calcium and vitamin D supplementation and cognitive impairment in the Women's Health Initiative. J Am Geriatr Soc 2012;60:2197-2205. PMID 23176129

- One thousand three hundred ninety-four of the 7,479 community-dwelling women 65 years of age and older enrolled in the Women's Health Initiative Memory Study, two parallel randomized, placebo-controlled clinical trials comparing unopposed and opposed post-menopausal hormone therapy with placebo, were studied. Study participants received annual assessments of global cognitive function with the Modified Mini Mental State exam. One thousand sixty-seven participants also received a supplemental neurocognitive battery and neuroimaging studies. Magnetic resonance imaging was used to calculate total ischemic lesion and brain volumes. Incident cases of probable dementia and mild cognitive impairment were centrally adjudicated. After adjustment for total lesion and total brain volumes (atrophy), higher educational attainment predicted better cognitive performance ($p<0.001$). Following conversion to dementia/MCI, higher education predicted steeper declines in cognitive function ($p<0.001$). Thus, higher educational attainment may have delayed the diagnosis of dementia/MCI in the face of a growing neuropathological load. Rapp S, Espeland MA, Manson JE, et al. Educational attainment, MRI changes and cognitive function in older postmenopausal women from the Women's Health Initiative Memory Study, Inter J Psych Med 2014:46:119-141 (in press).

- A supplemental proxy-based protocol, involving telephone administration of the dementia questionnaire, was designed to assess the cognitive status of women who could no longer attend clinic visits because they died (n = 1058) or became dependent (n = 228). Women who were eligible for proxy-based assessments tended to have worse cognitive impairment risk factor profiles and had higher rates of probable dementia (15.2% vs 3.5%) than clinic-assessed participants. Augmenting the clinic-based cases with those identified from proxy interviews reduced undercounting and materially altered observed relationships that years since menopause, smoking status, diabetes, and prior use of hormone therapy had with incidence of probable dementia. Although proxy interviews were successful in reducing biases in estimated incidence rates and risk factor relationships, it is unlikely that they will fully eliminate many biases. Proxy-based assessments are necessary in longer term studies to reduce undercounting of dementia cases and to characterize risk factor relationships. Gaussoin SA, Espeland MA, Absher J, et al. Ascertaining dementia-related outcomes for deceased or proxy-dependent participants: An overview of the Women's Health Initiative Memory Study supplemental case ascertainment protocol. Intern J Geriatr Psych 2012;27:205-214. PMID: 21416508.

- N=110 participants were randomly assigned to receive two administrations of the same cognitive test battery 6 months apart in one of four combinations (Time 1 administration/Time 2 administration): telephone/telephone, telephone/face to face, face to face/telephone, face to face/face to face. There were no statistically significant differences in scores on any of the cognitive tests or questionnaires between participants randomly assigned to telephone or face-to-face administration at the Time 1 assessment, indicating equivalence across administration modes. There was no significant bias for tests or questionnaires administered by telephone (P's > .01), nor was there a difference in mean change scores between administration modes except for Category Fluency (P = .01) and California Verbal Learning Test long-delay free recall (P = .004). Mean test-retest coefficients for the battery were not significantly different between groups, although individual test-retest correlation coefficients were generally higher within modes than between modes. Telephone administration of cognitive tests and questionnaires to older women is reliable and valid. Use of telephone batteries can substantially reduce the cost and burden of cognitive assessments and increase enrollment, retention, and data completeness, thereby improving study validity. Rapp SR, Legault C, Espeland MA, et al. Validation of a cognitive assessment battery administered by telephone. J Am Geriatr Soc 2012;60:1616-1623. PMID: 22985137.

- A total of 2,157 women with normal cognition enrolled in a clinical trial of postmenopausal hormone therapy were followed with annual cognitive testing for a median of 5.9 years. After adjustment for demographic, clinical, and behavioral characteristics, no significant ($p < 0.01$) cross-sectional cognitive differences were found between women in the high and low DHA + EPA tertiles at the time of the first annual cognitive battery. In addition, no significant ($p < 0.01$) differences were found between the high and low DHA + EPA tertiles in the rate of cognitive change over time. No association was found between RBC DHA + EPA levels and age-associated cognitive decline in a cohort of older, dementia-free women. Amman EM, Pottala JV, Harris WS, et al. Omega-3 fatty acids and domain-specific cognitive aging: secondary analysis of data from WHISCA. Neurology 2013 (EPub). PMID24068783.

Section 12.

Appendix

Appendix 1
WHIMS-ECHO and WHIMS-Y Study Measures

Study Measures

Hearing. Only women who can hear adequately over the phone are administered the measures. To determine this, we ask each woman standard questions (e.g., Do you usually have trouble hearing when one person speaks to you?) and administer a brief hearing screening test requiring participants to repeat a simple phrase. Women who report no or minimal hearing difficulty and who repeat the phrase correctly will be administered the cognitive measures.

Telephone Interview for Cognitive Status-modified [6] measures **global cognitive functioning** and is modeled after the Mini Mental State Exam (MMSE) [3,4,5,6]. The *TICS-m* is a 14-item test (range of scores 0 to 50) with items assessing participant's name (2 points), telephone number (2 points), date (5 points), counting backwards (2 points), word list recall (10 points), subtraction (5 points), responsive naming (4 points), repetition (2 points), President's name (2 points), Vice President's name (2 points), finger tapping (2 points), word opposites (2 points) and delayed word list recall (10 points). It has been previously validated for administration to older adults [5,6,15,16,17] and has been used in large-scale epidemiological studies of dementia [22] as well as clinical trials assessing MCI [19]. The TICS-m correlates highly with the MMSE (r=0.86), the Clinical Dementia Rating scale (r=-0.75), and with neurocognitive tests administered face-to-face [20,21,22]. The TICS-m has excellent sensitivity (0.87) and specificity (0.89) for differentiating older persons with dementia from normal controls. It is sensitive to racial and ethnic differences [23], is inversely correlated with age [7], has good sensitivity and specificity for detecting amnestic MCI [19] and yields normal distributions in population studies [7]. The TICS-m will be used in lieu of the 3MSE [24], the cognitive screening tool in the original WHIMS protocol. The TICS-m and the 3MSE are highly correlated (0.89) [20]. For women who score ≤ 30 on the TICS-m, a telephone interview is conducted with a previously identified friend or family member (proxy) during which the Dementia Questionnaire (described below) is administered.

East Boston Memory Test (EBMT) measures **verbal memory** [8]. Participants are read a short paragraph consisting of 12 distinct elements and immediately asked to recall as many elements as possible (immediate recall) and again 15 minutes later (delayed recall).

Verbal Fluency-Animals (VF-A) measures **verbal fluency and executive function** [10]. This task requires participants to spontaneously name as many animals as possible during one minute. The total number of unique words yields the score. The VF-A test is included in the CERAD battery, which was administered to participants in the original WHIMS protocol.

Digit Span Test (DST) measures **working memory** [11]. This task requires the participant to repeat sequentially a series of single digit numbers of increasing length presented orally, first as presented (Digits Forward) and subsequently in reverse order (Digits Backwards). The score is the longest span of digits recalled. The sum of Digits Forward and Digits Backward (DST-Total) is used.

Oral Trail Making Test (OTMT) [9] measures **attention** (Part A) and **executive function** (Part B) and visual motor skillfulness. The respondent is asked to count from 1 to 25 as quickly as possible (Part A) and recite sequentially and in alternating manner numbers from 1 to 13 and letters from A to L (i.e., 1-A-2-B..). The time it takes (sec) to complete each task is the score.

California Verbal Learning Test (CVLT) [30] measures **verbal learning** and **verbal memory**. It consists of 5 learning trials of the same 16-item word list with immediate recall of as many words as possible after each trial (Immediate Recall) plus a single learning trial of a different 16 item list with recall (Interference Trial) and both uncued recall (Free Recall) and cued recall (Cued Recall) of the first list approximately 20

minutes after the learning trials (Delayed Recall). The CVLT was modified in WHISCA by using only 3 learning trials instead of 5 to reduce administration time and participant burden [2]. Our analyses of WHISCA data supported that decision by revealing that total score of the 3 learning trials was the most sensitive CVLT parameter to the effects of CEE+MPA [3]. For these reasons and to be consistent with WHISCA, *we propose to administer the same 3 learning trials with immediate recall in ECHO and WHIMS-Y in addition to the assessments currently in use in WHIMS-ECHO/ Y*. Another change we are proposing is to omit the second list learning task and the short-and delayed recall tasks to reduce the risk of proactive interference between the TICS-m word list learning and delayed recall tasks and the CVLT. To further reduce interference between measures, we propose to administer the 3 CVLT learning and immediate recall trials at the end of the battery. After the study is underway, we will compare the CVLT scores and trends from WHISCA to the trends in ECHO and WHIMS-Y to help determine whether there is significant interference. With these two modifications to the current WHIMS-ECHO/Y protocols, we (1) include a well-validated and widely used learning and memory task in the battery, (2) reduce participant burden, (3) match the measure to the one we used in WHISCA and (3) reduce the proactive interference between the two similar tasks.

The TICS-m, EBMT, VF-A, and DST were previously used within the Nurses' Health Study [16]. Grodstein et al. reported a correlation of 0.70 (p=0.0001) between two administrations of the TICS-m (one month apart) and inter-rater reliability of 0.95. They also compared an overall composite score from the telephone-administered battery (mean of all tests after standardization to z-score) with a separate battery of 21 tests administered face-to-face to 61 women and reported a correlation of 0.81. They reported correlations between scores from the telephone-administered battery and major risk factors for cognitive impairment derived from their study as similar to other studies using face-to-face testing. Last, the overall composite score demonstrated sensitivity to change [16,17].

Dementia Questionnaire (DQ). The DQ [14] is a structured interview designed for a knowledgeable proxy to provide information needed to make a dementia diagnosis and to identify causes of cognitive impairment. It covers six domains: memory and cognition, verbal expression, daily functioning, recognition of problems/insight, other medical and psychiatric problems, and medical contacts. Proxies estimate dates of symptom onset. The DQ has been validated against the 'gold standard' of a clinical evaluation with sensitivities and specificities >90% and inter-rater (face to face vs. phone) agreement of >94% [14,25,26]. The WHIMS Supplemental Case Ascertainment Protocol (SCAP) currently uses the DQ to help classify women as normal, MCI and PD posthumously or among participants who have terminated full follow-up.

The TICS-m with the DQ have been previously validated for identifying dementia cases in community samples [14,18,26] with sensitivity of 83%, specificity of 100%, and agreement with face-to-face clinical evaluation of 89% [21].

Additional Moderating Variables

All participants in WHIMS-ECHO receive additional measures related to accurately assessing underlying factors associated with cognitive performance. Both depressed mood and sleep problems can influence cognitive functioning and these variables are assessed as covariates in WHIMS-ECHO. **Depression** is measured with the 15-item (Y/N) Geriatric Depression Scale-Short Form (GDS-SF) [12,13], which can be administered orally, has excellent demonstrated psychometric properties, and has excellent normative data available [27,28]. The GDS-SF was used in the original WHIMS protocol. **Sleep disturbance** is related to cognitive function, aging and co-morbidities associated with aging, and hormonal variations. It is assessed with the WHI Insomnia Rating Scale (WHIIRS). This 5-item self-report instrument has excellent reliability and construct validity, and is sensitive to change over time [29].

References

1. Rapp SR, Legault C, Espeland MA, Resnick SM, Hogan PE, Coker LH, Dailey M, Shumaker SA. Validation of a cognitive assessment battery administered over the telephone. JAGS 2012;60(9):1616-23.

2. Resnick SM, Coker LH, Maki PM, Rapp SR, Espeland MA, Shumaker SA. 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. Clin Trials 2004;1(5):440-50. PMID: 16279282.

3. Resnick SM, Maki PM, Rapp SR, Espeland MA, Brunner R, Coker LH, Granek IA, Hogan P, Ockene JK, Shumaker SA, Women's Health Initiative Study of Cognitive Aging Investigators. Effects of combination estrogen plus progestin hormone treatment on cognition and affect. J Clin Endocrinol Metab. 2006;91(5):1802-10. PMID:16522699.

4. Folstein MF, Folstein SE, McHugh PR. 'Mini Mental State': a practical method for grading the cognitive state of patients for the clinician. J Psychiatry 1975;12:189-98.

5. Brandt J, Spencer M, Folstein M. The Telephone Interview for Cognitive Status. Neuropsychiatr Neuropsychol Behav Neurol 1988;1(2):111-7.

6. Welsh KA, Breitner J, Magruder-Habib KM. Detection of dementia in the elderly using the telephone interview for cognitive status. Neuropsychiatry Neuropsychol Behav Neurol 1993;6:103-10.

7. De Jager CA, Hogervorst E, Combrinck M, Budge MM. Sensitivity and specificity of neuropsychological tests for mild cognitive impairment, vascular cognitive impairment and Alzheimer's disease. Psychol Med 2003;33(6):1039-50.

8. Albert M, Smith LA, Scherr PA, Taylor JO, Evans DA, Funkenstein HH. Use of brief cognitive tests to identify individuals in the community with clinically diagnosed Alzheimer's disease. Int J Neurosci 1991;57(3-4):167-78.

9. Abraham E, Axelrod BN, Ricker JH. Application of the Oral Trail Making Test to a mixed clinical sample. Arch Clin Neuropsych 1996;11:697-701.

10. Benton AL, Hamsher K. Multilingual Aphasia Examination. Iowa City, IA: Univ of Iowa Press; 1976.

11. Wechsler D. The Wechsler Memory Scale-3rd Edition (WMS-III). 1996. Psychological Corporation, Harcourt, Inc. Ref Type: Generic.

12. Yesavage JA. Geriatric Depression Scale. Psychopharm Bull 1988;24:709-11.

13. Burke WJ, Roccaforte WH, Wengel SP. The short form of the Geriatric Depression Scale: a comparison with the 30-item form. J Geriatr Psychiatry Neurol 1991;4(3):173-8.

14. Kawas C, Segal J, Stewart WF, Corrada M, Thal LJ. A validation study of the Dementia Questionnaire. Arch Neurol 1994;51(9):901-6.

15. Plassman B, Newman TT, Welsh KA, Helms MJ, Breitner J. Properties of the telephone interview for cognitive status. Neuropsychiatry Neuropsychol Behav Neurol 1994;7:235-41.

16. Grodstein F, Chen J, Pollen DA, Albert MS, Wilson RS, Folstein MF, Evans DA, Stampfer MJ. Postmenopausal hormone therapy and cognitive function in healthy older women. J Am Geriatr Soc 2000;48(7):746-52.

17. Grodstein F, Chen J, Wilson RS, Manson JE. Type 2 diabetes and cognitive function in community-dwelling elderly women. Diab Care 2001;24(6):1060-5.

18. Khachaturian AS, Gallo JJ, Breitner JC. Performance characteristics of a two-stage dementia screen in a population sample. J Clin Epidemiol 2000;53(5):531-40.

19. Lines CR, McCarroll KA, Lipton RB, Block GA. Telephone screening for amnestic mild cognitive impairment. Neurology 2003;60(2):261-6.

20. Rankin MW, Clemons TE, McBee WL. Correlation analysis of the in-clinic and telephone batteries from the AREDS cognitive function ancillary study. AREDS Report No. 15. Ophthalmic Epidemiol 2005;12(4):271-7.

21. Crooks VC, Clark L, Petitti DB, Chui H, Chiu V. Validation of multi-stage telephone-based dentification of cognitive impairment and dementia. BMC Neurol 2005;5(1):8.

22. Gallo JJ, Breitner JC. Alzheimer's disease in the NAS-NRC Registry of aging twin veterans, IV. Performance characteristics of a two-stage telephone screening procedure for Alzheimer's dementia. Psychol Med 1995;25(6):1211-9.

23. Sloan FA, Wang J. Disparities among older adults in measures of cognitive function by race or ethnicity. J Gerontol B Psychol Sci Soc Sci 2005;60(5):242-50.

24. Teng EL, Chui HC. The Modified Mini-Mental State (3MS) examination. J Clin Psychiatry 1987;48(8):314-8.

25. Ellis RJ, Jan K, Kawas C, Koller WC, Lyons KE, Jeste DV, Hansen LA, Thal LJ. Diagnostic validity of the dementia questionnaire for Alzheimer disease. Arch Neurol 1998;55(3):360-5.

26. Fritsch T, Smyth KA, McClendon MJ, Ogrocki PK, Santillan C, Larsen JD, Strauss ME. Associations between dementia/mild cognitive impairment and cognitive performance and activity levels in youth. J Am Geriatr Soc 2005;53(7):1191-6.

27. Osborn DP, Fletcher AE, Smeeth L, Stirling S, Nunes M, Breeze E, Siu-Woon NE, Bulpitt CJ, Jones D, Tulloch A, Siu-Woon E. Geriatric Depression Scale Scores in a representative sample of 14 545 people aged 75 and over in the United Kingdom: results from the MRC Trial of Assessment and Management of Older People in the Community. Int J Geriatr Psychiatry 2002;17(4):375-82.

28. De Craen AJ, Heeren TJ, Gussekloo J. Accuracy of the 15-item geriatric depression scale (GDS-15) in a community sample of the oldest old. Int J Geriatr Psychiatry 2003;18(1):63-6.

29. Levine DW, Kripke DF, Kaplan RM, Lewis MA, Naughton MJ, Bowen DJ, Shumaker SA. Reliability and validity of the Women's Health Initiative Insomnia Rating Scale. Psychol Assess 2003;15(2):137-48.

30. Delis DC, Kramer JH, Kaplan E. Reliability and validity of the Delis-Kaplan executive function system. J Int Neuropsychol Soc. 2004;10(2):301-3. PMID: 15012851.