Women's Health Initiative

2014 Annual Progress Report

Data as of: August 29 2014

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

2014 Annual Progress Report

Data as of: August 29, 2014

Prepared by
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Fred Hutchinson Cancer Research Center

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1. Overview

1.0 Background

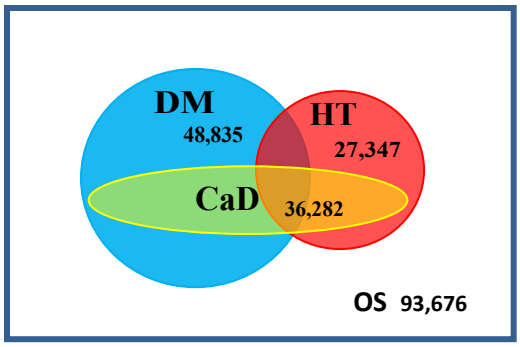


Figure 1: Original design of the WHI partial factorial trial and observational study of 161,808 postmenopausal women.

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=93,567).

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.

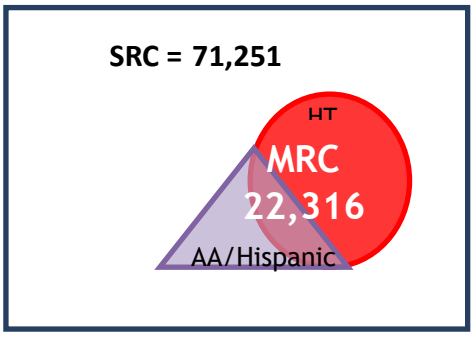


Figure 2: 2010-2015 Extension Study design reflecting differing levels of outcomes ascertainment: Medical Records Cohort (MRC) and the Self-Report Cohort (SRC).

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 August 2014, 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 and 3 had only slight reductions in response rates, with an overall response rate of 96.3% and 95.0%, respectively. Though not yet complete, year 4 response has been similarly high, with an overall response rate of 94.4% including phone follow-up. Year 4 mailings to participants also included a supplementary form (Form 156) with questions addressing health and safety issues of pronounced importance among older women. In the coming year, we have begun to include an additional supplemental form (Form 157) with questions addressing important health and emotional wellness issues for aging women.

For the designated WHI outcomes, clinical event rates using the fully adjudicated outcomes through August 2014 are presented by original study component, age and race (Sections 2-6). Using the new study components and extending those criteria back in time, we present data for the MRC and SRC, and women who would have been in those groups had they participated in the 2010-2015 Extension Study to comprise the MRC Supercohort and SRC Supercohort. Fully adjudicated events available through August 2014 are provided for the MRC Supercohort (Table 7.2 and 7.3). For the SRC Supercohort, fully adjudicated events are provided for the interval from enrollment to September 2010 or August 2014 as appropriate (Table 7.4 and 7.5). Self-reported events are shown in Tables 7.10 and 7.11, and cancers, self-reported fractures, and causes of death are presented in Tables 7.12-7.14.

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. In the last year, 2 papers were published comparing the agreement rates between WHI outcomes and outcomes based on Medicare billing data for both CHD and PAD (Mark Hlatky, et al, *Circ Cardiovasc Qual Outcomes*, 2014 and Matthew Well, et al, *J Vasc Surg*, 2014). The authors showed that agreement is good for cardiovascular outcomes, and that Medicare data may be a potentially strong adjunct to our rigorous primary data collection.

We continue efforts to centrally adjudicate suspected cases of heart failure for all women who participated in the HT and all African-American and Hispanic women (MRC Supercohort) from the beginning of the study through the current Extension. All reports of suspected heart failure are sent for verification, which includes multiple heart failure events for many participants. The review, conducted at University of North Carolina, confirmed 58.0% of reviewed events as possible or definite decompensated heart failure (Table 9.1), which agreed with 73.9% of the WHI events that had been previously adjudicated as heart failure (Table 9.2). UNC has additionally been able to further classify the type of heart failure into scientifically important subtypes (Table 9.3).

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).

We also provide a brief summary of the updated medication inventory data in Section 11. That form was included in the year 3 mailings to MRC participants. Among that group, salicylates have replaced multivitamins as the most commonly used medication. There has been increased reporting of vitamin D (34.7%, up from 22.6% in 2012) and reduced reporting of bisphosphonates (7.5%, down from 15.7% in 2012).

The WHI Long Life Study (LLS), which consisted of an in-person visit with 7,875 of the oldest women in the MRC (details in Section 12), was completed last year, and now post-LLS blood draw outcomes are beginning to be available for analyses. The CCC contracted with a nationwide organization, 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.

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), as well as both verified and self-reported outcomes (Tables 12.6-12.8) stratified by age at randomization and race. So far, 116 LLS participants have had verified cardiovascular outcomes and 89 have had a verified cancer after the LLS blood draw. The most frequent self-reported outcomes after the draw so far are: macular degeneration (N=268), osteoarthritis (N=213), and Alzheimer's disease (N=202).

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 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). The WHI Ancillary Studies Committee has reviewed over 500 ancillary study proposals, including approving 36 studies in the past year (Table 15.4). Twenty-nine percent of participants in Extension Study 2 have participated in ancillary studies, with most of those women participating in 1-2 ancillary studies (Table 15.6).

There have been 1,951 approved manuscript proposals and 953 are published or in press (Table 16.1), 115 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 such as *Circulation*, *JAMA*, *Annals of Internal Medicine*, 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. Two papers

showcased the continuing importance of examining the effects of the WHI Trial; authors presented both the continuing long-term effects of the hormone therapy interventions (JoAnn Manson, et al, *JAMA*, 2013), and the estimated $37 billion in economic savings due to significantly reduced use of hormone therapies (Josh Roth, et al, *Ann Int Med*, 2014).

The cohort continues to serve as the critical backbone for ancillary studies large and small. The Mars Company recently agreed to fund a randomized clinical trial to study the effect of cocoa flavanol and multivitamin pills on cardiovascular and cancer outcomes. The COcoa Supplement and Multivitamin Outcomes Study (COSMOS) trial (PI: JoAnn Manson) will begin in January 2015. In addition to the trial, 10 ancillary studies to the trial have been submitted for funding. The WHI Cancer Survivor Cohort (PIs: Garnet Anderson, Bette Caan, Electra Paskett) is currently expanding 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. A large pragmatic trial of physical activity, WHI – Strong and Healthy (WHISH, PIs: Marcia Stefanick, Andrea LaCroix, Charles Kooperberg) was scored well, and we are waiting for news from NHLBI regarding whether the trial will be funded. The study will recruit WHI participants to a randomized controlled trial involving a community-based exercise intervention to assess the effect on reducing cardiovascular outcomes.

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 cardiovascular disease, aging, bone health, cancer, 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 Principal Investigators

Principal Investigator	Institution	Location
Shirley Beresford, PhD	Fred Hutchinson Cancer Research Center	Seattle, WA
Robert Brunner, PhD	University of Nevada	Reno, NV
Robert Brzyski, MD	University of Texas	San Antonio, TX
Bette Caan, PhD	Kaiser Foundation Research Institute	Oakland, CA
Rowan Chlebowski, MD, PhD	University of California, Los Angeles	Torrance, CA
J. David Curb, MD	University of Hawaii	Honolulu, HI
Charles Eaton, MD	Memorial Hospital of Rhode Island	Pawtucket, RI
Gerardo Heiss, MD MPH	University of North Carolina, Chapel Hill	Chapel Hill, NC
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 UCSD/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
Ross Prentice, PhD	Fred Hutchinson Cancer Research Center	Seattle, WA
Haleh Sangi-Haghpeykar, PhD	Baylor College of Medicine	Houston, TX

Table 1.1 (continued)
WHI Centers and Principal Investigators

Former Principal Investigators

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: August 29, 2014

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	15584	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	5693	81.3
E-alone	3778	3479	2834	81.5
Placebo	3867	3526	2859	81.1
Dietary Modification	37858	35594	30690	86.2
Intervention	14769	13922	12014	86.3
Comparison	23089	21672	18676	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	41499	85.2
Observational Study	63231	59009	52068	88.2
Total	115407	107706	93567	86.9

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

Table 1.3
Consent Status by Age at Enrollment and Race/Ethnicity

Data as of: August 29, 2014

	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	41499	85.2	63231	59009	52068	88.2
Age								
50-54	7237	7068	6249	88.4	8996	8802	8225	93.4
55-59	11724	11329	10055	88.8	12732	12400	11481	92.6
60-69	24528	22940	19642	85.6	28582	26820	23716	88.4
70-79	8687	7360	5553	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	35363	86.9	55767	51969	46296	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: August 29, 2014

	Enrolled in Extension 2005-2010	Eligible for Extension 2010-2015[2]	Consented	
			N	%
Total	115407	107706	93567	86.9
Age on 8/29/2014				
<80	51571	50045	45335	90.6
≥80	63836	57661	48232	83.6
80-84	26615	25049	21996	87.8
85-89	22869	20754	17347	83.6
90-94	11860	10040	7622	75.9
95-101	2492	1818	1267	69.7
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	81659	88.1
Unknown	1419	1336	1102	82.5
Medical Record Cohort	29368	27221	22316	82.0
Age on 8/29/2014				
<80	13819	13280	11282	85.0
≥80	15549	13941	11034	79.1
80-84	6645	6213	5166	83.1
85-89	5489	4928	3898	79.1
90-94	2801	2359	1695	71.9
95-101	614	441	275	62.4
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	13204	85.0
Unknown	264	248	200	80.6
Self Report Cohort	86039	80485	71251	88.5
Age on 8/29/2014				
<80	37752	36765	34053	92.6
≥80	48287	43720	37198	85.1
80-84	19970	18836	16830	89.4
85-89	17380	15826	13449	85.0
90-94	9059	7681	5927	77.2
95-100	1878	1377	992	72.0
Race/Ethnicity				
American Indian	323	303	254	83.8
Asian/Pacific Islander	2033	1946	1640	84.3
White	82528	77148	68455	88.7
Unknown	1155	1088	902	82.9

[1] Medical Record Cohort (MRC) defined as Extension Study 2010-2015 participants randomized to the hormone trial, or race/ethnicity is Black or Hispanic; the Self Report Cohort are those Extension Study 2010-2015 participants 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: August 29, 2014

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	597	87.9	332	286	86.1	615	547	88.9	886	774	87.4	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	1520	87.5
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: August 29, 2014

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	1403	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	1677	88.1
Stonybrook	753	656	87.1	373	310	83.1	482	423	87.8	1016	873	85.9	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	30690	86.2	18794	15584	82.9	27975	24231	86.6	48697	41499	85.2	59009	52068	88.2

Table 1.6
Extension 2010-2015 Consent Summary by Regional Center

Data as of: August 29, 2014

	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	1690	82.2	3014	2593	86.0	5356	4550	85.0	6563	5844	89.0
Seattle	1775	1606	90.5	815	713	87.5	1318	1195	90.7	2397	2146	89.5	2721	2406	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	1428	88.5	808	691	85.5	1298	1144	88.1	2160	1887	87.4	2608	2315	88.8
Stanford	6060	5365	88.5	2913	2513	86.3	4759	4204	88.3	8089	7118	88.0	9892	8831	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	30690	86.2	18794	15584	82.9	27975	24231	86.6	48697	41499	85.2	59009	52068	88.2

Table 1.7
Response Rates to CCC Annual Mailings
Extension Study 2010-2015, Follow-up Years 1, 2, 3 and 4

Data as of: August 29, 2014

	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	87098	70464	80.9%	87098	14262	16.4%	5410	37.9%	88.1%
	151	87110	69663	80.0%	87110	15118	17.4%	5942	39.3%	87.8%
	153	20350	14664	72.1%	20350	4593	22.6%	1510	32.9%	81.0%
HT	33	14273	10722	75.1%	14273	2984	20.9%	1002	33.6%	83.5%
	151	14274	10619	74.4%	14274	3106	21.8%	1064	34.3%	83.2%
	153	14275	10687	74.9%	14275	2923	20.5%	985	33.7%	83.1%
DM	33	28622	22965	80.2%	28622	4758	16.6%	1783	37.5%	87.6%
	151	28628	22714	79.3%	28628	5048	17.6%	1943	38.5%	87.3%
	153	6869	4811	70.0%	6869	1654	24.1%	554	33.5%	79.8%
CaD	33	22617	18038	79.8%	22617	3925	17.4%	1441	36.7%	87.3%
	151	22618	17863	79.0%	22618	4118	18.2%	1566	38.0%	87.1%
	153	10571	7903	74.8%	10571	2198	20.8%	739	33.6%	83.2%
OS	33	48590	40033	82.4%	48590	7460	15.4%	2957	39.6%	89.4%
	151	48596	39557	81.4%	48596	7946	16.4%	3281	41.3%	89.0%
	153	3594	2405	66.9%	3594	954	26.5%	300	31.5%	77.0%

[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 1.7 (continued)
Response Rates to CCC Annual Mailings
Extension Study 2010-2015, Follow-up Years 1, 2, 3 and 4

Data as of: August 29, 2014

	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 4										
Total	33	65917	53261	80.8%	53829	9383	17.4%	3406	36.3%	87.4%
	151	65913	52925	80.3%	53825	9697	18.0%	3574	36.9%	87.1%
	156	65922	53322	80.9%	53834	9455	17.6%	3615	38.2%	87.7%
HT	33	10728	8359	77.9%	9128	1730	19.0%	597	34.5%	85.1%
	151	10728	8288	77.3%	9128	1792	19.6%	633	35.3%	84.8%
	156	10729	8366	78.0%	9129	1741	19.1%	636	36.5%	85.5%
DM	33	21636	17241	79.7%	18237	3324	18.2%	1218	36.6%	87.0%
	151	21636	17139	79.2%	18237	3421	18.8%	1260	36.8%	86.7%
	156	21640	17272	79.8%	18241	3336	18.3%	1267	38.0%	87.2%
CaD	33	17005	13607	80.0%	14353	2563	17.9%	943	36.8%	87.3%
	151	17005	13509	79.4%	14353	2653	18.5%	991	37.4%	87.0%
	156	17007	13621	80.1%	14355	2578	18.0%	984	38.2%	87.5%
OS	33	36847	30194	81.9%	29274	4879	16.7%	1787	36.6%	88.1%
	151	36843	30015	81.5%	29270	5049	17.3%	1880	37.2%	88.0%
	156	36848	30221	82.0%	29275	4928	16.8%	1920	39.0%	88.5%

[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); Form 156 = Supplemental Questionnaire.
[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, 3 and 4

Data as of: August 29, 2014

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%	97.0%
	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	11647	9064	77.8%	95.0%
	151	12466	6073	48.7%	91.4%
	153	3845	765	19.9%	84.7%
HT	33	2597	2237	86.1%	94.5%
	151	2802	1405	50.1%	88.7%
	153	2399	461	19.2%	86.3%
DM	33	4029	3217	79.9%	95.2%
	151	4313	2187	50.7%	91.4%
	153	1382	292	21.1%	84.0%
CaD	33	3209	2628	81.9%	95.4%
	151	3424	1751	51.1%	91.4%
	153	1772	334	18.9%	86.3%
OS	33	5853	4311	73.7%	95.0%
	151	6245	2925	46.8%	91.9%
	153	822	159	19.3%	81.4%

[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 (continued)
Response Rates to Regional Center Follow-up and Cumulative Response
Extension Study 2010-2015 Follow-up Years 1, 2, 3 and 4

Data as of: August 29, 2014

Study	Form[1,2]	Eligible for RC Follow-up	Respondents		Total Estimated Response Rate
Year 4					
Total	33	921	682	74.1%	94.4%
	151	976	436	44.7%	90.5%
	156	1007	35	3.5%	85.0%
HT	33	204	178	87.3%	94.5%
	151	215	112	52.1%	89.2%
	156	228	9	4.0%	81.4%
DM	33	353	257	72.8%	94.3%
	151	370	165	44.6%	90.3%
	156	385	13	3.4%	84.5%
CaD	33	282	218	77.3%	94.5%
	151	292	133	45.6%	90.2%
	156	311	9	2.9%	83.9%
OS	33	438	311	71.0%	94.5%
	151	469	200	42.7%	90.9%
	156	476	16	3.4%	86.1%

[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); Form 156 = Supplemental Questionnaire.
[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: August 29, 2014

	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: August 29, 2014

	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: August 29, 2014

	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	87098	70464	80.9%	87098	14262	16.4%	5410	37.9%	88.1%
	151	87110	69663	80.0%	87110	15118	17.4%	5942	39.3%	87.8%
	153	20350	14664	72.1%	20350	4593	22.6%	1510	32.9%	81.0%
Medical Record	33	20348	14726	72.4%	20348	4675	23.0%	1528	32.7%	81.5%
Cohort	151	20348	14570	71.6%	20348	4867	23.9%	1627	33.4%	81.2%
	153	20350	14664	72.1%	20350	4593	22.6%	1510	32.9%	81.0%
Self Report	33	66750	55738	83.5%	66750	9587	14.4%	3882	40.5%	90.2%
Cohort	151	66762	55093	82.5%	66762	10251	15.4%	4315	42.1%	89.8%
Regional Center										
Boston	33	9293	7548	81.2%	9293	1491	16.0%	585	39.2%	88.2%
	151	9293	7481	80.5%	9293	1570	16.9%	637	40.6%	88.0%
	153	1488	1123	75.5%	1488	307	20.6%	101	32.9%	83.0%
Buffalo	33	9428	7634	81.0%	9428	1660	17.6%	633	38.1%	89.0%
	151	9430	7543	80.0%	9430	1757	18.6%	682	38.8%	88.5%
	153	2239	1566	69.9%	2239	578	25.8%	194	33.6%	80.8%
Columbus	33	10267	8330	81.1%	10267	1629	15.9%	612	37.6%	88.0%
	151	10269	8237	80.2%	10269	1730	16.9%	668	38.6%	87.6%
	153	2380	1739	73.1%	2380	486	20.4%	129	26.5%	79.3%
Gainesville	33	7848	6081	77.5%	7848	1592	20.3%	539	33.9%	86.1%
	151	7847	5993	76.4%	7847	1697	21.6%	598	35.2%	85.7%
	153	2234	1497	67.0%	2234	651	29.1%	194	29.8%	78.3%
Iowa	33	8279	6967	84.2%	8279	1226	14.8%	480	39.2%	91.0%
	151	8280	6886	83.2%	8280	1314	15.9%	546	41.6%	90.9%
	153	1934	1570	81.2%	1934	335	17.3%	118	35.2%	89.0%
Medstar	33	4217	3277	77.7%	4217	780	18.5%	266	34.1%	85.1%
	151	4216	3237	76.8%	4216	823	19.5%	292	35.5%	84.8%
	153	1451	946	65.2%	1451	381	26.3%	127	33.3%	75.1%
Pittsburgh	33	3934	3074	78.1%	3934	687	17.5%	265	38.6%	85.8%
	151	3934	3032	77.1%	3934	727	18.5%	289	39.8%	85.4%
	153	1029	721	70.1%	1029	239	23.2%	81	33.9%	79.1%
Seattle	33	4205	3475	82.6%	4205	552	13.1%	232	42.0%	88.7%
	151	4205	3430	81.6%	4205	596	14.2%	260	43.6%	88.3%
	153	911	695	76.3%	911	168	18.4%	68	40.5%	84.6%
Stanford	33	14996	12487	83.3%	14996	2015	13.4%	853	42.3%	89.8%
	151	15002	12363	82.4%	15002	2134	14.2%	937	43.9%	89.4%
	153	3089	2342	75.8%	3089	546	17.7%	222	40.7%	84.3%
Tucson	33	5735	4559	79.5%	5735	1070	18.7%	381	35.6%	87.4%
	151	5736	4515	78.7%	5736	1124	19.6%	413	36.7%	87.2%
	153	1192	838	70.3%	1192	300	25.2%	89	29.7%	79.5%
Wake Forest	33	8896	7032	79.1%	8896	1560	17.5%	564	36.2%	86.5%
	151	8898	6946	78.1%	8898	1646	18.5%	620	37.7%	86.1%
	153	2403	1627	67.7%	2403	602	25.1%	187	31.1%	77.1%

[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 1.9 (continued for year 4)
Response Rates to CCC Annual Mailings, Extension Study 2010-2015 Year 4 by Cohort and Regional Center

Data as of: August 29, 2014

	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	65917	53261	80.8%	53829	9383	17.4%	3406	36.3%	87.4%
	151	65913	52925	80.3%	53825	9697	18.0%	3574	36.9%	87.1%
	156	65922	53322	80.9%	53834	9455	17.6%	3615	38.2%	87.7%
Medical Record	33	15229	11546	75.8%	12840	2641	20.6%	862	32.6%	83.3%
Cohort	151	15229	11444	75.2%	12840	2731	21.3%	915	33.5%	83.0%
	156	15231	11550	75.8%	12842	2661	20.7%	918	34.5%	83.6%
Self Report	33	50688	41715	82.3%	40989	6742	16.5%	2544	37.7%	88.7%
Cohort	151	50684	41481	81.8%	40985	6966	17.0%	2659	38.2%	88.4%
	156	50691	41772	82.4%	40992	6794	16.6%	2697	39.7%	89.0%
Regional Center										
Boston	33	8055	6459	80.2%	5936	1018	17.2%	375	36.8%	85.4%
	151	8055	6424	79.8%	5936	1051	17.7%	399	38.0%	85.3%
	156	8055	6472	80.4%	5936	1039	17.5%	397	38.2%	85.8%
Buffalo	33	7488	6077	81.2%	5626	1039	18.5%	378	36.4%	88.8%
	151	7488	6044	80.7%	5626	1066	19.0%	398	37.3%	88.6%
	156	7488	6074	81.1%	5626	1037	18.4%	409	39.4%	89.1%
Columbus	33	7117	5817	81.7%	6218	1133	18.2%	403	35.6%	88.3%
	151	7117	5791	81.4%	6218	1156	18.6%	415	35.9%	88.1%
	156	7119	5817	81.7%	6220	1134	18.2%	433	38.2%	88.6%
Gainesville	33	6404	5025	78.5%	4862	982	20.2%	308	31.4%	85.6%
	151	6403	4997	78.0%	4861	1028	21.2%	327	31.8%	85.4%
	156	6405	5040	78.7%	4863	1009	20.8%	327	32.4%	85.9%
Iowa	33	5941	4990	84.0%	5276	758	14.4%	340	44.9%	90.5%
	151	5941	4951	83.3%	5276	795	15.1%	361	45.4%	90.2%
	156	5942	4995	84.1%	5277	767	14.5%	362	47.2%	90.9%
Medstar	33	3397	2676	78.8%	2571	459	17.9%	158	34.4%	85.0%
	151	3397	2654	78.1%	2571	483	18.8%	170	35.2%	84.8%
	156	3397	2688	79.1%	2571	455	17.7%	159	35.0%	85.3%
Pittsburgh	33	2908	2293	78.9%	2577	509	19.8%	190	37.3%	86.7%
	151	2908	2275	78.2%	2577	527	20.5%	200	38.0%	86.4%
	156	2908	2294	78.9%	2577	505	19.6%	197	39.0%	86.8%
Seattle	33	3031	2440	80.5%	2677	518	19.4%	179	34.6%	87.2%
	151	3030	2422	79.9%	2676	529	19.8%	184	34.8%	86.7%
	156	3031	2450	80.8%	2677	515	19.2%	182	35.3%	87.6%
Stanford	33	10294	8558	83.1%	8943	1291	14.4%	511	39.6%	89.2%
	151	10293	8509	82.7%	8942	1327	14.8%	525	39.6%	88.9%
	156	10294	8565	83.2%	8943	1295	14.5%	537	41.5%	89.4%
Tucson	33	4098	3243	79.1%	3545	672	19.0%	244	36.3%	86.7%
	151	4097	3222	78.6%	3544	690	19.5%	253	36.7%	86.3%
	156	4099	3245	79.2%	3546	686	19.4%	264	38.5%	87.1%
Wake Forest	33	7184	5683	79.1%	5598	1004	17.9%	320	31.9%	84.9%
	151	7184	5636	78.5%	5598	1045	18.7%	342	32.7%	84.5%
	156	7184	5682	79.1%	5598	1013	18.1%	348	34.4%	85.3%

[1] Form 33 = Medical History Update; Form 151 = Activities of Daily Living; Form 153 = Medication and Supplement Inventory; Form 156 = Supplemental Questionnaire.
[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: August 29, 2014

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%	96.3%
	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: August 29, 2014

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: August 29, 2014

Cohort	Form[1,2]	Eligible for RC Follow-up	Respondents		Total Estimated Response Rate
Total	33	11647	9064	77.8%	95.0%
	151	12466	6073	48.7%	91.4%
	153	3845	765	19.9%	84.7%
Medical Record Cohort	33	4186	3579	85.5%	93.7%
	151	4505	2288	50.8%	87.4%
	153	3845	765	19.9%	84.7%
Self Report Cohort	33	7461	5485	73.5%	95.4%
	151	7961	3785	47.5%	92.6%
Regional Center					
Boston	33	1418	966	68.1%	93.6%
	151	1507	736	48.8%	91.1%
	153	251	36	14.3%	85.4%
Buffalo	33	1151	1306	113.5%	97.2%
	151	1272	1057	83.1%	94.2%
	153	429	74	17.3%	84.1%
Columbus	33	1257	1057	84.1%	96.4%
	151	1336	629	47.1%	91.9%
	153	489	104	21.3%	83.7%
Gainesville	33	1132	760	67.1%	91.8%
	151	1218	375	30.8%	86.7%
	153	483	61	12.6%	81.0%
Iowa	33	849	618	72.8%	96.0%
	151	903	465	51.5%	94.0%
	153	211	21	10.0%	90.1%
Medstar	33	705	638	90.5%	94.7%
	151	787	321	40.8%	87.2%
	153	360	90	25.0%	81.3%
Pittsburgh	33	592	543	91.7%	96.7%
	151	623	449	72.1%	94.0%
	153	215	56	26.1%	84.6%
Seattle	33	503	488	97.0%	96.9%
	151	552	265	48.0%	91.4%
	153	140	36	25.7%	88.6%
Stanford	33	1744	1310	75.1%	96.3%
	151	1833	754	41.1%	92.3%
	153	481	132	27.4%	88.6%
Tucson	33	771	516	66.9%	93.7%
	151	844	292	34.6%	89.6%
	153	245	33	13.5%	82.2%
Wake Forest	33	1525	862	56.5%	91.9%
	151	1591	730	45.9%	90.1%
	153	541	122	22.6%	82.2%

[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 1.10 (continued for year 4)
Response Rates to Regional Center Follow-up and Cumulative Response
Extension Study 2010-2015 Follow-up, Year 4 by Cohort and Regional Center

Data as of: August 29, 2014

Cohort	Form[1]	Eligible for RC Follow-up	Respondents		Total Estimated Response Rate
Total	33	921	682	74.1%	94.4%
	151	976	436	44.7%	90.5%
	156	1007	35	3.5%	85.0%
Medical Record	33	325	269	82.8%	93.5%
Cohort	151	340	163	47.9%	87.4%
	156	357	14	3.9%	79.3%
Self Report	33	596	413	69.3%	94.7%
Cohort	151	636	273	42.9%	91.6%
	156	650	21	3.2%	87.0%
Regional Center					
Boston	33	98	67	68.4%	93.4%
	151	105	55	52.4%	91.0%
	156	109	0	0.0%	83.0%
Buffalo	33	104	104	100.0%	95.9%
	151	110	87	79.1%	93.6%
	156	123	33	26.8%	87.1%
Columbus	33	101	83	82.2%	96.0%
	151	105	40	38.1%	90.5%
	156	105	0	0.0%	86.0%
Gainesville	33	80	60	75.0%	92.5%
	151	85	20	23.5%	85.6%
	156	92	0	0.0%	82.3%
Iowa	33	67	59	88.1%	97.4%
	151	72	45	62.5%	95.5%
	156	74	0	0.0%	90.1%
Medstar	33	47	45	95.7%	96.0%
	151	52	15	28.9%	85.5%
	156	56	0	0.0%	80.5%
Pittsburgh	33	54	38	70.4%	93.0%
	151	57	31	54.4%	90.4%
	156	62	0	0.0%	81.7%
Seattle	33	30	33	110.0%	98.5%
	151	37	11	29.7%	89.1%
	156	36	0	0.0%	86.5%
Stanford	33	139	105	75.5%	96.3%
	151	144	64	44.4%	92.2%
	156	143	0	0.0%	86.5%
Tucson	33	63	31	49.2%	91.0%
	151	67	22	32.8%	88.8%
	156	67	0	0.0%	85.1%
Wake Forest	33	138	57	41.3%	88.2%
	151	142	46	32.4%	86.2%
	156	140	2	1.4%	80.7%

[1] Form 33 = Medical History Update; Form 151 = Activities of Daily Living; Form 156 = Supplemental Questionnaire.

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

Data as of: August 29, 2014
WHI Extension Study 2010-2015 Participants

	Without Uterus (N = 5,693)		With Uterus (N =9,891)		HT Participants (N =15,584)	
	N	%	N	%	N	%
Vital Status/Participation						
Deceased	487	8.6	743	7.5	1230	7.9
Alive: Current Participation[1]	4863	85.4	8658	87.5	13521	86.8
Alive: Recent Participation[2]	140	2.5	220	2.2	360	2.3
Alive: Past/Unknown Participation[3]	6	0.1	12	0.1	18	0.1
Stopped Follow-Up[4]	110	1.9	147	1.5	257	1.6
Lost to Follow-Up[5]	87	1.5	111	1.1	198	1.3

Data as of: August 29, 2014; 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: August 29, 2014; 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 at Enrollment for Hormone Therapy

Data as of: August 29, 2014; Events through August 29, 2014

Outcomes	Total	Age at Enrollment 50-54	55-59	60-69	70-79
Number randomized	27347	3420	5413	12360	6154
Mean follow-up (months)	165.2	177.1	174.7	166.5	147.5
Cardiovascular					
CHD[1]	2023 (0.54%)	102 (0.20%)	226 (0.29%)	936 (0.55%)	759 (1.00%)
CHD death[2]	719 (0.19%)	23 (0.05%)	53 (0.07%)	290 (0.17%)	353 (0.47%)
Total MI[3]	1520 (0.40%)	83 (0.16%)	194 (0.25%)	724 (0.42%)	519 (0.69%)
Clinical MI	1490 (0.40%)	82 (0.16%)	192 (0.24%)	709 (0.41%)	507 (0.67%)
Angina[4]	1086 (0.49%)	52 (0.18%)	139 (0.31%)	526 (0.53%)	369 (0.77%)
CABG/PTCA	1996 (0.53%)	119 (0.24%)	298 (0.38%)	1023 (0.60%)	556 (0.74%)
Carotid artery disease	383 (0.10%)	11 (0.02%)	55 (0.07%)	209 (0.12%)	108 (0.14%)
Congestive heart failure, WHI[4]	806 (0.36%)	41 (0.14%)	75 (0.17%)	333 (0.34%)	357 (0.75%)
Heart failure, UNC[5]	1496 (0.40%)	59 (0.12%)	129 (0.16%)	648 (0.38%)	660 (0.87%)
Stroke	1501 (0.40%)	65 (0.13%)	135 (0.17%)	701 (0.41%)	600 (0.79%)
Non-disabling stroke[6]	804 (0.21%)	48 (0.10%)	94 (0.12%)	371 (0.22%)	291 (0.38%)
Fatal/disabling stroke[6]	629 (0.17%)	14 (0.03%)	33 (0.04%)	295 (0.17%)	287 (0.38%)
Unknown status from stroke[6]	68 (0.02%)	3 (0.01%)	8 (0.01%)	35 (0.02%)	22 (0.03%)
PVD	398 (0.11%)	21 (0.04%)	50 (0.06%)	205 (0.12%)	122 (0.16%)
DVT	782 (0.21%)	53 (0.11%)	119 (0.15%)	378 (0.22%)	232 (0.31%)
Pulmonary embolism	610 (0.16%)	44 (0.09%)	89 (0.11%)	298 (0.17%)	179 (0.24%)
Coronary disease[7]	4373 (1.16%)	239 (0.47%)	542 (0.69%)	2046 (1.19%)	1546 (2.04%)
DVT/PE	1112 (0.30%)	72 (0.14%)	161 (0.20%)	553 (0.32%)	326 (0.43%)
Aortic aneurysm[8]	27 (0.03%)	0 (0.00%)	4 (0.02%)	19 (0.05%)	4 (0.02%)
Atrial fibrillation[8]	581 (0.66%)	31 (0.27%)	78 (0.43%)	324 (0.81%)	148 (0.81%)
Valvular heart disease[8]	141 (0.16%)	8 (0.07%)	11 (0.06%)	88 (0.22%)	34 (0.19%)
Total cardiovascular disease[9]	6667 (1.77%)	379 (0.75%)	832 (1.06%)	3168 (1.85%)	2288 (3.03%)
Cancer					
Breast cancer	1654 (0.44%)	186 (0.37%)	334 (0.42%)	783 (0.46%)	351 (0.46%)
Invasive breast cancer	1355 (0.36%)	142 (0.28%)	275 (0.35%)	631 (0.37%)	307 (0.41%)
Non-invasive breast cancer	322 (0.09%)	45 (0.09%)	63 (0.08%)	165 (0.10%)	49 (0.06%)
Ovarian cancer	142 (0.04%)	11 (0.02%)	29 (0.04%)	74 (0.04%)	28 (0.04%)
Endometrial cancer[10]	204 (0.05%)	29 (0.06%)	47 (0.06%)	89 (0.05%)	39 (0.05%)
Colorectal cancer	552 (0.15%)	40 (0.08%)	73 (0.09%)	275 (0.16%)	164 (0.22%)
Other cancer[11]	2495 (0.66%)	190 (0.38%)	392 (0.50%)	1230 (0.72%)	683 (0.90%)
Total cancer	4738 (1.26%)	432 (0.86%)	832 (1.06%)	2286 (1.33%)	1188 (1.57%)
Fractures					
Hip fracture	967 (0.26%)	22 (0.04%)	66 (0.08%)	399 (0.23%)	480 (0.63%)
Deaths					
Cardiovascular deaths	1481 (0.39%)	47 (0.09%)	96 (0.12%)	585 (0.34%)	753 (1.00%)
Cancer deaths	1651 (0.44%)	97 (0.19%)	222 (0.28%)	810 (0.47%)	522 (0.69%)
Other known cause	1257 (0.33%)	48 (0.10%)	115 (0.15%)	529 (0.31%)	565 (0.75%)
Unknown cause	60 (0.02%)	2 (<0.01%)	7 (0.01%)	26 (0.02%)	25 (0.03%)
Not yet adjudicated	206 (0.05%)	9 (0.02%)	20 (0.03%)	100 (0.06%)	77 (0.10%)
Total death	4655 (1.24%)	203 (0.40%)	460 (0.58%)	2050 (1.20%)	1942 (2.57%)
Death plus post-WHI deaths[12]	5866 (1.42%)	240 (0.43%)	540 (0.62%)	2509 (1.34%)	2577 (3.07%)

[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] Definite or possible decompensated heart failure adjudicated by UNC.
[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, UNC 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: August 29, 2014; Events through August 29, 2014

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)	149.8	150.8	156.1	144.2	168.3	155.7
Cardiovascular						
CHD[1]	8 (0.49%)	25 (0.38%)	184 (0.52%)	49 (0.27%)	1728 (0.56%)	29 (0.58%)
CHD death[2]	4 (0.25%)	9 (0.14%)	84 (0.24%)	14 (0.08%)	601 (0.19%)	7 (0.14%)
Total MI[3]	6 (0.37%)	21 (0.32%)	120 (0.34%)	37 (0.20%)	1311 (0.42%)	25 (0.50%)
Clinical MI	6 (0.37%)	20 (0.30%)	119 (0.33%)	35 (0.19%)	1286 (0.42%)	24 (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 (0.62%)	22 (0.33%)	149 (0.42%)	64 (0.35%)	1722 (0.56%)	29 (0.58%)
Carotid artery disease	1 (0.06%)	2 (0.03%)	15 (0.04%)	4 (0.02%)	358 (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 (0.37%)	17 (0.26%)	149 (0.42%)	35 (0.19%)	1275 (0.41%)	14 (0.28%)
Stroke	9 (0.55%)	17 (0.26%)	172 (0.48%)	31 (0.17%)	1250 (0.40%)	22 (0.44%)
Non-disabling stroke[6]	4 (0.25%)	9 (0.14%)	98 (0.28%)	19 (0.10%)	665 (0.22%)	9 (0.18%)
Fatal/disabling stroke[6]	5 (0.31%)	8 (0.12%)	63 (0.18%)	8 (0.04%)	535 (0.17%)	10 (0.20%)
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 (0.18%)	6 (0.09%)	44 (0.12%)	5 (0.03%)	338 (0.11%)	2 (0.04%)
DVT	4 (0.25%)	4 (0.06%)	81 (0.23%)	11 (0.06%)	678 (0.22%)	4 (0.08%)
Pulmonary embolism	4 (0.25%)	2 (0.03%)	72 (0.20%)	6 (0.03%)	518 (0.17%)	8 (0.16%)
Coronary disease[7]	18 (1.11%)	53 (0.80%)	430 (1.21%)	132 (0.71%)	3684 (1.19%)	56 (1.12%)
DVT/PE	7 (0.43%)	4 (0.06%)	121 (0.34%)	14 (0.08%)	956 (0.31%)	10 (0.20%)
Aortic aneurysm[8]	0 (0.00%)	0 (0.00%)	4 (0.05%)	1 (0.02%)	22 (0.03%)	0 (0.00%)
Atrial fibrillation[8]	0 (0.00%)	1 (0.06%)	14 (0.16%)	8 (0.16%)	551 (0.78%)	7 (0.57%)
Valvular heart disease[8]	1 (0.25%)	1 (0.06%)	5 (0.06%)	5 (0.10%)	126 (0.18%)	3 (0.24%)
Total cardiovascular disease[9]	31 (1.91%)	75 (1.13%)	686 (1.93%)	174 (0.94%)	5626 (1.82%)	75 (1.50%)
Cancer						
Breast cancer	6 (0.37%)	32 (0.48%)	144 (0.40%)	54 (0.29%)	1401 (0.45%)	17 (0.34%)
Invasive breast cancer	5 (0.31%)	24 (0.36%)	116 (0.33%)	45 (0.24%)	1152 (0.37%)	13 (0.26%)
Non-invasive breast cancer	1 (0.06%)	9 (0.14%)	30 (0.08%)	10 (0.05%)	267 (0.09%)	5 (0.10%)
Ovarian cancer	1 (0.06%)	3 (0.05%)	10 (0.03%)	1 (0.01%)	124 (0.04%)	3 (0.06%)
Endometrial cancer[10]	1 (0.06%)	2 (0.03%)	13 (0.04%)	6 (0.03%)	180 (0.06%)	2 (0.04%)
Colorectal cancer	1 (0.06%)	17 (0.26%)	45 (0.13%)	19 (0.10%)	461 (0.15%)	9 (0.18%)
Other cancer[11]	11 (0.68%)	42 (0.63%)	171 (0.48%)	76 (0.41%)	2164 (0.70%)	31 (0.62%)
Total cancer	19 (1.17%)	93 (1.40%)	358 (1.00%)	147 (0.80%)	4063 (1.31%)	58 (1.16%)
Fractures						
Hip fracture	4 (0.25%)	8 (0.12%)	22 (0.06%)	17 (0.09%)	907 (0.29%)	9 (0.18%)
Deaths						
Cardiovascular deaths	9 (0.55%)	16 (0.24%)	165 (0.46%)	24 (0.13%)	1253 (0.41%)	14 (0.28%)
Cancer deaths	8 (0.49%)	31 (0.47%)	132 (0.37%)	56 (0.30%)	1403 (0.45%)	21 (0.42%)
Other known cause	5 (0.31%)	15 (0.23%)	87 (0.24%)	26 (0.14%)	1111 (0.36%)	13 (0.26%)
Unknown cause	0 (0.00%)	2 (0.03%)	6 (0.02%)	3 (0.02%)	47 (0.02%)	2 (0.04%)
Not yet adjudicated	1 (0.06%)	0 (0.00%)	14 (0.04%)	4 (0.02%)	183 (0.06%)	4 (0.08%)
Total Death	23 (1.42%)	64 (0.97%)	404 (1.13%)	113 (0.61%)	3997 (1.29%)	54 (1.08%)
Death plus post-WHI deaths[12]	27 (1.44%)	90 (1.16%)	528 (1.31%)	169 (0.74%)	4974 (1.48%)	78 (1.38%)

[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] Definite or possible decompensated heart failure adjudicated by UNC.
[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, UNC 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 at Enrollment and Race/Ethnicity for HT Participants Who Did Not Report a Prevalent Condition at Baseline

Data as of: August 29, 2014; Events through August 29, 2014

Outcome	Total	Age at Enrollment 50-54	55-59	60-69	70-79
Number randomized	27347	3420	5413	12360	6154
Mean follow-up (months)	165.1	177.0	174.6	166.5	147.4
Hospitalizations					
Ever	19161 (5.09%)	1853 (3.67%)	3288 (4.17%)	9005 (5.25%)	5015 (6.63%)
Two or more	13548 (3.60%)	1124 (2.23%)	2107 (2.67%)	6480 (3.78%)	3837 (5.07%)
Other					
Diabetes (treated)	4064 (1.13%)	593 (1.22%)	839 (1.12%)	1908 (1.17%)	724 (1.01%)
Gallbladder disease[1,2]	2117 (1.18%)	282 (1.14%)	443 (1.18%)	988 (1.24%)	404 (1.07%)
Hysterectomy	1159 (0.50%)	135 (0.44%)	274 (0.53%)	551 (0.52%)	199 (0.45%)
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]	7765 (3.21%)	1084 (2.72%)	1675 (2.94%)	3553 (3.36%)	1453 (3.71%)
Rheumatoid arthritis[2]	1696 (0.82%)	211 (0.76%)	341 (0.81%)	763 (0.83%)	381 (0.87%)
Intestinal polyps	6336 (1.81%)	795 (1.63%)	1350 (1.80%)	3087 (1.94%)	1104 (1.65%)
Lupus	427 (0.11%)	50 (0.10%)	88 (0.11%)	200 (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%)
Hypertension treated w/pills	10526 (3.88%)	1318 (3.21%)	2156 (3.51%)	4836 (4.02%)	2216 (4.57%)
COPD[4]	911 (1.03%)	83 (0.73%)	207 (1.15%)	474 (1.19%)	147 (0.81%)
Macular degeneration[4]	2499 (2.84%)	129 (1.13%)	331 (1.84%)	1221 (3.06%)	818 (4.48%)
Alzheimer's disease[4]	1994 (2.26%)	63 (0.55%)	179 (1.00%)	952 (2.38%)	800 (4.38%)
Parkinson's disease[4]	299 (0.34%)	21 (0.18%)	48 (0.27%)	166 (0.42%)	64 (0.35%)

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)	149.8	150.7	156.1	144.2	168.3	155.6
Hospitalizations						
Ever	90 (5.55%)	275 (4.15%)	1830 (5.14%)	808 (4.37%)	15903 (5.15%)	255 (5.11%)
Two or more	66 (4.07%)	162 (2.45%)	1272 (3.57%)	448 (2.43%)	11432 (3.70%)	168 (3.37%)
Other						
Diabetes (treated)	23 (1.60%)	82 (1.33%)	559 (1.78%)	309 (1.80%)	3032 (1.02%)	59 (1.27%)
Gallbladder disease[1,2]	13 (1.72%)	32 (0.89%)	187 (0.97%)	129 (1.46%)	1730 (1.19%)	26 (1.08%)
Hysterectomy	4 (0.61%)	11 (0.24%)	77 (0.52%)	56 (0.52%)	997 (0.50%)	14 (0.45%)
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]	46 (4.09%)	157 (3.29%)	737 (3.30%)	517 (3.92%)	6197 (3.15%)	111 (3.36%)
Rheumatoid arthritis[2]	15 (1.70%)	30 (0.79%)	272 (1.39%)	219 (1.96%)	1125 (0.67%)	35 (1.27%)
Intestinal polyps	32 (2.13%)	101 (1.69%)	674 (2.03%)	291 (1.65%)	5160 (1.80%)	78 (1.71%)
Lupus	3 (0.18%)	5 (0.08%)	47 (0.13%)	31 (0.17%)	337 (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%)
Hypertension treated w/pills	57 (4.89%)	183 (3.92%)	861 (4.77%)	603 (4.32%)	8694 (3.78%)	128 (3.78%)
COPD[4]	8 (1.97%)	7 (0.42%)	68 (0.78%)	27 (0.55%)	789 (1.11%)	12 (0.97%)
Macular degeneration[4]	9 (2.22%)	22 (1.32%)	122 (1.40%)	72 (1.47%)	2251 (3.17%)	23 (1.87%)
Alzheimer's disease[4]	7 (1.73%)	23 (1.38%)	193 (2.21%)	86 (1.75%)	1664 (2.34%)	21 (1.71%)
Parkinson's disease[4]	2 (0.49%)	6 (0.36%)	16 (0.18%)	14 (0.29%)	258 (0.36%)	3 (0.24%)

[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: August 29, 2014
WHI Extension Study 2010-2015 Participants

	DM Participants (N = 30,690) N	%
Vital Status/Participation		
Deceased	1981	6.5
Alive: Current Participation[1]	27472	89.5
Alive: Recent Participation[2]	663	2.2
Alive: Past/Unknown Participation[3]	21	0.1
Stopped Follow-Up[4]	294	1.0
Lost to Follow-Up[5]	259	0.8

Data as of: August 29, 2014; 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: August 29, 2014; 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 at Enrollment for Dietary Modification

Data as of: August 29, 2014; Events through September 30, 2010

Outcome	Total	Age at Enrollment 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	3238 (0.54%)	413 (0.45%)	761 (0.54%)	1536 (0.55%)	528 (0.58%)
Invasive breast cancer	2622 (0.43%)	309 (0.34%)	620 (0.44%)	1254 (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]	3427 (0.57%)	306 (0.33%)	623 (0.44%)	1747 (0.63%)	751 (0.82%)
Total cancer	7725 (1.28%)	817 (0.89%)	1596 (1.13%)	3793 (1.36%)	1519 (1.66%)
Cardiovascular					
CHD[3]	2344 (0.39%)	129 (0.14%)	283 (0.20%)	1129 (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]	1785 (0.30%)	101 (0.11%)	234 (0.17%)	862 (0.31%)	588 (0.64%)
Clinical MI	1733 (0.29%)	95 (0.10%)	227 (0.16%)	836 (0.30%)	575 (0.63%)
Angina[6]	1630 (0.40%)	94 (0.15%)	231 (0.24%)	860 (0.46%)	445 (0.69%)
CABG/PTCA	2664 (0.44%)	147 (0.16%)	378 (0.27%)	1458 (0.52%)	681 (0.74%)
Carotid artery disease	440 (0.07%)	23 (0.03%)	58 (0.04%)	237 (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	1870 (0.31%)	95 (0.10%)	212 (0.15%)	894 (0.32%)	669 (0.73%)
PVD	398 (0.07%)	17 (0.02%)	52 (0.04%)	210 (0.08%)	119 (0.13%)
Coronary disease[7]	5222 (0.87%)	301 (0.33%)	710 (0.50%)	2652 (0.95%)	1559 (1.71%)
Total cardiovascular disease	7280 (1.21%)	411 (0.45%)	973 (0.69%)	3649 (1.31%)	2247 (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	43 (0.01%)	1 (<0.01%)	8 (0.01%)	20 (0.01%)	14 (0.02%)
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; 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: August 29, 2014; 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	138.5
Cancer						
Breast cancer	7 (0.30%)	74 (0.56%)	280 (0.46%)	77 (0.38%)	2765 (0.55%)	35 (0.46%)
Invasive breast cancer	5 (0.21%)	56 (0.42%)	213 (0.35%)	62 (0.30%)	2257 (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%)	2993 (0.60%)	42 (0.55%)
Total cancer	18 (0.77%)	139 (1.05%)	645 (1.05%)	174 (0.85%)	6661 (1.34%)	88 (1.16%)
Cardiovascular						
CHD[3]	4 (0.17%)	28 (0.21%)	248 (0.40%)	41 (0.20%)	1993 (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%)	167 (0.27%)	32 (0.16%)	1535 (0.31%)	22 (0.29%)
Clinical MI	4 (0.17%)	25 (0.19%)	162 (0.26%)	31 (0.15%)	1490 (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%)	2299 (0.46%)	24 (0.32%)
Carotid artery disease	2 (0.09%)	1 (0.01%)	31 (0.05%)	4 (0.02%)	396 (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%)	249 (0.40%)	47 (0.23%)	1513 (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%)	622 (1.01%)	126 (0.62%)	4333 (0.87%)	63 (0.83%)
Total cardiovascular disease	27 (1.16%)	91 (0.69%)	884 (1.44%)	177 (0.86%)	6010 (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%)	33 (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; 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 at Enrollment and Race/Ethnicity for DM Participants Who Did Not Report a Prevalent Condition at Baseline

Data as of: August 29, 2014; Events through August 29, 2014

Outcome	Total	Age at Enrollment 50-54	55-59	60-69	70-79
Number randomized	48835	6961	11037	22715	8122
Mean follow-up (months)	173.0	185.8	182.3	172.4	150.9
Hospitalizations					
Ever	34270 (4.87%)	3941 (3.66%)	6942 (4.14%)	16773 (5.14%)	6614 (6.48%)
Two or more	23821 (3.38%)	2367 (2.20%)	4465 (2.66%)	11976 (3.67%)	5013 (4.91%)
Other					
DVT[1]	1107 (0.16%)	81 (0.08%)	180 (0.11%)	564 (0.18%)	282 (0.29%)
Pulmonary embolism	875 (0.13%)	74 (0.07%)	154 (0.09%)	464 (0.14%)	183 (0.18%)
Diabetes (treated)	7152 (1.06%)	1094 (1.04%)	1699 (1.05%)	3349 (1.07%)	1010 (1.04%)
Gallbladder disease[2, 3]	3830 (1.16%)	573 (1.07%)	902 (1.15%)	1802 (1.22%)	553 (1.09%)
Hysterectomy	2454 (0.61%)	391 (0.63%)	633 (0.62%)	1139 (0.62%)	291 (0.52%)
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]	14906 (3.29%)	2422 (2.86%)	3647 (3.05%)	6816 (3.47%)	2021 (3.84%)
Rheumatoid arthritis[3]	2848 (0.75%)	399 (0.68%)	631 (0.71%)	1319 (0.76%)	499 (0.83%)
Intestinal polyps	12418 (1.90%)	1864 (1.79%)	3111 (1.95%)	5902 (1.97%)	1541 (1.70%)
Lupus	729 (0.10%)	107 (0.10%)	174 (0.10%)	350 (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%)
Hypertension treated w/pills	18298 (3.68%)	2598 (2.98%)	4272 (3.35%)	8667 (3.91%)	2761 (4.49%)

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)	159.9	167.1	159.7	150.8	176.2	159.8
Hospitalizations						
Ever	130 (4.83%)	590 (3.83%)	3440 (4.91%)	1019 (4.39%)	28667 (4.91%)	424 (4.83%)
Two or more	88 (3.27%)	340 (2.21%)	2364 (3.38%)	619 (2.67%)	20140 (3.45%)	270 (3.08%)
Other						
DVT[1]	3 (0.12%)	5 (0.03%)	133 (0.20%)	21 (0.09%)	932 (0.17%)	13 (0.15%)
Pulmonary embolism	4 (0.15%)	3 (0.02%)	99 (0.14%)	16 (0.07%)	743 (0.13%)	10 (0.11%)
Diabetes (treated)	35 (1.39%)	178 (1.22%)	1121 (1.79%)	331 (1.51%)	5387 (0.95%)	100 (1.20%)
Gallbladder disease[2,3]	14 (1.22%)	60 (0.77%)	304 (0.81%)	152 (1.42%)	3250 (1.21%)	50 (1.14%)
Hysterectomy	6 (0.48%)	41 (0.42%)	166 (0.53%)	76 (0.61%)	2145 (0.63%)	20 (0.40%)
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]	58 (3.52%)	352 (3.10%)	1467 (3.38%)	582 (3.58%)	12238 (3.27%)	209 (3.74%)
Rheumatoid arthritis[3]	23 (1.59%)	49 (0.59%)	505 (1.29%)	222 (1.65%)	1998 (0.64%)	51 (1.05%)
Intestinal polyps	60 (2.39%)	262 (1.86%)	1370 (2.10%)	401 (1.82%)	10165 (1.87%)	160 (1.98%)
Lupus	5 (0.19%)	11 (0.07%)	105 (0.15%)	25 (0.11%)	570 (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%)
Hypertension treated w/pills	66 (3.72%)	390 (3.73%)	1671 (4.70%)	712 (4.12%)	15234 (3.57%)	225 (3.76%)

[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: August 29, 2014
WHI Extension Study 2010-2015 Participants

	CaD Participants (N = 24,231) N	%
Vital Status/Participation		
Deceased	1586	6.5
Alive: Current Participation[1]	21643	89.3
Alive: Recent Participation[2]	493	2.0
Alive: Past/Unknown Participation[3]	17	0.1
Stopped Follow-Up[4]	270	1.1
Lost to Follow-Up[5]	222	0.9

Data as of: August 29, 2014; 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: August 29, 2014; 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 at Enrollment for Calcium and Vitamin D

Data as of: August 29, 2014; Events through September 30, 2010

Outcome	Total	Age at Enrollment 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					
Breast cancer	2181 (0.52%)	277 (0.44%)	522 (0.52%)	1023 (0.54%)	359 (0.53%)
Invasive breast cancer	1753 (0.42%)	208 (0.33%)	423 (0.43%)	824 (0.43%)	298 (0.44%)
Non-invasive breast cancer	458 (0.11%)	70 (0.11%)	104 (0.10%)	213 (0.11%)	71 (0.11%)
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%)
Colorectal cancer	556 (0.13%)	39 (0.06%)	89 (0.09%)	270 (0.14%)	158 (0.23%)
Other cancer[2]	2475 (0.59%)	212 (0.34%)	434 (0.44%)	1259 (0.66%)	570 (0.85%)
Total cancer	5400 (1.29%)	569 (0.90%)	1111 (1.12%)	2617 (1.38%)	1103 (1.64%)
Cardiovascular					
CHD[3]	1791 (0.43%)	94 (0.15%)	218 (0.22%)	851 (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]	1374 (0.33%)	76 (0.12%)	176 (0.18%)	682 (0.36%)	440 (0.65%)
Clinical MI	1325 (0.32%)	72 (0.11%)	171 (0.17%)	658 (0.35%)	424 (0.63%)
Angina[6]	1117 (0.44%)	59 (0.15%)	163 (0.27%)	581 (0.51%)	314 (0.73%)
CABG/PTCA	2033 (0.48%)	115 (0.18%)	300 (0.30%)	1084 (0.57%)	534 (0.79%)
Carotid artery disease	356 (0.08%)	16 (0.03%)	50 (0.05%)	200 (0.11%)	90 (0.13%)
Congestive heart failure, WHI[6]	806 (0.31%)	33 (0.08%)	84 (0.14%)	376 (0.33%)	313 (0.73%)
Stroke	1382 (0.33%)	72 (0.11%)	157 (0.16%)	646 (0.34%)	507 (0.75%)
PVD	330 (0.08%)	11 (0.02%)	48 (0.05%)	165 (0.09%)	106 (0.16%)
Coronary disease[7]	3880 (0.92%)	223 (0.35%)	546 (0.55%)	1927 (1.01%)	1184 (1.76%)
Total cardiovascular disease	5441 (1.30%)	309 (0.49%)	750 (0.75%)	2671 (1.41%)	1711 (2.54%)
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%)
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; evolving 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; evolving 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: August 29, 2014; 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)	131.3	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						
Breast cancer	5 (0.31%)	43 (0.54%)	173 (0.47%)	55 (0.35%)	1884 (0.53%)	21 (0.44%)
Invasive breast cancer	3 (0.18%)	31 (0.39%)	134 (0.37%)	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%)	385 (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%)
Colorectal cancer	2 (0.12%)	9 (0.11%)	56 (0.15%)	15 (0.09%)	467 (0.13%)	7 (0.15%)
Other cancer[2]	6 (0.37%)	38 (0.48%)	163 (0.45%)	56 (0.35%)	2189 (0.62%)	23 (0.49%)
Total cancer	13 (0.80%)	96 (1.20%)	398 (1.09%)	129 (0.82%)	4709 (1.33%)	55 (1.16%)
Cardiovascular						
CHD[3]	5 (0.31%)	14 (0.18%)	161 (0.44%)	37 (0.23%)	1551 (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%)	107 (0.29%)	30 (0.19%)	1200 (0.34%)	19 (0.40%)
Clinical MI	5 (0.31%)	13 (0.16%)	104 (0.28%)	29 (0.18%)	1156 (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%)	1770 (0.50%)	25 (0.53%)
Carotid artery disease	1 (0.06%)	1 (0.01%)	21 (0.06%)	4 (0.03%)	324 (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%)	1153 (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 (0.67%)	38 (0.48%)	383 (1.05%)	112 (0.71%)	3289 (0.93%)	47 (0.99%)
Total cardiovascular disease	19 (1.17%)	62 (0.78%)	544 (1.49%)	148 (0.94%)	4599 (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%)
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; evolving 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; evolving 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 at Enrollment and Race/Ethnicity for CaD Participants Who Did Not Report a Prevalent Condition at Baseline

Data as of: August 29, 2014; Events through August 29, 2014

Outcome	Total	Age at Enrollment 50-54	55-59	60-69	70-79
Number randomized	36282	5153	8269	16519	6341
Mean follow-up (months)	165.0	176.1	174.1	164.7	144.7
Hospitalizations					
Ever	25184 (5.05%)	2850 (3.77%)	5114 (4.26%)	12071 (5.32%)	5149 (6.73%)
Two or more	17251 (3.46%)	1648 (2.18%)	3236 (2.70%)	8523 (3.76%)	3844 (5.03%)
Other					
DVT[1]	834 (0.17%)	59 (0.08%)	141 (0.12%)	410 (0.19%)	224 (0.30%)
Pulmonary embolism	638 (0.13%)	54 (0.07%)	119 (0.10%)	336 (0.15%)	129 (0.17%)
Diabetes (treated)	5119 (1.07%)	802 (1.09%)	1191 (1.03%)	2389 (1.10%)	737 (1.01%)
Gallbladder disease[2,3]	2410 (1.12%)	355 (1.03%)	591 (1.14%)	1116 (1.18%)	348 (1.00%)
Hysterectomy	1675 (0.57%)	253 (0.58%)	455 (0.61%)	763 (0.58%)	204 (0.47%)
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]	10437 (3.23%)	1704 (2.89%)	2576 (3.01%)	4698 (3.40%)	1459 (3.63%)
Rheumatoid arthritis[3]	1773 (0.72%)	257 (0.68%)	405 (0.70%)	798 (0.73%)	313 (0.77%)
Intestinal polyps	8697 (1.87%)	1335 (1.82%)	2194 (1.92%)	4031 (1.92%)	1137 (1.67%)
Lupus	538 (0.11%)	76 (0.10%)	126 (0.11%)	242 (0.11%)	94 (0.12%)
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%)
Hypertension treated w/pills	13027 (3.62%)	1868 (3.01%)	3077 (3.31%)	6057 (3.85%)	2025 (4.23%)

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)	153.1	157.1	153.8	144.8	167.6	151.2
Hospitalizations						
Ever	95 (5.00%)	390 (4.13%)	2168 (5.10%)	800 (4.41%)	21442 (5.09%)	289 (5.21%)
Two or more	64 (3.37%)	226 (2.40%)	1459 (3.43%)	444 (2.45%)	14871 (3.53%)	187 (3.37%)
Other						
DVT[1]	6 (0.32%)	2 (0.02%)	95 (0.23%)	18 (0.10%)	705 (0.17%)	8 (0.15%)
Pulmonary embolism	4 (0.21%)	1 (0.01%)	57 (0.14%)	11 (0.06%)	557 (0.13%)	8 (0.15%)
Diabetes (treated)	24 (1.34%)	106 (1.18%)	639 (1.67%)	275 (1.61%)	4000 (0.98%)	75 (1.44%)
Gallbladder disease[2,3]	10 (1.25%)	36 (0.82%)	165 (0.79%)	120 (1.51%)	2053 (1.15%)	26 (1.04%)
Hysterectomy	4 (0.51%)	25 (0.41%)	96 (0.52%)	51 (0.50%)	1482 (0.58%)	17 (0.53%)
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]	50 (3.98%)	215 (3.05%)	870 (3.28%)	470 (3.68%)	8697 (3.20%)	135 (3.58%)
Rheumatoid arthritis[3]	17 (1.83%)	28 (0.60%)	288 (1.35%)	136 (1.38%)	1279 (0.62%)	25 (0.90%)
Intestinal polyps	42 (2.39%)	144 (1.66%)	851 (2.14%)	282 (1.63%)	7282 (1.85%)	96 (1.88%)
Lupus	5 (0.27%)	4 (0.04%)	62 (0.15%)	22 (0.12%)	438 (0.10%)	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%)
Hypertension treated w/pills	43 (3.53%)	236 (3.58%)	986 (4.43%)	541 (3.86%)	11088 (3.55%)	133 (3.71%)

[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: August 29, 2014
WHI Extension Study 2010-2015 Participants

	OS Participants (N = 52,068)	
	N	%
Vital Status/Participation		
Deceased	3743	7.2
Alive: Current Participation[1]	46238	88.8
Alive: Recent Participation[2]	1054	2.0
Alive: Past/Unknown Participation[3]	29	0.1
Stopped Follow-Up[4]	619	1.2
Lost to Follow-Up[5]	385	0.7

Data as of: August 29, 2014; 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: August 29, 2014; 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 at Enrollment for OS Participants

Data as of: August 29, 2014; Events through September 30, 2010

Outcome	Total		Age at Enrollment 50-54		55-59		60-69		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	3325	(0.31%)	102	(0.07%)	254	(0.12%)	1396	(0.30%)	1573	(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	13159	(1.23%)	541	(0.36%)	1274	(0.61%)	5771	(1.22%)	5573	(2.37%)
Cancer										
Breast cancer	6047	(0.57%)	722	(0.48%)	1087	(0.52%)	2831	(0.60%)	1407	(0.60%)
Invasive breast cancer	5021	(0.47%)	577	(0.38%)	885	(0.42%)	2347	(0.50%)	1212	(0.52%)
Non-invasive breast cancer	1090	(0.10%)	155	(0.10%)	211	(0.10%)	517	(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]	831	(0.08%)	77	(0.05%)	154	(0.07%)	385	(0.08%)	215	(0.09%)
Colorectal cancer	1354	(0.13%)	78	(0.05%)	144	(0.07%)	624	(0.13%)	508	(0.22%)
Other cancer[6]	6624	(0.62%)	491	(0.33%)	923	(0.44%)	3155	(0.67%)	2055	(0.87%)
Total cancer	14507	(1.36%)	1359	(0.90%)	2288	(1.09%)	6788	(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	(0.33%)	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	108	(0.01%)	7	(<0.01%)	12	(0.01%)	40	(0.01%)	49	(0.02%)
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: August 29, 2014; 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	113.5	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%)	271 (0.36%)	65 (0.19%)	2842 (0.31%)	58 (0.41%)
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%)	1119 (1.49%)	300 (0.88%)	11268 (1.23%)	194 (1.37%)
Cancer						
Breast cancer	17 (0.40%)	126 (0.47%)	375 (0.50%)	137 (0.40%)	5330 (0.58%)	62 (0.44%)
Invasive breast cancer	16 (0.38%)	106 (0.39%)	303 (0.40%)	108 (0.32%)	4435 (0.49%)	53 (0.38%)
Non-invasive breast cancer	1 (0.02%)	22 (0.08%)	78 (0.10%)	31 (0.09%)	948 (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%)	763 (0.08%)	15 (0.11%)
Colorectal cancer	4 (0.09%)	28 (0.10%)	124 (0.16%)	29 (0.08%)	1155 (0.13%)	14 (0.10%)
Other cancer[6]	23 (0.55%)	116 (0.43%)	375 (0.50%)	117 (0.34%)	5903 (0.65%)	90 (0.64%)
Total cancer	45 (1.07%)	274 (1.01%)	881 (1.17%)	307 (0.90%)	12825 (1.41%)	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%)	11 (0.03%)	84 (0.01%)	4 (0.03%)
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 at Enrollment and Race/Ethnicity for OS Participants Who Did Not Report a Prevalent Condition at Baseline

Data as of: August 29, 2014; Events through August 29, 2014

Outcome	Total	Age at Enrollment 50-54	55-59	60-69	70-79
Number enrolled	93676	12381	17329	41200	22766
Mean follow-up (months)	158.3	173.1	171.8	159.7	137.4
Hospitalizations					
Ever	61574 (4.98%)	6274 (3.51%)	10012 (4.04%)	28139 (5.13%)	17149 (6.58%)
Two or more	41064 (3.32%)	3549 (1.99%)	6214 (2.50%)	19098 (3.48%)	12203 (4.68%)
Other					
DVT[1]	1606 (0.13%)	122 (0.07%)	210 (0.09%)	769 (0.15%)	505 (0.20%)
Pulmonary embolism	1317 (0.11%)	124 (0.07%)	207 (0.08%)	627 (0.12%)	359 (0.14%)
Diabetes (treated)	10198 (0.85%)	1416 (0.81%)	2013 (0.83%)	4688 (0.89%)	2081 (0.83%)
Gallbladder disease[2,3]	5652 (0.95%)	832 (0.96%)	1141 (0.98%)	2534 (0.98%)	1145 (0.85%)
Hysterectomy	4502 (0.36%)	684 (0.38%)	1024 (0.41%)	2048 (0.37%)	746 (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]	24443 (3.37%)	3645 (2.82%)	5004 (3.07%)	10825 (3.53%)	4969 (3.97%)
Rheumatoid arthritis[3]	4571 (0.68%)	634 (0.67%)	877 (0.68%)	1880 (0.64%)	1180 (0.76%)
Intestinal polyps	20539 (1.83%)	2907 (1.71%)	4433 (1.91%)	9406 (1.91%)	3793 (1.69%)
Lupus	1441 (0.12%)	195 (0.11%)	275 (0.11%)	657 (0.12%)	314 (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%)
Hypertension treated w/pills	31636 (3.52%)	4048 (2.71%)	6022 (3.08%)	14227 (3.67%)	7339 (4.40%)

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)	135.8	136.0	131.0	126.2	163.5	145.0
Hospitalizations						
Ever	265 (5.56%)	1126 (3.72%)	4394 (5.27%)	1675 (4.41%)	53313 (5.01%)	801 (5.01%)
Two or more	185 (3.88%)	569 (1.88%)	2708 (3.25%)	935 (2.46%)	36140 (3.40%)	527 (3.29%)
Other						
DVT[1]	6 (0.13%)	9 (0.03%)	144 (0.18%)	27 (0.07%)	1403 (0.14%)	17 (0.11%)
Pulmonary embolism	4 (0.09%)	10 (0.03%)	94 (0.11%)	15 (0.04%)	1185 (0.11%)	9 (0.06%)
Diabetes (treated)	73 (1.74%)	288 (1.00%)	1181 (1.58%)	493 (1.38%)	8006 (0.77%)	157 (1.02%)
Gallbladder disease[2,3]	31 (1.32%)	81 (0.46%)	374 (0.77%)	230 (1.18%)	4860 (0.97%)	76 (0.94%)
Hysterectomy	11 (0.23%)	73 (0.24%)	163 (0.20%)	134 (0.35%)	4051 (0.38%)	70 (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]	89 (3.38%)	719 (3.35%)	1761 (3.62%)	973 (3.92%)	20549 (3.33%)	352 (3.57%)
Rheumatoid arthritis[3]	38 (1.39%)	98 (0.52%)	661 (1.33%)	382 (1.65%)	3306 (0.58%)	86 (0.95%)
Intestinal polyps	69 (1.59%)	464 (1.71%)	1520 (1.99%)	610 (1.72%)	17621 (1.83%)	255 (1.78%)
Lupus	10 (0.21%)	25 (0.08%)	138 (0.17%)	70 (0.19%)	1178 (0.11%)	20 (0.13%)
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%)
Hypertension treated w/pills	130 (4.18%)	763 (3.54%)	2040 (4.90%)	1128 (3.91%)	27125 (3.42%)	450 (3.92%)

[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: August 29, 2014
WHI Extension Study 2010-2015 Participants

	CT Participants (N = 41,499)	
	N	%
Vital Status/Participation		
Deceased	2864	6.9
Alive: Current Participation[1]	36810	88.7
Alive: Recent Participation[2]	909	2.2
Alive: Past/Unknown Participation[3]	35	0.1
Stopped Follow-Up[4]	492	1.2
Lost to Follow-Up[5]	389	0.9

Data as of: August 29, 2014; 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: August 29, 2014; 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 at Enrollment for CT Participants

Data as of: August 29, 2014; Events through September 30, 2010

Outcome	Total		Age at Enrollment 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]	3610	(0.43%)	193	(0.16%)	410	(0.22%)	1682	(0.44%)	1325	(0.92%)
CHD death[2]	1228	(0.15%)	48	(0.04%)	90	(0.05%)	524	(0.14%)	566	(0.39%)
Total MI[3]	2732	(0.33%)	155	(0.13%)	339	(0.18%)	1287	(0.34%)	951	(0.66%)
Clinical MI	2656	(0.32%)	149	(0.12%)	331	(0.18%)	1249	(0.33%)	927	(0.64%)
Angina[4]	2414	(0.43%)	129	(0.16%)	331	(0.27%)	1215	(0.48%)	739	(0.73%)
CABG/PTCA	3951	(0.48%)	217	(0.18%)	551	(0.30%)	2084	(0.55%)	1099	(0.76%)
Carotid artery disease	694	(0.08%)	27	(0.02%)	90	(0.05%)	372	(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	2739	(0.33%)	120	(0.10%)	274	(0.15%)	1285	(0.34%)	1060	(0.74%)
PVD	647	(0.08%)	29	(0.02%)	86	(0.05%)	333	(0.09%)	199	(0.14%)
Coronary disease[5]	7820	(0.94%)	442	(0.37%)	1019	(0.55%)	3810	(1.00%)	2549	(1.77%)
Total cardiovascular disease	10853	(1.31%)	586	(0.49%)	1365	(0.73%)	5253	(1.38%)	3649	(2.53%)
Cancer										
Breast cancer	4224	(0.51%)	514	(0.43%)	939	(0.50%)	1999	(0.52%)	772	(0.54%)
Invasive breast cancer	3423	(0.41%)	391	(0.33%)	768	(0.41%)	1616	(0.42%)	648	(0.45%)
Non-invasive breast cancer	856	(0.10%)	129	(0.11%)	182	(0.10%)	409	(0.11%)	136	(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	1115	(0.13%)	71	(0.06%)	181	(0.10%)	541	(0.14%)	322	(0.22%)
Other cancer[7]	4943	(0.59%)	406	(0.34%)	842	(0.45%)	2472	(0.65%)	1223	(0.85%)
Total cancer	10602	(1.27%)	1040	(0.87%)	2065	(1.11%)	5156	(1.35%)	2341	(1.63%)
Fractures										
Hip fracture	1638	(0.20%)	32	(0.03%)	115	(0.06%)	665	(0.17%)	826	(0.57%)
Deaths										
Cardiovascular deaths	2430	(0.29%)	86	(0.07%)	176	(0.09%)	990	(0.26%)	1178	(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	68	(0.01%)	2	(<0.01%)	14	(0.01%)	27	(0.01%)	25	(0.02%)
Total death	7545	(0.91%)	359	(0.30%)	803	(0.43%)	3398	(0.89%)	2985	(2.07%)
Death plus post-WHI deaths[8]	9228	(1.02%)	421	(0.32%)	927	(0.46%)	4065	(0.99%)	3815	(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: August 29, 2014; Events through September 30, 2010

	Race/Ethnicity					
Outcomes	**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%)	351 (0.43%)	72 (0.23%)	3085 (0.45%)	48 (0.45%)
CHD death[2]	2 (0.06%)	13 (0.07%)	165 (0.20%)	22 (0.07%)	1007 (0.15%)	19 (0.18%)
Total MI[3]	7 (0.21%)	40 (0.22%)	231 (0.29%)	56 (0.18%)	2361 (0.34%)	37 (0.34%)
Clinical MI	7 (0.21%)	39 (0.22%)	226 (0.28%)	54 (0.17%)	2295 (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%)	3412 (0.50%)	43 (0.40%)
Carotid artery disease	3 (0.09%)	3 (0.02%)	42 (0.05%)	6 (0.02%)	631 (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%)	340 (0.42%)	67 (0.21%)	2241 (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%)	855 (1.06%)	210 (0.67%)	6531 (0.95%)	100 (0.93%)
Total cardiovascular disease	40 (1.22%)	141 (0.79%)	1219 (1.50%)	279 (0.89%)	9035 (1.31%)	139 (1.30%)
Cancer						
Breast cancer	10 (0.30%)	95 (0.53%)	365 (0.45%)	104 (0.33%)	3607 (0.52%)	43 (0.40%)
Invasive breast cancer	7 (0.21%)	72 (0.40%)	288 (0.36%)	86 (0.27%)	2936 (0.43%)	34 (0.32%)
Non-invasive breast cancer	3 (0.09%)	25 (0.14%)	81 (0.10%)	20 (0.06%)	717 (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%)	922 (0.13%)	17 (0.16%)
Other cancer[7]	12 (0.37%)	79 (0.44%)	359 (0.44%)	124 (0.39%)	4311 (0.63%)	58 (0.54%)
Total cancer	29 (0.88%)	203 (1.14%)	852 (1.05%)	263 (0.83%)	9134 (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%)	1998 (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%)	51 (0.01%)	1 (0.01%)
Total death	33 (1.00%)	105 (0.59%)	770 (0.95%)	181 (0.57%)	6365 (0.93%)	91 (0.85%)
Death plus post-WHI deaths[8]	47 (1.26%)	141 (0.70%)	988 (1.08%)	243 (0.64%)	7682 (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 at Enrollment and Race/Ethnicity for CT Participants Who Did Not Report a Prevalent Condition at Baseline

Data as of: August 29, 2014; Events through August 29, 2014

Outcome	Total	Age at Enrollment 50-54	55-59	60-69	70-79
Number randomized	68132	9188	14661	31389	12894
Mean follow-up (months)	170.3	183.3	180.2	170.3	149.4
Hospitalizations					
Ever	47784 (4.94%)	5129 (3.65%)	9116 (4.14%)	23041 (5.17%)	10498 (6.54%)
Two or more	33311 (3.45%)	3079 (2.19%)	5845 (2.65%)	16417 (3.68%)	7970 (4.96%)
Other					
DVT[1]	1627 (0.17%)	117 (0.09%)	251 (0.12%)	797 (0.18%)	462 (0.30%)
Pulmonary embolism	1224 (0.13%)	103 (0.07%)	203 (0.09%)	634 (0.14%)	284 (0.18%)
Diabetes (treated)	9778 (1.05%)	1432 (1.05%)	2203 (1.04%)	4598 (1.08%)	1545 (1.01%)
Gallbladder disease[2,3]	5248 (1.15%)	746 (1.07%)	1195 (1.15%)	2463 (1.21%)	844 (1.05%)
Hysterectomy	3282 (0.58%)	467 (0.57%)	826 (0.60%)	1545 (0.60%)	444 (0.49%)
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]	20256 (3.27%)	3106 (2.82%)	4753 (3.02%)	9258 (3.44%)	3139 (3.79%)
Rheumatoid arthritis[3]	4009 (0.76%)	538 (0.70%)	866 (0.74%)	1822 (0.77%)	783 (0.84%)
Intestinal polyps	16785 (1.87%)	2376 (1.75%)	3992 (1.91%)	8041 (1.96%)	2376 (1.67%)
Lupus	1048 (0.11%)	145 (0.10%)	238 (0.11%)	495 (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%)
Hypertension treated w/pills	25675 (3.72%)	3450 (3.02%)	5695 (3.37%)	12042 (3.93%)	4488 (4.51%)

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)	154.7	162.3	157.9	147.8	173.5	158.0
Hospitalizations						
Ever	194 (5.15%)	807 (3.93%)	4607 (5.01%)	1553 (4.39%)	40016 (4.99%)	607 (4.92%)
Two or more	135 (3.59%)	466 (2.27%)	3145 (3.42%)	907 (2.56%)	28265 (3.52%)	393 (3.18%)
Other						
DVT[1]	6 (0.17%)	8 (0.04%)	188 (0.21%)	31 (0.09%)	1378 (0.18%)	16 (0.13%)
Pulmonary embolism	6 (0.16%)	6 (0.03%)	125 (0.14%)	20 (0.06%)	1054 (0.13%)	13 (0.11%)
Diabetes (treated)	48 (1.40%)	242 (1.25%)	1449 (1.77%)	537 (1.61%)	7367 (0.95%)	135 (1.16%)
Gallbladder disease[2,3]	22 (1.31%)	86 (0.81%)	420 (0.85%)	243 (1.45%)	4403 (1.18%)	74 (1.20%)
Hysterectomy	8 (0.49%)	51 (0.38%)	218 (0.54%)	116 (0.58%)	2858 (0.59%)	31 (0.43%)
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]	88 (3.74%)	478 (3.16%)	1911 (3.35%)	926 (3.70%)	16564 (3.24%)	289 (3.61%)
Rheumatoid arthritis[3]	32 (1.55%)	74 (0.66%)	682 (1.33%)	357 (1.70%)	2787 (0.65%)	77 (1.13%)
Intestinal polyps	77 (2.21%)	339 (1.81%)	1783 (2.08%)	585 (1.73%)	13784 (1.85%)	217 (1.91%)
Lupus	8 (0.22%)	16 (0.08%)	139 (0.15%)	50 (0.14%)	820 (0.10%)	15 (0.12%)
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%)
Hypertension treated w/pills	103 (4.11%)	540 (3.81%)	2203 (4.72%)	1102 (4.14%)	21413 (3.62%)	314 (3.75%)

[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 Primary and Other Cancers (Annualized Percentages): CT and OS Participants
Data as of: August 29, 2014; Events through August 29, 2014

	CT		OS	
Number of participants	68132		93676	
Mean follow-up time (months)	170.3		158.7	
Overall cancer	12330	(1.28%)	16604	(1.34%)
Primary cancer				
Breast cancer	4850	(0.50%)	6829	(0.55%)
Invasive breast cancer	3966	(0.41%)	5696	(0.46%)
In-situ breast cancer	958	(0.10%)	1212	(0.10%)
Ovarian cancer	426	(0.04%)	647	(0.05%)
Endometrial cancer[1]	668	(0.07%)	932	(0.07%)
Colorectal cancer	1287	(0.13%)	1548	(0.12%)
Other cancer				
Accessory sinus	2	(<0.01%)	6	(<0.01%)
Adrenal gland	6	(<0.01%)	9	(<0.01%)
Anus	39	(<0.01%)	56	(<0.01%)
Appendix	16	(<0.01%)	15	(<0.01%)
Biliary tract, parts of (other/unspecified)	75	(0.01%)	81	(0.01%)
Bladder	365	(0.04%)	444	(0.04%)
Bones/joints/articular cartilage (limbs)	5	(<0.01%)	6	(<0.01%)
Bones/joints/articular cartilage (other)	9	(<0.01%)	10	(<0.01%)
Brain	133	(0.01%)	166	(0.01%)
Cervix	55	(0.01%)	55	(<0.01%)
Central Nervous System (excludes brain)	1	(<0.01%)	3	(<0.01%)
Connective/subcutaneous/soft tissues	65	(0.01%)	77	(0.01%)
Endocrine glands, related structures	1	(<0.01%)	2	(<0.01%)
Esophagus	67	(0.01%)	70	(0.01%)
Eye and adnexa	44	(<0.01%)	30	(<0.01%)
Genital organs	41	(<0.01%)	65	(0.01%)
Kidney	279	(0.03%)	319	(0.03%)
Larynx	26	(<0.01%)	23	(<0.01%)
Leukemia	376	(0.04%)	484	(0.04%)
Liver	86	(0.01%)	120	(0.01%)
Lung	1410	(0.15%)	1861	(0.15%)
Lymph nodes	2	(<0.01%)	2	(<0.01%)
Lymphoma, Hodgkins	24	(<0.01%)	40	(<0.01%)
Lymphoma, Non-Hodgkins	599	(0.06%)	870	(0.07%)
Melanoma of the skin	852	(0.09%)	1110	(0.09%)
Multiple myeloma	230	(0.02%)	266	(0.02%)
Oral (mouth)	14	(<0.01%)	10	(<0.01%)
Palate	10	(<0.01%)	18	(<0.01%)
Pancreas	407	(0.04%)	531	(0.04%)
Parotid gland (Stensen's duct)	17	(<0.01%)	33	(<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%)	12	(<0.01%)
Stomach	109	(0.01%)	139	(0.01%)
Thyroid	188	(0.02%)	253	(0.02%)
Tongue, part of (other/unspecified)	30	(<0.01%)	38	(<0.01%)
Urinary organs (other/unspecified)	11	(<0.01%)	16	(<0.01%)
Uterus, not otherwise specified[1]	26	(0.03%)	39	(0.04%)
Other/unknown site of cancer	580	(0.06%)	780	(0.06%)
Other/unknown cancers reported on death	128	(0.01%)	249	(0.02%)

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

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

Data as of: August 29, 2014; Events through August 29, 2014

	CT		OS	
Number of participants	68132		93676	
Mean follow-up time (months)	170.3		158.7	
Elbow	1030	(0.11%)	1398	(0.11%)
Foot	3502	(0.36%)	4418	(0.36%)
Hand	973	(0.10%)	1121	(0.09%)
Hip	2320	(0.24%)	3224	(0.26%)
Knee	1463	(0.15%)	1932	(0.16%)
Lower arm	5013	(0.52%)	6334	(0.51%)
Lower leg	3833	(0.40%)	4771	(0.39%)
Pelvis	1205	(0.12%)	1936	(0.16%)
Tailbone	432	(0.04%)	616	(0.05%)
Upper arm	2807	(0.29%)	3468	(0.28%)
Upper leg	958	(0.10%)	1335	(0.11%)
Spine	3229	(0.33%)	4719	(0.38%)
Other	7220	(0.75%)	9385	(0.76%)
Any fracture	22659	(2.34%)	29704	(2.40%)

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

Data as of: August 29, 2014; Events through August 29, 2014

	CT		OS	
Number of participants	68132		93676	
Mean Follow-up Time (months)	186.2		182.1	
Death plus post-WHI deaths	12897	(1.22%)	20455	(1.44%)
Adjudicated death	11076	(1.05%)	16760	(1.18%)
Centrally adjudicated death	8075	(0.76%)	4718	(0.33%)
Locally adjudicated death (final)	1	(<0.01%)	5578	(0.39%)
Identified by NDI search	3000	(0.28%)	6464	(0.45%)
Not yet adjudicated	248	(0.02%)	44	(<0.01%)
Form 120 death[2]	1573	(0.15%)	3651	(0.26%)
Cardiovascular				
Atherosclerotic cardiac	1843	(0.17%)	2668	(0.19%)
Definite CHD deaths after 10/99	876	(0.08%)	1031	(0.07%)
Possible CHD deaths after 10/99	935	(0.09%)	1544	(0.11%)
Cerebrovascular	923	(0.09%)	1499	(0.11%)
Pulmonary embolism	96	(0.01%)	105	(0.01%)
Other cardiovascular	948	(0.09%)	1721	(0.12%)
Unknown cardiovascular	33	(<0.01%)	115	(0.01%)
Total cardiovascular deaths	3843	(0.36%)	6108	(0.43%)
Cancer				
Breast cancer	347	(0.03%)	883	(0.06%)
Ovarian cancer	268	(0.03%)	446	(0.03%)
Endometrial cancer	76	(0.01%)	100	(0.01%)
Colorectal cancer	361	(0.03%)	503	(0.04%)
Uterus cancer	29	(<0.01%)	54	(<0.01%)
Lung cancer	1063	(0.10%)	1369	(0.10%)
Pancreas cancer	374	(0.04%)	502	(0.04%)
Lymphoma (NHL only)	186	(0.02%)	293	(0.02%)
Leukemia	180	(0.02%)	244	(0.02%)
Brain cancer	130	(0.01%)	161	(0.01%)
Multiple myeloma	142	(0.01%)	158	(0.01%)
Other cancer	875	(0.08%)	1298	(0.09%)
Unknown cancer site	203	(0.02%)	312	(0.02%)
Total cancer deaths	4234	(0.40%)	6323	(0.44%)
Accident/injury				
Homicide	14	(<0.01%)	18	(<0.01%)
Accident	321	(0.03%)	455	(0.03%)
Suicide	25	(<0.01%)	51	(<0.01%)
Other injury	17	(<0.01%)	32	(<0.01%)
Total accident/injury deaths	377	(0.04%)	556	(0.04%)
Other				
Alzheimer's disease	403	(0.04%)	807	(0.06%)
COPD	495	(0.05%)	695	(0.05%)
Pneumonia	352	(0.03%)	574	(0.04%)
Pulmonary fibrosis	90	(0.01%)	131	(0.01%)
Renal failure	184	(0.02%)	303	(0.02%)
Sepsis	315	(0.03%)	446	(0.03%)
Dementia, NOS	360	(0.03%)	645	(0.05%)
Amyotrophic Lateral Sclerosis	80	(0.01%)	107	(0.01%)
Parkinson's	100	(0.01%)	166	(0.01%)
Hepatic cirrhosis	77	(0.01%)	114	(0.01%)
Other known cause	972	(0.09%)	1814	(0.13%)
Unknown cause	767	(0.07%)	1622	(0.11%)
Total other cause deaths	4195	(0.40%)	7424	(0.52%)

[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 7.1
Lost-to-Follow-up and Vital Status: WHI Participants by Extension Study Participation and Cohort

Data as of: August 29, 2014
WHI Extension Study 2010-2015 Participants

	MRC Super Cohort (N = 22,316)		SRC Super Cohort (N = 71,251)		Total Participants (N = 93,567)	
	N	%	N	%	N	%
Vital Status/Participation						
Deceased	1606	7.2	5001	7.0	6607	7.1
Alive: Current Participation[1]	19366	86.8	63682	89.4	83048	88.8
Alive: Recent Participation[2]	577	2.6	1386	1.9	1963	2.1
Alive: Past/Unknown Participation[3]	23	0.1	41	0.1	64	0.1
Stopped Follow-Up[4]	369	1.7	742	1.0	1111	1.2
Lost to Follow-Up[5]	375	1.7	399	0.6	774	0.8

Data as of: August 29, 2014; Status as of September 30, 2010
WHI Extension Study 2005-2010 Participants

	MRC Super Cohort (N = 29,368)		SRC Super Cohort (N = 86,039)		Total Participants (N = 115,407)	
	N	%	N	%	N	%
Vital Status/Participation						
Deceased	3943	13.4	11179	13.0	15122	13.1
Alive: Current Participation[1]	24309	82.8	73255	85.1	97564	84.5
Alive: Recent Participation[2]	314	1.1	466	0.5	780	0.7
Alive: Past/Unknown Participation[3]	30	0.1	35	<0.1	65	0.1
Stopped Follow-Up[4]	462	1.6	793	0.9	1255	1.1
Lost to Follow-Up[5]	310	1.1	311	0.4	621	0.5

Data as of: August 29, 2014; Status as of April 8, 2005
WHI Participants

	MRC Super Cohort (N = 44,174)		SRC Super Cohort (N = 117,634)		Total Participants (N = 161,808)	
	N	%	N	%	N	%
Vital Status/Participation						
Deceased	6750	15.6	18383	16.0	25133	15.9
Alive: Current Participation[6]	33260	77.0	91380	79.8	124640	79.0
Alive: Recent Participation[7]	336	0.8	405	0.4	741	0.5
Alive: Past/Unknown Participation[8]	20	<0.1	32	<0.1	52	<0.1
Stopped Follow-Up[4]	1701	3.9	2757	2.4	4458	2.8
Lost to Follow-Up[5]	1127	2.6	1602	1.4	2729	1.7

[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] CT participants who have filled in a Form 33 within the last 9 months; and OS participants who have filled in a Form 33 within the last 15 months.
[7] CT participants who last filled in a Form 33 between 9 and 18 months ago; and OS participants who last filled in a Form 33 between 15 and 24 months ago.
[8] CT participants without a Form 33 within the last 18 months, who have been located (as indicated on Form 23) within the last 6 months; and OS 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 7.2
Verified Outcomes (Annualized Percentages) by Age at Enrollment for MRC Super Cohort Participants
Data as of: August 29, 2014; Events through August 29, 2014

Outcomes	Total	Age at Enrollment 50-54	55-59	60-69	70-79
Number randomized	44174	6788	9352	19418	8616
Mean follow-up (months)	155.3	162.4	163.0	156.2	139.4
Cardiovascular					
CHD[1]	2806 (0.49%)	178 (0.19%)	344 (0.27%)	1298 (0.51%)	986 (0.99%)
CHD death[2]	1085 (0.19%)	50 (0.05%)	98 (0.08%)	448 (0.18%)	489 (0.49%)
Clinical MI	2001 (0.35%)	134 (0.15%)	272 (0.21%)	959 (0.38%)	636 (0.64%)
Angina[3]	1625 (0.47%)	114 (0.20%)	226 (0.30%)	785 (0.52%)	500 (0.76%)
CABG/PTCA	2715 (0.47%)	203 (0.22%)	430 (0.34%)	1387 (0.55%)	695 (0.69%)
Carotid artery disease	474 (0.08%)	21 (0.02%)	66 (0.05%)	263 (0.10%)	124 (0.12%)
Congestive heart failure, WHI[3]	1246 (0.36%)	84 (0.15%)	145 (0.19%)	531 (0.35%)	486 (0.74%)
Heart failure, UNC[4]	2005 (0.35%)	111 (0.12%)	204 (0.16%)	898 (0.36%)	792 (0.79%)
Stroke	2151 (0.38%)	121 (0.13%)	250 (0.20%)	1003 (0.40%)	777 (0.78%)
PVD	582 (0.10%)	38 (0.04%)	84 (0.07%)	296 (0.12%)	164 (0.16%)
DVT	856 (0.15%)	67 (0.07%)	133 (0.10%)	416 (0.16%)	240 (0.24%)
Pulmonary embolism	673 (0.12%)	57 (0.06%)	108 (0.08%)	326 (0.13%)	182 (0.18%)
Coronary disease[5]	6220 (1.09%)	451 (0.49%)	857 (0.67%)	2908 (1.15%)	2004 (2.00%)
DVT/PE	1223 (0.21%)	92 (0.10%)	189 (0.15%)	606 (0.24%)	336 (0.34%)
Aortic aneurysm[6]	37 (0.03%)	0 (0.00%)	5 (0.02%)	25 (0.04%)	7 (0.03%)
Atrial fibrillation[6]	678 (0.48%)	43 (0.19%)	94 (0.30%)	372 (0.60%)	169 (0.66%)
Valvular heart disease[6]	169 (0.12%)	11 (0.05%)	16 (0.05%)	99 (0.16%)	43 (0.17%)
Total cardiovascular disease[7]	8494 (1.49%)	588 (0.64%)	1165 (0.92%)	3972 (1.57%)	2769 (2.77%)
Cancer					
Breast cancer	2549 (0.45%)	362 (0.39%)	552 (0.43%)	1178 (0.47%)	457 (0.46%)
Invasive breast cancer	2072 (0.36%)	279 (0.30%)	445 (0.35%)	948 (0.38%)	400 (0.40%)
Non-invasive breast cancer	516 (0.09%)	87 (0.09%)	112 (0.09%)	252 (0.10%)	65 (0.06%)
Ovarian cancer	222 (0.04%)	20 (0.02%)	43 (0.03%)	116 (0.05%)	43 (0.04%)
Endometrial cancer[8]	291 (0.05%)	42 (0.04%)	76 (0.06%)	125 (0.05%)	48 (0.05%)
Colorectal cancer	818 (0.14%)	72 (0.08%)	133 (0.10%)	397 (0.16%)	216 (0.22%)
Other cancer[9]	3361 (0.59%)	290 (0.32%)	572 (0.45%)	1648 (0.65%)	851 (0.85%)
Total cancer	6805 (1.19%)	747 (0.81%)	1308 (1.03%)	3239 (1.28%)	1511 (1.51%)
Fractures					
Hip fracture	1085 (0.19%)	32 (0.03%)	75 (0.06%)	446 (0.18%)	532 (0.53%)
Deaths					
Cardiovascular deaths	2221 (0.39%)	101 (0.11%)	199 (0.16%)	888 (0.35%)	1033 (1.03%)
Cancer deaths	2371 (0.41%)	168 (0.18%)	352 (0.28%)	1151 (0.46%)	700 (0.70%)
Other known cause	1779 (0.31%)	99 (0.11%)	184 (0.14%)	781 (0.31%)	715 (0.71%)
Unknown cause	95 (0.02%)	4 (<0.01%	12 (0.01%)	43 (0.02%)	36 (0.04%)
Not yet adjudicated	292 (0.05%)	17 (0.02%)	30 (0.02%)	148 (0.06%)	97 (0.10%)
Total death	6758 (1.18%)	389 (0.42%)	777 (0.61%)	3011 (1.19%)	2581 (2.58%)
Death plus post-WHI deaths	8998 (1.36%)	501 (0.46%)	990 (0.67%)	3927 (1.36%)	3580 (3.09%)

[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] Definite or possible decompensated heart failure adjudicated by UNC.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, UNC heart failure, and CABG/PTCA; Q-wave MI, angina, and congestive heart failure are not collected in the WHI Extension Studies.
[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.

Table 7.3
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for MRC Super Cohort Participants
Data as of: August 29, 2014; Events through August 29, 2014

	Race/Ethnicity											
Outcomes	**American Indian/ Alaskan Native**		**Asian/Pacific Islander**		**Black/African American**		**Hispanic/ Latino**		**White**		**Unknown**	
Number randomized	130		527		14618		6484		22030		385	
Mean follow-up (months)	149.8		150.8		144.4		136.2		168.3		155.7	
Cardiovascular												
CHD[1]	8	(0.49%)	25	(0.38%)	833	(0.47%)	183	(0.25%)	1728	(0.56%)	29	(0.58%)
CHD death[2]	4	(0.25%)	9	(0.14%)	405	(0.23%)	59	(0.08%)	601	(0.19%)	7	(0.14%)
Clinical MI	6	(0.37%)	20	(0.30%)	526	(0.30%)	139	(0.19%)	1286	(0.42%)	24	(0.48%)
Angina[3]	7	(0.69%)	14	(0.34%)	548	(0.48%)	160	(0.33%)	884	(0.49%)	12	(0.40%)
CABG/PTCA	10	(0.62%)	22	(0.33%)	686	(0.39%)	246	(0.33%)	1722	(0.56%)	29	(0.58%)
Carotid artery disease	1	(0.06%)	2	(0.03%)	88	(0.05%)	22	(0.03%)	358	(0.12%)	3	(0.06%)
Congestive heart failure, WHI[3]	3	(0.30%)	9	(0.22%)	477	(0.42%)	91	(0.19%)	655	(0.36%)	11	(0.37%)
Heart failure, UNC[4]	6	(0.37%)	17	(0.26%)	590	(0.34%)	103	(0.14%)	1275	(0.41%)	14	(0.28%)
Stroke	9	(0.55%)	17	(0.26%)	702	(0.40%)	151	(0.21%)	1250	(0.40%)	22	(0.44%)
PVD	3	(0.18%)	6	(0.09%)	213	(0.12%)	20	(0.03%)	338	(0.11%)	2	(0.04%)
DVT	4	(0.25%)	4	(0.06%)	141	(0.08%)	25	(0.03%)	678	(0.22%)	4	(0.08%)
Pulmonary embolism	4	(0.25%)	2	(0.03%)	129	(0.07%)	12	(0.02%)	518	(0.17%)	8	(0.16%)
Coronary disease[5]	18	(1.11%)	53	(0.80%)	1921	(1.09%)	488	(0.66%)	3684	(1.19%)	56	(1.12%)
DVT/PE	7	(0.43%)	4	(0.06%)	215	(0.12%)	31	(0.04%)	956	(0.31%)	10	(0.20%)
Aortic aneurysm[6]	0	(0.00%)	0	(0.00%)	12	(0.03%)	3	(0.01%)	22	(0.03%)	0	(0.00%)
Atrial fibrillation[6]	0	(0.00%)	1	(0.06%)	86	(0.18%)	33	(0.16%)	551	(0.78%)	7	(0.57%)
Valvular heart disease[6]	1	(0.25%)	1	(0.06%)	28	(0.06%)	10	(0.05%)	126	(0.18%)	3	(0.24%)
Total cardiovascular disease[7]	26	(1.60%)	71	(1.07%)	2690	(1.53%)	649	(0.88%)	4988	(1.61%)	70	(1.40%)
Cancer												
Breast cancer	6	(0.37%)	32	(0.48%)	816	(0.46%)	277	(0.38%)	1401	(0.45%)	17	(0.34%)
Invasive breast cancer	5	(0.31%)	24	(0.36%)	652	(0.37%)	226	(0.31%)	1152	(0.37%)	13	(0.26%)
Non-invasive breast cancer	1	(0.06%)	9	(0.14%)	178	(0.10%)	56	(0.08%)	267	(0.09%)	5	(0.10%)
Ovarian cancer	1	(0.06%)	3	(0.05%)	61	(0.03%)	30	(0.04%)	124	(0.04%)	3	(0.06%)
Endometrial cancer[8]	1	(0.06%)	2	(0.03%)	80	(0.05%)	26	(0.04%)	180	(0.06%)	2	(0.04%)
Colorectal cancer	1	(0.06%)	17	(0.26%)	260	(0.15%)	70	(0.10%)	461	(0.15%)	9	(0.18%)
Other cancer[9]	11	(0.68%)	42	(0.63%)	832	(0.47%)	281	(0.38%)	2164	(0.70%)	31	(0.62%)
Total cancer	19	(1.17%)	93	(1.40%)	1922	(1.09%)	650	(0.88%)	4063	(1.31%)	58	(1.16%)
Fractures												
Hip fracture	4	(0.25%)	8	(0.12%)	104	(0.06%)	53	(0.07%)	907	(0.29%)	9	(0.18%)
Deaths												
Cardiovascular deaths	9	(0.55%)	16	(0.24%)	796	(0.45%)	133	(0.18%)	1253	(0.41%)	14	(0.28%)
Cancer deaths	8	(0.49%)	31	(0.47%)	687	(0.39%)	221	(0.30%)	1403	(0.45%)	21	(0.42%)
Other known cause	5	(0.31%)	15	(0.23%)	486	(0.28%)	149	(0.20%)	1111	(0.36%)	13	(0.26%)
Unknown cause	0	(0.00%)	2	(0.03%)	28	(0.02%)	16	(0.02%)	47	(0.02%)	2	(0.04%)
Not yet adjudicated	1	(0.06%)	0	(0.00%)	89	(0.05%)	15	(0.02%)	183	(0.06%)	4	(0.08%)
Total Death	23	(1.42%)	64	(0.97%)	2086	(1.19%)	534	(0.73%)	3997	(1.29%)	54	(1.08%)
Death plus post-WHI deaths	27	(1.44%)	90	(1.16%)	3000	(1.40%)	829	(0.86%)	4974	(1.48%)	78	(1.38%)

[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] Definite or possible decompensated heart failure adjudicated by UNC.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, UNC heart failure, and CABG/PTCA; Q-wave MI and angina, and congestive heart failure are not collected in the WHI Extension Studies.
[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.

Table 7.4
Verified Outcomes (Annualized Percentages) by Age at Enrollment for SRC Super Cohort Participants

Data as of: August 29, 2014; Events through September 30, 2010 and August 29, 2014

	Total	Age at Enrollment 50-54	55-59	60-69	70-79
Outcomes through Extension Study 2005-2010					
Number randomized	117634	14781	22638	53171	27044
Mean follow-up (months)	142.7	154.9	151.9	142.9	128.1
Cardiovascular[1]					
Clinical MI	5752 (0.41%)	209 (0.11%)	513 (0.18%)	2498 (0.39%)	2532 (0.88%)
CHD death[2]	2266 (0.16%)	59 (0.03%)	129 (0.05%)	854 (0.13%)	1224 (0.42%)
Clinical MI	4044 (0.29%)	159 (0.08%)	398 (0.14%)	1834 (0.29%)	1653 (0.57%)
Angina[3]	3623 (0.38%)	139 (0.11%)	423 (0.22%)	1749 (0.41%)	1312 (0.63%)
CABG/PTCA	6113 (0.44%)	241 (0.13%)	711 (0.25%)	3161 (0.50%)	2000 (0.69%)
Carotid artery disease	1111 (0.08%)	49 (0.03%)	117 (0.04%)	519 (0.08%)	426 (0.15%)
Congestive heart failure, WHI[3]	2797 (0.29%)	78 (0.06%)	201 (0.11%)	1096 (0.26%)	1422 (0.68%)
Stroke	4267 (0.30%)	123 (0.06%)	324 (0.11%)	1865 (0.29%)	1955 (0.68%)
PVD	984 (0.07%)	24 (0.01%)	88 (0.03%)	460 (0.07%)	412 (0.14%)
Coronary disease[4]	12035 (0.86%)	461 (0.24%)	1260 (0.44%)	5571 (0.88%)	4743 (1.64%)
Total cardiovascular disease	17374 (1.24%)	637 (0.33%)	1702 (0.59%)	7915 (1.25%)	7120 (2.47%)
Fractures[1]					
Hip fracture	2955 (0.21%)	63 (0.03%)	186 (0.06%)	1108 (0.18%)	1598 (0.55%)
Outcomes through Extension Study 2010-2015					
Number randomized	117634	14781	22638	53171	27044
Mean follow-up (months)	166.7	184.8	181.1	167.6	142.9
Cancer					
Breast cancer	9130 (0.56%)	1122 (0.49%)	1837 (0.54%)	4293 (0.58%)	1878 (0.58%)
Invasive breast cancer	7590 (0.46%)	886 (0.39%)	1510 (0.44%)	3589 (0.48%)	1605 (0.50%)
Non-invasive breast cancer	1654 (0.10%)	252 (0.11%)	349 (0.10%)	758 (0.10%)	295 (0.09%)
Ovarian cancer	851 (0.05%)	93 (0.04%)	166 (0.05%)	396 (0.05%)	196 (0.06%)
Endometrial cancer[5]	1330 (0.08%)	140 (0.06%)	286 (0.08%)	619 (0.08%)	285 (0.09%)
Colorectal cancer	2017 (0.12%)	107 (0.05%)	252 (0.07%)	972 (0.13%)	686 (0.21%)
Other cancer[6]	10480 (0.64%)	890 (0.39%)	1645 (0.48%)	5117 (0.69%)	2828 (0.88%)
Total cancer	22129 (1.35%)	2203 (0.97%)	3899 (1.14%)	10551 (1.42%)	5476 (1.70%)
Deaths					
Cardiovascular deaths	5095 (0.31%)	107 (0.05%)	286 (0.08%)	1866 (0.25%)	2836 (0.88%)
Cancer deaths	6597 (0.40%)	388 (0.17%)	819 (0.24%)	3125 (0.42%)	2265 (0.70%)
Other known cause	4670 (0.29%)	144 (0.06%)	315 (0.09%)	1860 (0.25%)	2351 (0.73%)
Unknown cause	2045 (0.13%)	63 (0.03%)	167 (0.05%)	877 (0.12%)	938 (0.29%)
Total death	18407 (1.13%)	702 (0.31%)	1587 (0.46%)	7728 (1.04%)	8390 (2.61%)
Death plus post-WHI deaths[7]	24354 (1.34%)	850 (0.34%)	1907 (0.51%)	9843 (1.20%)	11754 (3.17%)

[1] Cardiovascular diseases and hip fracture are not adjudicated for SRC Super Cohort participants during the WHI Extension Study 2010-2015. Reported statistics represent experience during the original program and the Extension Study 2005-2010.
[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] "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 Studies.
[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 7.5
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for SRC Super Cohort Participants

Data as of: August 29, 2014; Events through September 30, 2010 and August 29, 2014

	Race/Ethnicity			
	American Indian/ Alaskan Native	**Asian/Pacific Islander**	**White**	**Unknown**
Outcomes through Extension Study 2005-2010				
Number randomized	583	3663	111511	1877
Mean follow-up (months)	125.1	127.8	143.5	131.0
Cardiovascular[1]				
Clinical MI	27 (0.44%)	91 (0.23%)	5549 (0.42%)	85 (0.41%)
CHD death[2]	14 (0.23%)	34 (0.09%)	2178 (0.16%)	40 (0.20%)
Clinical MI	16 (0.26%)	66 (0.17%)	3906 (0.29%)	56 (0.27%)
Angina[3]	23 (0.52%)	56 (0.20%)	3492 (0.39%)	52 (0.36%)
CABG/PTCA	30 (0.49%)	77 (0.20%)	5922 (0.44%)	84 (0.41%)
Carotid artery disease	7 (0.12%)	10 (0.03%)	1075 (0.08%)	19 (0.09%)
Congestive heart failure, WHI[3]	18 (0.41%)	30 (0.11%)	2702 (0.30%)	47 (0.32%)
Stroke	17 (0.28%)	101 (0.26%)	4070 (0.31%)	79 (0.39%)
PVD	6 (0.10%)	8 (0.02%)	951 (0.07%)	19 (0.09%)
Coronary disease[4]	68 (1.12%)	181 (0.46%)	11612 (0.87%)	174 (0.85%)
Total cardiovascular disease	90 (1.48%)	298 (0.76%)	16711 (1.25%)	275 (1.34%)
Fractures[1]				
Hip fracture	7 (0.12%)	29 (0.07%)	2892 (0.22%)	27 (0.13%)
Outcomes through Extension Study 2010-2015				
Number randomized	583	3663	111511	1877
Mean follow-up (months)	142.5	145.5	167.8	149.7
Cancer				
Breast cancer	29 (0.42%)	216 (0.49%)	8780 (0.56%)	105 (0.45%)
Invasive breast cancer	23 (0.33%)	179 (0.40%)	7300 (0.47%)	88 (0.38%)
Non-invasive breast cancer	6 (0.09%)	40 (0.09%)	1590 (0.10%)	18 (0.08%)
Ovarian cancer	2 (0.03%)	13 (0.03%)	828 (0.05%)	8 (0.03%)
Endometrial cancer[5]	1 (0.01%)	21 (0.05%)	1284 (0.08%)	24 (0.10%)
Colorectal cancer	10 (0.14%)	39 (0.09%)	1938 (0.12%)	30 (0.13%)
Other cancer[6]	34 (0.49%)	182 (0.41%)	10122 (0.65%)	142 (0.61%)
Total cancer	73 (1.05%)	443 (1.00%)	21325 (1.37%)	288 (1.23%)
Deaths				
Cardiovascular deaths	29 (0.42%)	93 (0.21%)	4894 (0.31%)	79 (0.34%)
Cancer deaths	25 (0.36%)	123 (0.28%)	6365 (0.41%)	84 (0.36%)
Other known cause	39 (0.56%)	69 (0.16%)	4511 (0.29%)	51 (0.22%)
Unknown cause	5 (0.07%)	28 (0.06%)	1975 (0.13%)	37 (0.16%)
Total death	98 (1.42%)	313 (0.70%)	17745 (1.14%)	251 (1.07%)
Death plus post-WHI deaths[7]	151 (1.80%)	498 (0.89%)	23311 (1.35%)	394 (1.41%)

[1] Cardiovascular diseases and hip fracture are not adjudicated for SRC Super Cohort participants during the WHI Extension Study 2010-2015. Reported statistics represent experience during the original program and the Extension Study 2005-2010.
[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] "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 Studies.
[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 7.6
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age at Enrollment and Race/Ethnicity for MRC Super Cohort Participants Who Did Not Report a Prevalent Condition at Baseline

Data as of: August 29, 2014; Events through August 29, 2014

Outcome	Total	Age at Enrollment 50-54	55-59	60-69	70-79
Number randomized	44174	6788	9352	19418	8616
Mean follow-up (months)	155.1	162.1	162.8	156.0	139.2
Angina[1]	3383 (0.59%)	393 (0.43%)	571 (0.45%)	1599 (0.63%)	820 (0.82%)
Diabetes (treated)	6856 (1.20%)	1178 (1.28%)	1546 (1.22%)	3102 (1.23%)	1030 (1.03%)
Hysterectomy	1657 (0.29%)	241 (0.26%)	409 (0.32%)	763 (0.30%)	244 (0.24%)
Osteoarthritis	12082 (2.12%)	2012 (2.19%)	2712 (2.14%)	5336 (2.11%)	2022 (2.02%)
Intestinal polyps	9869 (1.73%)	1496 (1.63%)	2254 (1.78%)	4614 (1.83%)	1505 (1.51%)
Lupus	746 (0.13%)	124 (0.14%)	156 (0.12%)	342 (0.14%)	124 (0.12%)
Hypertension treated w/pills	15535 (2.72%)	2474 (2.70%)	3407 (2.69%)	6846 (2.71%)	2808 (2.81%)
COPD	1221 (0.21%)	155 (0.17%)	284 (0.22%)	607 (0.24%)	175 (0.18%)
Macular degeneration	3190 (0.56%)	217 (0.24%)	481 (0.38%)	1561 (0.62%)	931 (0.93%)
Alzheimer's disease	2701 (0.47%)	125 (0.14%)	284 (0.22%)	1330 (0.53%)	962 (0.96%)
Parkinson's disease	430 (0.08%)	44 (0.05%)	66 (0.05%)	233 (0.09%)	87 (0.09%)

Outcomes	Race/Ethnicity: Am Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	130	527	14618	6484	22030	385
Mean follow-up (months)	149.8	150.7	143.9	135.8	168.3	155.6
Angina[1]	17 (1.05%)	24 (0.36%)	1192 (0.68%)	345 (0.47%)	1773 (0.57%)	32 (0.64%)
Diabetes (treated)	23 (1.42%)	82 (1.24%)	2630 (1.50%)	1030 (1.40%)	3032 (0.98%)	59 (1.18%)
Hysterectomy	4 (0.25%)	11 (0.17%)	381 (0.22%)	250 (0.34%)	997 (0.32%)	14 (0.28%)
Osteoarthritis	46 (2.84%)	157 (2.37%)	3672 (2.09%)	1899 (2.59%)	6197 (2.01%)	111 (2.22%)
Intestinal polyps	32 (1.97%)	101 (1.53%)	3303 (1.88%)	1195 (1.63%)	5160 (1.67%)	78 (1.56%)
Lupus	3 (0.18%)	5 (0.08%)	277 (0.16%)	120 (0.16%)	337 (0.11%)	4 (0.08%)
Hypertension treated w/pills	57 (3.51%)	183 (2.76%)	4243 (2.42%)	2230 (3.04%)	8694 (2.81%)	128 (2.56%)
COPD	8 (0.49%)	7 (0.11%)	291 (0.17%)	114 (0.16%)	789 (0.26%)	12 (0.24%)
Macular degeneration	9 (0.55%)	22 (0.33%)	553 (0.32%)	332 (0.45%)	2251 (0.73%)	23 (0.46%)
Alzheimer's disease	7 (0.43%)	23 (0.35%)	709 (0.40%)	277 (0.38%)	1664 (0.54%)	21 (0.42%)
Parkinson's disease	2 (0.12%)	6 (0.09%)	110 (0.06%)	51 (0.07%)	258 (0.08%)	3 (0.06%)

[1] During WHI Extension Study 2005-2010, the outcome was angina with hospitalization for a heart condition that may or may not have been related to the angina.

Table 7.7
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age at Enrollment and Race/Ethnicity for SRC Super Cohort Participants Who Did Not Report a Prevalent Condition at Baseline

Data as of: August 29, 2014; Events through August 29, 2014

Outcome	Total	Age at Enrollment 50-54	55-59	60-69	70-79
Number randomized	117634	14781	22638	53171	27044
Mean follow-up (months)	166.4	184.5	181.0	167.4	142.5
DVT, IP/OP	3438 (0.21%)	253 (0.11%)	495 (0.14%)	1691 (0.23%)	999 (0.31%)
PE, IP/OP	1957 (0.12%)	158 (0.07%)	304 (0.09%)	979 (0.13%)	516 (0.16%)
PE, IP	1813 (0.11%)	148 (0.07%)	281 (0.08%)	909 (0.12%)	475 (0.15%)
PE, OP	68 (<0.01%)	6 (<0.01%)	11 (<0.01%)	41 (0.01%)	10 (<0.01%)
Diabetes (treated)	13120 (0.80%)	1670 (0.73%)	2670 (0.78%)	6184 (0.83%)	2596 (0.81%)
Hysterectomy	6127 (0.38%)	910 (0.40%)	1441 (0.42%)	2830 (0.38%)	946 (0.29%)
Osteoarthritis	32617 (2.00%)	4739 (2.08%)	7045 (2.06%)	14747 (1.99%)	6086 (1.89%)
Intestinal polyps	27455 (1.68%)	3787 (1.67%)	6171 (1.81%)	12833 (1.73%)	4664 (1.45%)
Lupus	1743 (0.11%)	216 (0.10%)	357 (0.10%)	810 (0.11%)	360 (0.11%)
Pills for hypertension	41776 (2.56%)	5024 (2.21%)	8310 (2.43%)	19423 (2.62%)	9019 (2.81%)
COPD	3381 (0.21%)	328 (0.14%)	641 (0.19%)	1830 (0.25%)	582 (0.18%)
Macular degeneration	11258 (0.69%)	634 (0.28%)	1422 (0.42%)	5611 (0.76%)	3591 (1.12%)
Alzheimer's disease	7469 (0.46%)	241 (0.11%)	633 (0.19%)	3679 (0.50%)	2916 (0.91%)
Parkinson's disease	1531 (0.09%)	80 (0.04%)	225 (0.07%)	860 (0.12%)	366 (0.11%)

Outcomes	Race/Ethnicity Am Indian/ Alaskan Native	Asian/Pacific Islander	White	Unknown
Number randomized	583	3663	111511	1877
Mean follow-up (months)	142.1	144.8	167.6	149.3
DVT, IP/OP	13 (0.19%)	25 (0.06%)	3350 (0.22%)	50 (0.21%)
PE, IP/OP	6 (0.09%)	15 (0.03%)	1916 (0.12%)	20 (0.09%)
PE, IP	6 (0.09%)	13 (0.03%)	1777 (0.11%)	17 (0.07%)
PE, OP	0 (0.00%)	2 (<0.01%)	65 (<0.01%)	1 (<0.01%)
Diabetes (treated)	98 (1.42%)	448 (1.01%)	12341 (0.79%)	233 (1.00%)
Hysterectomy	15 (0.22%)	113 (0.26%)	5912 (0.38%)	87 (0.37%)
Osteoarthritis	131 (1.90%)	1040 (2.35%)	30916 (1.99%)	530 (2.27%)
Intestinal polyps	114 (1.65%)	702 (1.59%)	26245 (1.69%)	394 (1.69%)
Lupus	15 (0.22%)	36 (0.08%)	1661 (0.11%)	31 (0.13%)
Pills for hypertension	176 (2.55%)	1120 (2.53%)	39844 (2.56%)	636 (2.72%)
COPD	18 (0.26%)	34 (0.08%)	3289 (0.21%)	40 (0.17%)
Macular degeneration	40 (0.58%)	164 (0.37%)	10927 (0.70%)	127 (0.54%)
Alzheimer's disease	24 (0.35%)	115 (0.26%)	7224 (0.46%)	106 (0.45%)
Parkinson's disease	5 (0.07%)	20 (0.05%)	1484 (0.10%)	22 (0.09%)

IP = Inpatient; OP = Outpatient

Table 7.8
Verified Other Cancers (Annualized Percentages): MRC and SRC Super Cohort Participants
Data as of: August 29, 2014; Events through August 29, 2014

	MRC Super Cohort	SRC Super Cohort
Number of participants	44174	117634
Mean follow-up time (months)	155.3	166.7
Overall cancer	6805 (1.19%)	22129 (1.35%)
Primary cancer		
Breast cancer	2549 (0.45%)	9130 (0.56%)
Invasive breast cancer	2072 (0.36%)	7590 (0.46%)
In-situ breast cancer	516 (0.09%)	1654 (0.10%)
Ovarian cancer	222 (0.04%)	851 (0.05%)
Endometrial cancer[1]	289 (0.05%)	1311 (0.08%)
Colorectal cancer	818 (0.14%)	2017 (0.12%)
Other cancer		
Accessory sinus	1 (<0.01%)	7 (<0.01%)
Adrenal gland	4 (<0.01%)	11 (<0.01%)
Anus	21 (<0.01%)	74 (<0.01%)
Appendix	11 (<0.01%)	20 (<0.01%)
Biliary tract, parts of (other/unspecified)	47 (0.01%)	109 (0.01%)
Bladder	195 (0.03%)	614 (0.04%)
Bones/joints/articular cartilage (limbs)	1 (<0.01%)	10 (<0.01%)
Bones/joints/articular cartilage (other)	6 (<0.01%)	13 (<0.01%)
Brain	51 (0.01%)	248 (0.02%)
Cervix	37 (0.01%)	73 (<0.01%)
Central Nervous System (excludes brain)	1 (<0.01%)	3 (<0.01%)
Connective/subcutaneous/soft tissues	33 (0.01%)	109 (0.01%)
Endocrine glands, related structures	0 (0.00%)	3 (<0.01%)
Esophagus	42 (0.01%)	95 (0.01%)
Eye and adnexa	22 (<0.01%)	52 (<0.01%)
Genital organs	17 (<0.01%)	89 (0.01%)
Kidney	167 (0.03%)	431 (0.03%)
Larynx	19 (<0.01%)	30 (<0.01%)
Leukemia	205 (0.04%)	655 (0.04%)
Liver	72 (0.01%)	134 (0.01%)
Lung	922 (0.16%)	2349 (0.14%)
Lymph nodes	1 (<0.01%)	3 (<0.01%)
Lymphoma, Hodgkins	21 (<0.01%)	43 (<0.01%)
Lymphoma, Non-Hodgkins	312 (0.05%)	1157 (0.07%)
Melanoma of the skin	306 (0.05%)	1656 (0.10%)
Multiple myeloma	164 (0.03%)	332 (0.02%)
Oral (mouth)	5 (<0.01%)	19 (<0.01%)
Palate	5 (<0.01%)	23 (<0.01%)
Pancreas	243 (0.04%)	695 (0.04%)
Parotid gland (Stensen's duct)	10 (<0.01%)	40 (<0.01%)
Peripheral nerves and autonomic nervous	0 (0.00%)	2 (<0.01%)
Pyriform sinus	0 (0.00%)	2 (<0.01%)
Respiratory system, intrathoracic, other	0 (0.00%)	2 (<0.01%)
Salivary glands, major (other/unspecified)	3 (<0.01%)	14 (<0.01%)
Stomach	80 (0.01%)	168 (0.01%)
Thyroid	90 (0.02%)	351 (0.02%)
Tongue, part of (other/unspecified)	12 (<0.01%)	56 (<0.01%)
Urinary organs (other/unspecified)	9 (<0.01%)	18 (<0.01%)
Uterus, not otherwise specified[1]	22 (0.06%)	43 (0.03%)
Other/unknown site of cancer	326 (0.06%)	1034 (0.06%)
Other/unknown cancers reported on death	84 (0.01%)	293 (0.02%)

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

Table 7.9
Self Reported Fractures (Annualized Percentages): MRC and SRC Super Cohort Participants

Data as of: August 29, 2014; Events through August 29, 2014

	MRC Super Cohort		SRC Super Cohort	
Number of participants	44174		117634	
Mean follow-up time (months)	155.3		166.7	
Elbow	555	(0.10%)	1873	(0.11%)
Foot	1740	(0.30%)	6180	(0.38%)
Hand	509	(0.09%)	1585	(0.10%)
Hip	1189	(0.21%)	4355	(0.27%)
Knee	892	(0.16%)	2503	(0.15%)
Lower arm	2737	(0.48%)	8610	(0.53%)
Lower leg	2099	(0.37%)	6505	(0.40%)
Pelvis	564	(0.10%)	2577	(0.16%)
Tailbone	214	(0.04%)	834	(0.05%)
Upper arm	1500	(0.26%)	4775	(0.29%)
Upper leg	483	(0.08%)	1810	(0.11%)
Spine	1523	(0.27%)	6425	(0.39%)
Other	3678	(0.64%)	12927	(0.79%)
Any fracture	12070	(2.11%)	40293	(2.47%)

Table 7.10
Cause of Death (Annualized Percentages): MRC and SRC Super Cohort Participants

Data as of: August 29, 2014; Events through August 29, 2014

	MRC Super Cohort		SRC Super Cohort	
Number of participants	44174		117634	
Mean Follow-up Time (months)	179.7		185.4	
Death plus post-WHI deaths	8998	(1.36%)	24354	(1.34%)
Adjudicated death	8638	(1.31%)	19198	(1.06%)
Centrally adjudicated death	5279	(0.80%)	7514	(0.41%)
Locally adjudicated death	695	(0.11%)	4884	(0.27%)
Identified by NDI search	2664	(0.40%)	6800	(0.37%)
Not yet adjudicated	292	(0.04%)	0	(0.00%)
Form 120 death[1]	68	(0.01%)	5156	(0.28%)
Cardiovascular				
Atherosclerotic cardiac	1425	(0.22%)	3086	(0.17%)
Definite CHD deaths after 10/99	673	(0.10%)	1234	(0.07%)
Possible CHD deaths after 10/99	751	(0.11%)	1728	(0.10%)
Cerebrovascular	694	(0.10%)	1728	(0.10%)
Pulmonary embolism	67	(0.01%)	134	(0.01%)
Other cardiovascular	737	(0.11%)	1932	(0.11%)
Unknown cardiovascular	35	(0.01%)	113	(0.01%)
Total cardiovascular deaths	2958	(0.45%)	6993	(0.38%)
Cancer				
Breast cancer	275	(0.04%)	955	(0.05%)
Ovarian cancer	143	(0.02%)	571	(0.03%)
Endometrial cancer	34	(0.01%)	142	(0.01%)
Colorectal cancer	267	(0.04%)	597	(0.03%)
Uterus cancer	27	(<0.01%)	56	(<0.01%)
Lung cancer	750	(0.11%)	1682	(0.09%)
Pancreas cancer	252	(0.04%)	624	(0.03%)
Lymphoma (NHL only)	116	(0.02%)	363	(0.02%)
Leukemia	103	(0.02%)	321	(0.02%)
Brain cancer	54	(0.01%)	237	(0.01%)
Multiple myeloma	111	(0.02%)	189	(0.01%)
Other cancer	553	(0.08%)	1620	(0.09%)
Unknown cancer site	127	(0.02%)	388	(0.02%)
Total cancer deaths	2812	(0.43%)	7745	(0.43%)
Accident/injury				
Homicide	16	(<0.01%)	16	(<0.01%)
Accident	227	(0.03%)	549	(0.03%)
Suicide	16	(<0.01%)	60	(<0.01%)
Other injury	13	(<0.01%)	36	(<0.01%)
Total accident/injury deaths	272	(0.04%)	661	(0.04%)
Other				
Alzheimer's disease	256	(0.04%)	954	(0.05%)
COPD	323	(0.05%)	867	(0.05%)
Pneumonia	249	(0.04%)	677	(0.04%)
Pulmonary fibrosis	63	(0.01%)	158	(0.01%)
Renal failure	190	(0.03%)	297	(0.02%)
Sepsis	248	(0.04%)	513	(0.03%)
Dementia, NOS	271	(0.04%)	734	(0.04%)
Amyotrophic Lateral Sclerosis	37	(0.01%)	150	(0.01%)
Parkinson's	59	(0.01%)	207	(0.01%)
Hepatic cirrhosis	65	(0.01%)	126	(0.01%)
Other known cause	733	(0.11%)	2053	(0.11%)
Unknown cause	170	(0.03%)	2219	(0.12%)
Total other cause deaths	2664	(0.40%)	8955	(0.49%)

[1] SRC Super Cohort or non-Extension Study 2010-2015 MRC Super Cohort Participants only.

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

Data as of: August 29, 2014

	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	263	252	96%	148	(59%)	63	(25%)	3	(1%)	38	(15%)	0	(0%)
CABG	107	105	98%	69	(66%)	26	(25%)	4	(4%)	6	(6%)	0	(0%)
PTCA	314	304	97%	196	(64%)	60	(20%)	3	(1%)	45	(15%)	0	(0%)
Carotid artery disease	98	97	99%	50	(52%)	32	(33%)	1	(1%)	14	(14%)	0	(0%)
Stroke/TIA[4]	474	435	92%	278	(64%)	47	(11%)	0	(0%)	107	(25%)	3	(1%)
PVD	119	116	97%	52	(45%)	15	(13%)	13	(11%)	36	(31%)	0	(0%)
DVT	322	305	95%	168	(55%)	17	(6%)	59	(19%)	61	(20%)	0	(0%)
Pulmonary embolism	172	163	95%	132	(81%)	5	(3%)	11	(7%)	15	(9%)	0	(0%)
Atrial fibrillation	987	954	97%	496	(52%)	130	(14%)	10	(1%)	318	(33%)	0	(0%)
Valvular heart disease	176	171	97%	124	(73%)	25	(15%)	1	(1%)	21	(12%)	0	(0%)
Cancers													
Breast cancer	1413	1396	99%	1365	(98%)	2	(0%)	0	(0%)	29	(2%)	0	(0%)
Ovarian cancer	175	171	98%	104	(61%)	50	(29%)	6	(4%)	11	(6%)	0	(0%)
Endometrial cancer	246	241	98%	198	(82%)	37	(15%)	1	(0%)	5	(2%)	0	(0%)
Cervical cancer	35	34	97%	9	(26%)	19	(56%)	2	(6%)	4	(12%)	0	(0%)
Colorectal cancer	405	399	99%	331	(83%)	42	(11%)	2	(1%)	23	(6%)	1	(0%)
Bladder cancer	163	162	99%	137	(85%)	17	(10%)	1	(1%)	7	(4%)	0	(0%)
Brain cancer	60	59	98%	18	(31%)	22	(37%)	3	(5%)	16	(27%)	0	(0%)
Esophagus cancer	29	27	93%	17	(63%)	5	(19%)	0	(0%)	5	(19%)	0	(0%)
Gallbladder/bile duct cancer	28	28	100%	11	(39%)	15	(54%)	0	(0%)	2	(7%)	0	(0%)
Kidney cancer	121	121	100%	68	(56%)	36	(30%)	2	(2%)	15	(12%)	0	(0%)
Leukemia	150	148	99%	113	(76%)	14	(9%)	3	(2%)	18	(12%)	0	(0%)
Liver cancer	125	122	98%	22	(18%)	69	(57%)	8	(7%)	23	(19%)	0	(0%)
Lung cancer	518	510	98%	433	(85%)	38	(7%)	4	(1%)	35	(7%)	0	(0%)
Lymphoma/Hodgkin's	205	202	99%	156	(77%)	32	(16%)	6	(3%)	8	(4%)	0	(0%)
Melanoma	587	577	98%	403	(70%)	23	(4%)	3	(1%)	148	(26%)	0	(0%)
Multiple myeloma	85	83	98%	70	(84%)	7	(8%)	0	(0%)	6	(7%)	0	(0%)
Pancreas cancer	167	165	99%	139	(84%)	15	(9%)	1	(1%)	10	(6%)	0	(0%)
Stomach cancer	62	61	98%	22	(36%)	26	(43%)	0	(0%)	13	(21%)	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: August 29, 2014

	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	84	84	100%	70	(83%)	5	(6%)	0	(0%)	9	(11%)	0	(0%)
Other genital organ cancer	57	56	98%	7	(13%)	42	(75%)	5	(9%)	2	(4%)	0	(0%)
Other cancer[5]	370	366	99%	170	(46%)	76	(21%)	14	(4%)	106	(29%)	0	(0%)
Fractures													
Hip fracture	215	191	89%	155	(81%)	0	(0%)	0	(0%)	35	(18%)	1	(1%)
Upper leg fracture[6]	143	135	94%	0	(0%)	53	(39%)	12	(9%)	69	(51%)	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: August 29, 2014

	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	300	150	50%	114	38%	36	12%
CABG	76	69	91%	7	9%	0	0%
PTCA	216	195	90%	21	10%	0	0%
Carotid artery disease	48	39	81%	5	10%	4	8%
Stroke	311	277	89%	11	4%	23	7%
PVD	79	52	66%	9	11%	18	23%
DVT	211	166	79%	14	7%	31	15%
Pulmonary embolism	164	126	77%	19	12%	19	12%
Atrial fibrillation	678	438	65%	125	18%	115	17%
Valvular heart disease	169	104	62%	54	32%	11	7%
Cancers							
Breast cancer	1382	1368	99%	9	1%	5	<1%
Ovarian cancer	108	104	96%	4	4%	0	0%
Endometrial cancer	216	198	92%	18	8%	0	0%
Cervical cancer	9	9	100%	0	0%	0	0%
Colorectal cancer	342	328	96%	11	3%	3	1%
Bladder cancer	144	137	95%	6	4%	1	1%
Brain Cancer	18	18	100%	0	0%	0	0%
Kidney cancer	71	69	97%	1	1%	1	1%
Leukemia	130	113	87%	14	11%	3	2%
Liver cancer	29	22	76%	6	21%	1	3%
Lung cancer	450	436	97%	11	2%	3	1%
Lymphoma/Hodgkin's	213	156	73%	55	26%	2	1%
Melanoma	411	403	98%	8	2%	0	0%
Multiple myeloma	80	70	88%	10	13%	0	0%
Pancreas cancer	143	139	97%	2	1%	2	1%
Thyroid cancer	70	70	100%	0	0%	0	0%
Fractures							
Hip fracture	203	155	76%	47	23%	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 (MRC Super Cohort) Participants with a Form 135[1] by Age at Enrollment and Race/Ethnicity

Data as of: August 29, 2014; Events through August 29, 2014

	Total # of Cases (N = 5,247)		# Cases by Age at Enrollment							
			50-54 (N = 294)		55-59 (N = 540)		60-69 (N = 2,341)		70-79 (N = 2,072)	
	N	%	N	%	N	%	N	%	N	%
Heart failure diagnosis										
Definite decompensated	1874	35.7	91	31.0	180	33.3	822	35.1	781	37.7
Possible decompensated	1170	22.3	68	23.1	129	23.9	523	22.3	450	21.7
Chronic stable heart failure	1064	20.3	65	22.1	113	20.9	469	20.0	417	20.1
Heart failure unlikely	742	14.1	44	15.0	76	14.1	356	15.2	266	12.8
Unclassifiable	397	7.6	26	8.8	42	7.8	171	7.3	158	7.6

	# Cases by Race/Ethnicity											
	American Indian/ Alaskan Native (N = 16)		Asian/Pacific Islander (N = 33)		Black/African American (N = 1,502)		Hispanic/ Latino (N = 270)		White (N = 3,388)		Unknown (N = 38)	
	N	%	N	%	N	%	N	%	N	%	N	%
Heart failure diagnosis												
Definite decompensated	12	75.0	13	39.4	529	35.2	89	33.0	1213	35.8	18	47.4
Possible decompensated	0	0	9	27.3	318	21.2	54	20.0	786	23.2	3	7.9
Chronic stable heart failure	3	18.8	2	6.1	347	23.1	54	20.0	648	19.1	10	26.3
Heart failure unlikely	1	6.3	7	21.2	178	11.9	45	16.7	505	14.9	6	15.8
Unclassifiable	0	0	2	6.1	130	8.7	28	10.4	236	7.0	1	2.6

[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 MRC Super Cohort participants.

Table 9.2
Comparison of WHI CHF vs. UNC HF[1] for HT, African American and Hispanic (MRC Super Cohort) Participants

Data as of: August 29, 2014; Events through April 8, 2005

	Congestive Heart Failure, WHI			
	No		Yes	
	# of Participants	%	# of Participants	%
All MRC Super Cohort participants				
Heart failure, UNC				
No	42549	99.1	254	20.4
Yes[2]	159	0.4	921	73.9
Unclassifiable[3]	152	0.4	62	5.0
Insufficient documentation[4]	68	0.2	9	0.7
HT participants				
Heart failure, UNC				
No	26260	98.9	77	9.6
Yes[2]	128	0.5	685	85.0
Unclassifiable[3]	103	0.4	40	5.0
Insufficient documentation[4]	50	0.2	4	0.5
MRC participants				
Heart failure, UNC				
No	21862	99.3	67	21.8
Yes[2]	32	0.1	214	69.7
Unclassifiable[3]	63	0.3	20	6.5
Insufficient documentation[4]	52	0.2	6	2.0

[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 Participants with Definite or Possible Decompensated Heart Failure (HF)
Overall and by Race/Ethnicity

Data as of: August 29, 2014; Events through August 29, 2014

	Total # of Participants[1] (N = 2,005)		Race/Ethnicity White (N = 1,275)		Black (N = 590)		Hispanic (N = 103)	
	N	%	N	%	N	%	N	%
Total								
Definite decompensated HF	1317	65.7	828	64.9	387	65.6	72	69.9
Possible decompensated HF	688	34.3	447	35.1	203	34.4	31	30.1
Type								
Preserved ejection fraction acute decompensated HF	830	41.4	547	42.9	222	37.6	49	47.6
Recovered ejection fraction acute decompensated HF	13	0.6	8	0.6	4	0.7	1	1.0
Systolic acute decompensated HF	707	35.3	434	34.0	222	37.6	35	34.0
Unknown	455	22.7	286	22.4	142	24.1	18	17.5

[1] Refer to tables 7.2 and 7.3 for annualized rates overall, and by age and race/ethnicity.

Table 9.4
Number of UNC Cases Per Participant Adjudicated as Definite or Possible Decompensated Heart Failure (HF) by Cohort

Data as of: August 29, 2014; Events through August 29, 2014

	MRC Super Cohort participants[1]		HT participants		MRC participants	
	N	%	N	%	N	%
Total number of cases sent to UNC						
1	1820	62.2	1295	60.6	770	60.7
2	552	18.9	415	19.4	260	20.5
3	269	9.2	208	9.7	115	9.1
4	126	4.3	94	4.4	53	4.2
≥5	160	5.5	126	5.9	71	5.6
Number of confirmed HF[2] cases						
0	922	31.5	642	30.0	435	34.3
1	1412	48.2	1035	48.4	589	46.4
2	349	11.9	270	12.6	142	11.2
3	146	5.0	105	4.9	62	4.9
≥4	98	3.3	86	4.0	41	3.2

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

Table 9.5
Agreement of the UNC Heart Failure (HF) Adjudications with Self-Reports among MRC Super Cohort Participants

Data as of: August 29, 2014

	Potential Case[1]	Case Eligible for UNC[2]		Case Sent to UNC[2]		Case Confirmed[3]		Case Denied		Case Unclassifiable	
		N	%	N	(%)[4]	N	(%)[5]	N	(%)[4]	N	(%)[4]
Overall	5849	5325	91	5265	(99)	4119	(78)	746	(14)	397	(8)
By Self Report											
Self-reported HF	2206	1736	79	1691	(97)	1444	(85)	174	(10)	70	(4)
No HF self-report	3643	3589	99	3574	(100)	2675	(75)	572	(16)	327	(9)

[1] Includes 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 MRC Super Cohort participants.
[2] Cases are eligible if they self-reported HF, or if not, were forwarded by another outcomes committee for possible HF; cases are sent to UNC when all required records have been received.
[3] Diagnosis was either definite or probable decompensated heart failure, or chronic stable heart failure.
[4] Percentages are relative to "Case Eligible for UNC".
[5] Percentages are relative to "Case Sent to UNC"

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

Data as of: August 29, 2014

Age at start of Extension 2010-2015 (September 30, 2010)	Total (N = 83,044)		Race/Ethnicity: American Indian/ Alaskan Native (N = 277)		Asian/Pacific Islander (N = 1,712)		Black/African American (N = 5,298)		Hispanic/ Latino (N = 2,160)		White (N = 72,637)		Unknown (N = 960)	
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
<65	956	1.2	10	3.6	51	3.0	150	2.8	79	3.7	652	0.9	14	1.5
65-69	14585	17.6	71	25.6	395	23.1	1240	23.4	606	28.1	12095	16.7	178	18.5
70-79	42809	51.5	133	48.0	839	49.0	2865	54.1	1088	50.4	37420	51.5	464	48.3
80-89	23340	28.1	62	22.4	398	23.2	983	18.6	377	17.5	21237	29.2	283	29.5
90+	1354	1.6	1	0.4	29	1.7	60	1.1	10	0.5	1233	1.7	21	2.2

[1] Age on September 30, 2010.
[2] Vital status is alive with current participation on August 29, 2014.

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: August 29, 2014

	Total (N = 93,567)		Age on September 30, 2010									
			<65 (N = 1,014)		65-69 (N = 15,267)		70-79 (N = 46,380)		80-89 (N = 28,699)		90+ (N = 2,207)	
	N	%	N	%	N	%	N	%	N	%	N	%
Never completed Form 151/155	19	<0.1	1	0.1	4	<0.1	8	<0.1	6	<0.1	0	0.0
Perceived Health Status[1]												
Excellent	9652	10.3	184	18.2	2569	16.8	5041	10.9	1733	6.0	125	5.7
Very good	36313	38.8	432	42.6	7012	45.9	19167	41.3	9118	31.8	584	26.5
Good	34628	37.0	306	30.2	4538	29.7	16779	36.2	12079	42.1	926	42.0
Fair	11205	12.0	79	7.8	1007	6.6	4763	10.3	4892	17.1	464	21.0
Poor	1746	1.9	12	1.2	137	0.9	620	1.3	869	3.0	108	4.9
Quality of Life[1]												
Worst, 0-3	2444	2.6	17	1.7	212	1.4	870	1.9	1179	4.1	166	7.5
Halfway, 4-6	16622	17.8	122	12.0	1614	10.6	7272	15.7	6954	24.2	660	29.9
Best, 7-10	74478	79.6	874	86.3	13437	88.0	38229	82.4	20557	71.7	1381	62.6
Functional Capacity, ADL Dependencies[1]												
None[2]	63948	68.4	840	82.9	12612	82.6	34583	74.6	15315	53.4	598	27.1
Eating	1129	1.2	3	0.3	57	0.4	323	0.7	625	2.2	121	5.5
Dressing	3662	3.9	10	1.0	153	1.0	1090	2.4	2003	7.0	406	18.4
Transferring	2295	2.5	7	0.7	92	0.6	664	1.4	1264	4.4	268	12.1
Bathing	5878	6.3	14	1.4	225	1.5	1633	3.5	3336	11.6	670	30.4
Grocery Shopping	15471	16.5	50	4.9	739	4.8	4986	10.8	8415	29.3	1281	58.0
Taking Medication	6541	7.0	10	1.0	211	1.4	1752	3.8	3873	13.5	695	31.5
Performance Measures, Rand-36 Scale[1]												
0-25	12431	13.3	55	5.4	765	5.0	4351	9.4	6303	22.0	957	43.4
25-50	16043	17.2	68	6.7	1394	9.1	7048	15.2	7011	24.4	522	23.7
51-75	22853	24.4	158	15.6	2787	18.3	11754	25.4	7717	26.9	437	19.8
76-100	42196	45.1	732	72.3	10315	67.6	23211	50.1	7648	26.7	290	13.1
Independence[1]												
Supportive Services Availability	17435	18.6	72	7.1	1148	7.5	6232	13.4	8834	30.8	1149	52.2
Supportive Services Use	11126	24.9	29	8.6	386	7.3	3046	14.8	6623	39.3	1042	64.8
Need for nursing care	3756	4.0	6	0.6	197	1.3	1340	2.9	1961	6.8	252	11.4
Use of walking aid [3]	21043	22.5	66	6.5	1039	6.8	7103	15.3	11333	39.5	1502	68.1
Lives alone[4]	31604	41.4	240	27.2	4015	30.0	14863	37.7	11700	54.7	786	61.8
Falls[5]												
None	32331	35.0	433	43.0	6210	40.9	16868	36.7	8275	29.5	545	26.1
One time	19226	20.8	203	20.2	3168	20.9	9686	21.1	5782	20.6	387	18.5
Two times	12817	13.9	123	12.2	1961	12.9	6268	13.6	4122	14.7	343	16.4
Three or more times	27894	30.2	247	24.6	3852	25.4	13141	28.6	9842	35.1	812	38.9

[1] Based on the latest non-missing value from Form151/Form 155
[2] No limitations or need for help reported in any follow-up year.
[3] Cane, crutches, walker, or wheelchair.
[4] Collected on Form 151 only.
[5] 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

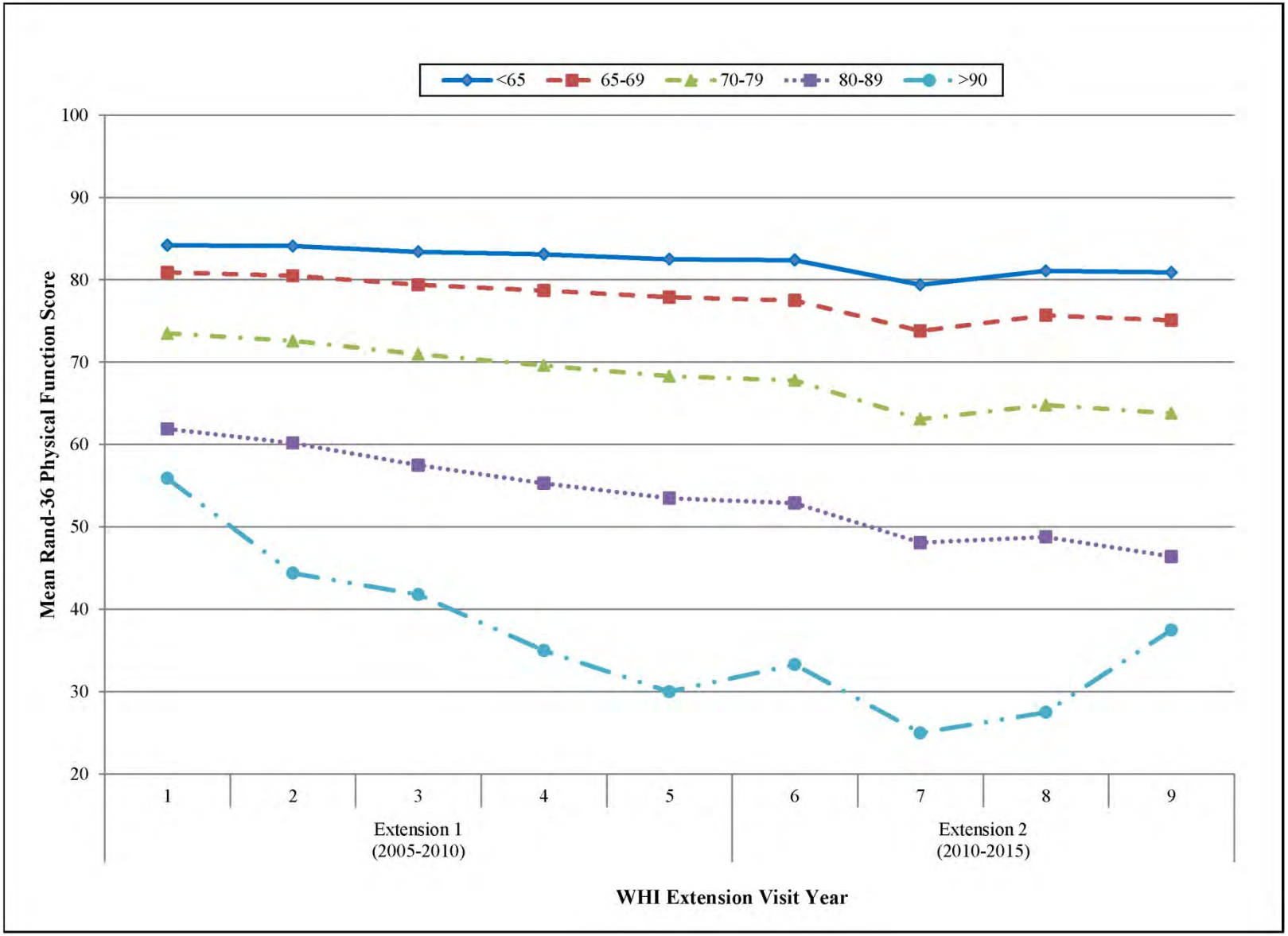
Data as of: August 29, 2014

	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 = 81,659)		Unknown (N = 1,102)	
	N	%	N	%	N	%	N	%	N	%	N	%
Never completed Form 151 or 155	0	0.0	4	0.2	4	0.1	0	0.0	10	<0.1	1	0.1
Perceived Health Status[1]												
Excellent	37	11.6	150	8.0	311	5.1	244	9.9	8811	10.8	99	9.0
Very good	115	36.2	710	37.8	1861	30.4	826	33.4	32384	39.7	417	37.9
Good	118	37.1	767	40.9	2807	45.8	998	40.4	29518	36.2	420	38.1
Fair	43	13.5	224	11.9	1044	17.0	357	14.4	9394	11.5	143	13.0
Poor	5	1.6	25	1.3	108	1.8	46	1.9	1540	1.9	22	2.0
Quality of Life[1]												
Worst, 0-3	5	1.6	26	1.4	78	1.3	50	2.0	2251	2.8	34	3.1
Halfway, 4-6	67	21.1	306	16.3	1223	20.0	487	19.7	14330	17.6	209	19.0
Best, 7-10	246	77.4	1544	82.3	4829	78.8	1934	78.3	65067	79.7	858	77.9
Functional Capacity, ADL Dependencies[1]												
None[2]	198	62.3	1369	73.0	4009	65.4	1729	69.9	55931	68.5	712	64.7
Eating	1	0.3	14	0.7	61	1.0	30	1.2	1012	1.2	11	1.0
Dressing	10	3.1	33	1.8	201	3.3	63	2.5	3315	4.1	40	3.6
Transferring	8	2.5	17	0.9	112	1.8	42	1.7	2087	2.6	29	2.6
Bathing	23	7.2	41	2.2	381	6.2	88	3.6	5275	6.5	70	6.4
Grocery Shopping	54	17.0	219	11.7	1048	17.1	327	13.2	13619	16.7	204	18.5
Taking Medication	22	6.9	69	3.7	315	5.1	117	4.7	5948	7.3	70	6.4
Performance Measures, Rand-36 Scale[1]												
0-25	50	15.7	143	7.6	888	14.5	225	9.1	10978	13.4	147	13.4
25-50	53	16.7	208	11.1	1161	18.9	332	13.4	14101	17.3	188	17.1
51-75	67	21.1	463	24.7	1489	24.3	616	24.9	19952	24.4	266	24.2
76-100	148	46.5	1061	56.6	2590	42.3	1296	52.5	36601	44.8	500	45.4
Independence[1]												
Supportive Services Availability	68	21.5	369	19.7	950	15.5	343	13.9	15502	19.0	203	18.4
Supportive Services Use	43	22.2	158	15.0	681	21.6	211	16.2	9911	25.8	122	20.7
Need for nursing care	11	3.5	21	1.1	169	2.8	42	1.7	3471	4.3	42	3.8
Use of walking aid[3]	84	26.4	265	14.1	1693	27.6	407	16.5	18335	22.5	259	23.5
Lives alone[4]	105	43.9	451	29.0	2100	47.7	644	34.6	27978	41.5	326	37.6
Falls[5]												
None	122	39.0	783	42.3	2830	46.7	1023	42.0	27129	33.7	444	40.9
One time	57	18.2	400	21.6	1269	21.0	500	20.5	16792	20.9	208	19.2
Two times	42	13.4	253	13.7	747	12.3	325	13.3	11315	14.1	135	12.4
Three or more times	92	29.4	417	22.5	1209	20.0	587	24.1	25290	31.4	299	27.5

[1] Based on the latest non-missing value from Form 151/Form 155.
[2] No limitations or need for help reported in any follow-up year.
[3] Cane, crutches, walker, or wheelchair.
[4] Collected on Form 151 only.
[5] Falls data is collected on 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: August 29, 2014



[1] Age on April 1, 2005.

Table 11.1
Medication Inventory: Response Rates Collected During
WHI Extension Studies 2005-2010 and 2010-2015

Data as of: August 29, 2014

Form	# Mailed	Total Response	% Total Response
Extension Study 2005-2010			
153 (Medication and Supplement Inventory)	108296	97462	90.0
154 (Breast Health Supplement to Medication Inventory)	6584	5792	88.0
Extension Study 2010-2015 (MRC only)			
153 (Medication and Supplement Inventory)	21272	17945	84.4

Table 11.2

Barriers to Prescription Medication Collected During
WHI Extension Studies 2005-2010 and 2010-2015

Data as of: September 17, 2012 and August 29, 2014

Description	WHI Extension Study 2005-2010 Participants N	%	WHI Extension Study 2010-2015 MRC Participants N	%	WHI Extension Study 2010-2015 SRC Participants N	%
WHI Extension Study 2005-2010						
Data as of: September 17, 2012	(N = 97,448)		(N = 20,735)		(N = 68,773)	
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
WHI Extension Study 2010-2015						
Data as of: August 29, 2014			(N= 17,492)			
Did not experience any barriers to taking prescription medications			11424	65.3		
No Response to Barriers Question			3836	21.9		
Concerned about possible side effects or complications			1200	6.9		
Don't like taking medications			937	5.4		
The medication or copayment cost too much			747	4.3		
Health insurance would not cover the medication			590	3.4		
Taking too many medications			338	1.9		
Problem getting to the medical facility/physician			107	0.6		
Family discouraged me from taking the medication			116	0.5		
Taking the medication would be inconvenient			69	0.4		
Friends discouraged me from taking the medication			48	0.3		
Concerned about missing work due to taking the medication			67	0.4		

Table 11.3

Top 20 Therapeutic Classes from the WHI Extension Studies 2005-2010 and 2010-2015
Medication Inventory

Data as of: September 17, 2012 and August 29, 2014

Therapeutic Class	WHI Extension Study 2005-2010 Participants N	%	WHI Extension Study 2010-2015 MRC Participants N	%	WHI Extension Study 2010-2015 SRC Participants N	%
WHI Extension Study 2005-2010 Data as of: September 17, 2012	(N = 97,448)		(N = 20,735)		(N = 68,773)	
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
WHI Extension Study 2010-2015 Data as of: August 29, 2014			(N = 17,492)			
Salicylates			9002	51.5		
Multiple Vitamins w/ Minerals			8303	47.5		
Calcium Combinations			7823	44.7		
HMG Coa Reductase Inhibitors			7515	43.0		
Vitamin D			6062	34.7		
Nonsteroidal Anti-Inflammatory Agents (NSAID)			5296	30.3		
Calcium Channel Blockers			4162	23.8		
Beta Blockers Cardio-Selective			4023	23.0		
Proton Pump Inhibitors			3987	22.8		
Thyroid Hormones			3783	21.6		
Ace Inhibitors			3257	18.6		
Angiotensin II Receptor Antagonists			2407	13.8		
Thiazides and Thiazide-like Diuretics			2314	13.2		
Loop Diuretics			1656	9.5		
Biguanides			1615	9.2		
Analgesics Other			1448	8.3		
Antacids - Calcium Salts			1350	7.7		
Potassium			1331	7.6		
Bisphosphonates			1319	7.5		
H-2 Antagonists			1230	7.0		

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 at Visit for Long Life Study Participants

Data as of: August 29, 2014

	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	37.7	340	47.1	1177	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	97.2	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	(0.4)

[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: August 29, 2014

	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	44.3
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)	159.2	(7.2)	161.6	(7.0)	156.5	(7.0)
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 at Visit 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 at Visit 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 12.6
Verified Outcomes by Age at Visit for Long Life Study (LLS) Participants After LLS Blood Draw

Data as of: August 29, 2014; Events through August 29, 2014

Outcomes	Total	Age at Visit			
		63-69	70-79	80-89	≥ 90
Number randomized	7875	723	3052	3688	412
Cardiovascular					
CHD[1]	61	2	15	37	7
CHD death[2]	23	2	2	14	5
Clinical MI	49	1	15	29	4
CABG/PTCA	32	0	13	18	1
Carotid artery disease	8	0	3	5	0
Heart failure, UNC	21	0	4	15	2
Stroke	39	0	11	23	5
Non-disabling stroke[3]	15	0	5	9	1
Fatal/disabling stroke[3]	13	0	0	9	4
Unknown status from stroke[3]	0	0	0	0	0
PVD	14	0	2	10	2
DVT	34	3	11	18	2
Pulmonary embolism	25	1	8	15	1
Coronary disease	74	1	17	47	9
DVT/PE	45	3	16	25	1
Aortic aneurysm	4	0	1	3	0
Atrial fibrillation	92	0	18	65	9
Valvular heart disease	25	0	6	16	3
Total cardiovascular disease	116	0	30	73	13
Cancer					
Breast cancer	29	4	14	11	0
Invasive breast cancer	26	3	12	10	1
Non-invasive breast cancer	4	1	2	1	0
Ovarian cancer	2	0	2	0	0
Endometrial cancer	2	0	1	1	0
Colorectal cancer	10	1	5	4	0
Other cancer[4]	53	3	18	28	4
Total cancer	89	8	38	41	2
Fractures					
Hip fracture	35	0	2	29	4
Deaths					
Cardiovascular deaths	47	3	5	29	10
Cancer deaths	25	4	6	13	2
Other known cause	44	1	3	32	8
Unknown cause	6	0	1	4	1
Not yet adjudicated	72	1	16	46	9
Total death	193	9	31	124	29

[1] CHD includes clinical MI and CHD death.
[2] CHD death includes definite and possible CHD death.
[3] 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.
[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 12.7
Verified Outcomes by Race/Ethnicity for Long Life Study (LLS) Participants After LLS Blood Draw

Data as of: August 29, 2014; Events through August 29, 2014

	Race/Ethnicity		
Outcomes	**Black/African American**	**Hispanic/Latino**	**White**
Number randomized	2651	1314	3910
Cardiovascular			
CHD[1]	13	5	43
CHD death[2]	3	1	19
Clinical MI	11	5	33
CABG/PTCA	8	3	21
Carotid artery disease	4	0	4
Heart failure, UNC	6	0	15
Stroke	12	1	26
Non-disabling stroke[3]	2	0	13
Fatal/disabling stroke[3]	0	0	13
Unknown status from stroke[3]	0	0	0
PVD	5	1	8
DVT	10	6	18
Pulmonary embolism	11	1	13
Coronary disease	13	6	55
DVT/PE	17	7	21
Aortic aneurysm	2	0	2
Atrial fibrillation	12	5	75
Valvular heart disease	2	1	22
Total cardiovascular disease	30	8	78
Cancer			
Breast cancer	10	6	13
Invasive breast cancer	8	6	12
Non-invasive breast cancer	2	0	2
Ovarian cancer	2	0	0
Endometrial cancer	1	0	1
Colorectal cancer	1	2	7
Other cancer[4]	12	9	32
Total cancer	25	16	48
Fractures			
Hip fracture	4	2	29
Deaths			
Cardiovascular deaths	9	3	35
Cancer deaths	7	2	16
Other known cause	4	3	37
Unknown cause	2	0	4
Not yet adjudicated	21	7	44
Total death	43	15	135

[1] CHD includes clinical MI and CHD death.
[2] CHD death includes definite and possible CHD death.
[3] 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.
[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 12.8
Self-Reported Outcomes by Age at Visit and Race/Ethnicity for Long Life Study (LLS) Participants Who Did Not Report a Prevalent Condition at Baseline After LLS Blood Draw

Data as of: August 29, 2014; Events through August 29, 2014

Outcome	Total	Age at Visit 63-69	70-79	80-89	≥ 90
Number randomized	7875	723	3052	3688	412
Angina	131	11	45	68	7
Diabetes (treated)	162	11	68	77	6
Hysterectomy	34	5	18	11	0
Osteoarthritis	213	20	103	79	11
Intestinal polyps	158	18	92	47	1
Lupus	13	2	5	6	0
Pills for hypertension	189	20	62	95	12
COPD	180	17	59	95	9
Macular degeneration	268	9	71	165	23
Alzheimer's disease	202	6	50	125	21
Parkinson's disease	25	3	7	14	1

Outcome	Race/Ethnicity Black/African American	Hispanic/Latino	White
Number randomized	2651	1314	3910
Angina	50	17	64
Diabetes (treated)	56	31	75
Hysterectomy	10	6	18
Osteoarthritis	78	40	95
Intestinal polyps	68	33	57
Lupus	3	3	7
Pills for hypertension	36	34	119
COPD	53	27	100
Macular degeneration	56	48	164
Alzheimer's disease	53	23	126
Parkinson's disease	8	5	12

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

Data as of August 31, 2014

	Form 33 -- Due 05-01-13 thru 04-30-14[1]														Cases to Forward to CCC[7]	
	Self-Report and Screening Outcomes Qxs 2-16										Outcomes Qxs 17-46					
	Total		CCC Mailings[2] Not Collected		Participants Due for RC Collection[3]				Incomplete Qx 2-16		# Required[4]	Incomplete[5] Qx 17-end		Incomplete Form 33[6]		
	# Due	% Collected	#	%	#	% of Due	Not Collected #	Not Collected %	#	% of Collected		#	% of Collected	# Forms	# Cases	# Not Processed at CCC
Boston	9,597	94.5	1,325	13.8	816	8.5	20	2.5	10	0.1	618	2	0.3	10	1,728	31
Buffalo	9,840	97.7	1,371	13.9	1,173	11.9	27	2.3	0		870	0		0	2,447	15
Columbus	10,227	97.7	1,136	11.1	981	9.6	85	8.7	6	0.1	912	4	0.4	6	2,357	20
Gainesville	8,022	93.2	1,212	15.1	731	9.1	68	9.3	4	0.1	616	6	1.0	6	1,534	10
Iowa	8,237	99.2	683	8.3	681	8.3	65	9.5	2	0.0	718	4	0.6	4	1,640	39
Medstar	4,457	96.3	752	16.9	632	14.2	43	6.8	2	0.0	534	2	0.4	2	918	20
Pittsburgh	4,030	93.4	585	14.5	330	8.2	10	3.0	2	0.1	400	0		2	1,088	13
Seattle/LaJolla	4,240	97.3	538	12.7	449	10.6	24	5.3	0		302	0		0	898	0
Stanford	15,039	97.5	1,560	10.4	1,246	8.3	66	5.3	4	0.0	1,038	2	0.2	4	2,803	23
Tucson	5,870	95.1	754	12.8	523	8.9	56	10.7	2	0.0	356	0		2	943	10
Wakeforest	9,163	92.2	1,391	15.2	699	7.6	26	3.7	0		684	0		0	1,531	6
All RCs	88,722	96.0	11,307	12.7	8,261	9.3	490	5.9	32	0.0	7,048	20	0.3	36	17,887	187

[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, 2014

	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	2,116	2,060	97.4	1,728	83.9	56	2.6	2	3.6	38	67.9	16	28.6	2
Buffalo	2,862	2,745	95.9	2,447	89.1	117	4.1	39	33.3	44	37.6	34	29.1	0
Columbus	2,644	2,557	96.7	2,357	92.2	87	3.3	4	4.6	80	92.0	3	3.4	0
Gainesville	1,750	1,669	95.4	1,534	91.9	81	4.6	18	22.2	49	60.5	14	17.3	4
Iowa	1,953	1,849	94.7	1,640	88.7	104	5.3	26	25.0	48	46.2	30	28.8	2
Medstar	1,139	1,073	94.2	918	85.6	66	5.8	21	31.8	27	40.9	18	27.3	2
Pittsburgh	1,315	1,257	95.6	1,088	86.6	58	4.4	22	37.9	23	39.7	13	22.4	0
Seattle/LaJolla	1,086	1,065	98.1	898	84.3	21	1.9	6	28.6	10	47.6	5	23.8	0
Stanford	3,331	3,210	96.4	2,803	87.3	121	3.6	34	28.1	7	5.8	80	66.1	0
Tucson	1,166	1,102	94.5	943	85.6	64	5.5	3	4.7	26	40.6	35	54.7	2
Wakeforest	1,866	1,740	93.2	1,531	88.0	126	6.8	33	26.2	52	41.3	41	32.5	3
All RCs	21,228	20,327	95.8	17,887	88.0	901	4.2	208	23.1	404	44.8	289	32.1	15

[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, 2014

	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	30	66	0.5	56	57	1.0	1.4	133	14	10.5	20
Buffalo	27	96	0.3	117	66	1.8	2.1	211	27	12.8	37
Columbus	91	75	1.2	87	68	1.3	2.5	200	15	7.5	19
Gainesville	74	55	1.3	81	44	1.8	3.2	175	42	24.0	16
Iowa	69	51	1.3	104	52	2.0	3.3	150	18	12.0	26
Medstar	45	49	0.9	66	22	3.1	4.0	72	11	15.3	14
Pittsburgh	12	27	0.5	58	28	2.1	2.6	75	6	8.0	14
Seattle/LaJolla	24	35	0.7	21	29	0.7	1.4	78	5	6.4	5
Stanford	70	98	0.7	121	92	1.3	2.0	250	24	9.6	37
Tucson	58	39	1.5	64	28	2.3	3.8	101	18	17.8	22
Wakeforest	26	56	0.5	126	48	2.6	3.1	157	34	21.7	34
All RCs	526	648	0.8	901	533	1.7	2.5	1,602	214	13.4	244

[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, 2014

	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	2,060	1,728	83.9	152	7.4	148	7.2	6	0.3	26	1.3	0	
Buffalo	2,745	2,447	89.1	197	7.2	48	1.7	13	0.5	40	1.5	0	
Columbus	2,557	2,357	92.2	66	2.6	90	3.5	4	0.2	40	1.6	0	
Gainesville	1,669	1,534	91.9	64	3.8	30	1.8	9	0.5	32	1.9	0	
Iowa	1,849	1,640	88.7	107	5.8	62	3.4	12	0.6	28	1.5	0	
Medstar	1,073	918	85.6	87	8.1	28	2.6	22	2.1	18	1.7	0	
Pittsburgh	1,257	1,088	86.6	41	3.3	87	6.9	4	0.3	37	2.9	0	
Seattle/LaJolla	1,065	898	84.3	79	7.4	76	7.1	10	0.9	2	0.2	0	
Stanford	3,210	2,803	87.3	246	7.7	113	3.5	11	0.3	37	1.2	0	
Tucson	1,102	943	85.6	58	5.3	73	6.6	8	0.7	20	1.8	0	
Wakeforest	1,740	1,531	88.0	96	5.5	67	3.9	9	0.5	36	2.1	1	0.1
All RCs	20,327	17,887	88.0	1,193	5.9	822	4.0	108	0.5	316	1.6	1	0.0

[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, 2014

	# Participants	Full		Partial/Custom		Proxy		Lost		No Follow-up		Absolutely No Contact		Deceased	
		#	%	#	%	#	%	#	%	#	%	#	%	#	%
Boston	10,093	8,884	88.0	281	2.8	153	1.5	36	0.4	19	0.2	55	0.5	665	6.6
Buffalo	10,394	8,469	81.5	737	7.1	279	2.7	8	0.1	54	0.5	25	0.2	822	7.9
Columbus	10,825	9,127	84.3	589	5.4	119	1.1	41	0.4	21	0.2	161	1.5	767	7.1
Gainesville	8,478	6,817	80.4	713	8.4	37	0.4	170	2.0	71	0.8	112	1.3	558	6.6
Iowa	8,744	7,463	85.3	439	5.0	120	1.4	10	0.1	65	0.7	89	1.0	558	6.4
Medstar	4,576	3,835	83.8	343	7.5	19	0.4	66	1.4	45	1.0	31	0.7	237	5.2
Pittsburgh	4,202	3,461	82.4	325	7.7	82	2.0	32	0.8	0		18	0.4	284	6.8
Seattle/LaJolla	4,552	3,883	85.3	101	2.2	104	2.3	9	0.2	23	0.5	26	0.6	406	8.9
Stanford	15,949	13,291	83.3	953	6.0	269	1.7	50	0.3	13	0.1	151	0.9	1,222	7.7
Tucson	6,117	5,159	84.3	320	5.2	54	0.9	114	1.9	0		59	1.0	411	6.7
Wakeforest	9,637	8,158	84.7	404	4.2	78	0.8	247	2.6	37	0.4	36	0.4	677	7.0
All RCs	93,567	78,547	83.9	5,205	5.6	1,314	1.4	783	0.8	348	0.4	763	0.8	6,607	7.1

[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, 2014

	Form 151 - Activities of Daily Living 05-01-13 thru 04-30-14				Form 156- Supplemental Questionnaire 10-1-13 thru 04-30-14			
	Total Collected		Not Collected		Total Collected		Not Collected	
	# Due[1]	% Collected	#	%	# Due[1]	% Collected	#	%
Boston	9,576	92.9	683	7.1	5,018	85.3	738	14.7
Buffalo	9,830	96.0	398	4.0	5,058	85.8	717	14.2
Columbus	10,118	94.1	594	5.9	5,383	89.1	586	10.9
Gainesville	7,988	87.5	998	12.5	4,333	84.1	688	15.9
Iowa	8,225	98.1	156	1.9	4,655	90.9	425	9.1
Medstar	4,427	89.0	488	11.0	2,375	83.0	403	17.0
Pittsburgh	3,996	92.0	321	8.0	2,343	85.5	339	14.5
Seattle/LaJolla	4,206	92.6	311	7.4	2,253	86.6	303	13.4
Stanford	14,966	94.2	874	5.8	7,864	88.7	891	11.3
Tucson	5,840	93.5	381	6.5	3,098	87.2	395	12.8
Wakeforest	9,143	91.1	812	8.9	4,988	85.2	739	14.8
All RCs	88,315	93.2	6,016	6.8	47,368	86.9	6,224	13.1

[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
September 1, 2013 to August 31, 2014

Form	Forms					Sheets Scanned[3]	Forms with Comments[4]	
	Total[1]	Key-Entered[2]		Forms Scanned				
	#	#	%	#	%	#	#	%
Return Mail Processing								
33 – Medical History Update (16 pages)	75,324	591	0.8	74,733	99.2	597,864	10,942	14.5
115 – Extension 2 Consent Status (1 page)	4	4	100	0	0	0	0	0
120 – Initial Report Of Death (1 page)	5,152	5,152	100	0	0	0	0	0
151 – Activities Of Daily Life (2 pages)	74,927	303	0.4	74,624	99.6	74,624	537	0.7
153 – Current Medications and Supplements	1,351	1,351	100	0	0	0	0	0
155 – Lifestyle Questionnaire (16 pages)	39	1	2.6	38	97.4	304	0	0
156 – Supplemental Questionnaire (4 pages)	72,009	57	0.1	71,952	99.9	143,904	80	0.1
Totals	228,806	7,459	3.3	221,347	96.7	816,696	11,559	5.2
Outcomes Data Entry								
121 – Report of Cardiovascular Outcomes (7 pages)[5]	962	1,895	100					
123 – Report of Fracture Outcome (1 page)[5]	120	240	100					
124 – Report of Death (Final) (3 pages)[5]	7,728	15,456	100					
126 – Report of Venous Thromboembolic Disease (2 pages)[5]	189	371	100					
130 – Report of Cancer Outcome (4 pages)[5]	1,650	3,299	100					
132 – Report of Stroke Outcome (3 pages)[5]	445	888	100					
Totals	11,094	22,149	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] Scanable forms are key-entered if the form is damaged, ripped, or otherwise not able to be scanned.
[3] For scanable 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 10-15-14

		Cases at RCs Not Yet Sent to CCC				Cases at CCC					
						Referred From					
	Total # Cases in WHIX	< 14 Days	14-29 Days	≥ 30 Days	Total (not sent)	Rec'd from RCs	From F125 Review	Other Committee	Cases From RCs and Referrals	QA Cases	# Cases to Adjudicate
ES 2010-2015 (ES2)[1]											
Cancers[2]	6,225	44	13	8	65	6,131	15	14	6,160	296	6,456
CVD[3]	3,942	17	4	4	25	3,450	255	212	3,917	378	4,295
Heart Failure	1,240	5			5	1,065	131	39	1,235		1,235
Fatal Events[4]	2,970	9	6	5	20	2,945		5	2,950	132	3,082
Stroke	1,028		4	2	6	907	78	37	1,020		1,020
Fracture	435	2	2		4	426	3	2	431		431
Extension Total	**15,840**	**77**	**29**	**19**	**125**	**14,950**	**482**	**309**	**15,713**	**836**	**16,549**
Form 125-Hospitalization	4,464	17	9	3	29	4,435			5,072		5,072
Retrospective Cases[5]											
HF (UNC)[6]	4,464					4,464			4,464		4,464
Stroke[7]	3,285					3,282		3	3,285		3,285

[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] Includes 1,494 ES2 NDI Deaths
[5] Retrospective cases identified during Extension Study 2005 and scheduled to be adjudicated during Extension Study 2010
[6] Number of cases received from UNC 9-13-13
[7] Includes DM and OS strokes

Table 13.9
Extension Study 2010-2015 Status of Outcomes Adjudication

Data as of 10-15-14

	# 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]	6,456	6,367	89	10	43		35		1
CVD[3]	4,295	4,047	248	29	158		1	2	58
Heart Failure	1,235	265	970	71	390		0		0
Fatal Events	3,082	2,986	96	14	22		3		57
Stroke	1,020	933	87	4	80		2	1	0
Fracture	431	385	46	12	11		0	1	22
Extension Total	**16,549**	**14,983**	**1,536**	**140**	**739**	**0**	**41**	**4**	**138**
Form 125-Hospitalization	5,072	4,969	103	70	32		1		0
Retrospective Cases[5]									
HF (UNC)[6]	4,461	4,460	1		1				
Stroke[7]	3,285	1,130	2,155	2,155					

[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] Includes 1,494 ES2 NDI Deaths

[5] Retrospective cases identified during Extension Study 2005 and scheduled to be adjudicated during Extension Study 2010

[6] Number of cases received from UNC 9-13-13

[7] Includes DM and OS strokes

Table 14.1
CT Outcomes Cases with Remaining Blood Sample by Estimated Volume (in ml): Baseline and AV1

					Volume of Designated Blood Components (mL)** as of 8/2014																			
Visit	Outcome As of 8/14	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	4850	21	Serum	21	0%	1	0%	6	0%	42	1%	35	1%	112	2%	173	4%	659	14%	450	9%	3351	69%
				Citrate	41	1%	1	0%	10	0%	49	1%	33	1%	282	6%	42	1%	4262	88%	7	0%	123	3%
				EDTA	73	2%	1	0%	2	0%	29	1%	23	0%	329	7%	99	2%	4160	86%	13	0%	121	2%
	Breast Cancer Invasive	3966	15	Serum	15	0%			5	0%	37	1%	33	1%	101	3%	153	4%	585	15%	357	9%	2680	68%
				Citrate	34	1%			7	0%	43	1%	29	1%	228	6%	36	1%	3479	88%	7	0%	103	3%
				EDTA	61	2%	1	0%	2	0%	20	1%	20	1%	269	7%	84	2%	3398	86%	10	0%	101	3%
	Colorectal Cancer	1287	4	Serum	4	0%			2	0%	20	2%	11	1%	56	4%	77	6%	291	23%	167	13%	659	51%
				Citrate	13	1%	2	0%	4	0%	14	1%	8	1%	82	6%	27	2%	1109	86%	1	0%	27	2%
				EDTA	23	2%	1	0%	1	0%	11	1%	6	0%	105	8%	45	3%	1062	83%	6	0%	27	2%
	Endometrial Cancer	674	5	Serum	5	1%	1	0%	1	0%	7	1%	4	1%	9	1%	14	2%	63	9%	49	7%	521	77%
				Citrate	7	1%			2	0%	6	1%	7	1%	38	6%	3	0%	600	89%			11	2%
				EDTA	8	1%					5	1%	5	1%	47	7%	8	1%	589	87%	2	0%	10	1%
	Ovarian Cancer	426	1	Serum	1	0%			2	0%	5	1%	2	0%	13	3%	7	2%	44	10%	54	13%	298	70%
				Citrate	6	1%			1	0%	7	2%	4	1%	26	6%			371	87%	1	0%	10	2%
				EDTA	3	1%					8	2%	3	1%	33	8%	6	1%	361	85%	2	0%	10	2%
	CHD	4037	23	Serum	23	1%	4	0%	25	1%	70	2%	98	2%	175	4%	233	6%	457	11%	507	13%	2445	61%
				Citrate	37	1%	16	0%	36	1%	191	5%	110	3%	343	8%	84	2%	3096	77%	9	0%	115	3%
				EDTA	68	2%	12	0%	28	1%	129	3%	227	6%	403	10%	329	8%	2703	67%	28	1%	110	3%
	Clinical MI	2916	18	Serum	18	1%	3	0%	17	1%	49	2%	80	3%	132	5%	176	6%	320	11%	371	13%	1750	60%
				Citrate	27	1%	14	0%	28	1%	148	5%	84	3%	245	8%	59	2%	2219	76%	7	0%	85	3%
				EDTA	53	2%	9	0%	22	1%	105	4%	169	6%	294	10%	234	8%	1935	66%	11	0%	84	3%
	DVT/PE	1148	4	Serum	4	0%	1	0%	6	1%	17	1%	20	2%	64	6%	114	10%	269	23%	205	18%	448	39%
				Citrate	12	1%	5	0%	25	2%	110	10%	112	10%	82	7%	18	2%	743	65%	2	0%	39	3%
				EDTA	14	1%	4	0%	3	0%	40	3%	29	3%	268	23%	52	5%	692	60%	6	1%	40	3%
	Stroke	3051	19	Serum	19	1%	4	0%	11	0%	39	1%	54	2%	137	4%	253	8%	400	13%	295	10%	1839	60%
				Citrate	45	1%	13	0%	29	1%	221	7%	100	3%	289	9%	126	4%	2157	71%	7	0%	64	2%
				EDTA	50	2%	4	0%	3	0%	54	2%	59	2%	431	14%	114	4%	2257	74%	16	1%	63	2%
	Hip Fracture	1831	10	Serum	10	1%	1	0%	4	0%	19	1%	21	1%	50	3%	89	5%	231	13%	265	14%	1141	62%
				Citrate	21	1%	4	0%	8	0%	42	2%	36	2%	99	5%	26	1%	1542	84%	6	0%	47	3%
				EDTA	25	1%	1	0%	5	0%	17	1%	27	1%	156	9%	47	3%	1496	82%	10	1%	47	3%

* 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):
Baseline and AV1

					Volume of Designated Blood Components (mL)** as of 8/2014																			
Visit	Outcome As of 8/14	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	4649	254	Serum	254	5%			2	0%	24	1%	11	0%	50	1%	76	2%	404	9%	424	9%	3404	73%
				Citrate	266	6%			4	0%	50	1%	13	0%	283	6%	32	1%	3994	86%			7	0%
				EDTA	308	7%					23	0%	15	0%	308	7%	24	1%	3963	85%	1	0%	7	0%
	Breast Cancer Invasive	3808	222	Serum	222	6%			2	0%	21	1%	11	0%	43	1%	70	2%	341	9%	399	10%	2699	71%
				Citrate	230	6%			2	0%	42	1%	11	0%	233	6%	24	1%	3259	86%			7	0%
				EDTA	263	7%					19	0%	12	0%	256	7%	18	0%	3232	85%	1	0%	7	0%
	Colorectal Cancer	1208	74	Serum	74	6%			1	0%	10	1%	5	0%	17	1%	13	1%	181	15%	47	4%	860	71%
				Citrate	78	6%	1	0%	3	0%	13	1%	7	1%	86	7%	15	1%	1004	83%			1	0%
				EDTA	88	7%			1	0%	8	1%	4	0%	92	8%	7	1%	1007	83%			1	0%
	Endometrial Cancer	634	29	Serum	29	5%					5	1%			9	1%	3	0%	54	9%	18	3%	516	81%
				Citrate	35	6%					9	1%	3	0%	36	6%	2	0%	548	86%			1	0%
				EDTA	33	5%			1	0%	1	0%	2	0%	46	7%	2	0%	548	86%			1	0%
	Ovarian Cancer	406	19	Serum	19	5%					4	1%			2	0%	1	0%	44	11%	27	7%	309	76%
				Citrate	21	5%	1	0%	1	0%	3	1%	3	1%	32	8%	2	0%	343	84%				
				EDTA	25	6%			1	0%	1	0%	3	1%	35	9%	3	1%	338	83%				
	CHD	3820	273	Serum	273	7%			2	0%	26	1%	7	0%	45	1%	46	1%	347	9%	227	6%	2847	75%
				Citrate	306	8%	12	0%	15	0%	126	3%	73	2%	327	9%	53	1%	2906	76%			2	0%
				EDTA	325	9%	4	0%	12	0%	53	1%	124	3%	374	10%	85	2%	2829	74%	12	0%	2	0%
	Clinical MI	2735	173	Serum	173	6%			2	0%	18	1%	6	0%	33	1%	34	1%	253	9%	152	6%	2064	75%
				Citrate	202	7%	10	0%	12	0%	97	4%	57	2%	230	8%	39	1%	2086	76%			2	0%
				EDTA	216	8%	4	0%	7	0%	44	2%	99	4%	267	10%	66	2%	2021	74%	9	0%	2	0%
	DVT/PE	1062	48	Serum	48	5%					2	0%	1	0%	10	1%	14	1%	122	11%	100	9%	765	72%
				Citrate	61	6%	4	0%	14	1%	62	6%	73	7%	92	9%	15	1%	740	70%			1	0%
				EDTA	60	6%	1	0%			27	3%	9	1%	204	19%	11	1%	749	71%			1	0%
	Stroke	2909	175	Serum	175	6%	2	0%	1	0%	17	1%	4	0%	28	1%	56	2%	275	9%	189	6%	2162	74%
				Citrate	195	7%	9	0%	25	1%	158	5%	68	2%	306	11%	103	4%	2044	70%			1	0%
				EDTA	214	7%	1	0%	3	0%	37	1%	28	1%	370	13%	22	1%	2228	77%	5	0%	1	0%
	Hip Fracture	1781	92	Serum	92	5%	1	0%			11	1%	6	0%	22	1%	27	2%	181	10%	122	7%	1319	74%
				Citrate	107	6%	3	0%	3	0%	42	2%	23	1%	101	6%	23	1%	1478	83%			1	0%
				EDTA	115	6%	1	0%	4	0%	16	1%	9	1%	136	8%	14	1%	1483	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): Baseline and AV3

					Volume of Designated Blood Components (mL)** as of 8/2014																	
Visit	Outcome As of 8/14	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	6829	19	Serum	19	0%	4	0%	7	0%	39	1%	33	0%	216	3%	274	4%	665	10%	660	10%	4912	72%
				Citrate	72	1%	2	0%	4	0%	46	1%	50	1%	315	5%	627	9%	5468	80%	110	2%	135	2%
				EDTA	139	2%	2	0%	7	0%	63	1%	100	1%	454	7%	746	11%	4927	72%	255	4%	136	2%
	Breast Cancer Invasive	5696	17	Serum	17	0%	4	0%	5	0%	33	1%	27	0%	192	3%	259	5%	596	10%	585	10%	3978	70%
				Citrate	64	1%	2	0%	4	0%	39	1%	43	1%	264	5%	553	10%	4518	79%	94	2%	115	2%
				EDTA	116	2%	2	0%	7	0%	54	1%	89	2%	374	7%	652	11%	4038	71%	248	4%	116	2%
	Colorectal Cancer	1548	5	Serum	5	0%	2	0%	2	0%	17	1%	27	2%	100	6%	129	8%	300	19%	210	14%	756	49%
				Citrate	18	1%			6	0%	23	1%	34	2%	167	11%	304	20%	903	58%	51	3%	42	3%
				EDTA	39	3%	4	0%	11	1%	68	4%	96	6%	520	34%	314	20%	448	29%	9	1%	39	3%
	Endometrial Cancer	948	9	Serum	9	1%	5	1%	14	1%	37	4%	42	4%	150	16%	118	12%	169	18%	132	14%	272	29%
				Citrate	12	1%					6	1%	12	1%	59	6%	113	12%	715	75%	12	1%	19	2%
				EDTA	22	2%					14	1%	20	2%	56	6%	84	9%	712	75%	21	2%	19	2%
	Ovarian Cancer	647	1	Serum	1	0%	2	0%	4	1%	18	3%	20	3%	77	12%	68	11%	132	20%	111	17%	214	33%
				Citrate	4	1%					4	1%	2	0%	29	4%	37	6%	553	85%	5	1%	13	2%
				EDTA	9	1%	1	0%	1	0%	6	1%	13	2%	40	6%	78	12%	468	72%	19	3%	12	2%
	CHD	4521	20	Serum	20	0%	5	0%	18	0%	57	1%	60	1%	298	7%	173	4%	340	8%	526	12%	3024	67%
				Citrate	68	2%	10	0%	39	1%	149	3%	150	3%	517	11%	709	16%	2734	60%	27	1%	118	3%
				EDTA	109	2%	5	0%	27	1%	150	3%	256	6%	726	16%	868	19%	2082	46%	180	4%	118	3%
	Clinical MI	3129	13	Serum	13	0%	4	0%	13	0%	42	1%	44	1%	230	7%	125	4%	247	8%	395	13%	2016	64%
				Citrate	50	2%	7	0%	36	1%	116	4%	117	4%	411	13%	514	16%	1780	57%	21	1%	77	2%
				EDTA	82	3%	4	0%	24	1%	111	4%	199	6%	547	17%	642	21%	1321	42%	120	4%	79	3%
	Stroke	3367	6	Serum	6	0%	6	0%	9	0%	32	1%	39	1%	130	4%	94	3%	289	9%	498	15%	2264	67%
				Citrate	38	1%	7	0%	18	1%	111	3%	217	6%	511	15%	417	12%	1947	58%	23	1%	78	2%
				EDTA	63	2%	15	0%	53	2%	302	9%	384	11%	462	14%	512	15%	1365	41%	130	4%	81	2%
	Hip Fracture	2209	7	Serum	7	0%	5	0%	20	1%	61	3%	82	4%	150	7%	184	8%	243	11%	245	11%	1212	55%
				Citrate	25	1%			2	0%	15	1%	24	1%	133	6%	170	8%	1773	80%	26	1%	41	2%
				EDTA	49	2%			2	0%	37	2%	47	2%	189	9%	239	11%	1564	71%	43	2%	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):
Baseline and AV3

					Volume of Designated Blood Components (mL)** as of 9/2014																	
Visit	Outcome As of 8/14	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	5221	623	Serum	623	12%					12	0%			30	1%	4	0%	69	1%	39	1%	4444	85%
				Citrate	660	13%					25	0%			58	1%	5	0%	4472	86%			1	0%
				EDTA	706	14%	1	0%	1	0%	27	1%	7	0%	110	2%	231	4%	4066	78%	70	1%	4	0%
	Breast Cancer Invasive	4354	535	Serum	535	12%					11	0%			27	1%	4	0%	57	1%	32	1%	3688	85%
				Citrate	562	13%					21	0%			50	1%	4	0%	3716	85%			1	0%
				EDTA	600	14%	1	0%	1	0%	25	1%	6	0%	90	2%	218	5%	3341	77%	68	2%	4	0%
	Colorectal Cancer	1214	180	Serum	180	15%			1	0%	2	0%	4	0%	4	0%	4	0%	24	2%	89	7%	906	75%
				Citrate	184	15%					3	0%			19	2%	10	1%	997	82%			1	0%
				EDTA	200	16%					11	1%	1	0%	36	3%	78	6%	884	73%	3	0%	1	0%
	Endometrial Cancer	735	95	Serum	95	13%									5	1%			14	2%	7	1%	614	84%
				Citrate	100	14%					4	1%			10	1%			620	84%			1	0%
				EDTA	106	14%					2	0%	1	0%	12	2%	15	2%	593	81%	4	1%	1	0%
	Ovarian Cancer	510	80	Serum	80	16%									2	0%			16	3%	26	5%	386	76%
				Citrate	82	16%					3	1%			3	1%			422	83%				
				EDTA	82	16%					1	0%	2	0%	7	1%	27	5%	384	75%	7	1%		
	CHD	3747	654	Serum	654	17%					9	0%	1	0%	25	1%	5	0%	68	2%	70	2%	2915	78%
				Citrate	683	18%					11	0%			104	3%	7	0%	2941	78%			1	0%
				EDTA	714	19%	1	0%			31	1%	26	1%	325	9%	337	9%	2306	62%	7	0%	1	0%
	Clinical MI	2487	370	Serum	370	15%					3	0%	1	0%	17	1%	5	0%	46	2%	46	2%	1999	80%
				Citrate	388	16%					6	0%			81	3%	6	0%	2006	81%				
				EDTA	408	16%	1	0%			24	1%	22	1%	250	10%	270	11%	1510	61%	3	0%		
	Stroke	2776	471	Serum	471	17%					7	0%			25	1%	2	0%	38	1%	29	1%	2204	79%
				Citrate	493	18%					14	1%			45	2%	3	0%	2220	80%			1	0%
				EDTA	529	19%					15	1%	1	0%	78	3%	74	3%	2068	74%	10	0%	1	0%
	Hip Fracture	1916	295	Serum	295	15%					1	0%			9	0%			23	1%	19	1%	1569	82%
				Citrate	312	16%					6	0%			20	1%	17	1%	1559	81%			1	0%
				EDTA	326	17%	1	0%			9	0%	2	0%	40	2%	42	2%	1490	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 9/2014

		No DNA Available[1]		< 25 ug Extracted, no Buffy Coat Available for Extraction[2]		< 25 ug Extracted, with Buffy Coat Available for Extraction[3]		> 25 ug Extracted[4]	
Outcome As of 8/2014	**Ppts**	**#**	**%**	**#**	**%**	**#**	**%**	**#**	**%**
CT									
Breast Cancer	4850	72	1.5%	39	0.8%	813	16.8%	3926	80.9%
Breast Cancer Invasive	3966	54	1.4%	36	0.9%	463	11.7%	3413	86.1%
CHD	4037	81	2.0%	59	1.5%	430	10.7%	3467	85.9%
Clinical MI	2916	54	1.9%	49	1.7%	250	8.6%	2563	87.9%
Colorectal Cancer	1287	18	1.4%	18	1.4%	164	12.7%	1087	84.5%
Endometrial Cancer	674	11	1.6%	7	1.0%	115	17.1%	541	80.3%
Hip Fracture	1831	45	2.5%	47	2.6%	122	6.7%	1617	88.3%
Ovarian Cancer	426	5	1.2%	3	0.7%	67	15.7%	351	82.4%
Stroke	3051	46	1.5%	84	2.8%	261	8.6%	2660	87.2%
OS									
Breast Cancer	6829	63	0.9%	17	0.2%	1258	18.4%	5491	80.4%
Breast Cancer Invasive	5696	57	1.0%	15	0.3%	766	13.4%	4858	85.3%
CHD	4521	59	1.3%	27	0.6%	237	5.2%	4198	92.9%
Clinical MI	3129	33	1.1%	20	0.6%	83	2.7%	2993	95.7%
Colorectal Cancer	1548	21	1.4%	7	0.5%	143	9.2%	1377	89.0%
Endometrial Cancer	948	9	0.9%	1	0.1%	143	15.1%	795	83.9%
Hip Fracture	2209	24	1.1%	14	0.6%	187	8.5%	1984	89.8%
Ovarian Cancer	647	7	1.1%	4	0.6%	131	20.2%	505	78.1%
Stroke	3367	44	1.3%	19	0.6%	272	8.1%	3032	90.1%

***** DNA measured by OD ratio or PicoGreen
[1] No 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	3	3		25
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
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					2
Pancreatic Cancer	1	3	2	2		1	6
Ovarian Cancer	5		1				6
Cardiovascular							
CHD	15	4	6	2		1	25
Hypertension		1					1
Stroke	10	2	7	3		1	19
VTE	2	1	2	1			5
Fracture							
Elbow, Lower Humerus	1						1
Hip Fracture	4	2	2	1		1	9
Spine	2						2
Overall Fracture	1						1
Other							
Cognitive decline		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	Publications (All time)
W1	CT core analytes on 6% subsample; Clinic CBC tests: Semi-annual core analytes on QC pools A and B	Complete	CT Controls:3800 *B, Y1, Y3, Y6 on 6% Blood Subsample	Y	Citrate 1ml: FVII:C; Fibrinogen; FVII Ag EDTA 1ml: Trig; Cholesterol; Lp(a); LDLC; HDL2; HDL3; HDLC EDTA .25ml: Trig; Creatinine; Glucose; Cholesterol; LDLC; CRP; HDLC; Insulin Serum 1ml: Tocopherol, alpha; Cryptoxan, beta; Glucose; Lycopene; Carotene, beta; Retinol; Tocopherol, gamma; Insulin; Lutein+Zeaxanthin; Carotene, alpha Serum .25ml: Trig; Cholesterol; CRP; Glucose; HDLC; LDLC; Insulin; Creatinine Whole 2ml: PLT; HCT; Hemoglobin; WBC	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:C; Fibrinogen EDTA 1ml: HDL3; Lp(a); Cholesterol; LDLC; Trig; HDLC; HDL2 Serum 1ml: Carotene, alpha; Insulin; Glucose; Lutein+Zeaxanthin; Tocopherol, alpha; Lycopene; Cryptoxan, beta; Tocopherol, gamma; Retinol; Carotene, beta	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 DM trial	Complete	DM Controls:300 *150 DM Intervention + 150 DM controls at B and Y1	Y	Serum 3ml: Albumin; SHBG; Estradiol (E2); Estrone sulfate; Progesterone; Estradiol, bioavailable; Androstenedione; DHT; DHES; Estradiol, bioavail (%); Prolactin; Testosterone; DHEA; Estrone (E1)	20, 280, 1218

Table 15.1 (continued)
Approved Core Studies[1]

Ref #	Title	Status	Study Population	Blood	Analytes/Data	Publications (All time)
W6	HT CVD Biomarkers: study of CHD, Stroke and VTE - Phase I	Complete	HT CHD:402 Stroke:272 VTE:223 Controls:877 *B, Y1	Y	Citrate 1ml: Protein C; ATIII; F1+2; vWF; CRP; TAFI; Protein S Free; Fibrinogen; FVIII Activity; Prothrombin Ag; PAP; D-dimers; FIX Conc; PAI-1 Ag; Protein S Total DNA 3ug: ESR1; ESR2; GP3A-P1A; GPIba; ITGA2807CT DNA 3ug: PAI-1; PROT; FXIII val34leu; FV Leiden; PRO2; FV-HR2; MTHFR EDTA .25ml: NMR Lipids EDTA 1ml: Trig; LDLC; HDL2; Homocysteine; IL-6; E-Selectin; Lipo-particles; HDL3; Lp(a); Cholesterol; HDLC Serum 1ml: MMP-9	204, 210, 222, 273, 345, 347, 350, 429, 445, 462, 526, 854, 866, 972
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 Core Studies[1]

Ref #	Title	Status	Study Population	Blood	Analytes/Data	Publications (All time)
W8	Nutritional biomarkers study (NBS)	Complete	DM	Y	NBS 24hr Urine 1.85ml: PABARCVR; PABARCVRH; PABACMP; 24 hr Urine Volume; Urine N g/L; Urine N g/day; Paba mg/L (hplc); PABA; Paba mg/24hr (hplc); PABA24; PABACMPH; 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: Urinary potassium; Urinary Sodium 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; Tocopherol, gamma; Folate; Tocopherol, alpha	464, 624, 646, 831, 941, 945, 2106
W9	Biological markers of the effect of HT on risk of fractures in the Women's Health Initiative clinical trial	Analysis	HT Fracture - Hip:750 Controls:750 *Cases=248 hip fractures + 502 non-spine fractures	Y	Serum .65ml: Estradiol, free; SHBG; Estradiol (E2); Estradiol, bioavailable	433, 1218
W10	Biological markers of the effect of HT on risk of breast cancer in the Women's Health Initiative clinical trial	Funded	HT Breast Cancer:755 Controls:755 *498 E+P and 260 E-Alone cases through Sept 2005; B+Y1	Y	Serum .95ml: Testosterone, free; Estradiol, bioavailable; Estrone (E1); Progesterone; Estradiol, free; SHBG; Testosterone; Testosterone, bioavail; Estradiol (E2); Estrone sulfate; (progesterone and testosterone at baseline only)	1033, 1218, 2028

Table 15.1 (continued)
Approved Core Studies[1]

Ref #	Title	Status	Study Population	Blood	Analytes/Data	Publications (All time)
W11	CVD biomarkers - Phase II: strokes after Feb. 2001	Funded	HT Stroke:326 Controls:326 *108 new E+P cases up to July 2002, 174 E alone cases up to March 2004; B+Y1	Y	Citrate .35ml: TFPI activity; TFPI, total; TFPI, free Univ Maastricht: Draw Requirements=B+AV1: Citrate .65ml: LT_APC; NAPCSR; APC-ETP DNA 1ug: ESR1 -1989; ESR1 IVS1 -1415 C/T; ESR1; GP3A-P1A; ESR2-1730AG; ITGA2807CT; GPIba M145T; ESR1 IVS1 -401 C/T; ESR1 IVS1 -1505 A/G; ESR1 IVS1 -354 A/G; ESR2; ESR1 ex1 +30 T/C; GPIba; Serum .25ml: Insulin; Glucose	462, 1114
W14	CVD biomarkers - Phase I: additional asays	Analysis	HT CHD:390 Stroke:270 VTE:220 Controls:880 *B, Y1	Y	Citrate .95ml: Split samples listed below. Citrate .35ml: TFPI, total; TFPI, free; TFPI activity Citrate .65ml: LT_APC; NAPCSR; APC-ETP Serum .25ml: Insulin; Glucose	866, 972, 1114
W15	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, 876, 878, 910, 1121
W18	HT Hormone Pretest	Analysis	HT Controls:240 *120 active + 120 placebo; B, Y1	Y	Serum .95ml: Testosterone, bioavail; Estrone (E1); Testosterone; Estradiol, bioavailable; Progesterone; Estradiol (E2); Estradiol, free; SHBG; Testosterone, free; (progesterone and testosterone only on E+P samples)	795, 1218
W19	WHI HT Proteomic Pilot Study	Complete	HT Controls:200 *100 active, 100 control; B, AV1	Y	Serum .1ml: Proteomics Serum .3ml: Phase II proteins	843, 921

Table 15.1 (continued)
Approved Core Studies[1]

Ref #	Title	Status	Study Population	Blood	Analytes/Data	Publications (All time)
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 Controls:600 *CaD at AV1 and AV3, about 200 AA, 100 Hispanics, and 300 Caucasians	Y	Serum .25ml: Vit D 25-OH	
W24	Vitamin D and breast cancer in CaD trial	Analysis	CaD Breast Cancer:1081 Controls:1081 *Use controls from W15 when possible	Y	Serum .2ml: Vit D 25-OH	470, 876, 878, 910, 1121
W25	WHI coronary artery calcification study in E-alone (WHI-CACS)	Complete	HT *1150 E-Alone ppts aged 50-59	N		503, 506, 570, 591, 816, 955
W26	Food grouping in WHI by FHCRC nutrition shared resource group	Funded	DM	N		
W27	Nutrition and physical activity assessment study (AS218) lab work	Funded	OS *450 ppts	Y	24hr Urine 4ml: 24 hr urine volume, unirary nitrogen g/day, urinary nitrogen g/L Serum 1ml: Carotene, alpha; Tocopherol, gamma; Cholesterol; Retinyl palmitate; Retinol; Lycopene, all trans; Crypt; Tocopherol, alpha; Carotene, beta; Lutein+Zeaxanthin; Lycopene, total	1178, 1385, 1532
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

Table 15.1 (continued)
Approved Core Studies[1]

Ref #	Title	Status	Study Population	Blood	Analytes/Data	Publications (All time)
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
W34	Extension of WHI stroke genome-wide association study (W-7)	Funded	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	Funded	General population	N		889, 1217, 1640, 1747, 1916
W39	27-hydroxycholesterol in CVD biomarkers (W-6)	Complete	HT 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	HT Controls:100 *100 E-Alone ppts in active treatment arm	Y	Serum .4ml: AHSG; MMP-2; IGFBP-4; IGFBP-6; FIX; VitD Binding; ACE; Nephroblastoma overexpressed; IGFBP-3; IGFBP-1; IGFBP-2; VTNbis; MCAM; TFF3; ICAM-1; FX; IGF-I; CP; KNG1; Protein Z; CCL16	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	HT E+P Breast Cancer:60 Controls:60 *60 active treatment. 60 placebo	Y	DNA 0ug: Gene seq; Use samples from W7 and W34	

Table 15.1 (continued)
Approved Core Studies[1]

Ref #	Title	Status	Study Population	Blood	Analytes/Data	Publications (All time)
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	HT Controls:50 *50 E+P ppts at baseline,AV1	Y	Serum .55ml: MMP-2; CCL18; LYVE1; ANG; ACE; MCSF1; IGFBP-1; VTNbis; TFF3; IGFBP-2; CP; AGTASE; Apolipoprotein F; TNC; XLKD1; PARCq; CAPPT; CSF1; LGALS3BP; LCN2; Nephroblastoma overexpressed; ICAM-1; IGF-I; FX; MCAM; B2M; IGFBP-4; KNG1; RNASE4; Apo D; THBS1	921
W45	Proteomic Colon Cancer Study	Funded	OS Colon cancer:100 Controls:100	Y	Citrate .15ml: LGALS3BP; IGFBP-1; IGFBP-2; CEA; PKM2; SPARC; MMP-2; NID1; ENO1; PPIA; Amyloid Precursor Protein; LRG1; IGFBP-6; MAPRE1; LTF; ADAMTS13; PPBP	
W47	Breast Tumor Tissue Pilot	Complete	DM Breast Cancer - Invasive:504 *504 ppts diagnosed in 1999-2007 eligible, with 248 tissue samples received .	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)	Funded	General population Controls:12008 *SHARe ppts (12,008)	Y	Serum .25ml: Glucose; CRP; Creatinine; LDLC; Cholesterol; Insulin; HDLC; Trig	1872
W57	Extend CVD Biomarker Study using HT Proteomics Study Findings on B2M and IGFBP4	Complete	General population CHD:354 Stroke:341 Controls:695	Y	Citrate .15ml: B2M Citrate .15ml: IGFBP-4	1065
W58	CVD, diabetes, and renal biomarkers in the EA HT Cohort	Funded	HT Controls:10254 *AS39-WHIMS (6061) + M13-GARNET (3015) + subset of HT EA aged 65 and over (279) and under 65 (899)	Y	Serum .25ml: Cholesterol; Creatinine; Trig; Glucose; HDLC; LDLC; Insulin; CRP	2024

Table 15.1 (continued)
Approved Core Studies[1]

Ref #	Title	Status	Study Population	Blood	Analytes/Data	Publications (All time)
W59	Collaborative telomere studies pilot study (Jacques)	Funded	HT Controls:60	Y	DNA .0625ug: TELO	
W61	DNA Extraction of Medical Records Cohort Participants	Complete	General population Controls:12000 *~12,000 Med Records Cohort ppts who need to be extracted. All to be done and billed by 9/30/11	Y		
W63	GWAS on WHIMS and subsample of HT EA women	Funded	HT Controls:5907 *Non-GARNET WHIMS (4661) + HT EA ppts aged 65+ (300) and under 65 (946)	Y	DNA 2ug: Illumina OmniExpress + Exome	1902, 1919, 1920, 1921, 1925, 1926, 1927, 1932, 1943, 2018, 2024, 2035, 2036, 2037, 2085, 2093
W64	Long Life Study (LLS)	Funded	General population Controls:7875 *7875 63+ year old MRC ppts with GWAS and Baseline Biomarkers	Y	Serum SST .25ml: Creatinine; Insulin; Cholesterol; Trig; Glucose; HDLC; CRP; LDLC Whole 2ml: 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	Long Life Study-Phase III Biomarkers and GWAS	Funded	General population Controls:1500 **Ppts are 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	DNA 1.5ug: Illumina Omn iExpress + Exome; Serum .25ml: Insulin; Creatinine; Glucose; HDLC; Cholesterol; LDLC	
286[2]	OPACH: Objective physical activity and cardiovascular health in women aged 80 and older	Analysis	General population *~7060 LLS eligible (W64)	N		2246

Table 15.1 (continued)
Approved Core Studies[1]

Ref #	Title	Status	Study Population	Blood	Analytes/Data	Publications (All time)
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
M5[2]	SHARe (SNP Health Association Resource) GWAS	Analysis	General population Controls:12007 *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 Core Studies[1]

Ref #	Title	Status	Study Population	Blood	Analytes/Data	Publications (All time)
M6[2]	Population Architecture using Genomics and Epidemiology (PAGE)	Analysis	General population Colorectal Cancer:1436 Endometrial Cancer:1103 CHD:4274 Type 2 Diabetes:4000 Stroke:3455 Ovarian Cancer:703 Cancer of Lung:1751 Melanoma - Skin:1102 Lymphoma, Non Hodgkins:843 Breast Cancer - Invasive:1961 Controls:16000 *~20,000 ppts (cases & controls) every year for 4 years (new set of outcomes each year)	Y	DNA 2ug: SNPs 96 DNA 1ug: Metabochip DNA 2ug: AIMS DNA 2ug: SNPs 384 EKG DNA 2ug: SNPs 384 Cancer	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]	GWAS of Hormone Treatment and CVD and Metabolic Outcomes in WHI GWAS of Hormone Treatment and CVD and Metabolic Outcomes in WHI	Complete	HT CHD:520 Type 2 Diabetes:1080 Stroke:351 VTE:313 Controls:2805 *Controls #s include 174 case/control pairs with multiple outcomes, 200 SHARe ppts **Validation in the OS	Y	DNA 2ug: GWAS; GWAS in HT DNA 1ug: Exome Chip DNA 1ug: Fluidigm Array	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 Core Studies[1]

Ref #	Title	Status	Study Population	Blood	Analytes/Data	Publications (All time)
M24[2]	WHI Sequencing Project (WHISP)	Analysis	General population MI:161 Type 2 Diabetes:165 Stroke:770 Controls:1865 *Phase I: BMI/T2D, early MI. Phase II: Stroke, Hypertension, Deeply Phenotyped Reference Group (DPR); Phase III: extra BMI and Stroke; Replication: 8950 samples (stroke+controls 3000; EOMI+Controls 5000; BP hi/lo 950)	Y	DNA 1ug: GWAS; DNA 5ug: EXOMIC SEQ DNA 1ug: Exome Chip	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	Publications (All time)
1	Ancestry association analyses of WHI traits	Dr. Michael Seldin	University of California - Davis	964, 1185, 1253, 1315, 1500, 1599, 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	
4	Proteomics and the health effects of postmenopausal hormone therapy	Dr. Ross Prentice	Fred Hutchinson Cancer Research Center	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, 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 School of Medicine	
7	Endogenous estradiol and the effects of estrogen therapy on major outcomes of WHI	Dr. Steve Cummings	UC-San Francisco	1033, 1218
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, 1218
10	Adipokines and risk of obesity-related disease	Dr. Gloria Ho	Albert Einstein College of Medicine	893, 894, 922, 1025, 1029, 1083, 1507
11	Physical activity, obesity, inflammation and CHD in a multi-ethnic cohort of women	Dr. I-Min Lee	Brigham and Women's/Harvard University	895
12	Hormone therapy, estrogen metabolism and risk of breast cancer or hip fracture in the WHI hormone trial	Dr. Lewis Kuller	University of Pittsburgh	916
13	Markers of B-cell stimulation as potential predictors of Non-Hodgkins lymphoma	Dr. Anne DeRoos	University of Washington	1283, 1374, 1817
14	Inflammation and thrombosis gene pathways and cardiovascular disease	Dr. Alex Reiner	Fred Hutchinson Cancer Research Center	1215, 1508, 1533, 1795, 2121

Table 15.2 (continued)
Broad Agency Announcement Activities

BAA	Title	PI	Institution	Publications (All time)
15	Discovery and confirmation of cancer specific serum protein markers for ovarian cancer early detection	Dr. Martin McIntosh	Fred Hutchinson Cancer Research Center	
16	Identifying biomarkers for pancreatic cancer	Dr. Sunil Hingorani	Fred Hutchinson Cancer Research Center	
17	Proteomics based discovery of blood based biomarkers and risk factors for lung cancer among women smokers and never smokers	Dr. Sam Hanash	MD Anderson Cancer Center	
18	Followup 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 Health	1058, 1259, 1558, 1746
20	Evaluation of specific markers of rheumatoid arthritis, Inflammation, thrombogenesis and risk of cardiovascular disease and total mortality	Dr. Larry Mooreland	University of Pittsburgh	1701, 1732, 2132
21	Understanding the role of sex hormones in colorectal cancer	Dr. Marc Gunter	Albert Einstein College of Medicine	1173, 1218
22	Predictive modeling for CVD in a multiethnic cohort in women	Dr. Nancy Cook	Brigham and Women's/Harvard University	1272, 1319, 1496, 1745
23	Integrative genomics for risk of CHD and related phenotypes in the WHI	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	
25	Leukocyte telomere dynamics, cardiovascular aging and survival in the WHI Long Life Study in the WHI Long Life Study	Dr. Alex Reiner	Fred Hutchinson Cancer Research Center	

Table 15.3
Summary of Ancillary Studies

Data as of October 2014

Current Status	Number of Studies	Led by WHI Investigator	
		Yes	No
Dropped	246	86	160
Seeking approval	20	8	12
Approved	61	18	43
Funded	30	11	19
Data analysis in progress*	91	55	36
Complete	101	57	44
Total	**549**	**230**	**319**

*Data analysis continuing after the funding end date.

Table 15.4
All Approved Ancillary Studies
(From Oct. 1, 2013)

AS #	Title	PI	WHI PI	Status	Study Dates	Case Controls	Blood Study
451	Screening for pre-clinical pernicious anemia in the WHI	Oakley, Jr. - Emory University - Rollins School of Public Health	N	Approved	04/01/15-03/31/17	OS	Y
453	Environmental cadmium, bone density and fracture in the Women's Health Initiative	Newcomb - Fred Hutchinson Cancer Research Center	N	Approved	04/01/15-03/30/18	General population Fracture (general):800 Controls:654 *Cases: Fracture of the hip, vertebrae, radius, ulna. Controls: 1,600 total, but ~1,000 will not need sample and instead use data from AS290	Y
455	Helicobacter pylori protein-specific antibodies and colorectal cancer risk	Epplein - Vanderbilt University	N	Approved	04/01/15-03/31/18	OS Colorectal Cancer:807 Controls:807	Y
456	Relationship between markers of bone remodeling and coronary calcification in post-menopausal women	Poornima - Allegheny Singer Research Institute	N	Approved	07/01/14-06/30/16	CT	Y
457	Genome-wide association study (GWAS) of thyroid cancer	Hsing - Cancer Prevention Institute of California	N	Approved	07/01/15-06/30/20	OS Cancer of Thyroid:300 Controls:300	Y
458	Phthalate metabolites and breast cancer risk in the Women's Health Initiative	Reeves - University of Massachusetts	N	Approved	04/01/15-03/31/18	General population Breast Cancer - Invasive:500 Controls:1000 *from BMD sites	Y
460	Erythrocyte omega-3 fatty acids and the risk of breast and endometrial cancer in the WHI	Brasky - The Ohio State University College of Medicine	N	Approved	04/01/15-03/31/20	General population Endometrial Cancer:1000 Breast Cancer - Invasive:1089	Y
461	Early Detection of Ovarian Cancer through Epigenetic Factors in the WHI	Genkinger - Mailman School of Public Health at Columbia University	N	Approved	07/01/15-06/30/20	General population Ovarian Cancer:610 Controls:610	Y
462	Development of a biomarker risk score for breast cancer in older Latina and non-Hispanic women	Patterson - University of California, San Diego	N	Approved	09/01/14-08/31/19	General population Breast Cancer - Invasive:350 Controls:350	Y

Table 15.4 (continued)
All Approved Ancillary Studies
(From Oct. 1, 2013)

AS #	Title	PI	WHI PI	Status	Study Dates	Case Controls	Blood Study
463	Development of a sex hormone risk score for breast cancer in postmenopausal women	Laughlin - University of California, San Diego	N	Approved	07/01/15-06/30/18	General population Breast Cancer - Invasive:350 Controls:350	Y
464	Classification of Participants in the WHI by Rural-Urban Residence	Simon - Wayne State University Medical School	Y	Funded		General population	N
465	Biomarkers of environmental exposures in hepatocellular carcinoma	Shen - Columbia University Medical Center	N	Approved	07/01/15-06/30/19	General population Cancer of Liver:130 Controls:260 *130 cases of hepatocellular cancer	Y
466	Melatonin and risk of diabetes and cardiovascular disease	Sturgeon - University of Massachusetts	N	Approved	09/01/14-08/31/17	General population	Y
468	Erythrocyte Polyunsaturated Fatty Acids and Changes in Fat Mass in Women	Wang - Brigham and Women's Hospital	N	Approved	04/01/15-03/31/19	DM	Y
471	Macular pigment in aging and disease	Mares - University of Wisconsin	N	Approved	12/01/14-11/30/18	OS	Y
472	The PEACE Consortium: Cardiometabolic and Aging Outcomes in Parkinson Disease	Ton - University of Washington	N	Approved		General population	N
473	Examining the effectiveness of tobacco control policies on smoking behaviors and tobacco-related health outcomes among post-menopausal women: An analysis of the WHI	McCausland - Brown University	N	Approved	02/01/14-06/30/14	General population	N
476	APOL1, sickle cell trait genotypes and black-white disparities in chronic kidney disease	Franceschini - University of North Carolina at Chapel Hill	N	Approved	04/01/15-03/31/19	General population Controls:29416 *29,416 total ppts (11,911 blacks + 17,505 whites)	Y
477	Genetic determinants of variability in white blood cell count and platelet count	Reiner - FHCRC	N	Approved	04/01/15-03/31/19	General population	Y
478	Comprehensive blood pressure loci discovery in postmenopausal women	Franceschini - University of North Carolina at Chapel Hill	N	Approved	04/01/15-03/31/19	General population	Y

Table 15.4 (continued)
All Approved Ancillary Studies
(From Oct. 1, 2013)

AS #	Title	PI	WHI PI	Status	Study Dates	Case Controls	Blood Study
479	Plasma melatonin and risk of colorectal cancer in the WHI	Jiao - Baylor College of Medicine	N	Approved	01/01/15-12/31/15	General population Colorectal Cancer:220 Controls:356 *From AS292	Y
480	Sex hormones, gene variants, and pancreatic cancer	Bao - Brigham and Women's Hospital	N	Approved	04/01/15-03/31/17	OS Pancreatic Cancer:131 Controls:131 *Cases and controls from AS214	Y
481	Cardiovascular disease and aircraft noise exposure	Peters - Boston University	N	Approved	07/01/14-06/30/18	General population	N
483	Mechanisms of cocoa flavanols and/or multivitamin for arterial health	Allison - University of California, San Diego	N	Approved	03/01/15-06/30/20	General population	Y
486	Effect of Cocoa-Flavanol Supplementation on Heart Failure Burden	Eaton - Memorial Hospital of RI	N	Approved	07/01/15-06/30/20	General population	Y
487	Cocoa flavanols and multivitamin for prevention of diabetes in men and women	Liu - Brown University	N	Approved	07/01/15-06/30/19	General population	Y
488	Vascular, cognitive and white matter responses to cocoa flavanols: COSMOS substudy	Fisher - Brigham and Women's Hospital	N	Approved	07/01/15-06/30/19	General population	N
492	Cocoa flavanols and risk for sarcopenia	Jackson - Ohio State University	N	Approved	07/01/15-06/30/20	General population	Y
493	Effects of cocoa flavanols on fractures and bone health	LeBoff - Partners Health Care	N	Approved	07/01/15-06/30/20	General population	Y
494	Effect of cocoa flavanol and multivitamin supplements on blood pressure and hypertension	Sesso - Brigham and Women's Hospital	N	Approved	07/01/15-06/30/19	General population	Y
495	COSMOS-Mind	Shumaker - Wake Forest School of Medicine	N	Approved	06/01/15-05/31/20	General population	N
497	Cataract and age-related macular degeneration in a supplementation trial of a multivitamin and cocoa flavanol	Christen - Brigham and Women's Hospital	N	Approved	07/01/15-06/30/30	General population	N

Table 15.4 (continued)
All Approved Ancillary Studies
(From Oct. 1, 2013)

AS #	Title	PI	WHI PI	Status	Study Dates	Case Controls	Blood Study
500	Identification of rare variants interacting with hormone therapy for breast cancer risk	Sun - Wake Forest University	N	Approved	08/01/14-06/30/18	General population Breast Cancer:2890 Controls:2000 *890 HT cases + 2,000 OS case/control pairs	Y
501	Validating inflammation and insulin-IFG markers for risk prediction in a lung cancer consortium	Ho - Albert Einstein College of Medicine	N	Approved	07/01/15-06/30/19	General population Cancer of Lung:633 Controls:633 *current and former smokers, exclude those already in AS266	Y
502	A prospective study of metabolomic profiles and cutaneous melanoma	Han - Brigham and Women's Hospital	N	Approved	01/01/15-12/31/19	General population	Y
503	Biomarkers of choline and vitamin B6 status and liver cancer risk	Butler - University of Pittsburgh	N	Approved	07/01/15-06/30/20	General population Cancer of Liver:190 Controls:380	Y

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

Data as of September 2014

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 2014

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 2014

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	449 Validity of self-reported medication use compared with pharmacy records among a cohort of postmenopausal women	W47[2] Breast Tumor Tissue Pilot	W64 Long Life Study
Midwest														
Columbus	217		133		1061	108	707	14	31	77	49		31	1152
Iowa		224	155		656	65	669	12	142	61	27		45	718
Pittsburgh			74		412	43	263	7	27	34	19		10	461
Northeast														
Boston			104		570	78	733	15		63	27		36	613
Buffalo			131		1037	100	691	21		59	57		45	1116
Medstar			72		661	58	302	9		27	40		11	720
Southeast														
Gainesville		180	146		871	107	507	12		41	48		14	934
Wake Forest		161	160		1039	78	595	12		57	75		28	1119
West														
CCC			87	154	417	28	339	6		22	27		23	436
Stanford		173	239		1404	131	1176	21		101	89		61	1476
Tucson			72		436	39	400	7		35	42		36	469
TOTAL	**217**	**738**	**1373**	**154**	**8564**	**835**	**6382**	**136**	**200**	**599**	**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 2014

CT+OS

	Ppts	%	
CT+OS	161,808		
Not Enrolled in Ancillary Studies	126,567	78.2	
Enrolled in Ancillary Studies	35,241	21.8	
Number of Studies	**Ppts**	**%**	**Enrollments**
1	21,365	13.2	21,365
2	8,318	5.1	16,636
3	3,005	1.9	9,015
4	1,376	0.9	5,504
5	798	0.5	3,990
6	309	0.2	1,854
7	61	0.0	427
8	7	0.0	56
9	1	0.0	9
10	1	0.0	10
Total	**35,241**	**21.8**	**58,866**

Extension 1

	Ppts	%	
Consented to Extension 1	115,407		
Not Enrolled in Ancillary Studies	84,385	73.1	
Enrolled in Ancillary Studies	31,022	26.9	
Number of Studies	**Ppts**	**%**	**Enrollments**
1	17,857	15.5	17,857
2	7,721	6.7	15,442
3	2,899	2.5	8,697
4	1,369	1.2	5,476
5	797	0.7	3,985
6	309	0.3	1,854
7	61	0.1	427
8	7	0.0	56
9	1	0.0	9
10	1	0.0	10
Total	**31,022**	**27.0**	**53,813**

Extension 2

	Ppts	%	
Consented to Extension 2	93,567		
Not Enrolled in Ancillary Studies	66,460	71.0	
Enrolled in Ancillary Studies	27,107	29.00	
Number of Studies	**Ppts**	**%**	**Enrollments**
1	15,375	16.4	15,375
2	6,862	7.3	13,724
3	2,460	2.6	7,380
4	1,247	1.3	4,988
5	785	0.8	3,925
6	308	0.3	1,848
7	61	0.1	427
8	7	0.0	56
9	1	0.0	9
10	1	0.0	10
Total	**27,107**	**28.8**	**47,742**

Table 15.7
Funded BAA and Ancillary Studies PI List
(As of Oct. 2014)

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	370, 384, 97	97, 150, 282, 297, 311, 337, 370, 384, 415, 440, M11, W47, W64	97, 121, 129, 140, 150, 282, 297, 370, 384, 440, M8, M9, M11, BA6, BA11, BA15, BA21, W47
Assimes	Themistocles (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		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		139, 56	
Burrows	Beth	Fred Hutchinson Cancer Research Center	Yes	50		
Caan	Bette	Kaiser Foundation Research Institute - Oakland	Yes		100, 243	
Carty	Cara	George Washington University	Yes			M16
Cauley	Jane	University of Pittsburgh	Yes	161, 181, BA9		

Table 15.7 (continued)
Funded BAA and Ancillary Studies PI List
(As of Oct. 2014)

Last Name	First Name	PI Institution	WHI Investigator	Anc PI for	WHI PI for	CCC PI for
Cene	Crystal	University of North Carolina at Chapel Hill	No	414		
Chang	Shine	University of Texas MD Anderson Cancer Center	No	100		
Chanock	Stephen	National Institute of Health	No	M3, M8		
Chen	Jiu-Chiuan	University 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	
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	University 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		
Drieling	Rebecca	Fred Hutchinson Cancer Research Center	No	449		
Driscoll	Ira	University of Wisconsin - Milwaukee	No	250		
Dunn	Julie	Tufts University	Former	84		
Eaton	Charles	Memorial Hospital of RI	Yes	391	251, 391	

Table 15.7 (continued)
Funded BAA and Ancillary Studies PI List
(As of Oct. 2014)

Last Name	First Name	PI Institution	WHI Investigator	Anc PI for	WHI PI for	CCC PI for
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		
Greenland	Philip	Northwestern University	Yes	438		
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	University of Oklahoma - Tulsa	Yes	163	137, 163	
He	Ka	Indiana University Bloomington	No	187		
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		

Table 15.7 (continued)
Funded BAA and Ancillary Studies PI List
(As of Oct. 2014)

Last Name	First Name	PI Institution	WHI Investigator	Anc PI for	WHI PI for	CCC PI for
Ho	Gloria	Albert Einstein College of Medicine	Yes	152, 208, 266, BA10		
Hofmann	Jonathan	National Institute of Health - NCI	No	389		
Howard	Barbara	MedStar Research Institute	Yes		217, 397, 403	
Hsia	Judith	George Washington University	Yes	68	68	
Hubble	Allan	University 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, M24, BA3, BA18	117, 223, 271, 301, M24, BA3, W22	
Jeffcoat	Marjorie	Penn Dental School	No	9		
Jiao	Li	Baylor College of Medicine	Yes	292, 362		
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, M4, BA10, BA12, BA18, BA19, BA20
Kotchen	Jane	Medical College of Wisconsin	Yes		235	
Kripke	Daniel	University of California, San Diego	No	11		
Kuller	Lew	University of Pittsburgh	Yes	BA12	13, 121, 134, 161, 181, 189, 411, M9	

Table 15.7 (continued)
Funded BAA and Ancillary Studies PI List
(As of Oct. 2014)

Last Name	First Name	PI Institution	WHI Investigator	Anc PI for	WHI PI for	CCC PI for
LaCroix	Andrea	Fred Hutchinson Cancer Research Center	Yes	179, 286, W64	179, 286, 290, 321, 340, 416, 429, 449, M4, BA25	83, 137, 153, 165, 179, 181, 191, 199, 286, 290, 340, 416, 429, 449, M2, BA3, BA7, BA9, BA13, BA14, BA22
LaMonte	Michael	University of Buffalo	No	287		
Lane	Dorothy	Stony Brook University - New York	Yes		216	
Langer	Robert	University of California - San Diego	Former	47	11, 24, 47, 73, 93, 124	
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	
Li	Rongling	University of Tennessee Health Science Center	No	BA5		
Li	Christopher	Fred Hutchinson Cancer Research Center	No	316		
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	FHCRC	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	

Table 15.7 (continued)
Funded BAA and Ancillary Studies PI List
(As of Oct. 2014)

Last Name	First Name	PI Institution	WHI Investigator	Anc PI for	WHI PI for	CCC PI for
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		
Namie	Joylin	University 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	272, 327, 440	389, 439	130, 195, 207, 236, 275, 389, BA8
Newcomb	Polly	Fred Hutchinson Cancer Research Center	Yes	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		
O'Brien	Diane	University of Alaska Fairbanks	No	423		

Table 15.7 (continued)
Funded BAA and Ancillary Studies PI List
(As of Oct. 2014)

Last Name	First Name	PI Institution	WHI Investigator	Anc PI for	WHI PI for	CCC PI for
Ober	Beth	UC-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	University of California, San Diego	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, 343, 377, BA2, BA4	195, 206, 218, 224, 272, 289, 294, 316, 343, 377, 417, 423, 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	Fred Hutchinson Cancer Research Center	No		408	
Reding	Kerryn	University of Washington/Fred Hutchinson Cancer Research Center	No	321		
Reiner	Alexander	Fred Hutchinson Cancer Research Center	Yes	421, M13, BA14, BA25		337
Reis	Robert	University of Arkansas for Medical Sciences and VA Med. Ctr	No	416		

Table 15.7 (continued)
Funded BAA and Ancillary Studies PI List
(As of Oct. 2014)

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, 362	
Sarto	Gloria	University of Wisconsin	Yes		105, 219, 257, M1	
Schenken	Robert	University of Texas - San Antonio	Former		86	
Schneider	Diane	University of California - San Diego	No	24		
Seguin	Rebecca	Cornell University	No	429		
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, 250, 262, 373, 413, 414	
Siega-Riz	Anna Maria	University of North Carolina	No	236		
Simon	Michael	Wayne State University Medical School	Yes	464	400	
Smith-Warner	Stephanie	Harvard School of Public Health	No	383		

Table 15.7 (continued)
Funded BAA and Ancillary Studies PI List
(As of Oct. 2014)

Last Name	First Name	PI Institution	WHI Investigator	Anc PI for	WHI PI for	CCC PI for
Song	Yiqing	Brigham and Women's Hospital	No	325		
Stefanick	Marcia	Stanford University	Yes		332, 346	
Sternfeld	Barbara	Kaiser Permanente Division of Research	No	243		
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		
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, M14	
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, 362, 376, 383, 391, 398, 403, 411, 438, M1, M12, M14, BA23, BA24
Trevisan	Maurizio	State University of New York - Buffalo	Yes		15, 74, 98, 141	
Tsao	Phil	Stanford University School of Medicine	No	BA23		
Ulrich	Cornelia		No	195		
Urban	Nicole	Fred Hutchinson Cancer Research Center	Yes	282		
Vajaranant	Thasarat	University of Illinois at Chicago	No	407		

Table 15.7 (continued)
Funded BAA and Ancillary Studies PI List
(As of Oct. 2014)

Last Name	First Name	PI Institution	WHI Investigator	Anc PI for	WHI PI for	CCC PI for
Valanis	Barbara	Kaiser Permanente Center for Health Research, Portland	Former	160		
Van Horn	Linda	Northwestern University	Yes		84, 187, 196, 315, 438	
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	C.Y.	Fred Hutchinson Cancer Research Center	Former			9
Wassertheil-Smoller	Sylvia	Albert Einstein College of Medicine	Yes	40, 48, 126, M16	40, 48, 126, 127, 129, 130, 152, 208, 266, 284, M16, BA10	
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 University of New York - 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 2014)

Stage #	Definition	Number
12*	Published	941
11	In press / accepted by journal	12
10	Submitted to journal	46
9	Final manuscript approved by P&P Committee	152
8	Final manuscript submitted to P&P Committee	41
7	Draft manuscript	21
6	Analysis completed	37
5	Analysis in progress	59
4	Analysis proposed	8
3	Manuscript proposal and writing group approved	562
2	Approved/Writing group nominations open	72
Total		**1,951**

*Only Stage 12 peer-reviewed papers are included in Table 16.1

Table 16.2
Publications since October 2013

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
152	Magnesium intake, bone mineral density, and fractures: results from the Women's Health Initiative Observational Study	Orchard, Larson, Algothani, Cauley, Chen, LaCroix, Wactawski-Wende, Jackson	12	OS	Am J Clin Nutr. 2014 Feb 5. [Epub ahead of print]	
403	Subclinical hypothyroidism and risk for incident ischemic stroke among postmenopausal women	Giri, Edwards, LeGrys, Lorenz, Jonsson, Schectman, Heiss, Robinson, Hartmann	12	OS	Thyroid. 2014 May 14. [Epub ahead of print]	AS165
457	Hypertension and obesity and the risk of kidney cancer in 2 large cohorts of US men and women	Sanfilippo, McTigue, Chang, Fried, Liu, Kuller	12	OS	Hypertension. 2014;published online before print March 17 2014, doi:10.1161/HYPERTENSIONAHA.113.02953	
608	Estimating personal exposures from ambient air pollution measures: using meta-analysis to assess measurement error	Holliday, Avery, Poole, McGraw, Liao, Smith, Whitsel	12	CT	Epidemiology. 2014 Jan;25(1):35-43. doi: 10.1097/EDE.0000000000000006.	AS140
629	Potassium intake and risk of stroke in women with hypertension and nonhypertension in the Women's Health Initiative	Seth, Mossavar-Rahmani, Kamensky, Silver, Lakshminarayan, Prentice, Van Horn, Wassertheil-Smoller	12	OS	Stroke. 2014 Sep 4. pii: STROKEAHA.114.006046. [Epub ahead of print]	
838	Biomarker-calibrated protein intake and bone health in the Women's Health Initiative clinical trial and observational study	Beasley, Larson, LaCroix, Neuhouser, Tinker, Jackson, Huang, Snetselaar, Eaton, Prentice	12	Gen	Am J Clin Nutr. 2014 Feb 19. [Epub ahead of print]	
891	Self-rated health and medical outcomes in the Women's Health Initiative: The aging continuum, health, morbidity, mortality	Brunner, Hubbell, LaCroix, Lane, Stefanick, Safford, Woods, Watts, Beresford, Rapp, Aragaki	12	Gen	J Gerontol Geriat Res 3:139. doi: 10.4172/2167-7182.1000139	
939	Investigating the association of lactation history and postmenopausal breast cancer risk in the Women's Health Initiative	Stendall-Hollis, Thompson, Thomson, O'Sullivan, Ray, Chlebowski	12	Gen	Nutr Cancer. 2013 Oct 15. [Epub ahead of print]	
980	Intraindividual variability in domain-specific cognition and risk of mild cognitive impairment and dementia	Vaughan, Espeland, Dagenbach, Jennings, Brunner, Resnick, Beavers, Simpson, Coker, Gaussoin, Sink, Rapp, for the Women's Health Initiative Study of Cognitive Aging, Leng	12	WHIMS	Curr Gerontol Geriatr Res. 2013;2013:495793. doi: 10.1155/2013/495793. Epub 2013 Dec 22.	AS103

Table 16.2
Publications since October 2013

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
1058	Higher RBC EPA + DHA corresponds with larger total brain and hippocampal volumes: WHIMS-MRI Study	Pottala, Yaffe, Robinson, Espeland, Wallace, Harris	12	CT	Neurology. 2014 Feb 4;82(5):435-42. doi: 10.1212/WNL.0000000000000080. Epub 2014 Jan 22.	AS183, BAA19
1099	Hysterectomy and urinary incontinence in postmenopausal women	Kudish, Shveiky, Gutman, Iglesia, Sokol, Howard, Blanchette, Jacoby	12	CT	Int Urogynecol J. 2014 Jun 26. [Epub ahead of print]	
1103	Mediterranean and dietary approaches to stop hypertension dietary patterns and risk of sudden cardiac death in postmenopausal women	Bertoia, Triche, Michaud, Baylin, Hogan, Neuhouser, Tinker, Van Horn, Waring, Li, Shikany, Eaton	12	Gen	Am J Clin Nutr. 2014 Feb;99(2):344-51. doi: 10.3945/ajcn.112.056135. Epub 2013 Dec 18.	
1152	Mediterranean and DASH diet scores and mortality in women with heart failure: the Women's Health Initiative	Levitan, Lewis, Tinker, Eaton, Ahmed, Manson, Snetselaar, Martin, Trevisan, Howard, Shikany	12	OS	Circ Heart Fail. 2013 Oct 9. [Epub ahead of print]	
1194	Multi-ancestral analysis of inflammation-related genetic variants and C-reactive protein in the Population Architecture using Genomics and Epidemiology Study	Kocarnik, Pendergrass, Carty, Pankow, Schumacher, Cheng, Durda, Ambite, Deelman, Cook, Liu, Wactawski-Wende, Hutter, Brown-Gentry, Wilson	12	Gen	Circ Cardiovasc Genet. 2014 Apr 1;7(2):178-88. doi: 10.1161/CIRCGENETICS.113.000173. Epub 2014 Mar 12.	M6
1217	Validity of diabetes self-reports in the Women's Health Initiative	Jackson, Defor, Crain, Kerby, Strayer, Lewis, Whitlock, Williams, Vitolins, Rodabough, Larson, Habermann, Margolis	12	Gen	Menopause. 2014 Feb 3. [Epub ahead of print]	AS197, W35
1223	The adipokine profile of metabolically benign obese and at-risk normal weight postmenopausal women: The Women's Health Initiative Observational Study	Ogorodnikova, Xu, Wassertheil-Smoller, Ho, Sowers, Rajpathak, Allison, Mackey, Vitolins, Wildman, Manson	12	OS	Obesity (Silver Spring). 2012 Nov 6. doi: 10.1002/oby.20139. [Epub ahead of print]	AS126
1228	Sedentary behavior and mortality in older women: the Women's Health Initiative	Seguin, Buchner, Liu, Allison, Manini, Manson, Messina, Patel, Moreland, LaCroix	12	OS	Am J Prev Med. 2014 Feb;46(2):122-35. doi: 10.1016/j.amepre.2013.10.021.	
1271	Associations of lifetime active and passive smoking with spontaneous abortion, stillbirth and tubal ectopic pregnancy: A cross-sectional analysis of historical data from the Women's Health Initiative	Hyland, Wactawski-Wende, Hovey, Ockene, Andrews, Piazza	12	Gen	Tob Control. 2014 Feb 26. doi: 10.1136/tobaccocontrol-2013-051458. [Epub ahead of print]	

Table 16.2
Publications since October 2013

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
1281	Does CHA2DS2-VASc improve stroke risk stratification in postmenopausal women with atrial fibrillation	Abraham, Stefanick, Wassertheil-Smoller, Wilcoff, Newman, Chung, Torner, Solomon, Shara, Rexrode, Lakshminarayan, Curtis, Curb	12	Gen	Am J Med. 2013 Oct 17. pii: S0002-9343(13)00671-2. doi: 10.1016/j.amjmed.2013.05.023. [Epub ahead of print]	
1295	Cardiovascular disease and cognitive decline in postmenopausal women: results from the Women's Health Initiative Memory Study	Haring, Leng, Robinson, Johnson, Jackson, Beyth, Wactawski-Wende, Wyler von Ballmoos, Goveas, Kuller, Wassertheil-Smoller	12	CT	J Am Heart Assoc. 2013 Dec 18;2(6):e000369. doi: 10.1161/JAHA.113.000369.	AS39
1302	Calcium plus vitamin D supplementation and health outcomes 5 years after active intervention ended: The Women's Health Initiative	Cauley, Chlebowski, Wactawski-Wende, Robbins, Rodabough, Chen, Johnson, O'Sullivan, Jackson, Manson	12	CT	J Womens Health (Larchmt). 2013 Oct 16. [Epub ahead of print]	
1303	Trajectories of positive aging: observations from the Women's Health Initiative Study	Zaslavsky, Cochrane, Woods, LaCroix, Liu, Herting, Goveas, Johnson, Kuller, Martin, Michael, Robinson, Stefanick, Tinker	12	Gen	Int Psychogeriatr. 2014 Apr 17:1-12. [Epub ahead of print]	
1310	Beyond crosswalks: reliability of exposure assessment following automated coding of free-text job descriptions for occupational epidemiology	Burstyn, Slutsky, Lee, Singer, An, Michael	12	OS	Ann Occup Hyg. 2014 May;58(4):482-92. doi: 10.1093/annhyg/meu006. Epub 2014 Feb 6.	
1313	Genome-wide association and admixture analysis of glaucoma in the Women's Health Initiative	Hoffmann, Tang, Thornton, Caan, Millen, Thomas, Risch	12	CT	Hum Mol Genet. 2014 Jul 15. pii: ddu364. [Epub ahead of print]	M5
1319	Comparison of lifestyle based to traditional CVD prediction in a multiethnic cohort of non-smoking women	Paynter, LaMonte, Manson, Martin, Phillips, Ridker, Robinson, Cook	12	OS	Circulation. 2014 Aug 25. pii: CIRCULATIONAHA.114.012069. [Epub ahead of print]	BAA22
1332	Better postdiagnosis diet quality is associated with reduced risk of death among postmenopausal women with invasive breast cancer in the Women's Health Initiative	George, Ballard-Barbash, Shikany, Caan, Freudenheim, Kroenke, Vitolins, Beresford, Neuhouser	12	Gen	Cancer Epidemiol Biomarkers Prev. 2014 Feb 3. [Epub ahead of print]	

Table 16.2
Publications since October 2013

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
1389	Biomarker-calibrated protein intake and physical function in the Women's Health Initiative	Beasley, Wertheim, LaCroix, Prentice, Neuhouser, Tinker, Kritchevsky, Shikany, Eaton, Chen, Thomson	12	Gen	J Am Geriatr Soc. 2013 Nov;61(11):1863-71. doi: 10.1111/jgs.12503. Epub 2013 Oct 28.	
1391	Obesity and the late-age survival without major disease or disability in older women	Rillamas-Sun, LaCroix, Waring, Kroenke, LaMonte, Vitolins, Seguin, Bell, Manini, Gass, Masaki, Wallace	12	Gen	JAMA Intern Med. 2013 Nov 11. doi: 10.1001/jamainternmed.2013.12051. [Epub ahead of print]	
1395	Osteoporosis screening in postmenopausal women 50-64 years-old: Comparison of U.S. Preventive Services Task Force strategy and two traditional strategies in the Women's Health Initiative	Crandall, Larson, Gourlay, Donaldson, LaCroix, Cauley, Wactawski-Wende, Gass, Robbins, Watts, Ensrud	12	Gen	J Bone Miner Res. 2014 Jan 16. doi: 10.1002/jbmr.2174. [Epub ahead of print]	
1412	Dietary cadmium exposure and risk of breast, endometrial, and ovarian cancer in the Women's Health Initiative	Adams, Quraishi, Passarelli, Freney, Chlebowski, Luo, Meliker, Mu, Neuhouser, Newcomb, Shafer	12	Gen	Environ Health Perspect. 2014 Mar 14. [Epub ahead of print]	
1414	Change in brain and lesion volumes after CEE therapies: The WHIMS-MRI studies	Coker, Espeland, Bryan, Davatzikos, Goveas, Hogan, Kuller, Resnick, Robinson, Shumaker, Williamson, Bushnell	12	CT	Neurology. 2014 Jan 2. [Epub ahead of print]	AS183
1415	Depressive symptoms and longitudinal declines in cognition: Women's Health Initiative Study of Cognitive Aging	Goveas, Espeland, Tindle, Hogan, Shih, Kotchen, Robinson, Barnes, Resnick	12	CT	J Geriatr Psychiatry Neurol. 2014 Feb 28. [Epub ahead of print]	AS103
1443	Urinary levels of melatonin and risk of postmenopausal breast cancer: Women's Health Initiative Observational Cohort	Sturgeon, Doherty, Reeves, Bigelow, Stanczyk, Ockene, Liu, Manson, Neuhouser	12	Gen	Cancer Epidemiol Biomarkers Prev. 2014 Feb 7. [Epub ahead of print]	AS275
1456	Non-steroidal anti-inflammatory drugs and cardiovascular outcomes in women: results from the Women's Health Initiative	Bavry, Thomas, Allison, Johnson, Howard, Hlatky, Manson, Limacher	12	CT	Circ Cardiovasc Qual Outcomes. 2014 Jul 8. pii: CIRCOUTCOMES.113.000800. [Epub ahead of print]	
1460	Risk of cardiovascular disease among postmenopausal women with prior pregnancy loss: the Women's Health Initiative	Parker, Lu, Sands, Brzyski, Kroenke, Lee, O'Sullivan, Park, Parikh, Schenken, Eaton	12	OS	Ann Fam Med. 2014 Jul;12(4):302-9. doi: 10.1370/afm.1668.	

Table 16.2
Publications since October 2013

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
1462	Association between sleep and breast cancer incidence among postmenopausal women in the Women's Health Initiative	Vogtmann, Shikany, Waterbor, Lewis, Manson, Hale, Chlebowski, Endeshaw, Shah, Levitan	12	Gen	Sleep. 2013 Oct 1;36(10):1437-1444.	
1467	Calcium/vitamin D supplementation, serum 25-hydroxyvitamin D concentrations, and cholesterol profiles in the Women's Health Initiative calcium/vitamin D randomized trial	Schnatz, Jiang, Vila-Wright, Aragaki, Nudy, O'Sullivan, Jackson, LeBlanc, Robinson, Shikany, Womack, Martin, Neuhouser, Vitolins, Song, Kritchevsky, et al.	12	CT	Menopause. 2014 Mar 3. [Epub ahead of print]	
1523	Caregiving frequency and physical function: the Women's Health Initiative	Rosso, Lee, Kroenke, Coker, Woods, Stefanick, Michael	12	Gen	J Gerontol A Biol Sci Med Sci. 2014 Jul 24. pii: glu104. [Epub ahead of print]	
1540	Non-steroidal anti-inflammatory drugs and cancer risk in women: results from the Women's Health Initiative	Brasky, Wactawski-Wende, White, Peters, Walter, Vitolins, Manson, Lane, Allison	12	Gen	Int J Cancer. 2014 Mar 6. doi: 10.1002/ijc.28823. [Epub ahead of print]	
1543	Whole-exome sequencing identifies rare and low-frequency coding variants associated with LDL cholesterol	Lange, Robinson, Martin, Assimes	12	Gen	Am J Hum Genet. 2014 Feb 6;94(2):233-45. doi: 10.1016/j.ajhg.2014.01.010.	M24
1545	Rare and low-frequency coding variants in CXCR2 and other genes are associated with hematological traits	Auer, Wallace, Schick, O'Shaughnessy, Sin Lo, Chami, Carlson, de Denus, Dube, Haessler, Jackson, Kooperberg, Lemieux Perreault, Peters	12	Gen	Nature Genetics. Published online: 28 April 2014 | doi:10.1038/ng.2962	M24
1561	Impact of folic acid fortification on global DNA methylation and one-carbon biomarkers in the Women's Health Initiative Observational Study cohort	Bae, Ulrich, Bailey, Malysheva, Brown, Neuhouser, Cheng, Miller, Zheng, Xiao, Hou, Song, Buck, Beresford, Caudill	12	OS	Epigenetics. 2013 Dec 3;9(3). [Epub ahead of print]	AS195
1562	Nutrition and physical activity cancer prevention guidelines, cancer risk, and mortality in the Women's Health Initiative	Thomson, McCullough, Wertheim, Chlebowski, Martinez, Stefanick, Rohan, Manson, Tindle, Ockene, Vitolins, Wactawski-Wende, Sarto, Lane, Neuhouser	12	Gen	Cancer Prevention Research. 2014; 7:42-53.	
1585	Association between diabetes, diabetes treatment and risk of developing endometrial cancer	Luo, Beresford, Chen, Chlebowski, Garcia, Kuller, Regier, Wactawski-Wende, Margolis	12	Gen	Br J Cancer. 2014 Jul 22. doi: 10.1038/bjc.2014.407. [Epub ahead of print]	

Table 16.2
Publications since October 2013

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
1586	Associations of serum insulin-like growth factor-I and insulin-like growth factor-binding protein 3 levels with biomarker-calibrated protein, dairy product and milk intake in the Women's Health Initiative	Beasley, Gunter, Neuhouser, Tinker, Vitolins, LaCroix, Strickler, Prentice	12	OS	Br J Nutr. 2013 Oct 7:1-7. [Epub ahead of print]	AS129
1608	Use of Medicare data to Identify coronary heart disease outcomes in the Women's Health Initiative (WHI)	Hlatky, Ray, Burwen, Margolis, Johnson, Stefanick, Tindle, Robinson, Safford, Martin, Liu, Li	12	CT	Circ Cardiovasc Qual Outcomes, Jan. 2014 [Epub ahead of print]	W35
1612	Circulating soluble cytokine receptors and colorectal cancer risk	Ho, Wang, Zheng, Tinker, Xu, Rohan, Wassertheil-Smoller, Xue, Augenlicht, Peters, Phipps, Strickler, Gunter, Cushman	12	OS	Cancer Epidemiol Biomarkers Prev. 2013 Nov 5. [Epub ahead of print]	AS208
1622	Alcohol consumption and risk of melanoma and nonmelanoma skin cancer in the Women's Health Initiative	Kubo, Henderson, Desai, Tang, Stefanick, Wactawski-Wende	12	OS	Cancer Causes Control. 2013 Oct 31. [Epub ahead of print]	
1634	Genetic evidence for role of carotenoids in age-related macular degeneration in the Carotenoids in Age-Related Eye Disease Study (CAREDS)	Meyers, Mares, Igo, Truitt, Liu, Millen, Klein, Johnson, Engelman, Karki, Blodi, Gehrs, Tinker, Wallace, Robinson, LeBlanc, et al.	12	OS	Invest Ophthalmol Vis Sci. 2014 Jan 29;55(1):587-99. doi: 10.1167/iovs.13-13216.	AS257
1640	Comparison of Medicare claims versus physician adjudication for identifying stroke outcomes in the Women's Health Initiative	Lakshminarayan, Schissel, Safford, Winklemayer, Burwen, Virnig, Limacher, Leira, Allen	12	Gen	Stroke. 2014 Mar;45(3):815-21. doi: 10.1161/STROKEAHA.113.003408. Epub 2014 Feb 13.	W35
1654	Biomarkers of one-carbon metabolism are associated with biomarkers of Inflammation in women	Abbenhardt, Miller, Song, Brown, Cheng, Wener, Zheng, Toriola, Neuhouser, Beresford, Makar, Maneval Jr, Manson, Van Horn, Ulrich	12	OS	J Nutr. 2014 Mar 19. [Epub ahead of print]	AS195
1661	Multivitamin and mineral use and breast cancer mortality in older women with invasive breast cancer in the Women's Health Initiative	Wassertheil-Smoller, McGinn, Budrys, Chlebowski, Ho, Johnson, Lane, Li, Neuhouser, Saquib, Shikany, Song, Thomson	12	Gen	Breast Cancer Res Treat. 2013 Oct;141(3):495-505. doi: 10.1007/s10549-013-2712-x. Epub 2013 Oct 9.	

Table 16.2
Publications since October 2013

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
1666	Effect of dietary modification on incident carotid artery disease in postmenopausal women: Results From the Women's Health Initiative Dietary Modification Trial	Allison, Eaton, Wassertheil-Smoller, Li, Van Horn, Daviglus, Berger	12	CT	Published online before print April 17, 2014, doi: 10.1161/STROKEAHA.114.005096	
1669	Associations of stressful life events and social strain with incident cardiovascular disease in the Women's Health Initiative	Kershaw, Van Horn, Daviglus, Brenes, Coday, Denburg, Kroenke, Charles, Safford, Savla, Tinker, Tindle	12	Gen	J Am Heart Assoc. 2014 Jun 27;3(3). pii: e000687. doi: 10.1161/JAHA.113.000687.	
1704	Activity, energy intake, obesity, and the risk of incident kidney stones in postmenopausal women: a report from the Women's Health Initiative	Sorensen, Chi, Shara, Wang, Hsi, Orchard, Kahn, Jackson, Miller, Reiner, Stoller	12	OS	J Am Soc Nephrol. 2013 Dec 12. [Epub ahead of print]	
1732	Determinants of mortality among postmenopausal women in the Women's Health Initiative who report rheumatoid arthritis	Kuller, Mackey, Walitt, Deane, Holers, Robinson, Sokolove, Chang, Liu, Parks, Wright, Moreland	12	Gen	Arthritis Rheumatol. 2014 Mar;66(3):497-507. doi: 10.1002/art.38268.	BAA20
1743	Optimism and diet quality in the Women's Health Initiative	Hingle, Wertheim, Tinker, Tindle, Seguin, Rosal, Thomson	12	Gen	J Acad Nutr Diet. 2014 Feb 18. pii: S2212-2672(13)01890-X. doi: 10.1016/j.jand.2013.12.018. [Epub ahead of print]	
1746	Omega-3 fatty acid biomarkers and depressive symptoms	Persons, Robinson, Ammann, Coryell, Espeland, Harris, Manson, Fiedorowicz	12	CT	Int J Geriatr Psychiatry. 2013 Dec 11. doi: 10.1002/gps.4058. [Epub ahead of print	AS103, BAA19
1747	Evaluation of Medicare claims data to ascertain peripheral vascular events in the Women's Health Initiative	Mell, Pettinger, Proulx-Burns, Heckbert, Allison, Criqui, Hlatky, Burwen	12	Gen	J Vasc Surg. 2014 Mar 10. pii: S0741-5214(14)00158-X. doi: 10.1016/j.jvs.2014.01.056. [Epub ahead of print]	W35
1804	Body mass index, physical activity, and mortality in women diagnosed with ovarian cancer: Results from the Women's Health Initiative	Zhou, Chlebowski, LaMonte, Bea, Qi, Wallace, Lavsani, Walsh, Anderson, Vitolins, Sarto, Irwin	12	Gen	Gynecol Oncol. 2014 Apr;133(1):4-10. doi: 10.1016/j.ygyno.2014.01.033.	
1807	Fine Mapping and Identification of BMI Loci in African Americans	Gong, Schumacher, Lim, Hindorff, Haessler, Buyske, Carlson, Wu, Buzkova, Fornage, Gross, Schreiner, Cooper, Ehret, Gu	12	Gen	Am J Hum Genet. 2013 Oct 3;93(4):661-71. doi: 10.1016/j.ajhg.2013.08.012.	M6

Table 16.2
Publications since October 2013

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
1810	History of periodontal disease diagnosis and lung cancer incidence in the Women's Health Initiative Observational Study	Mai, LaMonte, Hovey, Nwizu, Freudenheim, Tezal, Scannapieco, Hyland, Andrews, Genco, Wactawski-Wende	12	OS	Cancer Causes Control. 2014 Jun 10. [Epub ahead of print]	AS15
1827	Large-scale genetic study in East Asians identifies six new loci associated with colorectal cancer risk	Zheng, Jia, Matsuda	12	Gen	Nat Genet. 2014 May 18. doi: 10.1038/ng.2985. [Epub ahead of print]	AS224
1829	Genome-wide analyses highlights gene interaction with processed meat and vegetable intake for colorectal cancer risk	Figueiredo, Hsu, Hutter, Lin, Campbell, Baron, Berndt, Jiao, Casey, Fortini, Chan, Cotterchio, Lemire, Gallinger, Harrison	12	Gen	PLoS Genet. 2014 Apr 17;10(4):e1004228. doi: 10.1371/journal.pgen.1004228. eCollection 2014.	M24
1842	Economic return from the Women's Health Initiative estrogen plus progestin clinical trial: A Modeling Study	Roth, Etzioni, Waters, Pettinger, Rossouw, Anderson, Chlebowski, Manson, Hlatky, Johnson, Ramsey	12	CT	Ann Intern Med. 2014 May 6;160(9):594-602. doi: 10.7326/M13-2348.	
1870	Accuracy of self-reported periodontal disease in the Women's Health Initiative Observational Study	LaMonte, Hovey, Millen, Genco, Wactawski-Wende	12	OS	J Periodontol. 2013 Dec 19. [Epub ahead of print]	AS15
1878	Short sleep duration is associated with decreased serum leptin, increased energy intake, and decreased diet quality in postmenopausal women	Stern, Simone Grant, Thomson, Tinker, Hale, Brennan, Woods, Chen	12	OS	Obesity (Silver Spring). 2013 Dec 17. doi: 10.1002/oby.20683. [Epub ahead of print]	AS191, AS199
1899	Menopausal hormone therapy and health outcomes during the intervention and extended poststopping phases of the Women's Health Initiative Randomized Trials	Manson, Chlebowski, Stefanick, Howard, Thomson, Anderson, Rossouw, Prentice, Jackson	12	CT	JAMA. 2013 Oct 2;310(13):1353-1368.	
1916	Obesity, physical activity and their interaction in incident atrial fibrillation in post-menopausal women	Azarbal, Assimes, Hlatky, Stefanick, Perez, Manson, Larson, Albert, Garcia, LaMonte, Li, Martin, Nassir, Salmoirago-Blotcher, Tharp, Chen, et al.	12	OS	J Am Heart Assoc. 2014 Aug 20;3(4). pii: e001127. doi: 10.1161/JAHA.114.001127.	W35
1954	Large multiethnic candidate gene study for C-reactive protein levels: Identification of a novel association at CD36 in African Americans	Ellis, Lange, Dupuis, Baumert, Walston, Keating, Barbalic, Durda, Fox, Palmer, Meng, Young, Farlow, Schnabel, Marzi	12	Gen	Hum Genet. 2014 Mar 19. [Epub ahead of print]	M24, M5

Table 16.2
Publications since October 2013

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
1957	Electrocardiographic repolarization-Related Variables as Predictors of Coronary Heart Disease Death in the Women's Health Initiative Study	Rautaharju, Zhang, Vitolins, Perez, Allison, Greenland, Soliman	12		J Am Heart Assoc. 2014 Jul 28;3(4). pii: e001005. doi: 10.1161/JAHA.114.001005.	
1959	Ethnic differences in the relationship between birth weight and Type 2 Diabetes Mellitus in postmenopausal women	Ryckman, Rillamas-Sun, Spracklen, Wallace, Garcia, Tylavsky, Howard, Liu, Song, LeBlanc, White, Parikh, Robinson	12	OS	Diabetes Metab. 2014 Apr 18. pii: S1262-3636(14)00064-0. doi: 10.1016/j.diabet.2014.03.003. [Epub ahead of print]	
1963	Vitamin D intake determines vitamin D status of postmenopausal women, particularly those with limited sun exposure	Cheng, Millen, Wactawski-Wende, Beresford, LaCroix, Zheng, Goodman, Thornquist, Neuhouser	12	OS	J Nutr. 2014 Mar 5. [Epub ahead of print]	
1973	Dietary intake of fiber, fruit and vegetables decrease the risk of incident kidney stones in women: a Women's Health Initiative (WHI) report	Sorensen, Hsi, Stoller, Kahn, Shara, LaCroix, Hou, Wactawski-Wende, Chi	12	OS	J Urol. 2014 May 21. pii: S0022-5347(14)03618-0. doi: 10.1016/j.juro.2014.05.086. [Epub ahead of print]	
1977	Association between smoking and health outcomes in postmenopausal women living with multiple sclerosis	Jawahar, Oh, Eaton, Wright, Cirillo, Tindle	12	OS	Mult Scler Int. 2014;2014:686045. doi: 10.1155/2014/686045. Epub 2014 Apr 22.	
2002	Perineal powder use and risk of ovarian cancer	Houghton, Reeves, Hankinson, Crawford, Lane, Wactawski-Wende, Thomson, Ockene, Sturgeon	12	OS	J Natl Cancer Inst. 2014 Sep 10;106(9). pii: dju208. doi: 10.1093/jnci/dju208. Print 2014 Sep.	
2026	Measurement error corrected sodium and potassium intake estimation using 24-hour urinary excretion	Huang, Van Horn, Tinker, Neuhouser, Carbone, Mossavar-Rahmani, Thomas, Prentice	12	OS	Hypertension. 2013 Nov 25. [Epub ahead of print]	AS294
2028	Sex hormone associations with breast cancer risk and the mediation of randomized trial postmenopausal hormone therapy effects	Zhao, Chlebowski, Anderson, Kuller, Manson, Gass, Patterson, Rohan, Lane, Beresford, Lavasani, Rossouw, Prentice	12	CT	Breast Cancer Res. 2014 Mar 26;16(2):R30. [Epub ahead of print]	W10
2031	A variational Bayes discrete mixture burden test for rare variant association	Logsdon, Dai, Auer, Ganesh, Smith, Wilson, Tracy, Graubert, Lange, Rich, Lettre, Carlson, Jackson, O'Donnell, Wurfel, Nickerson, et al.	12	Gen	Genet. Epidemiol.. doi: 10.1002/gepi.21772	M24

Table 16.2
Publications since October 2013

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
2042	Meta-analysis of gene-level tests for rare variant association	Abecasis, Kathiresan, Kooperberg, Peters, Auer	12	Gen	Nat Genet. 2014 Feb;46(2):200-4. doi: 10.1038/ng.2852. Epub 2013 Dec 15.	AS224, M24
2045	Post GWAS gene-environment interplay in breast cancer: results from the Breast and Prostate Cancer Cohort Consortium and a meta-analysis on 79000 women	Barrdahl, Canzian, Joshi, Travis, Chang-Claude, Auer, Gapstur, Gaudet, Diver, Henderson, Haiman, Schumacher, LeMarchand, Berg, Chanock	12		Hum Mol Genet. 2014 Oct 1;23(19):5260-70. doi: 10.1093/hmg/ddu223. Epub 2014 May 8.	M18
2052	Relation between self-recalled childhood physical activity and adult physical activity: the Women's Health Initiative	Goodman, Park, LeBlanc, Bea, Qi, Kapphahn, Stefanick, LaMonte	12	OS	Open J Epidemiol. 2013;3(4):224-231	
2060	Bioavailable insulin-like growth factor-I inversely related to weight gain in postmenopausal women regardless of exogenous estrogen	Jung, Hursting, Guindani, Vitolins, Paskett, Chang	12		Cancer Epidemiol Biomarkers Prev. 2013 Dec 20. [Epub ahead of print]	AS100
2063	An exploratory study of respiratory quotient calibration and association with postmenopausal breast cancer	Prentice, Neuhouser, Tinker, Pettinger, Thomson, Mossavar-Rahmani, Thomas, Qi, Huang	12	Gen	Cancer Epidemiol Biomarkers Prev. 2013 Oct 9. [Epub ahead of print]	
2067	Birth weight and subsequent risk of cancer	Spracklen, Ryckman, Robinson, Wallace, Chlebowski, Freudenheim, Hou, Manson, Qi, Sealy-Jefferson, Snetselaar, Wellons, Saftlas	12	OS	Cancer Epidemiol. 2014 Aug 2. pii: S1877-7821(14)00130-1. doi: 10.1016/j.canep.2014.07.004. [Epub ahead of print]	
2071	Meta-analysis of loci associated with age at natural menopause in African-American Women	Chen, Liu, Arnold, Franceschini, Musani	12	Gen	Hum Mol Genet. 2014 Jun 15;23(12):3327-42. doi: 10.1093/hmg/ddu041. Epub 2014 Feb 2.	M5
2077	Pleiotropic associations of risk variants identified for other cancers with lung cancer risk: The PAGE and TRICL consortia	Park, Fesinmeyer, Kooperberg, North, Peters	12		J Natl Cancer Inst. 2014 Apr; 106(4):dju061. doi: 10.1093/jnci/dju061. Epub 2014 Mar 28.	

Table 16.2
Publications since October 2013

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
2119	Actionable, pathogenic incidental findings in 1000 participants' exomes	Dorschner, Amendola, Turner, Robertson, Shirts, Gallego, Bennett	12		Am J Hum Genet. 2013 Oct 3;93(4):631-40. doi: 10.1016/j.ajhg.2013.08.006. Epub 2013 Sep 19.	M24
2121	Causal effects of body mass index on cardiometabolic traits and events: a Mendelian randomization analysis	Holmes, Lange, Lanktree, North, Almoguera Castillo, Buxbaum, Chandrupatla, Elbers, Guo, Hoogeveen, Li, Swerdlow, Cushman, Fornage, Hakonarson	12		Am J Hum Genet. 2014 Feb 6;94(2):198-208. doi: 10.1016/j.ajhg.2013.12.014. Epub 2014 Jan 23.	BAA14
2123	Association of the selected dimensions of eudaimonic well-being with healthy survival to age 85 years in older women	Zaslavsky, LaCroix, Rillamas-Sun, Woods, Cochrane, Stefanick, Tindle, Tinker	12	Gen	Int Psychogeriatr. 2014 Aug 27:1-11. [Epub ahead of print]	
2125	Insulin, estrogen, inflammatory markers and risk of benign proliferative breast disease	Catsburg, Gunter, Chen, Cote, Kabat, Nassir, Tinker, Wactawski-Wende, Page, Rohan	12	CT	Cancer Res. 2014 Apr 22. [Epub ahead of print]	AS284
2132	Rheumatoid arthritis in the Women's Health Initiative: methods and baseline evaluation	Kuller, Mackey, Walitt, Deane, Holers, Robinson, Sokolove, Chang, Moreland	12	Gen	Am J Epidemiol. 2014 Apr 1;179(7):917-26. doi: 10.1093/aje/kwu003. Epub 2014 Feb 24.	BAA20
2135	Evidence of heterogeneity by race/ethnicity in genetic determinants of QT interval	Seyerle, Young, Jeff, Melton, Jorgenson, Lin, Carty, Deelman, Heckbert, Hindorff, Jackson, Martin, Perez, Psaty, Whitsel, North, et al.	12		Epidemiology. 2014 Aug 27. [Epub ahead of print]	M6
2145	Plasma phospholipid fatty acid biomarkers of dietary fat quality and fatty acid metabolism predict CHD risk: A nested case-control study within the Women's Health Initiative Observational Study	Matthan, Ooi, Booth, Van Horn, Neuhouser, Woodman, Lichtenstein	12		Being reviewed at JAHAJ Am Heart Assoc. 2014 Aug 13;3(4). pii: e000764. doi: 10.1161/JAHA.113.000764.	BAA8
2149	Association of anthropometric measures and hemostatic factors in postmenopausal women: A longitudinal study	Kabat, Heo, Allison, Hou, Nassir, Zaslavsky, Rohan	12	Gen	Nutr Metab Cardiovasc Dis. 2014 May 2. pii: S0939-4753(14)00140-9. doi: 10.1016/j.numecd.2014.04.008. [Epub ahead of print]	

Table 16.2
Publications since October 2013

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
2151	Replication of associations between GWAS SNPs and melanoma risk in the Population Architecture Using Genomics and Epidemiology (PAGE) Study	Kocarnik, Park, Han, Dumitrescu, Cheng, Wilkens, Schumacher, Kolonel, Carlson, Crawford, Goodloe, Dilks, Baker, Richardson, Ambite	12		J Invest Dermatol. 2014 Jul;134(7):2049-52. doi: 10.1038/jid.2014.53. Epub 2014 Jan 30.	M6
2155	Proteomic risk markers for coronary heart disease and stroke: Validation and mediation of hormone therapy effects on these diseases	Prentice, Zhao, Johnson, Aragaki, Hsia, Jackson, Rossouw, Manson, Hanash	12	CT	Genome Medicine 2013, 5:112	AS343
2162	Association of plasma 25-hydroxyvitamin D concentrations and pathogenic oral bacteria in postmenopausal women	Sahli, Wactawski-Wende, Ram, LaMonte, Hovey, Genco, Andrews, Millen	12	OS	J Periodontol. 2013 Nov 21. [Epub ahead of print]	AS15
2173	Estimating the heritability of colorectal cancer	Jiao, Peters, Berndt, Brenner, Butterbach, Caan, Carlson, Chan, Chang-Claude, Chanock, Curtis, Duggan, Gong, Harrison	12	OS	Hum Mol Genet. 2014 Mar 5. [Epub ahead of print]	AS224
2175	Analysis of metabolic syndrome components in >15 000 african americans identifies pleiotropic variants: results from the population architecture using genomics and epidemiology study	Carty, Bhattacharjee, Haessler, Cheng, Hindorff, Aroda, Carlson, Hsu, Wilkens, Liu, Jackson, North, Peters, Pankrow, Chatterjee, Kooperberg, et al.	12		Circ Cardiovasc Genet. 2014 Aug;7(4):505-13. doi: 10.1161/CIRCGENETICS.113.000386. Epub 2014 Jul 14.	M6
2179	Association between metabolic syndrome and periodontal disease measures in postmenopausal women: the Buffalo OsteoPerio Study	LaMonte, Williams, Genco, Andrews, Hovey, Millen, Browne, Trevisan, Wactawski-Wende	12		J Periodontol. 2014 May 26:1-15. [Epub ahead of print]	AS382
2191	Joint linkage and association analysis with exome sequence data implicates SLC25A40 in hypertriglyceridemia	Rosenthal, Jarvik, Crosslin	12		Am J Hum Genet. 2013 Dec 5;93(6):1035-45. doi: 10.1016/j.ajhg.2013.10.019. Epub 2013 Nov 21.	M24
2198	Combined conjugated esterified estrogen plus methyltestosterone supplementation and risk of breast cancer in postmenopausal women	Kabat, Kamensky, Heo, Bea, Hou, Lane, Liu, Wactawski-Wende, Rohan	12	OS	Maturitas. 2014 Jun 16. pii: S0378-5122(14)00202-3. doi: 10.1016/j.maturitas.2014.06.006. [Epub ahead of print]	

Table 16.2
Publications since October 2013

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
2200	Mendelian randomization of blood lipids for coronary heart disease	Holmes, Asselbergs, Palmer, Drenos, Lanktree, Nelson, North, Reiner, Yukawa, Fornage, Kumari, Keating, Lange, Casas, Hingorani	12		Eur Heart J. 2014 Jan 27. [Epub ahead of print]	
2203	Estrogens and cardiovascular disease risk revisited: the Women's Health Initiative	Howard, Rossouw	12		Curr Opin Lipidol. 2013 Oct 31. [Epub ahead of print]	
2234	Vitamin D Status and five year changes in periodontal disease measures among postmenopausal women: the Buffalo OsteoPerio Study	Millen, Andrews, LaMonte, Hovey, Swanson, Genco, Wactawski-Wende	12		J Periodontol. 2014 May 2. [Epub ahead of print]	AS382
2236	Association of low-frequency and rare coding sequence variants with blood lipids and coronary heart disease in 56,000 whites and blacks	Peloso, Auer, Bis, Voorman, Morrison, Stitziel, Brody, Crosby, Fornage, Isaacs, Jakobsdottir, Feitosa, Davies, Huffman, Manichaikul	12	Gen	Am J Hum Genet. 2014 Feb 6;94(2):223-32. doi: 10.1016/j.ajhg.2014.01.009.	M24
2259	Testing for non-linear causal effects using a binary genotype in a Mendelian randomisation study: application to alcohol and cardiovascular traits	Silverwood, Holmes, Dale, Lawlor, Whittaker, Smith, Leon, Palmer, Keating, Casas, Dudbridge	12		Int J Epidemiol. 2014 Sep 5. pii: dyu187. [Epub ahead of print]	
2286	Association of exome sequences with plasma C-reactive protein levels in >9000 participants	Schick, Auer, Bis, Morrison, Lin, Wei, Pankratz, Lange, Kim, Carlson, Fornage, Hsu, Jackson, Kooperberg, Leal	12		Hum Mol Genet. 2014 Sep 3. pii: ddu450. [Epub ahead of print]	M24
2292	Women's Health Initiative: View of estrogen avoidance and all-cause mortality	Prentice, Manson, Anderson, LaCroix, Shumaker, Chlebowski, Howard, Stefanick, Jackson, Wactawski-Wende, Rossouw	12		Am J Public Health. 2013 Dec;103(12):e2. doi: 10.2105/AJPH.2013.301604. Epub 2013 Oct 17.	
2309	Simultaneous association of energy consumption and activity-related energy expenditure with cardiovascular disease, cancer, and diabetes risk among postmenopausal women	Zheng, Beresford, Van Horn, Tinker, Thomson, Neuhouser, Di, Manson, Mossavar-Rahmani, Seguin, Manini, LaCroix, Prentice	12	Gen	Am J Epidemiol. 2014 Jul 12. pii: kwu152. [Epub ahead of print]	
2311	Noakes misses the point	Rossouw, Howard	12		S Afr Med J 2013;103(12):882.	

Table 16.2
Publications since October 2013

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
2398	Whole-exome imputation of sequence variants identified two novel alleles associated with adult body height in African Americans	Du, Auer, Jiao, Haessler, Altshuler, Boerwinkle, Carlson	12		Hum Mol Genet. 2014 Jul 15. pii: ddu361. [Epub ahead of print]	M24
2409	Current concepts: breast cancer chemoprevention	Chlebowski	12		Pol Arch Med Wewn. 2014 Mar 11. pii: AOP_14_019. [Epub ahead of print]	
2435	Menopausal hormone therapy and cancer: changing clinical observations of target site specificity	Chlebowski, Anderson	12		Steroids. 2014 Jun 6. pii: S0039-128X(14)00125-1. doi: 10.1016/j.steroids.2014.06.001. [Epub ahead of print]	

Appendix A

Women's Health Initiative

Memory Suite of Studies

2014 Annual Progress Report

Appendix A

Women's Health Initiative

Memory Suite of Studies

2014 Annual Progress Report

Report Date: October 10, 2014

Meeting Date: November 14, 2014

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.

Women's Health Initiative Memory Suite of Studies

2014 Annual Progress Report

Report Date: October 10, 2014

Meeting Date: November 14, 2014

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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 from October 2014 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 cognitive 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 10, 2014

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)

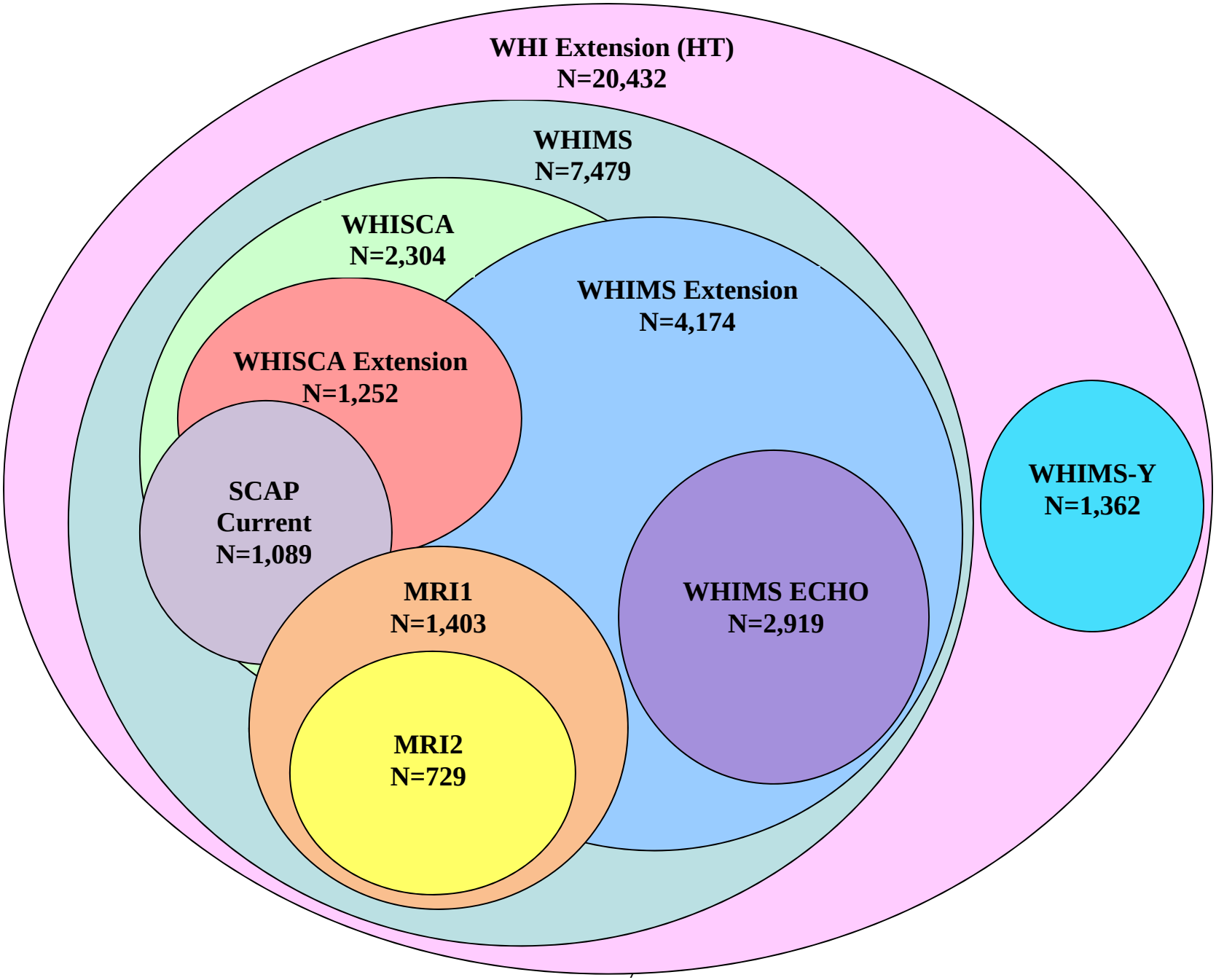
The Women's Health Initiative Memory Study of Younger Women (WHIMS-Y)

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



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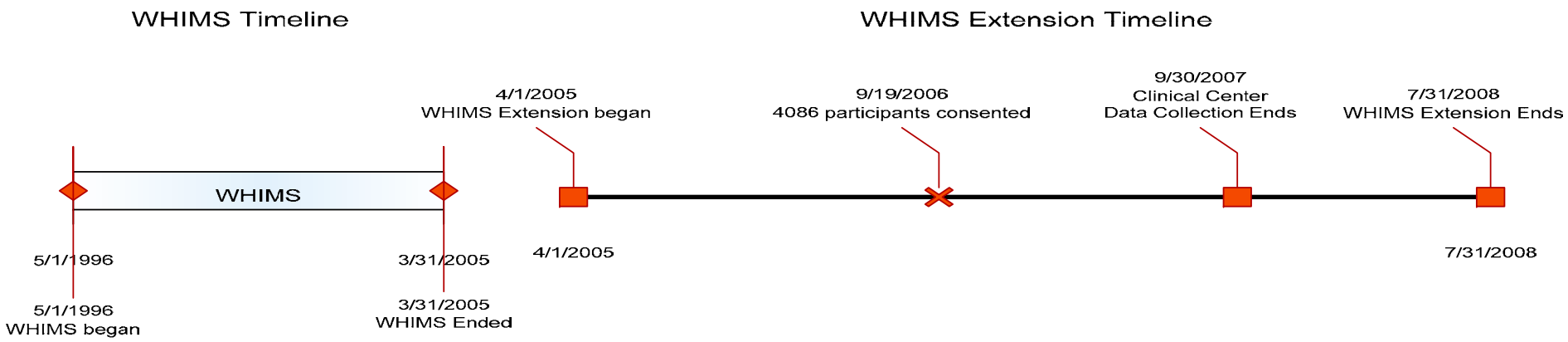
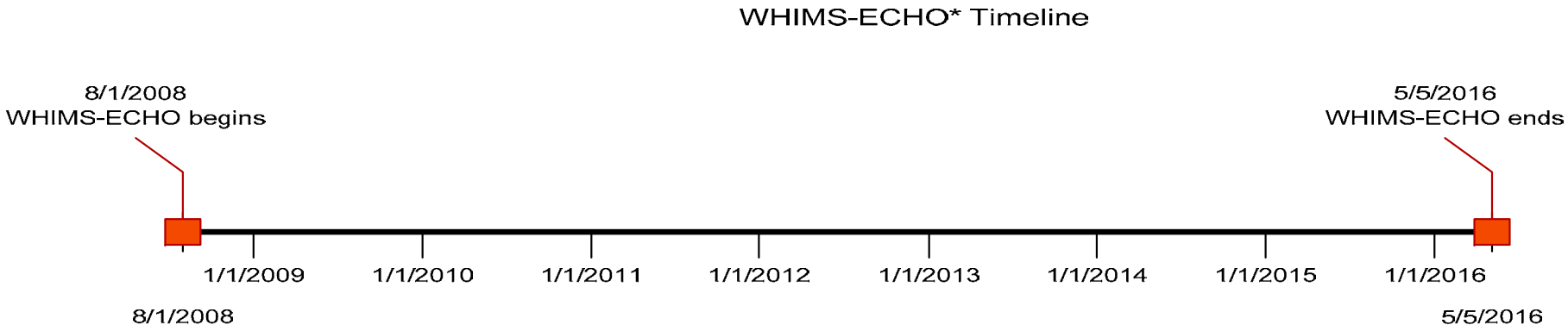
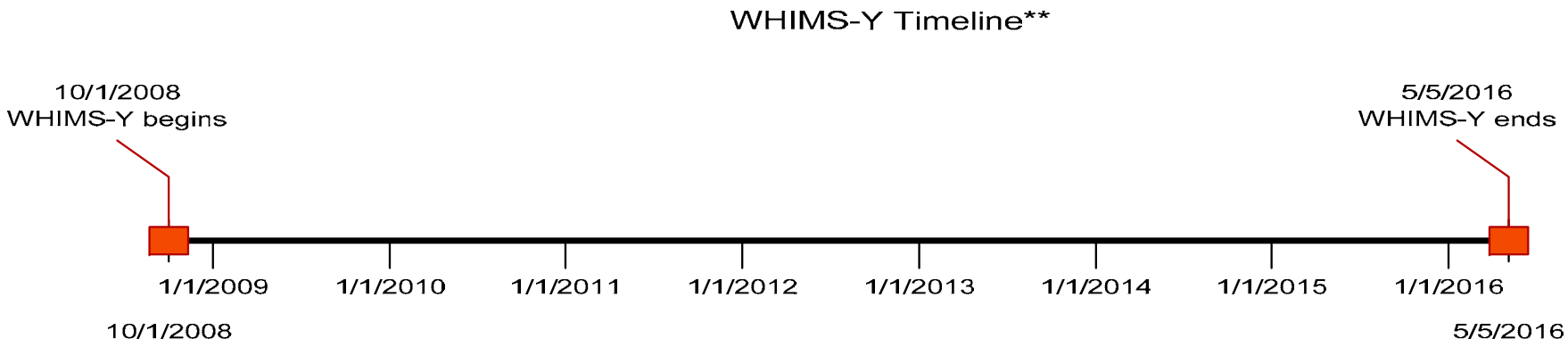


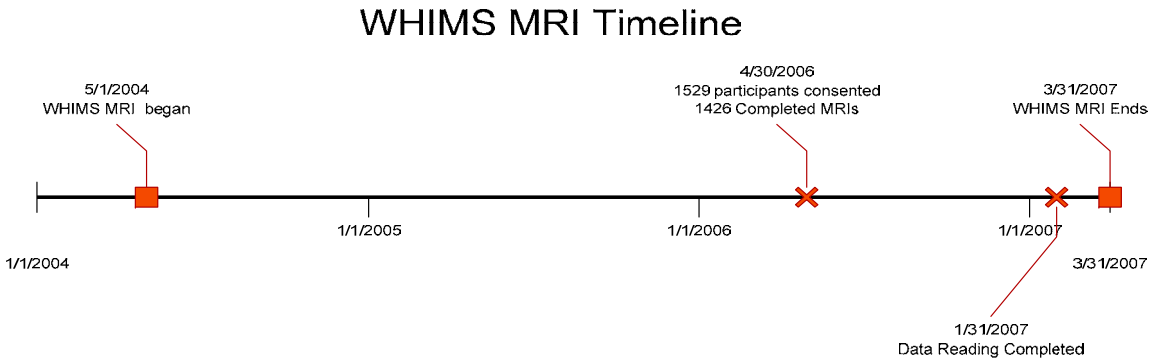


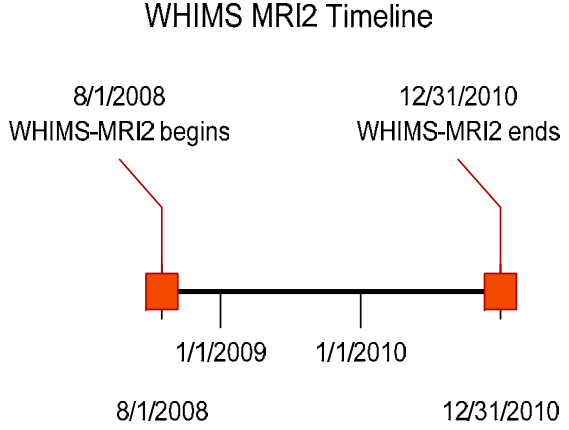
**Funding for WHIMS-ECHO: 8/1/2008-5/5/2011 – NHLBI
5/5/2011-5/6/2016 – NIA

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





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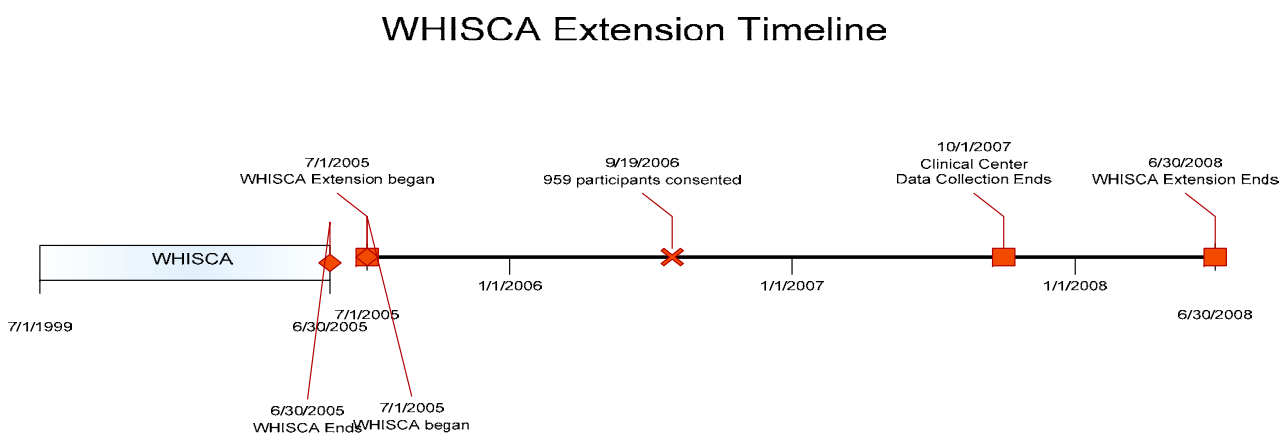
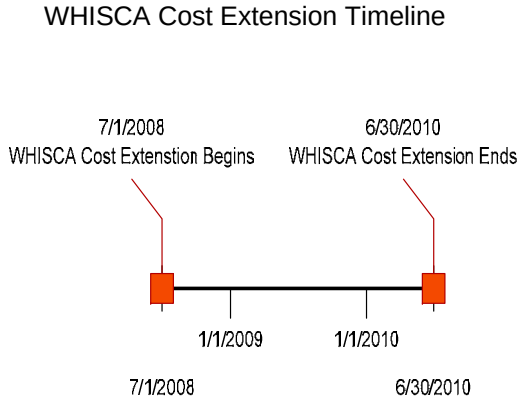




2.3 Studies Objectives

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, 2,922 participants enrolled in the WHIMS ECHO (Table 3.1).

3.3 Enrollment: Overall and by Clinical Site

Table 3-1 WHIMS-ECHO Recruitment Process as of October 9, 2014

	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***	***74***	***1.8***	***54***	***1.7***	***154***	***4.9***	***2922***	***93.4***
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**	**2**	**2.9**	**1**	**1.5**	**65**	**95.6**
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**	**0**	**0.0**	**5**	**9.1**	**50**	**90.9**
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**	**100.0**
25=Minneapolis	**126**	**96**	**76.2**	**2**	**1.6**	**0**	**0.0**	**3**	**3.2**	**91**	**96.8**
26=Newark	**74**	**57**	**77.0**	**2**	**2.7**	**0**	**0.0**	**3**	**5.5**	**52**	**94.5**
27=Phoenix	**49**	**39**	**79.6**	**2**	**4.1**	**1**	**2.7**	**1**	**2.7**	**35**	**94.6**
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**	**6.1**	**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**	**100.0**
61=Cincinnati	**118**	**94**	**79.7**	**4**	**3.4**	**4**	**4.4**	**7**	**7.8**	**79**	**87.8**
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**	**90.3**

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 as of October 9, 2014

	Year 1		Year 2		Year 3		Year 4		Year 5		Year 6		Year 7	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Agreed to participate	2663		238		21		0		0		0		0	
---- Cumulative number	2663	100.0	2901	100.0	2922	100.0	2922	100.0	2922	100.0	2922	100.0	2922	100.0
Lost to follow-up														
---- Deceased	0		63		90		107		75		71		17	
---- Withdrew	0		6		82		131		98		100		66	
---- Attempts to locate exhausted	0		0		0		0		0		0		0	
Due for telephone contact	2663	100.0	2832	97.6	2681	91.8	2443	83.6	2270	77.7	2099	71.8	2016	69.0
Completed test battery	2615	98.2	2469	87.2	2258	84.2	1998	81.8	1720	75.8	1254	59.7	45	2.2
Failed after 8 attempts	2	0.1	105	3.7	170	6.3	164	6.7	201	8.9	155	7.4	2	0.1
Declined	2	0.1	88	3.1	169	6.3	180	7.4	192	8.5	116	5.5	4	0.2
Phone disconnected	0	0.0	66	2.3	43	1.6	72	2.9	103	4.5	97	4.6	17	0.8
Unable to locate	0	0.0	10	0.4	8	0.3	4	0.2	3	0.1	0	0.0	0	0.0
Recontact	2	0.1	29	1.0	0	0.0	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	22	1.0	11	0.5	1	0.0
Discontinued	15	0.6	22	0.8	11	0.4	11	0.5	22	1.0	12	0.6	1	0.0
No answer	1	0.0	0	0.0	0	0.0	0	0.0	0	0.0	7	0.3	2	0.1
Left message	0	0.0	1	0.0	1	0.0	0	0.0	0	0.0	15	0.7	7	0.3

Table 3-2 WHIMS ECHO Overall Status of Last Call Attempt by Year as of October 9, 2014														
	Year 1		Year 2		Year 3		Year 4		Year 5		Year 6		Year 7	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Scheduled	0	0.0	1	0.0	0	0.0	0	0.0	3	0.1	75	3.6	25	1.2
Busy	0	0.0	1	0.0	0	0.0	0	0.0	0	0.0	1	0.0	0	0.0
No message	0	0.0	0	0.0	0	0.0	0	0.0	1	0.0	20	1.0	3	0.1
Other	0	0.0	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	0	0.0	3	0.1	336	16.0	1906	94.7

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=2922)

Characteristic	N (%)
WHI Treatment Assignment	
E-Alone Placebo	543 (19)
E-Alone	530 (18)
E+P	894 (31)
E+P Placebo	955 (33)
Age at WHI Enrollment	
64-69	1531 (52)
70-74	1028 (35)
75+	363 (12)
Age as of October 1, 2013	
80-84	962 (29)
85-89	1359 (47)
90+	701 (24)
Baseline WHIMS 3MS	
Less than 90	100 (3)
90-94	435 (15)
95-100	2329 (81)
Race/Ethnicity	
American Indian/Alaskan native	6 (0)
Asian/Pacific Islander	42 (1)
Black/African American	188 (6)
Hispanic/Latino	47 (2)
White	2595 (89)
Other	43 (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, 2,396 women were eligible for the DQ based on their TICSm scores which were below the study cut-point. Of these, 2,193 progressed to administration of the DQ.

Table 3-4 Dementia Questionnaire Progressions in WHIMS-ECHO as of October 9, 2014

	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	TOTAL
TICS Administrations	2624	2468	2262	2006	1742	1196	21	12319
DQ Progressions	446 (17.0%)	472 (19.1%)	427 (18.9%)	394 (19.6%)	360 (20.7%)	286 (23.9%)	11 (52.4%)	2396 (19.4%)
Withdrawals	47 (10.5%)	52 (11.0%)	22 (5.2%)	23 (5.8%)	12 (3.3%)	2 (0.7%)	0 (0%)	158 (6.6%)
Missing Proxy information	8 (1.8%)	12 (2.5%)	9 (2.1%)	7 (1.8%)	7 (1.9%)	2 (0.7%)	0 (0%)	45 (1.9%)
Total Eligible DQ Progressions	391 (87.7%)	408 (86.4%)	396 (92.7%)	364 (92.4%)	341 (94.7%)	282 (98.6%)	11 (100%)	2193 (91.5%)

Outcome	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	TOTAL
DQ's completed^^	242 (61.9%)	202 (49.5%)	250 (63.1%)	226 (62.1%)	163 (47.9%)	109 (38.7%)	0 (0.0%)	1192 (54.4%)
DQ's in process	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.9%)	51 (18.1%)	8 (72.7%)	62 (2.8%)
Phone Disconnected/Unable to locate/Hearing Impaired	23 (5.9%)	26 (6.4%)	27 (6.8%)	17 (4.7%)	11 (3.2%)	9 (3.2%)	1 (9.1%)	114 (5.2%)
Proxy Refused DQ	42 (10.7%)	41 (10.0%)	26 (6.6%)	11 (3.0%)	10 (2.9%)	6 (2.1%)	0 (0.0%)	136 (6.2%)
PD	14 (3.6%)	45 (11.0%)	40 (10.1%)	56 (15.4%)	68 (20.0%)	50 (17.7%)	2 (18.2%)	275 (12.5%)
4th attempt	59 (15.1%)	50 (12.3%)	52 (13.1%)	54 (14.8%)	85 (25.0%)	57 (20.2%)	0 (0.0%)	357 (16.3%)
Permanently Missing	11 (2.8%)	44 (10.8%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	56 (2.6%)
TOTAL	391	408	396	364	340	282	11	2192

There are 48 (2.3%) eligible adjudication cases in process. 862 (40.5%) adjudication complete and 1216 (57.2%) were not selected to further adjudication based on algorithm.

Table 3-6 Cases Eligible to be Reviewed by Adjudication Committee as of October 9, 2014						
	N (%)					
^	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Adjudication in process	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (1.0%)	48 (2.3%)
Adjudication complete	157 (35.0%)	133 (27.8%)	210 (52.1%)	182 (52.4%)	128 (44.1%)	862 (40.5%)
- - - - ND	30 (19.1%)	35 (26.3%)	50 (23.8%)	52 (28.6%)	29 (22.7%)	206 (23.9%)
- - - - MCI	73 (46.5%)	48 (36.1%)	85 (40.5%)	75 (41.2%)	61 (47.7%)	362 (42.0%)
- - - - PD	54 (34.4%)	46 (34.6%)	75 (35.7%)	55 (30.2%)	38 (29.7%)	288 (33.4%)
- - - - UTC-CI	0 (0.0%)	3 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.5%)
- - - - UTC-FI	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
Not Adjudicated (ND)	85 (18.9%)	70 (14.6%)	40 (9.9%)	44 (12.7%)	32 (11.0%)	281 (13.2%)
Not Adjudicated (UTC-CI)	84 (18.7%)	147 (30.8%)	85 (21.1%)	64 (18.4%)	75 (25.9%)	480 (22.6%)
Not Adjudicated (UTC-No CI+No DQ)	123 (27.4%)	128 (26.8%)	68 (16.9%)	57 (16.4%)	52 (17.9%)	455 (21.4%)
TOTAL	449	478	403	347	290	2126

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 1,089 participants who have either the status of proxy or deceased, who are SCAP-eligible. Of the 1,089 SCAP-eligible, 898 proxies have been contacted by the WHIMS CoC.

Table 4-1 shows the current progress as outlined as of October 9, 2014.

Call Outcome	N	%
Attempts at DQ completion ended		
-----Call Completed	**462**	**51.45**
-----Declined	**49**	**5.46**
-----Phone Disconnected	**63**	**7.02**
-----Unable to locate	**10**	**1.11**
-----Hearing Impaired	**0**	**0.00**
-----Discontinued	**0**	**0.00**
-----Deceased	**1**	**0.11**
-----No Proxy provided	**44**	**4.90**
-----No Answer - 4th and final attempt	**133**	**14.81**
DQ completion possible		
-----Other		
-----Left a Message	**127**	**14.14**
-----Scheduled	**0**	**0.00**
-----Re-Contact	**0**	**0.0**
-----Busy	**0**	**0.0**
-----No Message	**5**	**0.56**
-----No Answer - 1st attempt	**3**	**0.33**
-----No Answer - 2nd attempt	**1**	**0.11**
-----No Answer - 3rd attempt	**0**	**0.0**

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 501 cases of SCAP protocols for adjudication. Of those, 261 (52.1%) have been adjudicated and 57 (11.4%) are under review. There are 183 (36.5%) protocols that were not adjudicated (ND or MCI).

Additionally, 507 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 951 cases. Of those, 344 (36.2%) were classified as ND, 474 (49.8%) as PND, 29 (3.0%) were MCI 71 (7.5%) were PD and 33 (3.5%) were CC.

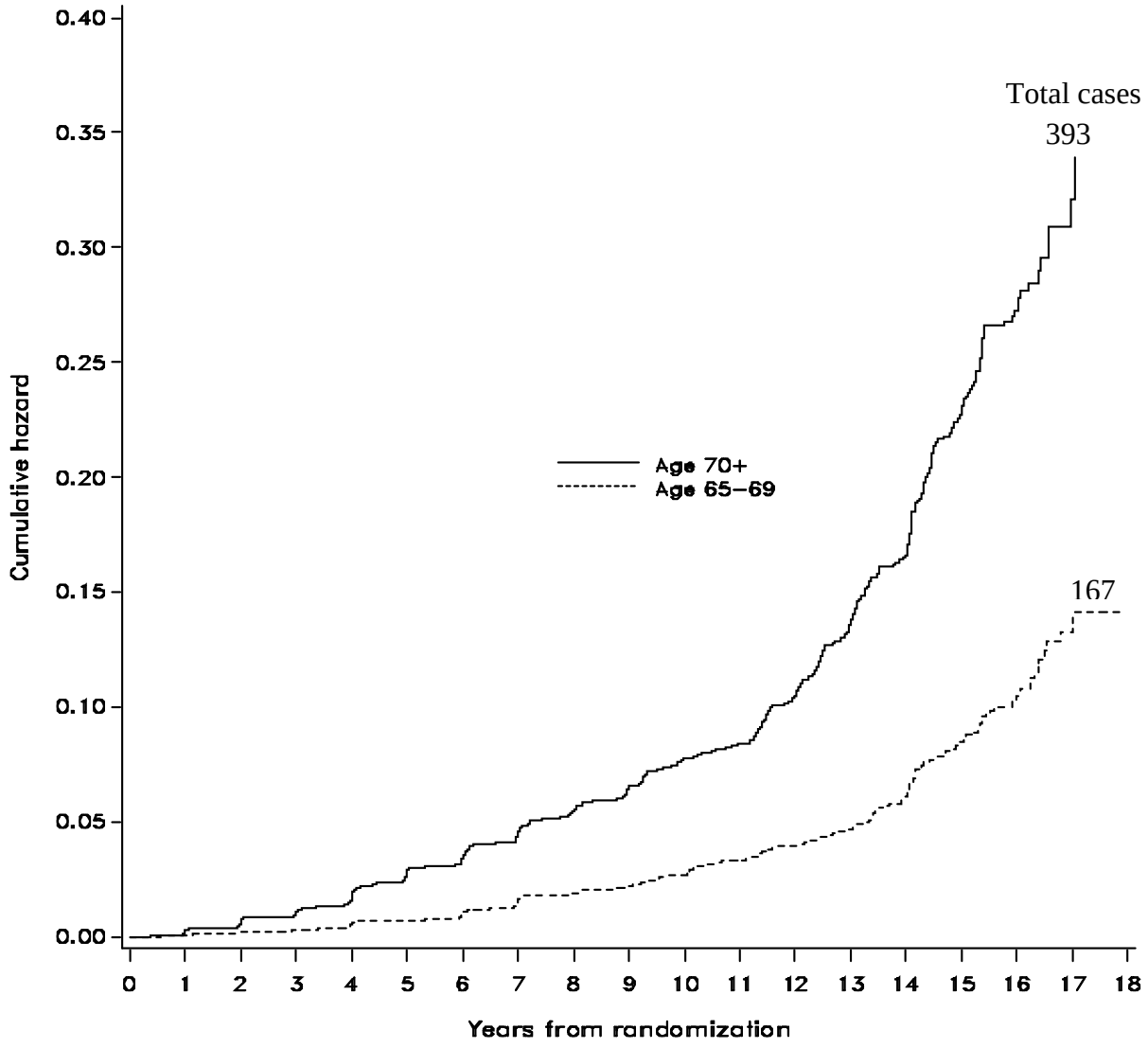
Table 4-2 SCAP Protocols		
	Subtotal	
	N	%
SCAP Phase 2 Protocols	1008	
- - - - Adjudicated Protocols	261	25.8
- - - - Protocols Under Review by Adjudicators	57	5.7
- - - - Protocols Not Adjudicated (ND or MCI)	183	18.2
- - - - Protocols Classified Without Full Adjudication (PND)	474	47.0
- - - - Protocols Classified Without Full Adjudication (CC)	33	3.3

Table 4-3 Overall Classification of SCAP Protocols		
	Subtotal	
	N	%
Overall Classification of Protocols	951	
----ND	344	36.2
----PND	474	49.8
----MCI	29	3.0
----PD	71	7.5
----CC	33	3.5

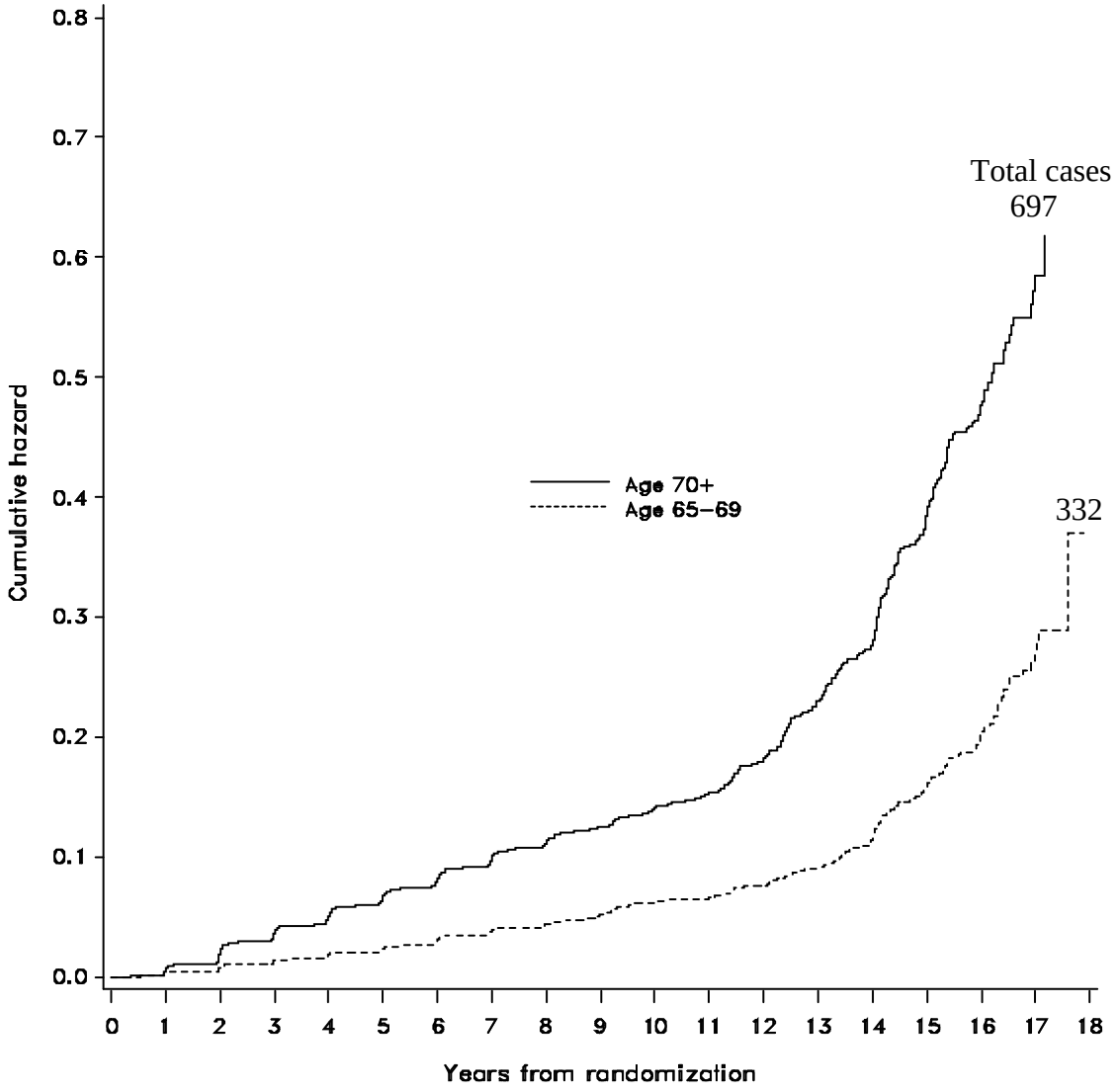
Section 5.

WHIMS Cohort

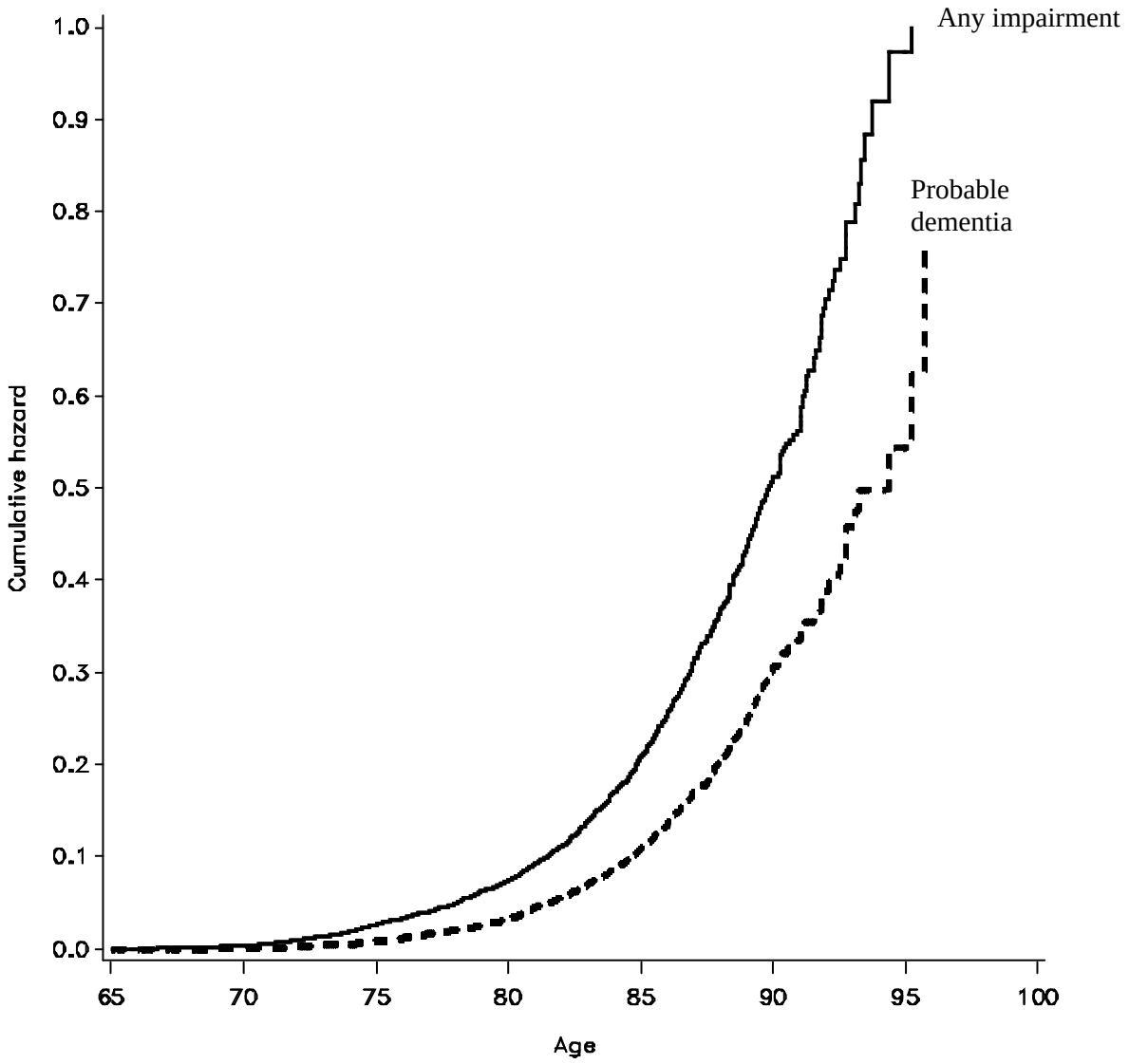
5.1 Incidence of Probable Dementia by Age at Enrollment



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

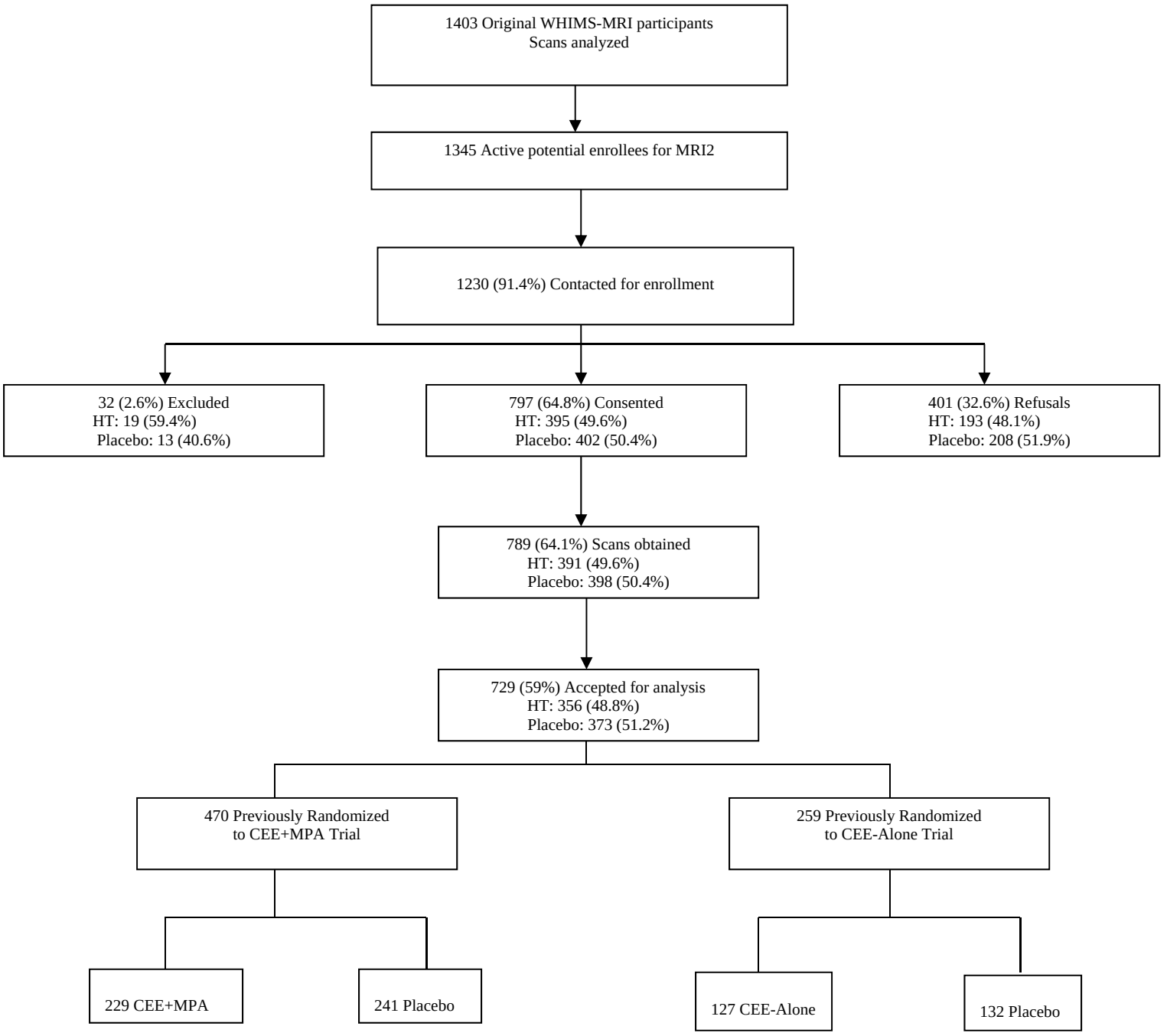
Approximately 4.7 years following the initial WHIMS MRI study, the WHIMS-MRI-2 study was initiated to collect a second MRI brain scan to assess incident neuropathology and the annual rates of change in brain volumes and lesions.

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 Presentations

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.

Goveas J. Antidepressant exposure and cross-sectional and longitudinal changes in brain volumes and ischemic lesion load in women: the WHIMS-MRI2 Study. Presented at the WHI Scientific Sessions, 2014 WHI Investigator's Meeting, May 2014, Seattle, WA.

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 as of October 9, 2014

	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	1362		0		0		0		0		0	
---- Cumulative number	1362	100.0	1362	100.0	1362	100.0	1362	100.0	1362	100.0	1362	100.0
Lost to follow-up												
---- Deceased	1		5		10		8		5		0	
---- Withdrew	2		5		31		26		32		24	
---- Attempts to locate exhausted	0		0		0		0		0		0	
Due for telephone contact	1359	99.7	1349	99.0	1308	96.0	1274	93.5	1237	90.8	1213	89.1
Completed test battery	1267	93.2	1175	87.1	1051	80.4	976	76.6	772	62.4	72	6.0
Failed after 8 attempts	65	4.8	113	8.4	190	14.5	203	15.9	166	13.4	9	0.7
Declined	4	0.3	45	3.3	52	4.0	67	5.3	52	4.2	3	0.2
Phone disconnected	18	1.3	11	0.8	13	1.0	26	2.0	20	1.6	1	0.1
Unable to locate	4	0.3	3	0.2	0	0.0	0	0.0	0	0.0	1	0.1
Recontact	0	0.0	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	2	0.2	2	0.2	1	0.1
Discontinued	0	0.0	1	0.1	0	0.0	0	0.0	0	0.0	0	0.0
No answer	0	0.0	0	0.0	0	0.0	0	0.0	1	0.1	4	0.3

Table 7-2 WHIMS-Y Overall Status of Last Call Attempts by Year as of October 9, 2014												
	Year 1		Year 2		Year 3		Year 4		Year 5		Year 6	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Left message	0	0.0	0	0.0	0	0.0	0	0.0	8	0.6	7	0.6
Scheduled	0	0.0	0	0.0	0	0.0	0	0.0	26	2.1	5	0.4
Busy	0	0.0	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	0	0.0	14	1.1	6	0.5
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	0	0.0	176	14.2	1101	91.0

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	255 (19)
70-74	1089 (80)
80+	18 (1)
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, 230 WHIMS-Y women were eligible for the DQ based on their TICSm scores which were below the study cut-points. Of these, 216 progressed to administration of the DQ.

Table 7-4 Dementia Questionnaire Progressions in WHIMS-Y as of October 9, 2014

	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	TOTAL
TICS Administrations	**1265**	**1174**	**1051**	**976**	**760**	**52**	**5278**
DQ Progressions	**61 (4.8%)**	**78 (6.6%)**	**44 (4.2%)**	**32 (3.3%)**	**15 (2.0%)**	**0 (0%)**	**230 (4.4%)**
Missing Proxy information	**5 (8.2%)**	**5 (6.4%)**	**1 (2.3%)**	**2 (6.3%)**	**1 (6.7%)**	**0 (0%)**	**14 (6.1%)**
Total Eligible DQ Progressions	**56 (91.8%)**	**73 (93.6%)**	**43 (97.7%)**	**30 (93.8%)**	**14 (93.3%)**	**0 (0%)**	**216 (93.9%)**

Table 7-5 Dementia Questionnaire Administration in WHIMS-Y as of October 9, 2014						
	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%)**	**12 (40.0%)**	**4 (28.6%)**	**109 (50.5%)**
DQ's in process	**0 (0.0%)**	**4 (5.5%)**	**1 (2.3%)**	**0 (0.0%)**	**3 (21.4%)**	**8 (3.7%)**
Phone Disconnected/Unable to locate/Hearing Impaired	**3 (5.4%)**	**3 (4.1%)**	**1 (2.3%)**	**1 (3.3%)**	**0 (0.0%)**	**8 (3.7%)**
Proxy Refused DQ	**8 (14.3%)**	**8 (11.0%)**	**3 (7.0%)**	**2 (6.7%)**	**1 (7.1%)**	**22 (10.2%)**
PD	**0 (0.0%)**	**0 (0.0%)**	**0 (0.0%)**	**1 (3.3%)**	**0 (0.0%)**	**1 (0.5%)**
4th attempt	**15 (26.8%)**	**20 (27.4%)**	**13 (30.2%)**	**14 (46.7%)**	**6 (42.9%)**	**68 (31.5%)**
TOTAL	**56**	**73**	**43**	**30**	**14**	**216**

There is 1 (0.9%) eligible adjudication case in process. 43 (39.4%) adjudication complete and 65 (59.6%) 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%)	1 (8.3%)	0 (0.0%)	1 (0.9%)
Adjudication complete	12 (40.0%)	14 (36.8%)	11 (44.0%)	4 (33.3%)	2 (50.0%)	43 (39.4%)
- - - - ND	7 (58.3%)	7 (50.0%)	2 (18.2%)	2 (50.0%)	1 (50.0%)	19 (44.2%)
- - - - MCI	5 (41.7%)	5 (35.7%)	6 (54.5%)	2 (50.0%)	0 (0.0%)	18 (41.9%)
- - - - PD	0 (0.0%)	2 (14.3%)	3 (27.3%)	0 (0.0%)	1 (50.0%)	6 (14.0%)
Not Adjudicated (ND)	18 (60.0%)	24 (63.2%)	14 (56.0%)	7 (58.3%)	2 (50.0%)	65 (59.6%)
TOTAL	30	38	25	12	4	109

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 49 WHIMS writing groups that have been approved by the WHI Publications Committee and are currently active.

WHIMS Manuscript Proposals Approved by the P&P September 2014			
Ms#	**Title**	**Chairs**	**Biostatistical Collaborators**
397	Is there an association between baseline macronutrient intake and changes in cognition? Results from WHIMS	Mara Vitolins	Iris Leng
670	Sleep duration, cognitive function, and neurocognitive impairment in older women (WHIMS)	Jiu-Chiuan Chen	Mark Espeland and Iris Leng
881	Change in cognitive function in cancer patients among WHIMS participants	Michelle Naughton	Mark Espeland and Sarah Gaussoin
884	Effects on dementia and cognitive functioning 3 years after stopping estrogen with and without progestin: the WHIMS	Sally Shumaker	Daniel Beavers and Leslie Vaughan
909	Spatial distribution of ischemic lesions in WHIMS-MRI and effects of postmenopausal hormone therapy	Christos Davatzikos	Ramon Casanova and Mark Espeland
937	Psychological attitudes, neuroanatomy and important health outcomes: the WHIMS-MRI Study	Hilary Tindle	Mark Espeland
938	Insomnia, snoring and sleepiness, and risk of cognitive impairments in older women	Jiu-Chiuan Chen	Iris Leng
1042	Relationships that cognitive function and changes in cognitive function have with incident cardiovascular disease: the WHIMS	Sally Shumaker	Mark Espeland and Iris Leng
1115	Obesity and brain volume in post-menopausal women: the WHIMS-MRI Study	Ira Driscoll	Ramon Casanova, Mark Espeland, Sarah Gaussoin, and Leslie Vaughan
1260	Omega-3 fatty acid biomarkers, global cognitive function, and cognitive impairment	Jennifer Robinson	Eric Amman and Mark Espeland
1267	The influence of the social environment on neurological health in aging	Natalie Denburg	Mark Espeland
1307	Social disparities in disturbed sleep: neighborhood and psychosocial determinants	Jiu-Chiuan Chen	Mark Espeland

1308	Neuropsychological mechanisms of social disparities in sleep disturbance	Jiu-Chiuan Chen	Mark Espeland
1309	Neural impacts of disparities in sleep disturbance associated with neighborhood characteristics	Jiu-Chiuan Chen	Mark Espeland
1498	Associations between physical activity and regional brain volume and white matter lesions in the WHIMS-MRI cohort	J. Carson Smith	Ramon Casanova, Patricia Hogan, and Beverly Snively
1525	Antidepressant exposure and cross-sectional and longitudinal changes in brain volumes and ischemic lesion load in women: the WHIMS-MRI2 Study	Joseph Goveas	Daniel Beavers, Ramon Casanova, and Mark Espeland
1526	Depression and longitudinal MRI changes in subclinical cerebrovascular disease and regional brain volumes: the WHIMS-MRI2 Study	Joseph Goveas	Daniel Beavers, Ramon Casanova, Mark Espeland, and Patricia Hogan
1556	A candidate gene study of genetic risk for dementia and mild cognitive impairment in women aged >65 years: results from WHIMS	Ira Driscoll	Ramon Casanova and Beverly Snively
1631	Effect of physical activity on brain volume in WHIMS-MRI	Kirk Erickson	Beverly Snively
1714	A candidate gene study of global and regional brain atrophy in older, post-menopausal women: results from WHIMS	Ira Driscoll	Beverly Snively
1715	A candidate gene study of cognitive impairment in older, post-menopausal women: results from WHIMS	Ira Driscoll	Beverly Snively
1748	Prevalence and predictors of driving among cognitively impaired older adults: the WHIMS	Kaycee Sink, Elizabeth Dugan, and Leslie Vaughan	Patricia Hogan and Beverly Snively
1816	Red blood cell fatty acid patterns and risk for incident age-related macular degeneration in WHIMS	William Harris	Mark Espeland
1851	Effects of physical and verbal abuse on cognitive function in postmenopausal women	Michael Cannell	Mark Espeland
1911	Projecting the incidence distribution for cognitive impairment and dementia in a clinical trial cohort	Mark Espeland	Mark Espeland
1914	Environmental determinants of brain volume and ischemia in older women: role of diesel exhaust particulate matter	Jiu-Chiuan Chen	Mark Espeland

1943	Pharmacogenomics of cognitive decline in hormone therapy using phylogenetic methods	Samuel Handelman	Beverly Snively
2043	Long-term effects of depression on cognitive function in women aged 50-54 years: the WHIMS-Y	Joseph Goveas	Mark Espeland
2074	Dietary sodium intake, blood pressure control and cognitive decline in postmenopausal women: results from WHIMS	Bernhard Haring	Laura Coker and Sarah Gaussoin
2086	The relationship between depressed mood and subtypes of mild cognitive impairment and dementia in post-menopausal women	Laura Korthauer	Mark Espeland
2146	Comparing the strength and costs of bi-directional associations between cognitive decline, falls, and fractures	Regina Shih	Mark Espeland
2153	Relationship that caffeine intake has with the risk of cognitive impairment and global cognitive function: results from WHIMS	Ira Driscoll	Mark Espeland and Beverly Snively
2183	Trajectories of cognitive function prior to and following stroke: pooled analysis from three cohorts	Leslie Vaughan	Mark Espeland
2219	Predictors of optimal cognitive aging in 80+ women: the WHIMS	Joseph Goveas	Mark Espeland and Patricia Hogan
2229	Post-stroke cognitive function and daily life function in WHIMS/WHISCA women	Leslie Vaughan	Mark Espeland
2249	Exposures to ambient fine particles and risk of dementia in older women	Jiu-Chiuan Chen	Mark Espeland
2280	Use of regularization in landmark estimation of hormone therapy treatment effects on dementia: identifying intermediate events	Layla Parast	Mark Espeland
2281	Use of inverse probability of censoring weights in landmark estimation to address noncompliance in WHIMS	Layla Parast	Mark Espeland
2282	Use of propensity scores in landmark estimation of the effect of diabetes on probable dementia and mild cognitive impairment	Layla Parast	Mark Espeland
2283	MRI biomarkers of cognitive outcomes in cancer patients among WHIMS participants	Shelli Kesler	Ramon Casanova
2302	The association between state affect and incidence of mild cognitive impairment and dementia in postmenopausal women	Ira Driscoll	Mark Espeland and Leslie Vaughan

2345	Gene x environment Interactions in brain aging	Ira Driscoll	Jasmin Divers
2349	Ambient air pollution and neurotoxicity on brain structure: evidence from WHIMS	Jiu-Chiuan Chen	Mark Espeland and Ramon Casanova
2384	Is the DNA methylation age of blood a better predictor of regional brain volumes and cognitive functioning than chronological age?	Steve Horvath	Leslie Vaughan
2428	Impact of postmenopausal hormone therapy and type 2 diabetes mellitus on dementia and hippocampal volume	Mark Espeland	Ramon Casanova, Mark Espeland, and Leslie Vaughan
2431	Geographic disparities in cognitive decline and dementia risks in older women	Jiu-Chiuan Chen	Ramon Casanova and Mark Espeland
2461	Cognitive trajectories of post-menopausal veteran and non-veteran women and associated risk factors	Claudia Padula	Mark Espeland
2463	Driving habits of older adult women: risk factors and compensatory strategies	Leslie Vaughan	Beverly Snively and Leslie Vaughan
2478	Fine particulate air pollutants and cognitive declines in older women	Jiu-Chiuan Chen	Mark Espeland

Section 9.

Publications Activities

9.1 WHIMS SUITE OF STUDIES BIBLIOGRAPHY

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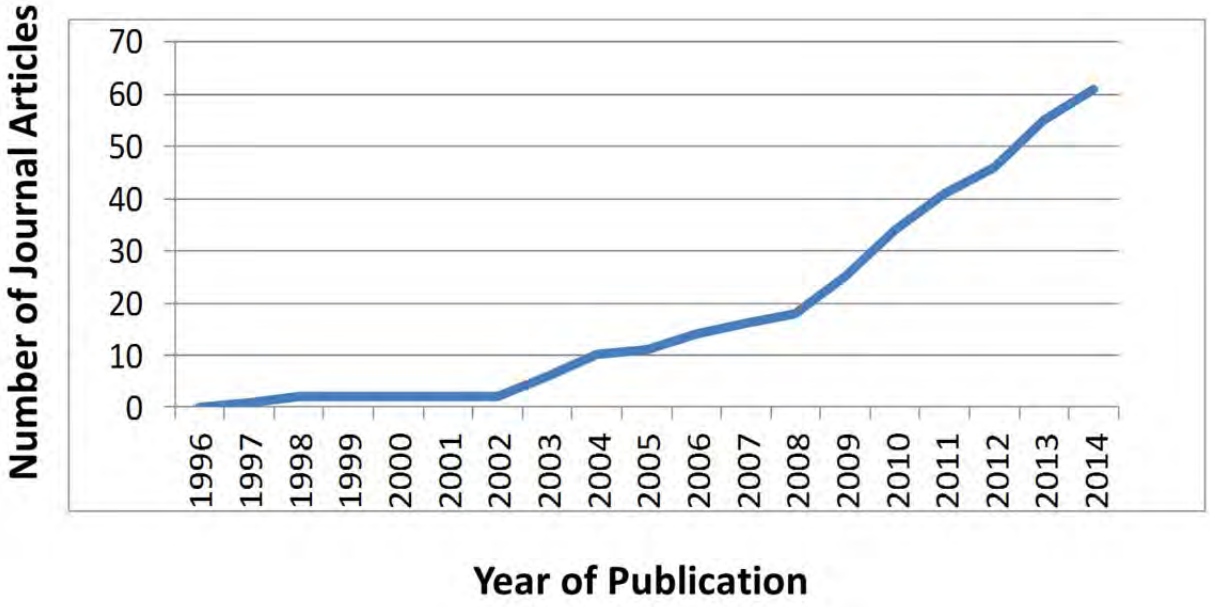
WHI Cognition Program Publications

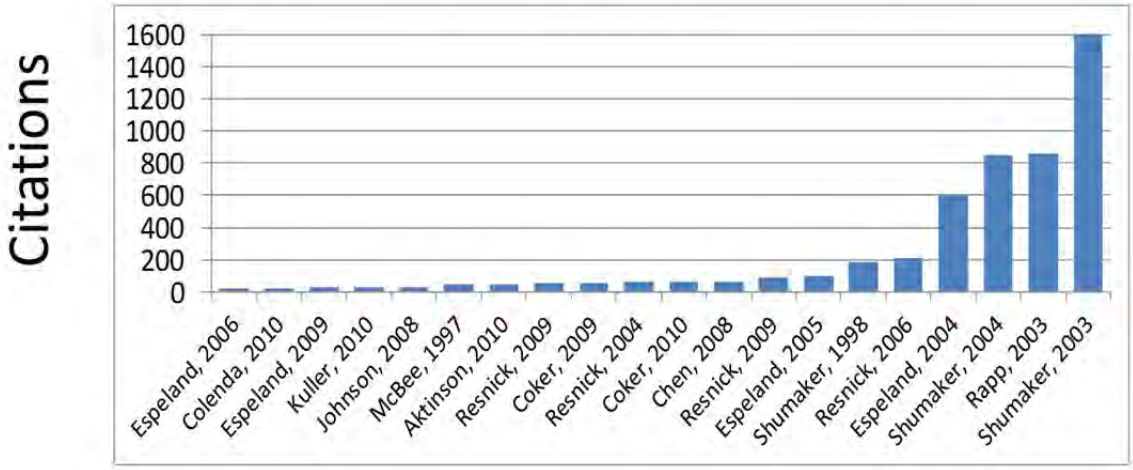
September, 2014: 61 Journal Articles



Most Highly Cited WHI Cognition Articles

Source: Google Scholar September 14, 2014

>5400 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:

- We investigated (a) cross-sectional associations between cognitive activity, cognitive performance, and MRI measures and (b) longitudinal associations between cognitive activity and change in cognitive performance, using structural equation modeling (SEM). Women's Health Initiative Memory Study (WHIMS) Extension participants who continued annual neuropsychological assessments by telephone and completed a concurrent questionnaire of cognitive activities and MRI scans were included (mean age = 81.4 years; N = 393). Cognitive performance was measured by tests of attention, working memory, verbal fluency, executive function, and memory. Cognitive activity was measured by self-reported participation in a variety of cognitive activities (e.g., reading books, playing games, computer activities; N = 11 items) during the previous 12 months. MRI measures included gray and white matter normal and white matter lesion volumes. SEM demonstrated a significant association between cognitive activity and baseline cognitive performance but not change over 2-3 years. Gray and white matter was associated with cognitive performance but not cognitive activity. All effects remained significant after modeling covariates (age, education, depressive symptoms, WHIMS intervention assignment, and intracranial volume). Cognitive activity benefits current cognitive performance but is not associated with change over 2-3 years. Cognitive activity and MRI volumes are independently associated with cognitive performance, suggesting distinct cognitive and brain reserve constructs. Vaughan L, Erickson KI, Espeland MA, Smith JC, Tindle HA, Rapp SR. Concurrent and longitudinal relationships between cognitive activity, cognitive performance, and brain volume in older adult women. J Gerontol B Psychol Sci Soc Sci. 2014 Sep 10. PMID: 25209372.

- To determine whether smaller brain volumes in older women who had completed Women's Health Initiative (WHI)-assigned conjugated equine estrogen-based hormone therapy (HT), reported by WHI Memory Study (WHIMS)-MRI, correspond to a continuing increased rate of atrophy an average of 6.1 to 7.7 years later in WHIMS-MRI2. A total of 1,230 WHI participants were contacted: 797 (64.8%) consented, and 729 (59%) were rescanned an average of 4.7 years after the initial MRI scan. Mean annual rates of change in total brain volume, the primary outcome, and rates of change in ischemic lesion volumes, the secondary outcome, were compared between treatment groups using mixed-effect models with adjustment for trial, clinical site, age, intracranial volumes, and time between MRI measures. Total brain volume decreased an average of 3.22 cm(3)/y in the active arm and 3.07 cm(3)/y in the placebo arm ($p = 0.53$). Total ischemic lesion volumes increased in both arms at a rate of 0.12 cm(3)/y ($p = 0.88$). Conjugated equine estrogen-based postmenopausal HT, 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 with placebo. Women with a history of cardiovascular disease treated with active HT, compared with 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. Coker LH1, Espeland MA, Hogan PE, Resnick SM, Bryan RN, Robinson JG, Goveas JS, Davatzikos C, Kuller LH,

Williamson JD, Bushnell CD, Shumaker SA; WHIMS-MRI Study Group. Change in brain and lesion volumes after CEE therapies: the WHIMS-MRI studies. Neurology. 2014 Feb 4;82(5):427-34. PMCID: PMC3917682.

- We sought to determine the relationship between the omega-3 fatty acid content of red blood cell membranes (RBC), in particular docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA), and baseline and new-onset depressive symptoms in post-menopausal women. We secondarily sought to characterize the association between dietary omega-3 fatty acid intake and depressive symptomatology. Study participants included 7086 members of the Women's Health Initiative Memory Study (aged 63-81 years) who had an assessment of RBC omega-3 fatty acid concentrations at the baseline screening visit. Depressive symptoms at baseline and follow-up were characterized using the Burnam eight-item scale for depressive disorders (Center for Epidemiologic Studies Depression Scale/Diagnostic Interview Schedule short form) and secondarily additionally inferred by antidepressant medication use. In multivariable-adjusted models, our primary exposure, RBC DHA + EPA, was not related to depressive symptoms by any measure at baseline or follow-up, nor were RBC total omega-3, DHA, or EPA (all $p > 0.2$). In contrast, dietary intake of omega-3 was positively associated with depressive symptoms at baseline (adjusted odds ratio 1.082, 95% confidence interval 1.004-1.166; $p = 0.04$ for dietary DHA + EPA and Burnam score ≥ 0.06), although this generally did not persist at follow-up. No relationship between RBC omega-3 levels and subsequent depressive symptoms was evident, and associations between dietary omega-3 and depressive symptoms were variable. Biomarkers of omega-3 status do not appear to be related to risk of new depression in post-menopausal women. Persons JE, Robinson JG, Ammann EM, Coryell WH, Espeland MA, Harris WS, Manson JE, Fiedorowicz JG. Omega-3 fatty acid biomarkers and subsequent depressive symptoms. Int J Geriatr Psychiatry. 2014 Jul;29(7):747-57. PMCID: PMC4048630.

- To test whether red blood cell (RBC) levels of marine omega-3 fatty acids measured in the Women's Health Initiative Memory Study were related to MRI brain volumes measured 8 years later. RBC eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA), and MRI brain volumes were assessed in 1,111 postmenopausal women from the Women's Health Initiative Memory Study. The endpoints were total brain volume and anatomical regions. Linear mixed models included multiple imputations of fatty acids and were adjusted for hormone therapy, time since randomization, demographics, intracranial volume, and cardiovascular disease risk factors. In fully adjusted models, a 1 SD greater RBC EPA + DHA (omega-3 index) level was correlated with 2.1 cm(3) larger brain volume ($p = 0.048$). DHA was marginally correlated ($p = 0.063$) with total brain volume while EPA was less so ($p = 0.11$). There were no correlations between ischemic lesion volumes and EPA, DHA, or EPA + DHA. A 1 SD greater omega-3 index was correlated with greater hippocampal volume (50 mm(3), $p = 0.036$) in fully adjusted models. Comparing the fourth quartile vs the first quartile of the omega-3 index confirmed greater hippocampal volume (159 mm(3), $p = 0.034$). A higher omega-3 index was correlated with larger total normal brain volume and hippocampal volume in postmenopausal women measured 8 years later. While normal aging results in overall brain atrophy, lower omega-3 index may signal increased risk of hippocampal atrophy. Future studies should examine whether maintaining higher RBC EPA + DHA levels slows the rate of hippocampal or overall brain atrophy. Pottala JV1, Yaffe K, Robinson JG,

Espeland MA, Wallace R, Harris WS. Higher RBC EPA + DHA corresponds with larger total brain and hippocampal volumes: WHIMS-MRI study. Neurology. 2014 Feb 4;82(5):435-42. PMCID: PMC3917688.

- Elevated depressive symptoms (DS) are associated with incident mild cognitive impairment and probable dementia in postmenopausal women. We examined the association of elevated DS with domain-specific cognitive changes and the moderating role of cardiovascular risk factor severity and cardiovascular disease (CVD). A total of 2221 elderly women who participated in the Women's Health Initiative Study of Cognitive Aging were separated into those with (N = 204) and without (N = 2017) elevated DS. The DS and multidomain cognitive outcomes were measured annually for an average follow-up of 5.04 years. Women with elevated DS showed baseline multidomain cognitive deficits but longitudinal declines in global cognition only. Persistent DS was related to greater global cognition, verbal knowledge and fluency, and memory declines. Significant DS-CVD interactions were observed cross-sectionally (but not longitudinally) for figural memory and fine motor speed. Future studies should investigate the role of nonvascular mechanisms linking DS and cognitive decline. Goveas JS, 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. J Geriatr Psychiatry Neurol. 2014 Feb 28;27(2):94-102. PMID: 24584465.

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].

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