Women's Health Initiative

2015 Annual Progress Report

Data as of: September 30, 2015

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

2015 Annual Progress Report

Data as of: September 30, 2015

Prepared by
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1. Overview

1.0 Background

Between 1993 and 1997, WHI investigators at 40 Clinical Centers recruited 161,808 women into the overall program; 68,132 were randomized into one or more arms of the clinical trial component (CT) and 93,676 were enrolled into the observational study (OS). During 2004-2005, the close-out period for the original program, 115,407 women consented to five additional years of follow-up, representing 76.9% of the 150,076 participants who were alive and in active follow-up at this time. At the end of the first extension period in 2010, participants were again offered the opportunity to continue and 86.9% of the 107,706 eligible women agreed (n=93,567).

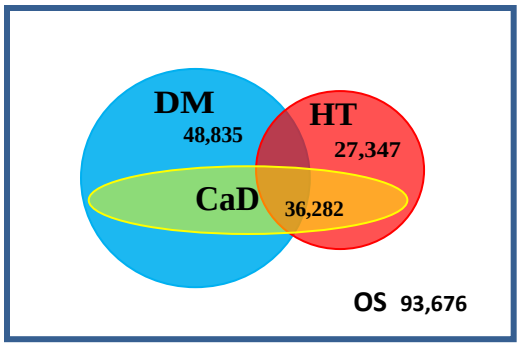


Figure 1: Original design of the WHI partial factorial trial and observational study of 161,808 postmenopausal women.

1.1 The 2010-2015 Extension Study

The follow-up protocol for 2010-2015 has incorporated 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.

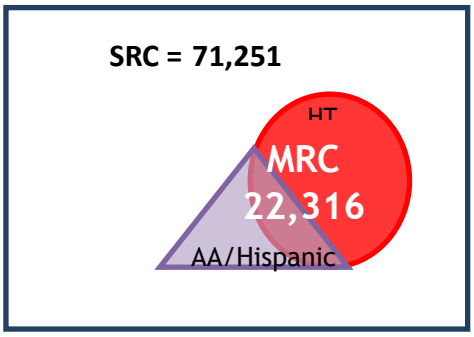


Figure 2: 2010-2015 Extension Study design reflecting differing levels of outcomes ascertainment: Medical Records Cohort (MRC) and Self-Report Cohort (SRC).

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 September 2015, 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 2-4 had modest reductions in response rates, with an overall response rates declining from 96.3% in year 2 to 93.2% in year 4. Though not yet complete, year 5 response has been similarly high, with an overall response rate of 92.2% including phone follow-up. Acknowledging that the high volume of ancillary studies recruitments in the last year could have an impact on retention, we present data showing the change in follow-up status over the last year in Figures 1.1-1.4. There does not appear to be any significant effect on retention from the recruitment mailings sent by two trials and several other ancillary studies in 2015, but only a minor and gradual attrition.

For the designated WHI outcomes, clinical event rates using the fully adjudicated outcomes through September 2015 are presented by original study component, age and race (Sections 2-7). Using the newer 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 September 2015 are provided for the MRC Supercohort (Table 8.2 and 8.3). For the SRC Supercohort, fully adjudicated events are provided for the interval from enrollment to September 2010 or September 2015 as appropriate (Table 8.4 and 8.5). There is a large volume of retrospective strokes among the DM and OS participants that were previously locally adjudicated, and have been centrally adjudicated by neurologists over the last year, resulting in denials of some of the locally adjudicated outcomes and so a smaller number of these outcomes relative to the previous report.

Table 9.1 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, especially myocardial infarction (MI), where only 53% of the adjudicated outcomes are triggered by self-reports of MI, and the remainder are discovered during investigation into self-reports of other outcomes.

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 59.7% of reviewed events as possible or definite decompensated heart failure (Table 10.1), which agreed with 73.9% of the WHI events that had been previously adjudicated as heart failure (Table 10.2). UNC has additionally been able to further classify the type of heart failure into scientifically important subtypes (Table 10.3), and enumerate the number of repeated cases per participant (Table 10.4).

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

11.2 stratified by age and 11.3 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 11.1), though there was a recent increase average physical functioning in the oldest group.

We also provide a brief summary of the updated medication inventory data in Section 12. That form was included in the year 3 mailings to MRC participants, and though no new data has been collected, the proportion of the cohort reporting use of common medications certainly facilitates future analyses using these data.

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 13), now has post-LLS blood draw outcomes available for analyses. 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 13.2). Verified and self-reported outcomes are available (Tables 13.6-13.8) stratified by age at randomization and race. So far, 268 LLS participants have had verified cardiovascular outcomes and 208 have had a verified cancer after the LLS blood draw (both more than doubled over last year). The most frequent self-reported outcomes after the draw so far are: macular degeneration (N=417), Alzheimer's disease (N=325), and osteoarthritis (N=323).

Regional Center performance in follow-up and outcomes documentation is summarized in Section 14. 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 15. Section 16 lists core, BAA and ancillary studies activities and Section 17 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 25 studies in the past year (Table 16.4). Among these AS are 8 investigators that won a feasibility study competition organized at the CCC, and these investigators were all able to submit proposals and complete their work in just 7 months. Most of these studies made use of stored biospecimens, including the first use of the RNA collected at the LLS visit. The 2 clinical trials launched this year have been successful at maintaining engagement among WHI participants, and the number enrolled in ancillary studies has increased from 29% last year to 49% this year of WHI participants have enrolled in 1 or more ancillary studies. Most of those women are participating in 1-2 ancillary studies (Table 16.6).

There have been 2,349 approved manuscript proposals and 1,208 are published or in press (Table 17.1), 127 of which were published in the last year (Table 17.2). 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 *Nature*, *PNAS*, and *JAMA*. 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. Additionally, a number of collaborative consortium projects have yielded high impact papers.

The cohort continues to serve as the critical backbone for ancillary studies large and small. The COcoa Supplement and Multivitamin Outcomes Study (COSMOS) trial (PIs: JoAnn Manson and Howard Sesso) and the WHI Strong and Healthy (WHISH) trial (PIs: Charles Kooperberg, Andrea LaCroix, Marcia Stefanick) both successfully launched early in 2015. In addition to the trials, 14 ancillary studies to the trials were submitted for funding. The WHI Cancer Survivor Cohort (PIs: Garnet Anderson, Bette Caan, Electra Paskett) also continues to expand the WHI data and biorepository for WHI participants diagnosed with cancer. Adding tumor tissue, treatment and recurrence data, and data on self-reported post-treatment effects will further increase the utility of the WHI resources for engaging investigators with an interest in cancer survivorship.

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 are shared through dbGaP and BIOLINCCC, providing an opportunity for outside investigators to use these resources. NHLBI recently selected WHI to participate in a large whole genome sequencing project, TopMED, that will further enhance our genetic data repository for investigators interested in the genetic epidemiology of stroke and vascular disease.

As the second Extension of the WHI comes to a close, we are working to identify ways to continue to engage outside investigators including junior investigators in using the WHI resources to efficiently address important scientific questions. In addition to the active scientific interest groups, we provide travel support for junior investigators to attend the annual WHI Investigator meeting, and have continued to seek out opportunities to collaborate with active consortium projects.

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, 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, AZ
Jean Wactawski-Wende, PhD	University at 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: September 30, 2015

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: September 30, 2015

	Clinical Trial				Observational Study			
WHI Enrollment	**Enrolled in WHI**	**Eligible for extension 2005-2010[1]**	**Consented N**	**Consented %**	**Enrolled in WHI**	**Eligible for extension 2005-2010[1]**	**Consented N**	**Consented %**
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			
WHI Enrollment	**Enrolled in extension 2005-2010**	**Eligible for extension 2010-2015[1]**	**Consented N**	**Consented %**	**Enrolled in extension 2005-2010**	**Eligible for extension 2010-2015[1]**	**Consented N**	**Consented %**
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: September 30, 2015

	Enrolled in Extension 2005-2010	Eligible for Extension 2010-2015[2]	Consented	
			N	%
Total	115407	107706	93567	86.9
Age on 9/30/2010				
<80	72424	69728	62661	89.9
<70	18291	17873	16281	91.1
70-74	26788	25974	23535	90.6
75-79	27345	25881	22845	88.3
≥80	42983	37978	30906	81.4
80-84	24565	22520	19110	84.9
85-89	14261	12303	9589	77.9
≥90	4157	3155	2207	70.0
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 9/30/2010				
<80	19048	18166	15338	84.4
<70	5216	5051	4255	84.2
70-74	6927	6642	5695	85.7
75-79	6905	6473	5388	83.2
≥80	10320	9055	6978	77.1
80-84	5949	5411	4360	80.6
85-89	3363	2883	2133	74.0
≥90	1008	761	485	63.7
Race/Ethnicity				
American Indian	79	75	64	85.3
Asian/Pacific Islander	363	328	240	73.2
Black	8354	7817	6136	78.5
Hispanic	3389	3228	2472	76.6
White	16919	15525	13204	85.0
Unknown	264	248	200	80.6
Self Report Cohort	86039	80485	71251	88.5
Age on 9/30/2010				
<80	53376	51562	47323	91.8
<70	13075	12822	12026	93.8
70-74	19861	19332	17840	92.3
75-79	20440	19408	17457	89.9
≥80	32663	28923	23928	82.7
80-84	18616	17109	14750	86.2
85-89	10898	9420	7456	79.2
≥90	3149	2394	1722	71.9
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
Counts of Participants with Active Participation[1] by Current Age, Race/Ethnicity and Cohort

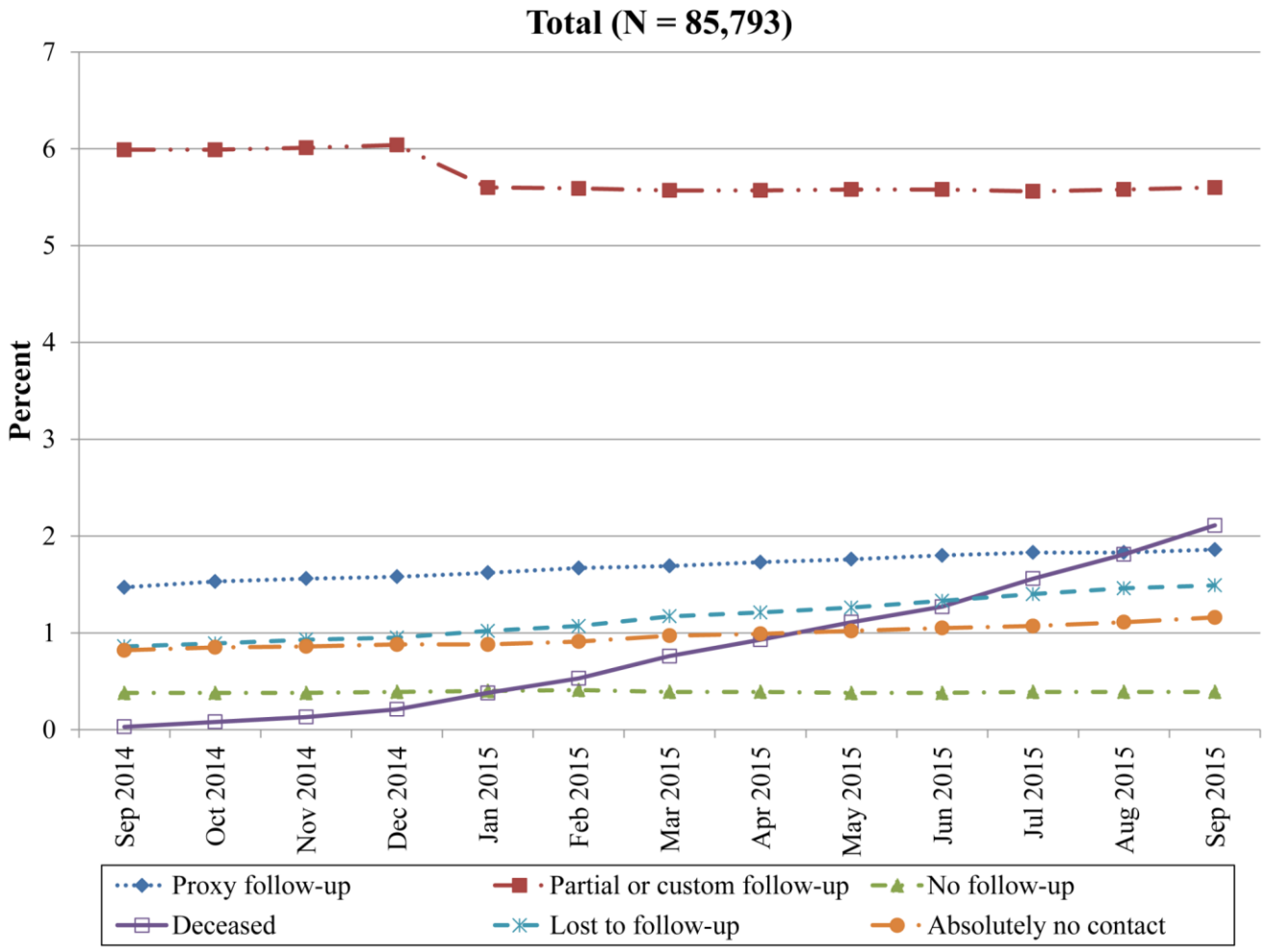
Data as of: September 30, 2015

	Clinical Trial (N=36,089)		Observational Study (N=45,241)		MRC Super Cohort (N=19,008)		SRC Super Cohort (N=62,322)		Total (N=81,330)	
	N	%	N	%	N	%	N	%	N	%
Age on 9/30/2015										
<75	6579	18.2	9001	19.9	3972	20.9	11608	18.6	15580	19.2
75-79	10268	28.5	11758	26.0	5223	27.5	16803	27.0	22026	27.1
80-84	9432	26.1	10968	24.2	4649	24.5	15751	25.3	20400	25.1
85-89	6741	18.7	8879	19.6	3486	18.3	12134	19.5	15620	19.2
90-94	2639	7.3	3900	8.6	1424	7.5	5115	8.2	6539	8.0
95+	430	1.2	735	1.6	254	1.3	911	1.5	1165	1.4
Race/Ethnicity										
American Indian	125	0.3	148	0.3	51	0.3	222	0.4	273	0.3
Asian/Pacific Islander	770	2.1	934	2.1	210	1.1	1494	2.4	1704	2.1
Black	2912	8.1	2328	5.1	5240	27.6	0	0.0	5240	6.4
Hispanic	1080	3.0	1107	2.4	2187	11.5	0	0.0	2187	2.7
White	30760	85.2	40218	88.9	11144	58.6	59834	96.0	70978	87.3
Unknown	442	1.2	506	1.1	176	0.9	772	1.2	948	1.2

[1] Active participation is defined as current (Form 33 within the last 15 months) or recent (Form 33 between 15 and 24 months ago) follow-up.

Figure 1.1
Follow-up Status Over Time for WHI Extension Study 2010-2015 Participants Alive on September 1, 2014[1]

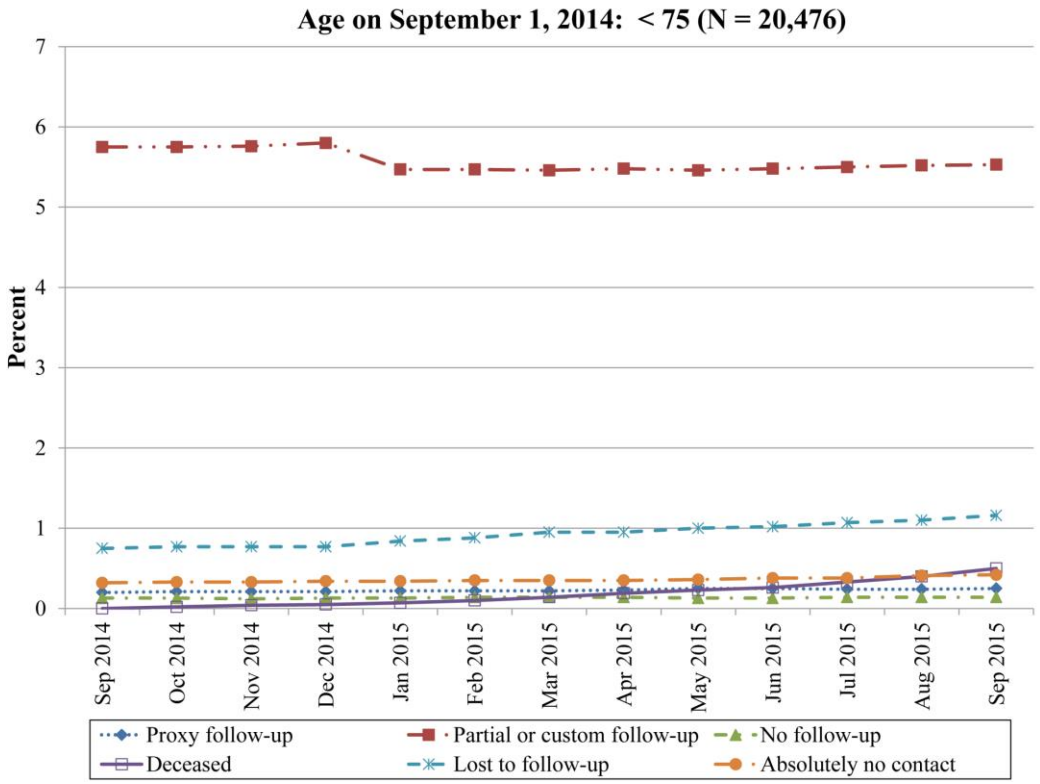
Data as of: September 30, 2015

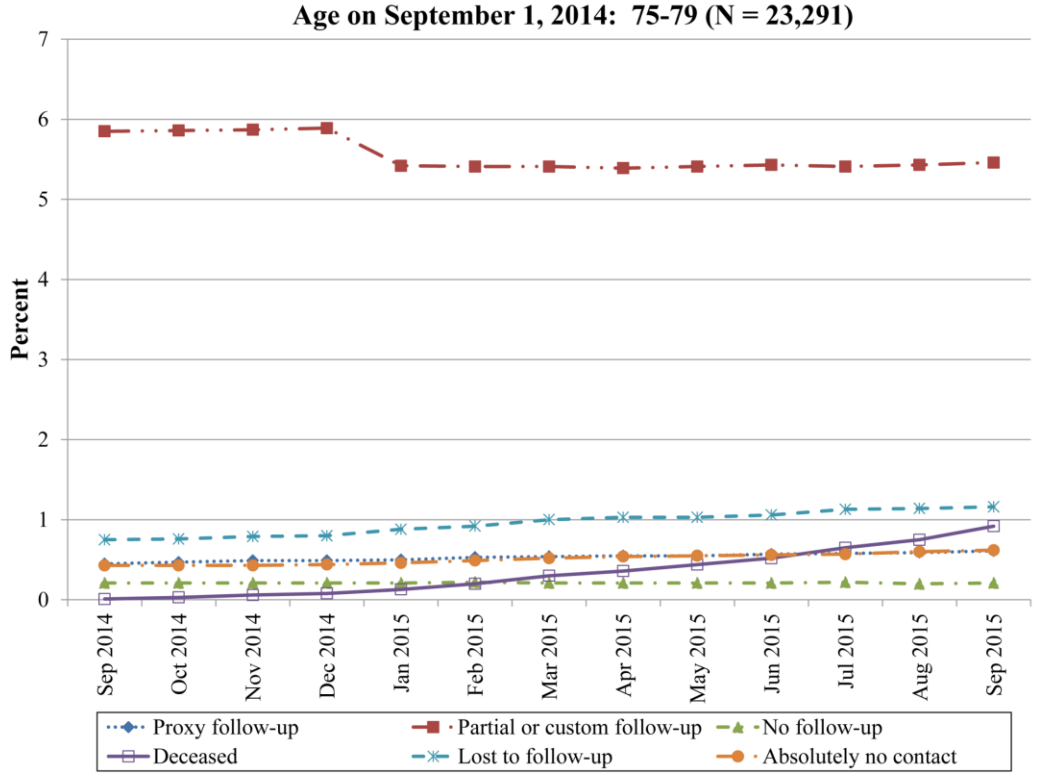


[1] Participants with full follow-up participation rates are not shown.

Figure 1.2
Follow-up Status Over Time for WHI Extension Study 2010-2015 Participants Alive on September 1, 2014[1]
By Age on September 1, 2014

Data as of: September 30, 2015

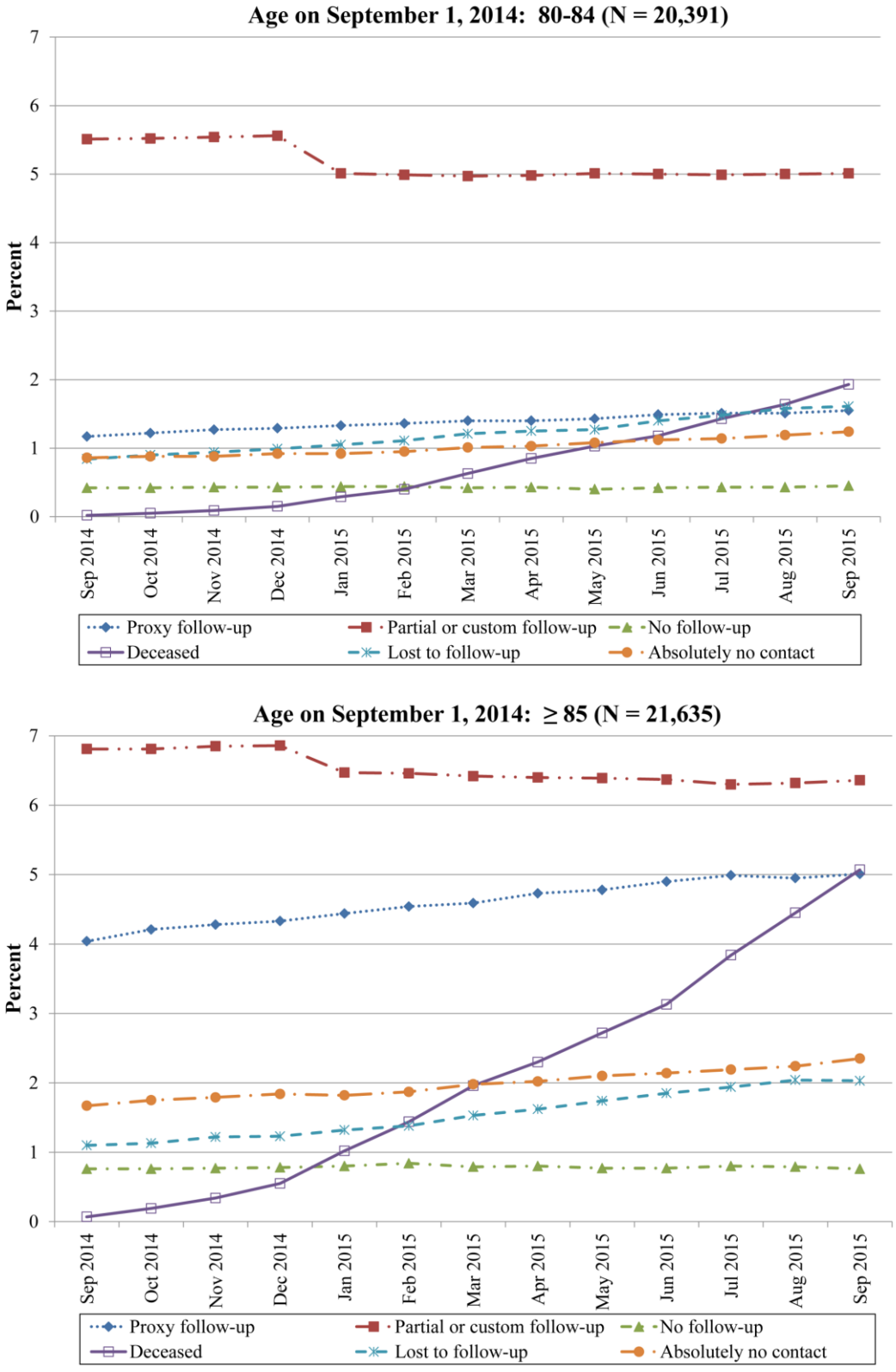




[1] Participants with full follow-up participation rates are not shown.

Figure 1.2 (continued)
Follow-up Status Over Time for WHI Extension Study 2010-2015 Participants Alive on September 1, 2014[1]
By Age on September 1, 2014

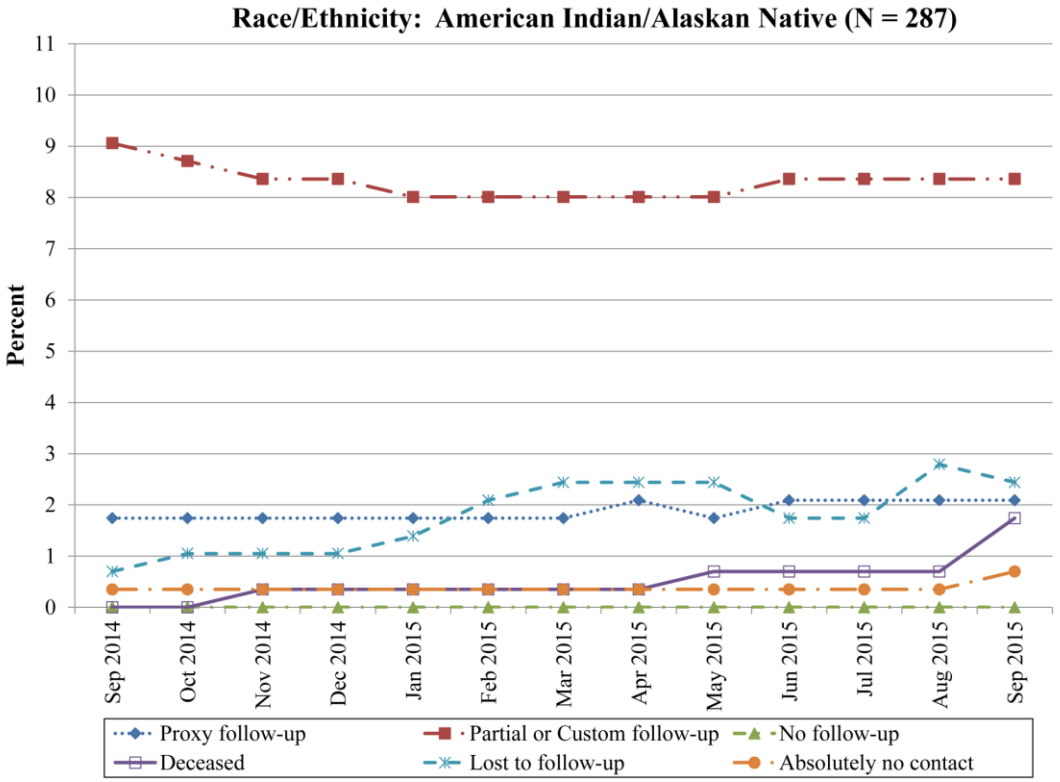
Data as of: September 30, 2015

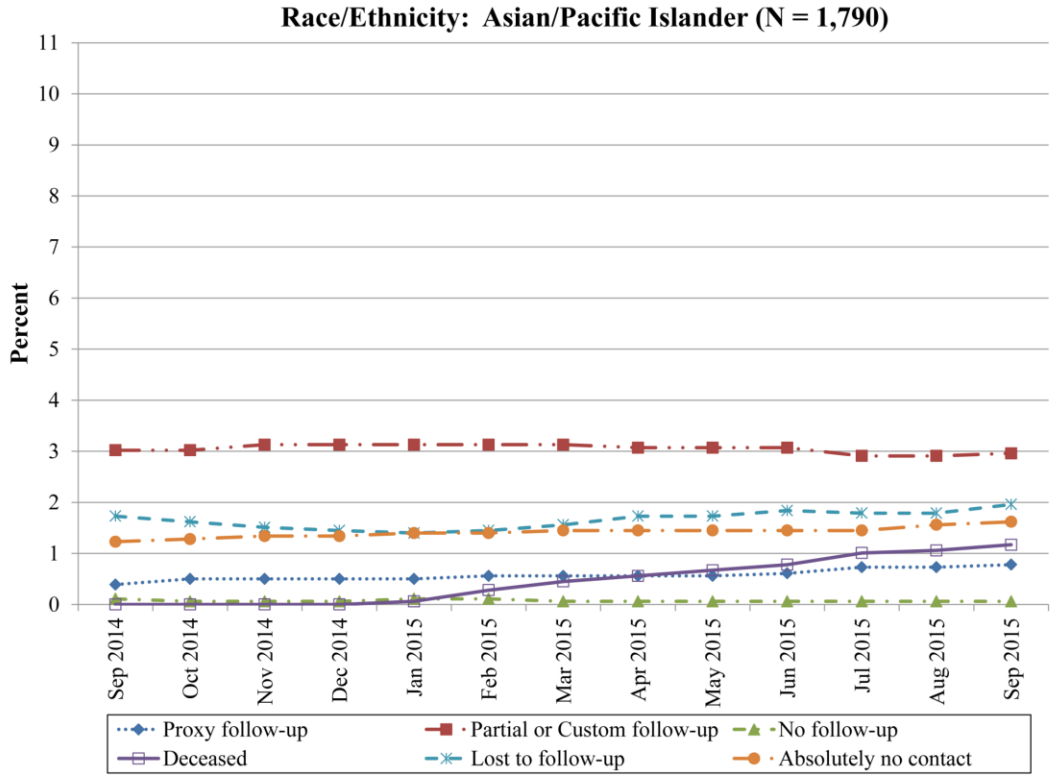


[1] Participants with full follow-up participation rates are not shown.

Figure 1.3
Follow-up Status Over Time for WHI Extension Study 2010-2015 Participants Alive on September 1, 2014[1]
By Race/Ethnicity

Data as of: September 30, 2015



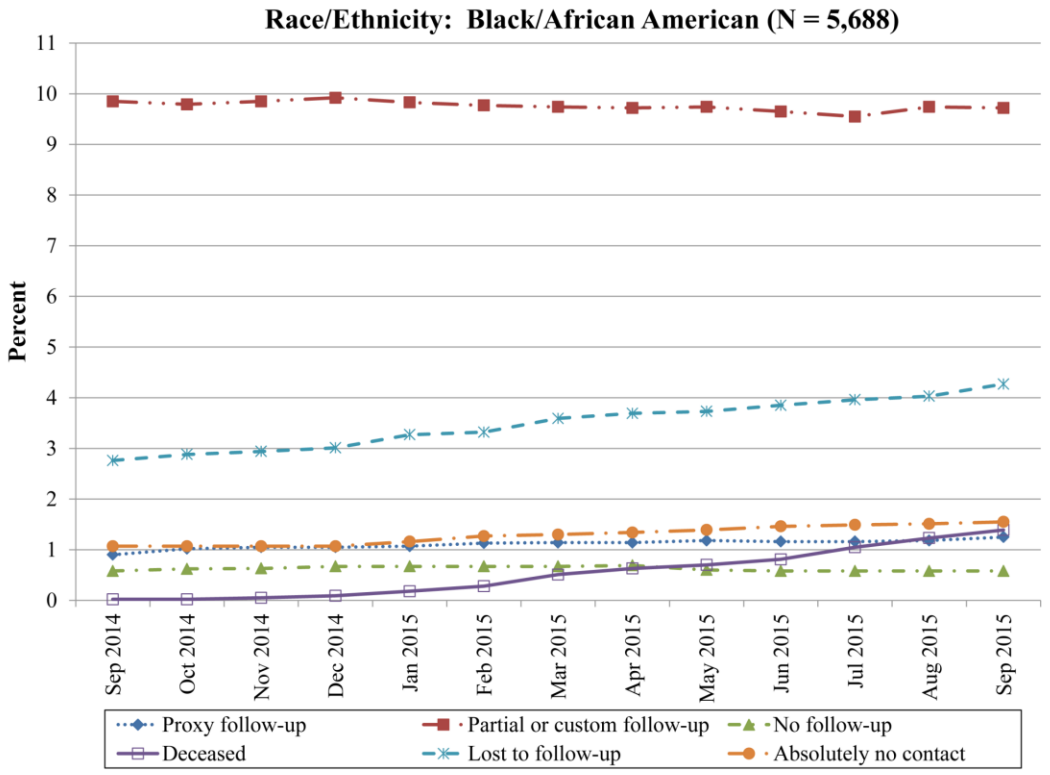


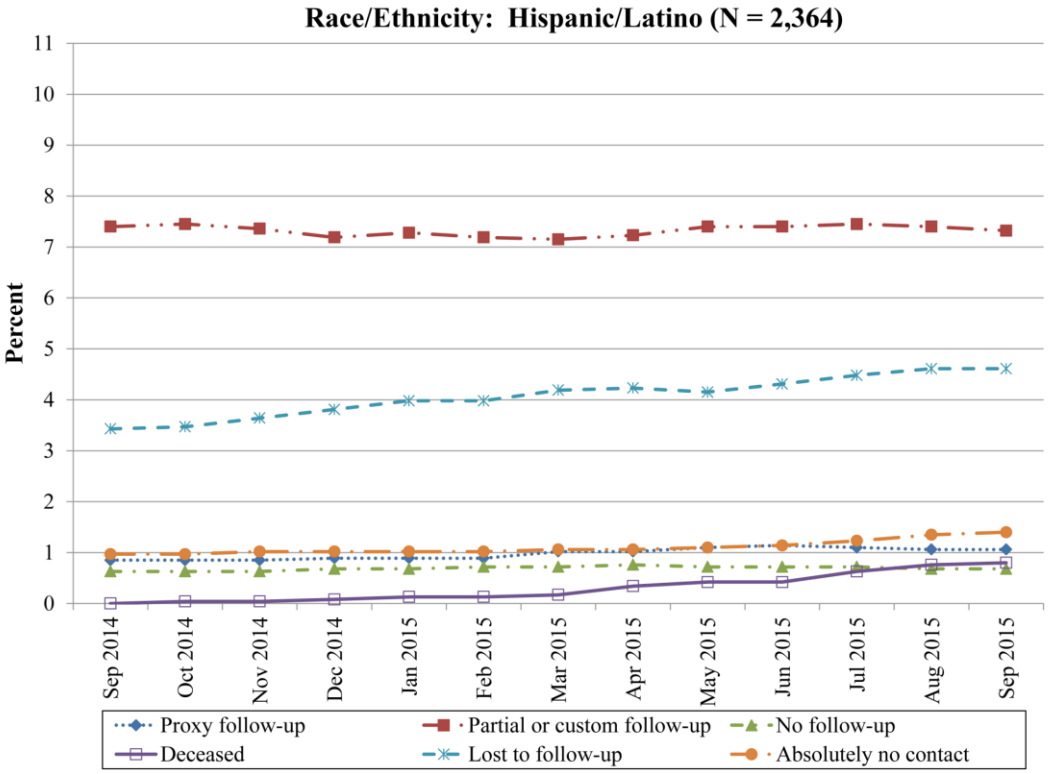
[1] Participants with full follow-up participation rates are not shown.

Figure 1.3 (continued)

Follow-up Status Over Time for WHI Extension Study 2010-2015 Participants Alive on September 1, 2014[1] By Race/Ethnicity

Data as of: September 30, 2015



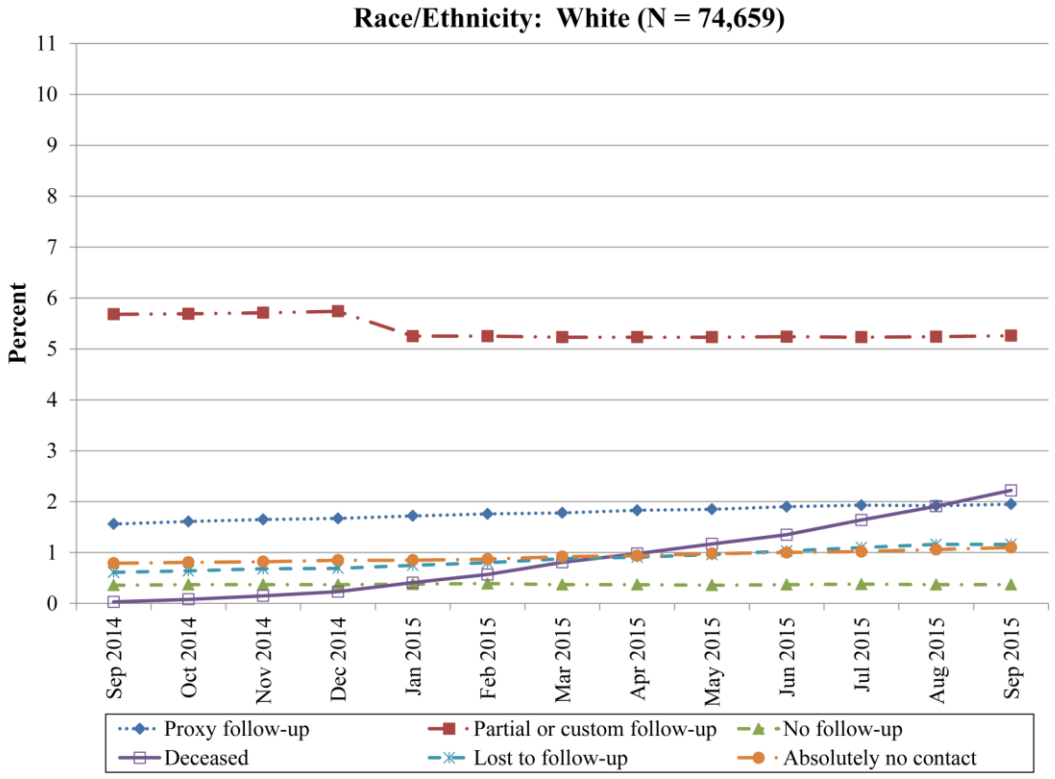


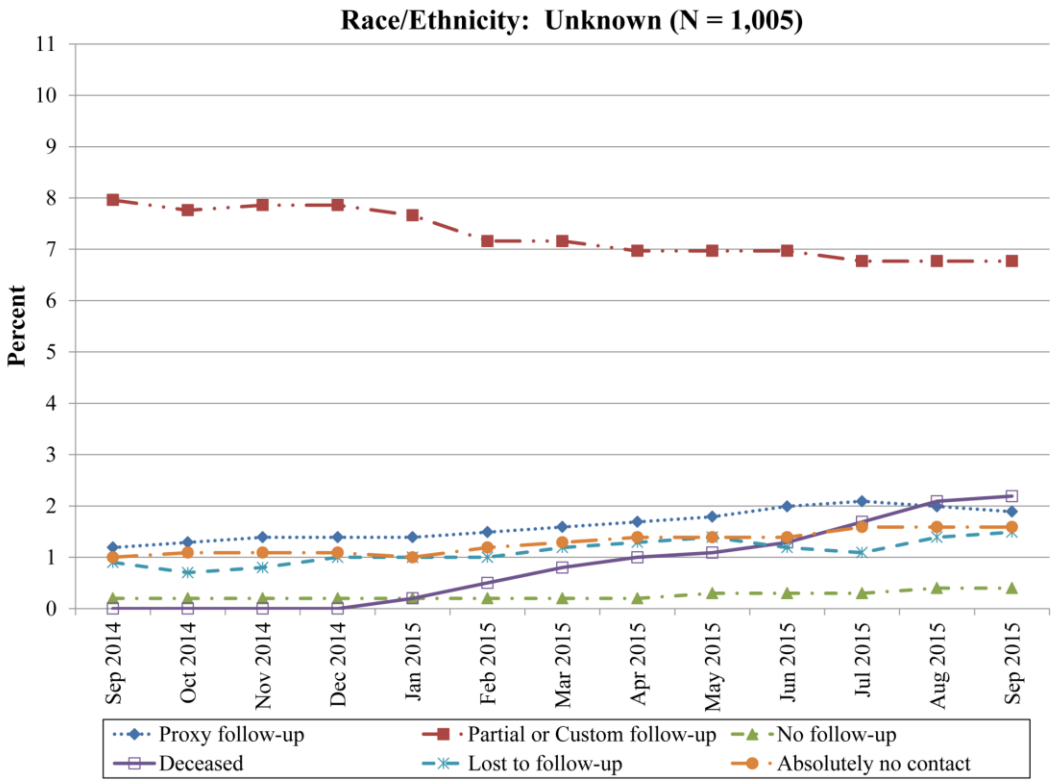
[1] Participants with full follow-up participation rates are not shown.

Figure 1.3 (continued)

Follow-up Status Over Time for WHI Extension Study 2010-2015 Participants Alive on September 1, 2014[1] By Race/Ethnicity

Data as of: September 30, 2015

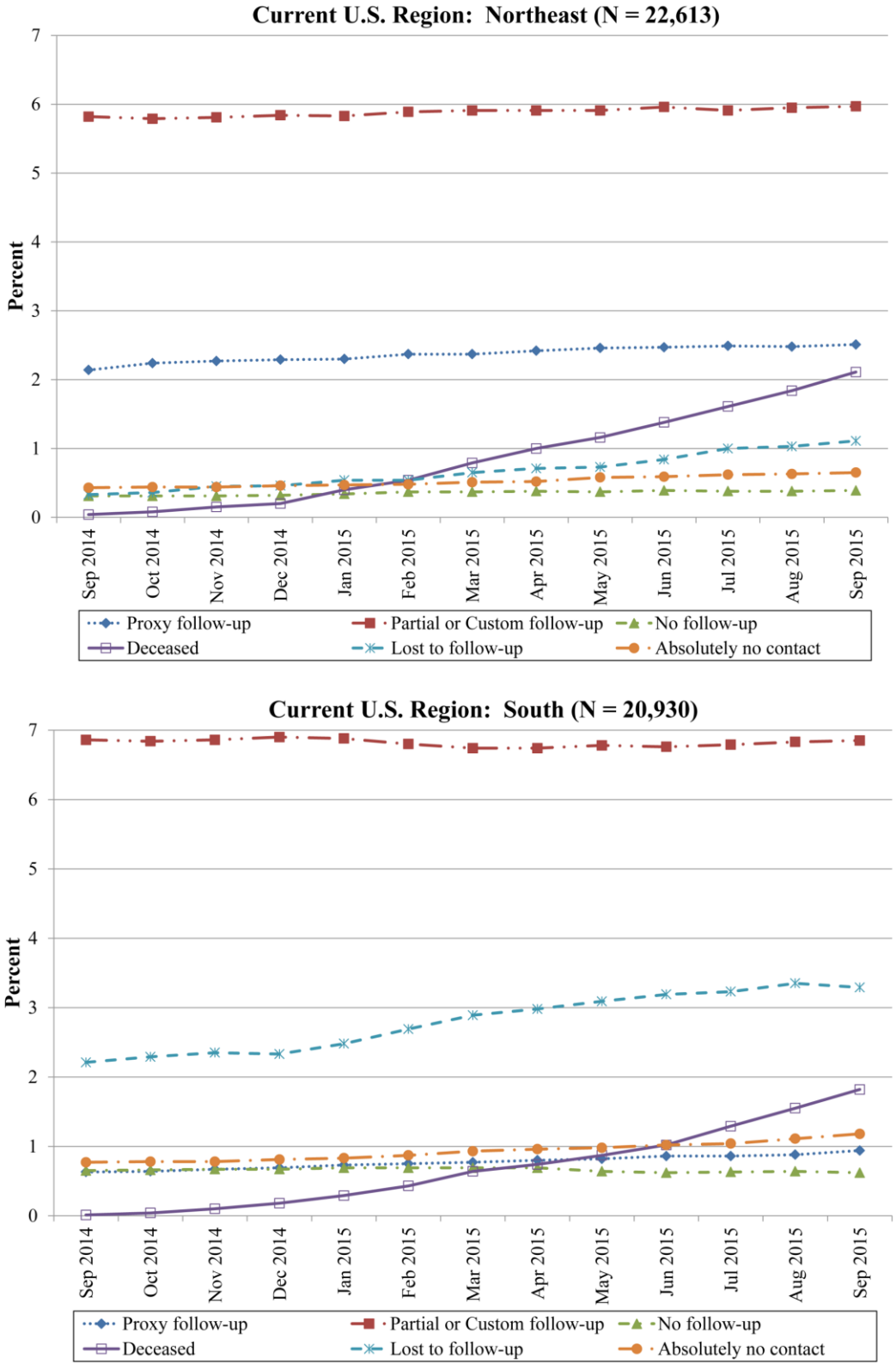




[1] Participants with full follow-up participation rates are not shown.

Figure 1.4
Follow-up Status Over Time for WHI Extension Study 2010-2015 Participants Alive on September 1, 2014[1]
By Current U.S. Region

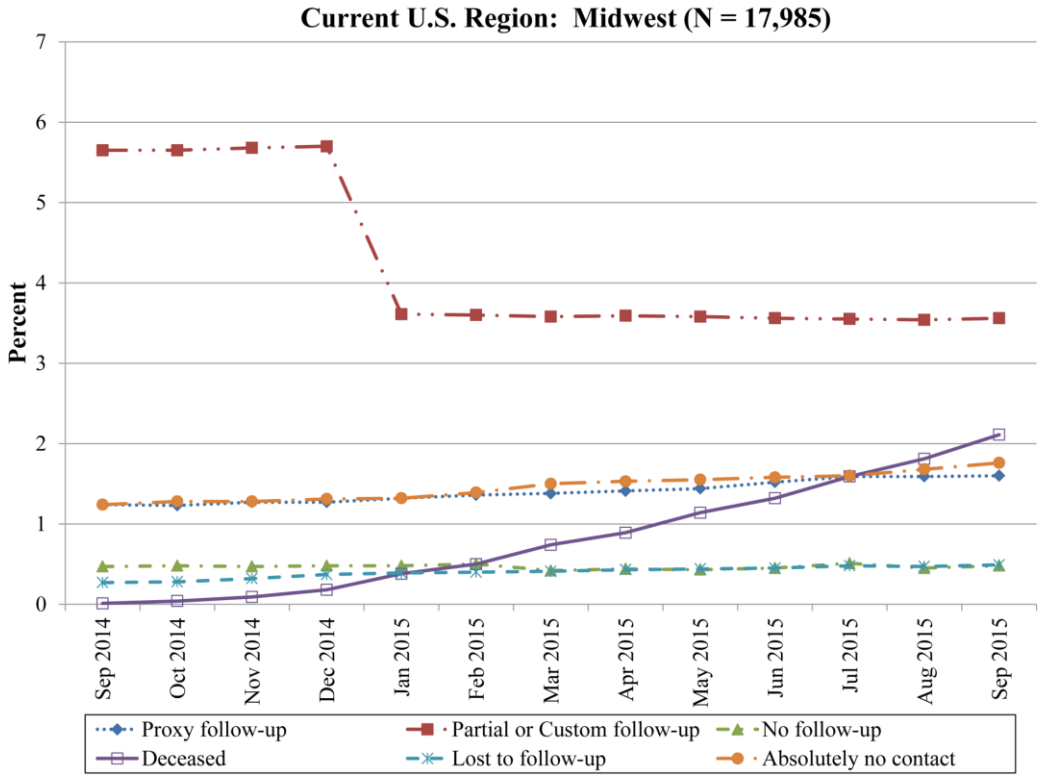
Data as of: September 30, 2015

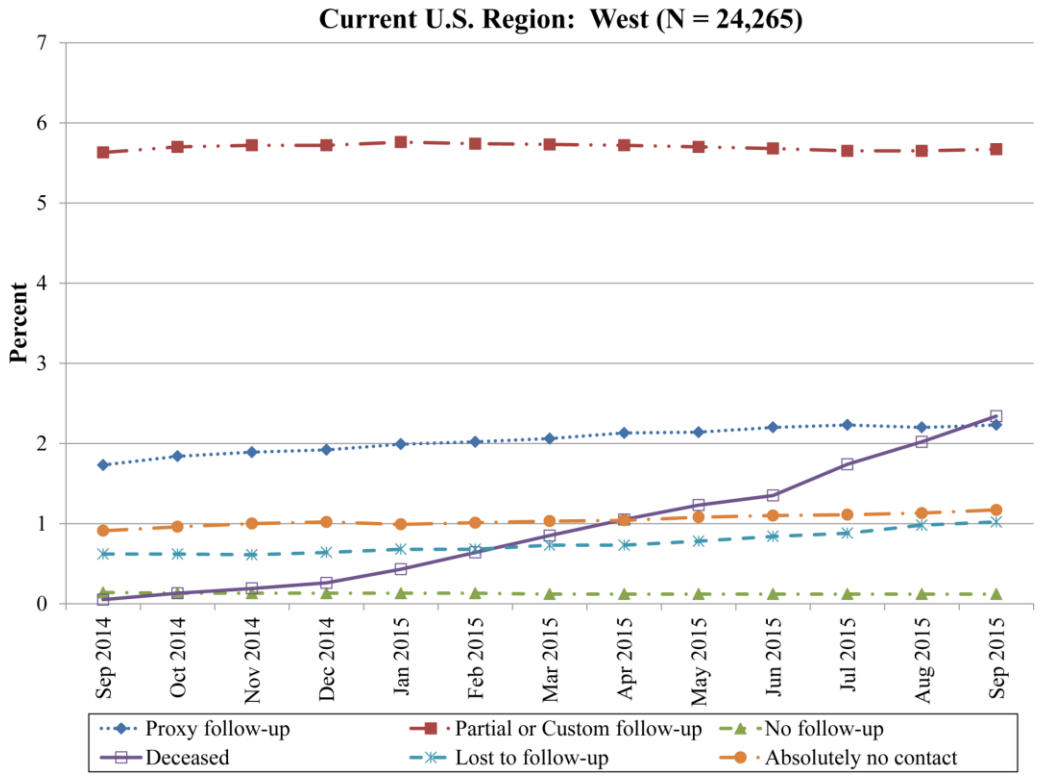


[1] Participants with full follow-up participation rates are not shown.

Figure 1.4 (continued)
Follow-up Status Over Time for WHI Extension Study 2010-2015 Participants Alive on September 1, 2014[1]
By Current U.S. Region

Data as of: September 30, 2015





[1] Participants with full follow-up participation rates are not shown.

Table 1.6
Extension 2010-2015 Consent Summary by Field Center

Data as of: September 30, 2015

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

Data as of: September 30, 2015

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 1.7
Extension 2010-2015 Consent Summary by Regional Center

Data as of: September 30, 2015

	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 1.8
Response Rates to CCC Annual Mailings
Extension Study 2010-2015, Follow-up Years 1, 2, 3, 4 and 5

Data as of: September 30, 2015

	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 1.8 (continued)
Response Rates to CCC Annual Mailings
Extension Study 2010-2015, Follow-up Years 1, 2, 3, 4 and 5

Data as of: September 30, 2015

	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	84702	67965	80.2%	84702	14687	17.3%	5240	35.7%	87.5%
	151	84700	67555	79.8%	84700	15149	17.9%	5451	36.0%	87.3%
	156	84710	68105	80.4%	84710	14603	17.2%	5459	37.4%	87.8%
HT	33	13746	10591	77.1%	13746	2637	19.2%	885	33.6%	84.7%
	151	13747	10506	76.4%	13747	2719	19.8%	929	34.2%	84.4%
	156	13749	10618	77.2%	13749	2624	19.1%	922	35.1%	85.0%
DM	33	27943	22134	79.2%	27943	5090	18.2%	1868	36.7%	87.1%
	151	27944	22013	78.8%	27944	5222	18.7%	1917	36.7%	86.8%
	156	27948	22193	79.5%	27948	5059	18.1%	1902	37.6%	87.2%
CaD	33	22011	17477	79.4%	22011	3948	18.0%	1423	36.0%	87.0%
	151	22012	17357	78.9%	22012	4069	18.5%	1487	36.5%	86.7%
	156	22015	17514	79.6%	22015	3936	17.9%	1462	37.1%	87.2%
OS	33	47282	38484	81.4%	47282	7817	16.5%	2787	35.7%	88.3%
	151	47279	38262	80.9%	47279	8086	17.1%	2910	36.0%	88.1%
	156	47284	38553	81.5%	47284	7768	16.4%	2943	37.9%	88.6%
Year 5										
Total	33	72993	58718	80.4%	68608	12222	17.8%	4047	33.1%	86.9%
	151	72992	58176	79.7%	68607	12707	18.5%	4336	34.1%	86.6%
	157	72999	58008	79.5%	68614	12939	18.9%	4463	34.5%	86.5%
HT	33	11820	9164	77.5%	11101	2251	20.0%	702	31.2%	84.4%
	151	11820	9070	76.7%	11101	2330	21.0%	742	31.9%	84.0%
	157	11820	9046	76.5%	11101	2366	21.3%	752	31.8%	83.9%
DM	33	23921	19085	79.8%	22390	4161	18.6%	1381	33.2%	86.5%
	151	23921	18925	79.1%	22390	4299	19.2%	1465	34.1%	86.2%
	157	23922	18845	78.8%	22391	4396	19.6%	1521	34.6%	86.1%
CaD	33	18833	15033	79.8%	17647	3303	18.7%	1072	32.5%	86.4%
	151	18833	14911	79.2%	17647	3411	19.3%	1144	33.5%	86.1%
	157	18834	14847	78.8%	17648	3485	19.8%	1182	33.9%	86.0%
OS	33	40897	33271	81.4%	38533	6519	16.9%	2199	33.7%	87.6%
	151	40896	32952	80.6%	38532	6813	17.7%	2374	34.9%	87.3%
	157	40902	32886	80.4%	38538	6918	18.0%	2433	35.2%	87.3%

[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; Form 157 = Supplemental Questionnaire 2014-2015.
[2] Form 153 was collected on MRC participants only.

Table 1.9
Response Rates to Regional Center Follow-up and Cumulative Response
Extension Study 2010-2015 Follow-up Years 1, 2, 3, 4 and 5

Data as of: September 30, 2015

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	4332	77.3%	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 1.9 (continued)
Response Rates to Regional Center Follow-up and Cumulative Response
Extension Study 2010-2015 Follow-up Years 1, 2, 3, 4 and 5

Data as of: September 30, 2015

Study	Form[1]	Eligible for RC Follow-up	Respondents		Total Estimated Response Rate
Year 4					
Total	33	11822	8120	68.7%	93.2%
	151	12497	5366	42.9%	89.8%
	156	12743	277	2.2%	84.6%
HT	33	2413	1841	76.3%	92.4%
	151	2581	1164	45.1%	87.5%
	156	2639	59	2.2%	80.5%
DM	33	4039	2861	70.8%	93.5%
	151	4265	1943	45.6%	90.1%
	156	4387	94	2.1%	84.2%
CaD	33	3191	2335	73.2%	93.6%
	151	3383	1544	45.6%	89.9%
	156	3470	76	2.2%	84.0%
OS	33	6128	3998	65.2%	93.2%
	151	6463	2619	40.5%	90.2%
	156	6543	145	2.2%	85.7%
Year 5					
Total	33	2722	1780	65.4%	92.2%
	151	2866	1180	41.2%	88.6%
	157	3035	18	0.6%	82.2%
HT	33	615	466	75.8%	91.8%
	151	657	279	42.5%	86.1%
	157	695	4	0.6%	78.3%
DM	33	1024	675	65.9%	92.1%
	151	1073	455	42.4%	88.3%
	157	1143	7	0.6%	81.4%
CaD	33	820	571	69.6%	92.5%
	151	858	369	43.0%	88.3%
	157	911	4	0.4%	81.4%
OS	33	1289	784	60.8%	92.3%
	151	1357	525	38.7%	89.2%
	157	1429	9	0.6%	83.6%

[1] Form 33 = Medical History Update; Form 151 = Activities of Daily Living (ADL); Form 156 = Supplemental Questionnaire; Form 157 = Supplemental Questionnaire 2014-2015.

Table 1.10
Response Rates to CCC Annual Mailings, Extension Study 2010-2015 Year 1 by Cohort and Regional Center

Data as of: September 30, 2015

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

Data as of: September 30, 2015

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

Data as of: September 30, 2015

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

Data as of: September 30, 2015

	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	84702	67965	80.2%	84702	14687	17.3%	5240	35.7%	87.5%
	151	84700	67555	79.8%	84700	15149	17.9%	5451	36.0%	87.3%
	156	84710	68105	80.4%	84710	14603	17.2%	5459	37.4%	87.8%
Medical Record	33	19647	14682	74.7%	19647	4104	20.9%	1306	31.8%	82.7%
Cohort	151	19648	14560	74.1%	19648	4223	21.5%	1365	32.3%	82.4%
	156	19651	14713	74.9%	19651	4077	20.8%	1360	33.4%	83.0%
Self Report	33	65055	53283	81.9%	65055	10583	16.3%	3934	37.2%	88.9%
Cohort	151	65052	52995	81.5%	65052	10926	16.8%	4086	37.4%	88.7%
	156	65059	53392	82.1%	65059	10526	16.2%	4099	38.9%	89.2%
Regional Center										
Boston	33	9275	7333	79.1%	9275	1566	16.9%	547	34.9%	85.9%
	151	9275	7299	78.7%	9275	1608	17.3%	575	35.8%	85.8%
	156	9275	7353	79.3%	9275	1581	17.1%	579	36.6%	86.3%
Buffalo	33	9118	7337	80.5%	9118	1691	18.6%	600	35.5%	88.5%
	151	9118	7294	80.0%	9118	1729	19.0%	627	36.3%	88.3%
	156	9118	7337	80.5%	9118	1670	18.3%	631	37.8%	88.7%
Columbus	33	9933	8044	81.0%	9933	1735	17.5%	624	36.0%	88.3%
	151	9933	8007	80.6%	9933	1779	17.9%	637	35.8%	88.0%
	156	9935	8057	81.1%	9935	1723	17.3%	650	37.7%	88.5%
Gainesville	33	7521	5812	77.3%	7521	1553	20.7%	488	31.4%	85.5%
	151	7521	5777	76.8%	7521	1617	21.5%	510	31.5%	85.2%
	156	7523	5835	77.6%	7523	1549	20.6%	512	33.1%	85.8%
Iowa	33	8052	6739	83.7%	8052	1145	14.2%	517	45.2%	90.7%
	151	8052	6689	83.1%	8052	1192	14.8%	541	45.4%	90.4%
	156	8053	6753	83.9%	8053	1138	14.1%	536	47.1%	91.1%
Medstar	33	4101	3201	78.1%	4101	746	18.2%	246	33.0%	85.1%
	151	4101	3179	77.5%	4101	772	18.8%	263	34.1%	85.1%
	156	4101	3217	78.4%	4101	725	17.7%	247	34.1%	85.5%
Pittsburgh	33	3816	3002	78.7%	3816	732	19.2%	260	35.5%	86.7%
	151	3816	2983	78.2%	3816	754	19.8%	272	36.1%	86.5%
	156	3817	3006	78.8%	3817	720	18.9%	270	37.5%	86.9%
Seattle	33	4046	3270	80.8%	4046	735	18.2%	263	35.8%	88.2%
	151	4045	3249	80.3%	4045	753	18.6%	266	35.3%	87.8%
	156	4046	3285	81.2%	4046	726	17.9%	260	35.8%	88.4%
Stanford	33	14444	11950	82.7%	14444	2086	14.4%	816	39.1%	89.3%
	151	14444	11887	82.3%	14444	2150	14.9%	832	38.7%	89.0%
	156	14445	11967	82.9%	14445	2079	14.4%	846	40.7%	89.5%
Tucson	33	5624	4386	78.0%	5624	1100	19.6%	372	33.8%	85.8%
	151	5623	4362	77.6%	5623	1128	20.1%	385	34.1%	85.6%
	156	5625	4399	78.2%	5625	1105	19.6%	395	35.8%	86.4%
Wake Forest	33	8772	6891	78.6%	8772	1598	18.2%	507	31.7%	85.3%
	151	8772	6829	77.9%	8772	1667	19.0%	543	32.6%	85.0%
	156	8772	6896	78.6%	8772	1587	18.1%	533	33.6%	85.6%

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

Table 1.10 (continued for year 5)
Response Rates to CCC Annual Mailings, Extension Study 2010-2015 Year 5 by Cohort and Regional Center

Data as of: September 30, 2015

	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	72993	58718	80.4%	68608	12222	17.8%	4047	33.1%	86.9%
	151	72992	58176	79.7%	68607	12707	18.5%	4336	34.1%	86.6%
	157	72999	58008	79.5%	68614	12939	18.9%	4463	34.5%	86.5%
Medical Record	33	16857	12696	75.3%	15805	3487	22.1%	1047	30.0%	82.6%
Cohort	151	16857	12571	74.6%	15805	3598	22.8%	1108	30.8%	82.3%
	157	16858	12538	74.4%	15806	3654	23.1%	1126	30.8%	82.2%
Self Report	33	56136	46022	82.0%	52803	8735	16.5%	3000	34.3%	88.1%
Cohort	151	56135	45605	81.2%	52802	9109	17.3%	3228	35.4%	87.8%
	157	56141	45470	81.0%	52808	9285	17.6%	3337	35.9%	87.8%
Regional Center										
Boston	33	8314	6578	79.1%	7842	1366	17.4%	447	32.7%	85.4%
	151	8314	6513	78.3%	7842	1426	18.2%	476	33.4%	85.0%
	157	8314	6501	78.2%	7842	1454	18.5%	496	34.1%	85.1%
Buffalo	33	7930	6412	80.9%	7257	1273	17.5%	460	36.1%	87.5%
	151	7930	6348	80.1%	7257	1331	18.3%	495	37.2%	87.3%
	157	7930	6322	79.7%	7257	1370	18.9%	507	37.0%	87.1%
Columbus	33	8659	7065	81.6%	7888	1335	16.9%	488	36.6%	88.1%
	151	8659	6994	80.8%	7888	1398	17.7%	519	37.1%	87.7%
	157	8660	6986	80.7%	7889	1409	17.9%	517	36.7%	87.6%
Gainesville	33	7012	5350	76.3%	6456	1452	22.5%	401	27.6%	83.2%
	151	7012	5280	75.3%	6456	1518	23.5%	446	29.4%	82.9%
	157	7013	5276	75.2%	6457	1532	23.7%	453	29.6%	82.9%
Iowa	33	7275	6037	83.0%	6593	1039	15.8%	426	41.0%	89.8%
	151	7275	5980	82.2%	6593	1082	16.4%	456	42.1%	89.4%
	157	7275	5960	81.9%	6593	1101	16.7%	468	42.5%	89.3%
Medstar	33	3617	2834	78.4%	3315	628	19.0%	211	33.6%	85.1%
	151	3617	2803	77.5%	3315	657	19.8%	233	35.5%	84.9%
	157	3617	2801	77.4%	3315	664	20.0%	234	35.2%	84.8%
Pittsburgh	33	3269	2615	80.0%	3010	540	17.9%	191	35.4%	86.8%
	151	3269	2602	80.0%	3010	550	18.3%	198	36.0%	86.7%
	157	3272	2592	79.2%	3013	558	18.5%	197	35.3%	86.4%
Seattle	33	3258	2656	81.5%	3258	542	16.6%	176	32.5%	87.4%
	151	3257	2631	80.8%	3257	569	17.5%	192	33.7%	87.2%
	157	3258	2624	80.5%	3258	578	17.7%	200	34.6%	87.2%
Stanford	33	11474	9608	83.7%	11474	1757	15.3%	591	33.6%	89.3%
	151	11474	9547	83.2%	11474	1812	15.8%	628	34.7%	89.1%
	157	11475	9509	82.9%	11475	1861	16.2%	667	35.8%	89.1%
Tucson	33	4535	3547	78.2%	4535	929	20.5%	249	26.8%	84.4%
	151	4535	3514	77.5%	4535	960	21.2%	268	27.9%	84.1%
	157	4535	3502	77.2%	4535	976	21.5%	279	28.6%	84.1%
Wake Forest	33	7650	6016	78.6%	6980	1361	19.5%	407	29.9%	85.1%
	151	7650	5964	78.0%	6980	1404	20.1%	425	30.3%	84.7%
	157	7650	5935	77.6%	6980	1436	20.6%	445	31.0%	84.6%

[1] Form 33 = Medical History Update; Form 151 = Activities of Daily Living; Form 157 = Supplemental Questionnaire 2014-2015.

Table 1.11
Response Rates to Regional Center Follow-up and Cumulative Response
Extension Study 2010-2015, Follow-up Year 1 by Cohort and Regional Center

Data as of: September 30, 2015

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

Data as of: September 30, 2015

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	5625	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	482	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 1.11 (continued for year 3)
Response Rates to Regional Center Follow-up and Cumulative Response
Extension Study 2010-2015 Follow-up, Year 3 by Cohort and Regional Center

Data as of: September 30, 2015

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	737	48.9%	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 1.11 (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: September 30, 2015

Cohort	Form[1]	Eligible for RC Follow-up	Respondents		Total Estimated Response Rate
Total	33	11822	8120	68.7%	93.2%
	151	12497	5366	42.9%	89.8%
	156	12743	277	2.2%	84.6%
Medical Record Cohort	33	3894	2918	74.9%	91.3%
	151	4164	1858	44.6%	85.9%
	156	4307	92	2.1%	78.1%
Self Report Cohort	33	7928	5202	65.6%	93.8%
	151	8333	3508	42.1%	91.1%
	156	8436	185	2.2%	86.6%
Regional Center					
Boston	33	1428	831	58.2%	92.1%
	151	1470	653	44.4%	90.2%
	156	1470	8	0.5%	83.9%
Buffalo	33	1191	1228	103.1%	95.6%
	151	1258	1061	84.3%	93.7%
	156	1434	176	12.3%	85.0%
Columbus	33	1213	891	73.5%	94.5%
	151	1284	398	31.0%	89.4%
	156	1288	6	0.5%	86.0%
Gainesville	33	1256	393	31.3%	85.2%
	151	1360	136	10.0%	81.7%
	156	1394	27	1.9%	80.9%
Iowa	33	794	701	88.3%	96.5%
	151	839	551	65.7%	94.4%
	156	838	8	1.0%	88.5%
Medstar	33	669	633	94.6%	94.1%
	151	761	366	48.1%	87.9%
	156	819	3	0.4%	80.1%
Pittsburgh	33	601	380	63.2%	93.2%
	151	622	267	42.9%	90.1%
	156	624	2	0.3%	83.8%
Seattle	33	504	428	84.9%	94.5%
	151	576	154	26.7%	87.6%
	156	600	3	0.5%	84.7%
Stanford	33	1871	1414	75.6%	95.6%
	151	1948	779	40.0%	91.1%
	156	1889	9	0.5%	86.4%
Tucson	33	801	552	68.9%	92.9%
	151	842	440	52.3%	90.8%
	156	875	4	0.5%	83.9%
Wake Forest	33	1494	669	44.8%	89.6%
	151	1537	561	36.5%	88.1%
	156	1512	31	2.1%	82.8%

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

Table 1.11 (continued for year 5)
Response Rates to Regional Center Follow-up and Cumulative Response
Extension Study 2010-2015 Follow-up, Year 5 by Cohort and Regional Center

Data as of: September 30, 2015

Cohort	Form[1]	Eligible for RC Follow-up	Respondents		Total Estimated Response Rate
Total	33	2722	1780	65.4%	92.2%
	151	2866	1180	41.1%	88.6%
	157	3035	18	0.6%	82.2%
Medical Record	33	956	695	72.7%	90.5%
Cohort	151	1009	447	44.3%	85.1%
	157	1076	5	0.5%	76.1%
Self Report	33	1766	1085	61.4%	92.8%
Cohort	151	1857	733	39.5%	89.8%
	157	1959	13	0.7%	84.4%
Regional Center					
Boston	33	324	168	51.9%	90.3%
	151	333	129	38.7%	87.9%
	157	334	1	0.3%	80.8%
Buffalo	33	293	278	94.9%	94.2%
	151	311	248	79.7%	92.5%
	157	376	9	2.4%	80.6%
Columbus	33	291	224	77.0%	94.0%
	151	315	42	13.3%	84.7%
	157	318	1	0.3%	82.9%
Gainesville	33	266	53	19.9%	83.1%
	151	284	28	9.9%	80.9%
	157	288	4	1.4%	79.4%
Iowa	33	218	185	84.9%	95.6%
	151	232	125	53.9%	92.2%
	157	243	1	0.4%	86.0%
Medstar	33	150	134	89.3%	92.6%
	151	158	103	65.2%	89.2%
	157	189	0	0.0%	78.0%
Pittsburgh	33	160	84	52.5%	90.0%
	151	167	63	37.7%	87.5%
	157	171	1	0.6%	80.5%
Seattle	33	96	31	32.3%	87.5%
	151	108	7	6.5%	84.0%
	157	113	0	0.0%	83.0%
Stanford	33	408	288	70.6%	95.0%
	151	418	160	38.3%	90.4%
	157	425	1	0.2%	85.2%
Tucson	33	194	143	73.7%	92.9%
	151	205	113	55.1%	90.3%
	157	219	0	0.0%	81.3%
Wake Forest	33	322	192	59.6%	91.4%
	151	335	162	48.4%	89.3%
	157	359	0	0.0%	80.8%

[1] Form 33 = Medical History Update; Form 151 = Activities of Daily Living; Form 157 = Supplemental Questionnaire 2014-2015.

Table 2.1
Participation and Vital Status: HT Participants by Hysterectomy Status

Data as of: September 30, 2015
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	696	12.2	1089	11.0	1785	11.5
Alive: Current Participation[1]	4554	80.0	8184	82.7	12738	81.7
Alive: Recent Participation[2]	183	3.2	280	2.8	463	3.0
Alive: Past/Unknown Participation[3]	2	<0.1	8	0.1	10	0.1
Stopped Follow-Up[4]	131	2.3	176	1.8	307	2.0
Lost to Follow-Up[5]	127	2.2	154	1.6	281	1.8

Data as of: September 30, 2015; 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	696	9.1	1061	8.3	1757	8.6
Alive: Current Participation[1]	6643	86.9	11277	88.2	17920	87.7
Alive: Recent Participation[2]	90	1.2	115	0.9	205	1.0
Alive: Past/Unknown Participation[3]	10	0.1	13	0.1	23	0.1
Stopped Follow-Up[4]	122	1.6	209	1.6	331	1.6
Lost to Follow-Up[5]	84	1.1	113	0.9	197	1.0

Data as of: September 30, 2015; 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	753	7.0	937	5.6	1690	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]	139	1.3	170	1.0	309	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 Participants

Data as of: September 30, 2015; Events through September 30, 2015

Outcomes	Total	Age at Enrollment 50-54	55-59	60-69	70-79
Number randomized	27347	3420	5413	12360	6154
Mean follow-up (months)	171.4	184.5	182.3	172.9	151.3
Cardiovascular					
CHD[1]	2154 (0.55%)	111 (0.21%)	240 (0.29%)	1000 (0.56%)	803 (1.03%)
CHD death[2]	782 (0.20%)	23 (0.04%)	59 (0.07%)	312 (0.18%)	388 (0.50%)
Total MI[3]	1615 (0.41%)	93 (0.18%)	204 (0.25%)	776 (0.44%)	542 (0.70%)
Clinical MI	1585 (0.41%)	92 (0.17%)	202 (0.25%)	761 (0.43%)	530 (0.68%)
Angina[4]	1086 (0.49%)	52 (0.18%)	139 (0.31%)	526 (0.53%)	369 (0.77%)
CABG/PTCA	2073 (0.53%)	130 (0.25%)	312 (0.38%)	1061 (0.60%)	570 (0.73%)
Carotid artery disease	388 (0.10%)	10 (0.02%)	56 (0.07%)	214 (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]	1678 (0.43%)	66 (0.13%)	146 (0.18%)	745 (0.42%)	721 (0.93%)
Stroke	1631 (0.42%)	73 (0.14%)	158 (0.19%)	766 (0.43%)	634 (0.82%)
Non-disabling stroke[6]	873 (0.22%)	54 (0.10%)	106 (0.13%)	405 (0.23%)	308 (0.40%)
Fatal/disabling stroke[6]	694 (0.18%)	16 (0.03%)	45 (0.05%)	329 (0.18%)	304 (0.39%)
Unknown status from stroke[6]	64 (0.02%)	3 (0.01%)	7 (0.01%)	32 (0.02%)	22 (0.03%)
PVD	419 (0.11%)	22 (0.04%)	51 (0.06%)	219 (0.12%)	127 (0.16%)
DVT	839 (0.21%)	57 (0.11%)	133 (0.16%)	400 (0.22%)	249 (0.32%)
Pulmonary embolism	659 (0.17%)	44 (0.08%)	103 (0.13%)	324 (0.18%)	188 (0.24%)
DVT/PE	1194 (0.31%)	76 (0.14%)	182 (0.22%)	589 (0.33%)	347 (0.45%)
Coronary disease[7]	4612 (1.18%)	256 (0.49%)	573 (0.70%)	2161 (1.21%)	1622 (2.09%)
Aortic aneurysm[8]	31 (0.03%)	0 (0.00%)	4 (0.02%)	21 (0.04%)	6 (0.03%)
Atrial fibrillation[8]	771 (0.68%)	44 (0.30%)	106 (0.45%)	425 (0.83%)	196 (0.86%)
Valvular heart disease[8]	200 (0.18%)	9 (0.06%)	26 (0.11%)	114 (0.22%)	51 (0.22%)
Total cardiovascular disease[9]	7051 (1.81%)	405 (0.77%)	891 (1.08%)	3354 (1.88%)	2401 (3.09%)
Cancer					
Breast cancer	1728 (0.44%)	198 (0.38%)	360 (0.44%)	809 (0.45%)	361 (0.47%)
Invasive breast cancer	1422 (0.36%)	152 (0.29%)	299 (0.36%)	654 (0.37%)	317 (0.41%)
Non-invasive breast cancer	333 (0.09%)	47 (0.09%)	67 (0.08%)	170 (0.10%)	49 (0.06%)
Ovarian cancer	157 (0.04%)	12 (0.02%)	31 (0.04%)	82 (0.05%)	32 (0.04%)
Endometrial cancer[10]	214 (0.05%)	34 (0.06%)	48 (0.06%)	93 (0.05%)	39 (0.05%)
Colorectal cancer	576 (0.15%)	42 (0.08%)	75 (0.09%)	291 (0.16%)	168 (0.22%)
Other cancer[11]	2634 (0.67%)	205 (0.39%)	415 (0.50%)	1301 (0.73%)	713 (0.92%)
Total cancer	4962 (1.27%)	463 (0.88%)	878 (1.07%)	2390 (1.34%)	1231 (1.59%)
Fractures					
Hip fracture	1070 (0.27%)	26 (0.05%)	78 (0.09%)	445 (0.25%)	521 (0.67%)
Deaths					
Cardiovascular deaths	1653 (0.42%)	50 (0.10%)	113 (0.14%)	659 (0.37%)	831 (1.07%)
Cancer deaths	1775 (0.45%)	106 (0.20%)	247 (0.30%)	870 (0.49%)	552 (0.71%)
Other known cause	1500 (0.38%)	54 (0.10%)	127 (0.15%)	658 (0.37%)	661 (0.85%)
Unknown cause	44 (0.01%)	3 (0.01%)	8 (0.01%)	18 (0.01%)	15 (0.02%)
Not yet adjudicated	260 (0.07%)	10 (0.02%)	19 (0.02%)	116 (0.07%)	115 (0.15%)
Total death	5232 (1.34%)	223 (0.42%)	514 (0.62%)	2321 (1.30%)	2174 (2.80%)
Death plus post-WHI deaths[12]	7427 (1.66%)	308 (0.50%)	670 (0.71%)	3196 (1.58%)	3253 (3.62%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Studies 2005-2015.
[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 2005-2015.
[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, angina and CHF are not collected in the WHI Extension Studies 2005-2015.
[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 Participants
Data as of: September 30, 2015; Events through September 30, 2015

	Race/Ethnicity					
Outcomes	**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)	154.7	156.2	161.1	148.6	174.9	161.6
Cardiovascular						
CHD[1]	10 (0.60%)	26 (0.38%)	191 (0.52%)	51 (0.27%)	1847 (0.58%)	29 (0.56%)
CHD death[2]	6 (0.36%)	10 (0.15%)	88 (0.24%)	14 (0.07%)	657 (0.20%)	7 (0.14%)
Total MI[3]	6 (0.36%)	21 (0.31%)	124 (0.34%)	39 (0.20%)	1400 (0.44%)	25 (0.48%)
Clinical MI	6 (0.36%)	20 (0.29%)	123 (0.33%)	37 (0.19%)	1375 (0.43%)	24 (0.46%)
Angina[4]	7 (0.69%)	14 (0.34%)	125 (0.57%)	44 (0.37%)	884 (0.49%)	12 (0.40%)
CABG/PTCA	10 (0.60%)	22 (0.32%)	150 (0.41%)	65 (0.34%)	1797 (0.56%)	29 (0.56%)
Carotid artery disease	1 (0.06%)	3 (0.04%)	16 (0.04%)	4 (0.02%)	361 (0.11%)	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]	7 (0.42%)	18 (0.26%)	161 (0.44%)	38 (0.20%)	1437 (0.45%)	17 (0.33%)
Stroke	10 (0.60%)	18 (0.26%)	181 (0.49%)	35 (0.18%)	1364 (0.42%)	23 (0.44%)
Non-disabling stroke[6]	5 (0.30%)	9 (0.13%)	103 (0.28%)	22 (0.12%)	724 (0.23%)	10 (0.19%)
Fatal/disabling stroke[6]	5 (0.30%)	9 (0.13%)	67 (0.18%)	10 (0.05%)	593 (0.18%)	10 (0.19%)
Unknown status from stroke[6]	0 (0.00%)	0 (0.00%)	11 (0.03%)	3 (0.02%)	47 (0.01%)	3 (0.06%)
PVD	3 (0.18%)	6 (0.09%)	46 (0.13%)	7 (0.04%)	353 (0.11%)	4 (0.08%)
DVT	5 (0.30%)	4 (0.06%)	84 (0.23%)	11 (0.06%)	731 (0.23%)	4 (0.08%)
Pulmonary embolism	4 (0.24%)	2 (0.03%)	77 (0.21%)	7 (0.04%)	560 (0.17%)	9 (0.17%)
DVT/PE	8 (0.48%)	4 (0.06%)	127 (0.35%)	15 (0.08%)	1029 (0.32%)	11 (0.21%)
Coronary disease[7]	20 (1.19%)	54 (0.79%)	443 (1.21%)	136 (0.71%)	3903 (1.22%)	56 (1.08%)
Aortic aneurysm[8]	0 (0.00%)	0 (0.00%)	6 (0.05%)	1 (0.02%)	24 (0.03%)	0 (0.00%)
Atrial fibrillation[8]	0 (0.00%)	2 (0.09%)	17 (0.15%)	11 (0.17%)	731 (0.80%)	10 (0.62%)
Valvular heart disease[8]	1 (0.19%)	1 (0.05%)	7 (0.06%)	7 (0.11%)	181 (0.20%)	3 (0.19%)
Total cardiovascular disease[9]	34 (2.03%)	77 (1.12%)	707 (1.92%)	184 (0.97%)	5972 (1.86%)	77 (1.49%)
Cancer						
Breast cancer	8 (0.48%)	32 (0.47%)	149 (0.41%)	57 (0.30%)	1464 (0.46%)	18 (0.35%)
Invasive breast cancer	7 (0.42%)	24 (0.35%)	120 (0.33%)	48 (0.25%)	1209 (0.38%)	14 (0.27%)
Non-invasive breast cancer	1 (0.06%)	9 (0.13%)	31 (0.08%)	10 (0.05%)	277 (0.09%)	5 (0.10%)
Ovarian cancer	1 (0.06%)	3 (0.04%)	11 (0.03%)	2 (0.01%)	136 (0.04%)	4 (0.08%)
Endometrial cancer[10]	1 (0.06%)	2 (0.03%)	15 (0.04%)	6 (0.03%)	188 (0.06%)	2 (0.04%)
Colorectal cancer	1 (0.06%)	17 (0.25%)	46 (0.13%)	20 (0.11%)	483 (0.15%)	9 (0.17%)
Other cancer[11]	12 (0.72%)	44 (0.64%)	175 (0.48%)	78 (0.41%)	2293 (0.71%)	32 (0.62%)
Total cancer	22 (1.31%)	95 (1.39%)	368 (1.00%)	154 (0.81%)	4262 (1.33%)	61 (1.18%)
Fractures						
Hip fracture	4 (0.24%)	8 (0.12%)	23 (0.06%)	18 (0.09%)	1007 (0.31%)	10 (0.19%)
Deaths						
Cardiovascular deaths	11 (0.66%)	16 (0.23%)	173 (0.47%)	28 (0.15%)	1410 (0.44%)	15 (0.29%)
Cancer deaths	8 (0.48%)	34 (0.50%)	143 (0.39%)	60 (0.32%)	1508 (0.47%)	22 (0.42%)
Other known cause	7 (0.42%)	19 (0.28%)	98 (0.27%)	32 (0.17%)	1328 (0.41%)	16 (0.31%)
Unknown cause	0 (0.00%)	1 (0.01%)	4 (0.01%)	3 (0.02%)	34 (0.01%)	2 (0.04%)
Not yet adjudicated	1 (0.06%)	2 (0.03%)	14 (0.04%)	2 (0.01%)	237 (0.07%)	4 (0.08%)
Total Death	27 (1.61%)	72 (1.05%)	432 (1.18%)	125 (0.66%)	4517 (1.41%)	59 (1.14%)
Death plus post-WHI deaths[12]	34 (1.63%)	119 (1.39%)	673 (1.52%)	241 (0.93%)	6267 (1.73%)	93 (1.49%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Studies 2005-2015.
[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 2005-2015.
[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, angina and CHF are not collected in the WHI Extension Studies 2005-2015.
[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: September 30, 2015; Events through September 30, 2015

Outcome	Total	Age at Enrollment 50-54	55-59	60-69	70-79
Number randomized	27347	3420	5413	12360	6154
Mean follow-up (months)	171.4	184.5	182.3	172.9	151.3
Hospitalizations					
Ever	19542 (5.00%)	1909 (3.63%)	3394 (4.13%)	9175 (5.15%)	5064 (6.53%)
Two or more	14089 (3.61%)	1197 (2.28%)	2222 (2.70%)	6743 (3.79%)	3927 (5.06%)
Conditions/Procedures					
Diabetes (treated)	4214 (1.13%)	612 (1.21%)	868 (1.11%)	1987 (1.17%)	747 (1.01%)
Gallbladder disease[1,2]	2117 (1.18%)	282 (1.14%)	443 (1.18%)	988 (1.24%)	404 (1.07%)
Hysterectomy	1194 (0.49%)	151 (0.48%)	282 (0.52%)	562 (0.51%)	199 (0.43%)
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]	7965 (3.17%)	1125 (2.71%)	1730 (2.91%)	3637 (3.31%)	1473 (3.67%)
Rheumatoid arthritis[2]	1696 (0.82%)	211 (0.76%)	341 (0.81%)	763 (0.83%)	381 (0.87%)
Intestinal polyps	6478 (1.78%)	829 (1.63%)	1394 (1.78%)	3143 (1.90%)	1112 (1.62%)
Lupus	438 (0.11%)	52 (0.10%)	93 (0.11%)	203 (0.11%)	90 (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	10691 (3.79%)	1351 (3.16%)	2194 (3.42%)	4911 (3.93%)	2235 (4.49%)
COPD[4]	1081 (0.99%)	102 (0.71%)	250 (1.10%)	554 (1.12%)	175 (0.80%)
Macular degeneration[5]	2738 (1.21%)	147 (0.49%)	359 (0.75%)	1359 (1.32%)	873 (1.97%)
Alzheimer's disease[5]	2226 (0.99%)	75 (0.25%)	208 (0.44%)	1070 (1.04%)	873 (1.97%)
Parkinson's disease[5]	323 (0.14%)	24 (0.08%)	55 (0.12%)	175 (0.17%)	69 (0.16%)

Outcomes	Race/Ethnicity Am Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	130	527	2738	1537	22030	385
Mean follow-up (months)	154.7	156.2	161.0	148.6	174.9	161.5
Hospitalizations						
Ever	90 (5.37%)	283 (4.13%)	1854 (5.05%)	817 (4.29%)	16239 (5.06%)	259 (5.00%)
Two or more	72 (4.30%)	167 (2.43%)	1308 (3.56%)	473 (2.49%)	11894 (3.70%)	175 (3.38%)
Conditions/Procedures						
Diabetes (treated)	24 (1.61%)	83 (1.29%)	575 (1.77%)	314 (1.78%)	3155 (1.02%)	63 (1.31%)
Gallbladder disease[1,2]	13 (1.72%)	32 (0.89%)	187 (0.97%)	129 (1.46%)	1730 (1.19%)	26 (1.08%)
Hysterectomy	4 (0.59%)	11 (0.23%)	78 (0.51%)	60 (0.54%)	1026 (0.50%)	15 (0.47%)
Glaucoma[2]	16 (1.72%)	60 (1.57%)	408 (2.06%)	190 (1.67%)	2480 (1.48%)	47 (1.73%)
Osteoporosis[2]	32 (3.40%)	141 (3.70%)	348 (1.68%)	338 (3.08%)	5159 (3.12%)	93 (3.36%)
Osteoarthritis[3]	46 (3.96%)	161 (3.26%)	755 (3.27%)	527 (3.88%)	6361 (3.10%)	115 (3.35%)
Rheumatoid arthritis[2]	15 (1.70%)	30 (0.79%)	272 (1.39%)	219 (1.96%)	1125 (0.67%)	35 (1.27%)
Intestinal polyps	32 (2.06%)	102 (1.65%)	688 (2.01%)	298 (1.64%)	5278 (1.77%)	80 (1.69%)
Lupus	3 (0.18%)	5 (0.07%)	48 (0.13%)	32 (0.17%)	346 (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 (4.74%)	184 (3.80%)	867 (4.65%)	610 (4.23%)	8842 (3.70%)	131 (3.71%)
COPD[4]	8 (1.71%)	8 (0.37%)	82 (0.77%)	31 (0.50%)	939 (1.06%)	13 (0.85%)
Macular degeneration[5]	10 (0.92%)	23 (0.57%)	129 (0.60%)	77 (0.66%)	2474 (1.34%)	25 (0.78%)
Alzheimer's disease[5]	9 (0.83%)	24 (0.59%)	203 (0.95%)	94 (0.81%)	1875 (1.02%)	21 (0.66%)
Parkinson's disease[5]	2 (0.19%)	6 (0.15%)	21 (0.10%)	14 (0.12%)	277 (0.15%)	3 (0.09%)

[1] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[2] Data not collected for WHI Extension Studies 2005-2015.
[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.
[5] Data only collected during the WHI Extension Studies 2005-2015.

Table 3.1
Participation and Vital Status: DM Participants

Data as of: September 30, 2015
WHI Extension Study 2010-2015 Participants

	DM Participants (N = 30,690) N	%
Vital Status/Participation		
Deceased	2897	9.4
Alive: Current Participation[1]	26161	85.2
Alive: Recent Participation[2]	815	2.7
Alive: Past/Unknown Participation[3]	19	0.1
Stopped Follow-Up[4]	374	1.2
Lost to Follow-Up[5]	424	1.4

Data as of: September 30, 2015; Status as of September 30, 2010
WHI Extension Study 2005-2010 Participants

	DM Participants (N = 37,858) N	%
Vital Status/Participation		
Deceased	2513	6.6
Alive: Current Participation[1]	34397	90.9
Alive: Recent Participation[2]	308	0.8
Alive: Past/Unknown Participation[3]	20	0.1
Stopped Follow-Up[4]	398	1.1
Lost to Follow-Up[5]	222	0.6

Data as of: September 30, 2015; Status as of April 8, 2005
WHI Participants

	DM Participants (N = 48,835) N	%
Vital Status/Participation		
Deceased	2468	5.1
Alive: Current Participation[6]	44101	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 Participants

Data as of: September 30, 2015; 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	281 (0.05%)	31 (0.03%)	52 (0.04%)	144 (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]	3436 (0.57%)	306 (0.33%)	625 (0.44%)	1751 (0.63%)	754 (0.82%)
Total cancer	7734 (1.28%)	817 (0.89%)	1598 (1.13%)	3798 (1.36%)	1521 (1.66%)
Cardiovascular					
CHD[3]	2315 (0.38%)	129 (0.14%)	280 (0.20%)	1114 (0.40%)	792 (0.87%)
CHD death[4]	757 (0.13%)	36 (0.04%)	59 (0.04%)	343 (0.12%)	319 (0.35%)
Total MI[5]	1786 (0.30%)	101 (0.11%)	234 (0.17%)	863 (0.31%)	588 (0.64%)
Clinical MI	1734 (0.29%)	95 (0.10%)	227 (0.16%)	837 (0.30%)	575 (0.63%)
Angina[6]	1630 (0.40%)	94 (0.15%)	231 (0.24%)	860 (0.46%)	445 (0.69%)
CABG/PTCA	2665 (0.44%)	147 (0.16%)	378 (0.27%)	1458 (0.52%)	682 (0.75%)
Carotid artery disease	444 (0.07%)	23 (0.03%)	58 (0.04%)	240 (0.09%)	123 (0.13%)
Congestive heart failure, WHI[6]	1170 (0.29%)	52 (0.08%)	120 (0.13%)	526 (0.28%)	472 (0.73%)
Stroke	1831 (0.30%)	94 (0.10%)	210 (0.15%)	877 (0.31%)	650 (0.71%)
PVD	398 (0.07%)	17 (0.02%)	52 (0.04%)	210 (0.08%)	119 (0.13%)
Coronary disease[7]	5196 (0.86%)	301 (0.33%)	707 (0.50%)	2640 (0.95%)	1548 (1.69%)
Total cardiovascular disease	7233 (1.20%)	411 (0.45%)	969 (0.68%)	3628 (1.30%)	2225 (2.43%)
Fractures					
Hip fracture	1047 (0.17%)	22 (0.02%)	74 (0.05%)	458 (0.16%)	493 (0.54%)
Deaths					
Cardiovascular deaths	1555 (0.26%)	62 (0.07%)	123 (0.09%)	662 (0.24%)	708 (0.77%)
Cancer deaths	2125 (0.35%)	139 (0.15%)	307 (0.22%)	1083 (0.39%)	596 (0.65%)
Other known cause	1321 (0.22%)	55 (0.06%)	128 (0.09%)	582 (0.21%)	556 (0.61%)
Unknown cause	32 (0.01%)	1 (<0.01%)	8 (0.01%)	15 (0.01%)	8 (0.01%)
Total death	5033 (0.83%)	257 (0.28%)	566 (0.40%)	2342 (0.84%)	1868 (2.04%)
Death plus post-WHI deaths[8]	6229 (0.94%)	298 (0.30%)	661 (0.43%)	2835 (0.93%)	2435 (2.39%)

[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 2005-2010.
[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 2005-2010.
[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 CHF are not collected in the WHI Extension Study 2005-2010.
[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 Participants

Data as of: September 30, 2015; 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%)	10 (0.05%)	238 (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%)	266 (0.43%)	70 (0.34%)	3001 (0.60%)	42 (0.55%)
Total cancer	18 (0.77%)	139 (1.05%)	646 (1.05%)	174 (0.85%)	6669 (1.34%)	88 (1.16%)
Cardiovascular						
CHD[3]	4 (0.17%)	28 (0.21%)	246 (0.40%)	42 (0.21%)	1965 (0.39%)	30 (0.39%)
CHD death[4]	0 (0.00%)	6 (0.05%)	109 (0.18%)	15 (0.07%)	613 (0.12%)	14 (0.18%)
Total MI[5]	4 (0.17%)	25 (0.19%)	168 (0.27%)	32 (0.16%)	1535 (0.31%)	22 (0.29%)
Clinical MI	4 (0.17%)	25 (0.19%)	163 (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%)	2300 (0.46%)	24 (0.32%)
Carotid artery disease	2 (0.09%)	1 (0.01%)	31 (0.05%)	4 (0.02%)	400 (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%)	242 (0.39%)	44 (0.21%)	1485 (0.30%)	26 (0.34%)
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%)	620 (1.01%)	127 (0.62%)	4308 (0.86%)	63 (0.83%)
Total cardiovascular disease	27 (1.16%)	91 (0.69%)	875 (1.42%)	176 (0.86%)	5974 (1.20%)	90 (1.18%)
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%)	224 (0.36%)	31 (0.15%)	1260 (0.25%)	18 (0.24%)
Cancer deaths	8 (0.34%)	27 (0.20%)	187 (0.30%)	54 (0.26%)	1818 (0.36%)	31 (0.41%)
Other known cause	11 (0.47%)	12 (0.09%)	133 (0.22%)	32 (0.16%)	1118 (0.22%)	15 (0.20%)
Unknown cause	0 (0.00%)	2 (0.02%)	6 (0.01%)	0 (0.00%)	24 (<0.01%	0 (0.00%)
Total death	23 (0.99%)	59 (0.45%)	550 (0.89%)	117 (0.57%)	4220 (0.85%)	64 (0.84%)
Death plus post-WHI deaths[8]	34 (1.27%)	86 (0.58%)	728 (1.03%)	154 (0.61%)	5138 (0.95%)	89 (1.02%)

[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 2005-2010.
[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 2005-2010.
[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 CHF are not collected in the WHI Extension Study 2005-2010.
[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: September 30, 2015; Events through September 30, 2015

Outcome	Total	Age at Enrollment 50-54	55-59	60-69	70-79
Number randomized	48835	6961	11037	22715	8122
Mean follow-up (months)	180.0	194.2	190.6	179.5	155.0
Hospitalizations					
Ever	34963 (4.77%)	4048 (3.59%)	7159 (4.08%)	17084 (5.03%)	6672 (6.36%)
Two or more	24743 (3.38%)	2509 (2.23%)	4721 (2.69%)	12412 (3.65%)	5101 (4.86%)
Other					
DVT[1]	1173 (0.17%)	86 (0.08%)	195 (0.11%)	595 (0.18%)	297 (0.30%)
Pulmonary embolism	940 (0.13%)	78 (0.07%)	173 (0.10%)	500 (0.15%)	189 (0.18%)
Diabetes (treated)	7451 (1.06%)	1141 (1.04%)	1769 (1.04%)	3507 (1.08%)	1034 (1.03%)
Gallbladder disease[2, 3]	3830 (1.16%)	573 (1.07%)	902 (1.15%)	1802 (1.22%)	553 (1.09%)
Hysterectomy	2525 (0.60%)	410 (0.64%)	656 (0.61%)	1167 (0.61%)	292 (0.51%)
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]	15318 (3.25%)	2523 (2.85%)	3760 (3.01%)	6988 (3.42%)	2047 (3.79%)
Rheumatoid arthritis[3]	2848 (0.75%)	399 (0.68%)	631 (0.71%)	1319 (0.76%)	499 (0.83%)
Intestinal polyps	12736 (1.87%)	1969 (1.80%)	3210 (1.93%)	6004 (1.92%)	1553 (1.66%)
Lupus	754 (0.10%)	112 (0.10%)	179 (0.10%)	359 (0.11%)	104 (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	18631 (3.59%)	2669 (2.93%)	4372 (3.28%)	8807 (3.81%)	2783 (4.39%)
COPD[5]	1837 (0.92%)	200 (0.67%)	399 (0.85%)	1015 (1.10%)	223 (0.75%)
Macular degeneration[6]	4900 (1.16%)	339 (0.53%)	767 (0.77%)	2614 (1.34%)	1180 (1.97%)
Alzheimer's disease[6]	3444 (0.82%)	147 (0.23%)	422 (0.42%)	1841 (0.94%)	1034 (1.73%)
Parkinson's disease[6]	632 (0.15%)	46 (0.07%)	128 (0.13%)	345 (0.18%)	113 (0.19%)

[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 2005-2015.
[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.
[5] Data only collected during the WHI Extension Study 2010-2015.
[6] Data only collected during the WHI Extension Studies 2005-2015.

Table 3.4 (continued)
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: September 30, 2015; Events through September 30, 2015

	Race/Ethnicity					
Outcomes	**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)	165.8	174.3	165.0	156.0	183.6	166.2
Hospitalizations						
Ever	133 (4.77%)	608 (3.79%)	3489 (4.82%)	1038 (4.33%)	29258 (4.81%)	437 (4.79%)
Two or more	92 (3.30%)	352 (2.19%)	2432 (3.36%)	652 (2.72%)	20933 (3.44%)	282 (3.09%)
Other						
DVT[1]	3 (0.11%)	5 (0.03%)	139 (0.20%)	23 (0.10%)	989 (0.17%)	14 (0.16%)
Pulmonary embolism	4 (0.15%)	3 (0.02%)	108 (0.15%)	17 (0.07%)	797 (0.13%)	11 (0.12%)
Diabetes (treated)	36 (1.38%)	188 (1.24%)	1145 (1.77%)	337 (1.49%)	5635 (0.95%)	110 (1.27%)
Gallbladder disease[2, 3]	14 (1.22%)	60 (0.77%)	304 (0.81%)	152 (1.42%)	3250 (1.21%)	50 (1.14%)
Hysterectomy	6 (0.46%)	41 (0.40%)	172 (0.53%)	80 (0.62%)	2206 (0.62%)	20 (0.38%)
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]	62 (3.61%)	363 (3.06%)	1510 (3.36%)	597 (3.55%)	12572 (3.22%)	214 (3.68%)
Rheumatoid arthritis[3]	23 (1.59%)	49 (0.59%)	505 (1.29%)	222 (1.65%)	1998 (0.64%)	51 (1.05%)
Intestinal polyps	61 (2.34%)	270 (1.84%)	1402 (2.08%)	410 (1.79%)	10426 (1.84%)	167 (1.98%)
Lupus	5 (0.18%)	11 (0.07%)	108 (0.15%)	26 (0.11%)	591 (0.10%)	13 (0.14%)
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	67 (3.64%)	398 (3.65%)	1687 (4.58%)	722 (4.04%)	15527 (3.49%)	230 (3.68%)
COPD[5]	11 (1.41%)	16 (0.35%)	145 (0.70%)	51 (0.68%)	1592 (0.98%)	22 (0.81%)
Macular degeneration[6]	20 (1.15%)	63 (0.66%)	242 (0.57%)	128 (0.86%)	4404 (1.27%)	43 (0.77%)
Alzheimer's disease[6]	11 (0.63%)	57 (0.59%)	322 (0.75%)	114 (0.76%)	2902 (0.84%)	38 (0.68%)
Parkinson's disease[6]	3 (0.17%)	11 (0.11%)	45 (0.11%)	18 (0.12%)	546 (0.16%)	9 (0.16%)

[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 2005-2015.
[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.
[5] Data only collected during the WHI Extension Study 2010-2015.
[6] Data only collected during the WHI Extension Studies 2005-2015.

Table 4.1
Participation and Vital Status: CaD Participants

Data as of: September 30, 2015
WHI Extension Study 2010-2015 Participants

	CaD Participants (N = 24,231)	
	N	%
Vital Status/Participation		
Deceased	2311	9.5
Alive: Current Participation[1]	20588	85.0
Alive: Recent Participation[2]	658	2.7
Alive: Past/Unknown Participation[3]	14	0.1
Stopped Follow-Up[4]	332	1.4
Lost to Follow-Up[5]	328	1.4

Data as of: September 30, 2015; Status as of September 30, 2010
WHI Extension Study 2005-2010 Participants

	CaD Participants (N = 29,862)	
	N	%
Vital Status/Participation		
Deceased	2071	6.9
Alive: Current Participation[1]	26978	90.3
Alive: Recent Participation[2]	240	0.8
Alive: Past/Unknown Participation[3]	18	0.1
Stopped Follow-Up[4]	354	1.2
Lost to Follow-Up[5]	201	0.7

Data as of: September 30, 2015; Status as of April 8, 2005
WHI Participants

	CaD Participants (N = 36,282)	
	N	%
Vital Status/Participation		
Deceased	1614	4.4
Alive: Current Participation[6]	32619	89.9
Alive: Recent Participation[7]	1092	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 Participants

Data as of: September 30, 2015; 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	2182 (0.52%)	277 (0.44%)	523 (0.53%)	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	459 (0.11%)	70 (0.11%)	105 (0.11%)	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]	2486 (0.59%)	212 (0.34%)	435 (0.44%)	1264 (0.67%)	575 (0.85%)
Total cancer	5411 (1.29%)	569 (0.90%)	1113 (1.12%)	2622 (1.38%)	1107 (1.65%)
Cardiovascular					
CHD[3]	1777 (0.42%)	94 (0.15%)	217 (0.22%)	843 (0.44%)	623 (0.93%)
CHD death[4]	563 (0.13%)	23 (0.04%)	48 (0.05%)	227 (0.12%)	265 (0.39%)
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	359 (0.09%)	16 (0.03%)	50 (0.05%)	201 (0.11%)	92 (0.14%)
Congestive heart failure, WHI[6]	806 (0.31%)	33 (0.08%)	84 (0.14%)	376 (0.33%)	313 (0.73%)
Stroke	1361 (0.32%)	72 (0.11%)	154 (0.15%)	640 (0.34%)	495 (0.74%)
PVD	330 (0.08%)	11 (0.02%)	48 (0.05%)	165 (0.09%)	106 (0.16%)
Coronary disease[7]	3867 (0.92%)	223 (0.35%)	545 (0.55%)	1920 (1.01%)	1179 (1.75%)
Total cardiovascular disease	5422 (1.29%)	311 (0.49%)	747 (0.75%)	2663 (1.40%)	1701 (2.53%)
Deaths					
Cardiovascular deaths	1146 (0.27%)	45 (0.07%)	93 (0.09%)	465 (0.24%)	543 (0.81%)
Cancer deaths	1532 (0.37%)	108 (0.17%)	224 (0.23%)	783 (0.41%)	417 (0.62%)
Other known cause	995 (0.24%)	43 (0.07%)	102 (0.10%)	432 (0.23%)	418 (0.62%)
Unknown cause	22 (0.01%)	1 (<0.01%)	7 (0.01%)	8 (<0.01%)	6 (0.01%)
Total death	3695 (0.88%)	197 (0.31%)	426 (0.43%)	1688 (0.89%)	1384 (2.06%)
Death plus post-WHI deaths[8]	4529 (1.07%)	233 (0.37%)	501 (0.50%)	2016 (1.05%)	1779 (2.57%)

[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 2005-2010.
[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 2005-2010.
[6] Angina and CHF are not verified outcomes in 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 2005-2010.
[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 Participants

Data as of: September 30, 2015; 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		126.5		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%)	1885	(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%)	386	(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%)	57	(0.36%)	2199	(0.62%)	23	(0.49%)
Total cancer	13	(0.80%)	96	(1.20%)	398	(1.09%)	130	(0.82%)	4719	(1.34%)	55	(1.16%)
Cardiovascular												
CHD[3]	5	(0.31%)	14	(0.18%)	161	(0.44%)	37	(0.23%)	1537	(0.44%)	23	(0.49%)
CHD death[4]	1	(0.06%)	3	(0.04%)	67	(0.18%)	11	(0.07%)	471	(0.13%)	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%)	327	(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%)	140	(0.38%)	33	(0.21%)	1135	(0.32%)	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%)	3276	(0.93%)	47	(0.99%)
Total cardiovascular disease	19	(1.17%)	62	(0.78%)	541	(1.48%)	150	(0.95%)	4581	(1.30%)	69	(1.46%)
Deaths												
Cardiovascular deaths	3	(0.18%)	13	(0.16%)	136	(0.37%)	25	(0.16%)	954	(0.27%)	15	(0.32%)
Cancer deaths	2	(0.12%)	26	(0.33%)	115	(0.31%)	46	(0.29%)	1325	(0.38%)	18	(0.38%)
Other known cause	8	(0.49%)	9	(0.11%)	81	(0.22%)	19	(0.12%)	870	(0.25%)	8	(0.17%)
Unknown cause	0	(0.00%)	3	(0.04%)	2	(0.01%)	1	(0.01%)	16	(<0.01%)	0	(0.00%)
Total death	13	(0.80%)	51	(0.64%)	334	(0.91%)	91	(0.57%)	3165	(0.90%)	41	(0.87%)
Death plus post-WHI deaths[8]	20	(1.21%)	70	(0.87%)	434	(1.17%)	123	(0.77%)	3821	(1.07%)	61	(1.28%)

[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 2005-2010.
[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 2005-2010.
[6] Angina and CHF are not verified outcomes in 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 2005-2010.
[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: September 30, 2015; Events through September 30, 2015

Outcome	Total	Age at Enrollment 50-54	55-59	60-69	70-79
Number randomized	36282	5153	8269	16519	6341
Mean follow-up (months)	172.5	184.9	182.9	172.2	149.3
Hospitalizations					
Ever	25795 (4.95%)	2936 (3.70%)	5300 (4.20%)	12357 (5.21%)	5202 (6.59%)
Two or more	18058 (3.46%)	1767 (2.23%)	3458 (2.74%)	8906 (3.76%)	3927 (4.98%)
Other					
DVT[1]	888 (0.17%)	63 (0.08%)	152 (0.12%)	432 (0.19%)	241 (0.32%)
Pulmonary embolism	685 (0.13%)	58 (0.07%)	131 (0.10%)	365 (0.16%)	131 (0.17%)
Diabetes (treated)	5349 (1.06%)	830 (1.07%)	1248 (1.03%)	2507 (1.10%)	764 (1.01%)
Gallbladder disease[2,3]	2410 (1.12%)	355 (1.03%)	591 (1.14%)	1116 (1.18%)	348 (1.00%)
Hysterectomy	1726 (0.56%)	269 (0.58%)	471 (0.60%)	782 (0.56%)	204 (0.46%)
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]	10772 (3.19%)	1774 (2.86%)	2669 (2.97%)	4849 (3.36%)	1480 (3.57%)
Rheumatoid arthritis[3]	1773 (0.72%)	257 (0.68%)	405 (0.70%)	798 (0.73%)	313 (0.77%)
Intestinal polyps	8944 (1.84%)	1410 (1.83%)	2276 (1.89%)	4107 (1.87%)	1151 (1.64%)
Lupus	556 (0.11%)	79 (0.10%)	132 (0.10%)	247 (0.10%)	98 (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	13288 (3.52%)	1927 (2.96%)	3149 (3.23%)	6164 (3.74%)	2048 (4.14%)
COPD[5]	1460 (0.98%)	143 (0.65%)	328 (0.94%)	797 (1.19%)	192 (0.83%)
Macular degeneration[6]	3824 (0.68%)	245 (0.28%)	579 (0.43%)	1999 (0.79%)	1001 (1.17%)
Alzheimer's disease[6]	2787 (0.49%)	120 (0.14%)	319 (0.23%)	1431 (0.56%)	917 (1.07%)
Parkinson's disease[6]	492 (0.09%)	40 (0.05%)	107 (0.08%)	253 (0.10%)	92 (0.11%)

[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 2005-2015.
[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.
[5] Data only collected during the WHI Extension Study 2010-2015.
[6] Data only collected during the WHI Extension Studies 2005-2015.

Table 4.4 (continued)
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: September 30, 2015; Events through September 30, 2015

	Race/Ethnicity					
Outcomes	**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)	159.5	164.6	159.8	150.4	175.4	157.5
Hospitalizations						
Ever	98 (4.95%)	405 (4.09%)	2209 (5.01%)	814 (4.32%)	21971 (4.98%)	298 (5.16%)
Two or more	71 (3.59%)	237 (2.40%)	1506 (3.41%)	468 (2.49%)	15580 (3.53%)	196 (3.39%)
Other						
DVT[1]	6 (0.31%)	2 (0.02%)	98 (0.23%)	20 (0.11%)	752 (0.18%)	10 (0.18%)
Pulmonary embolism	4 (0.20%)	1 (0.01%)	61 (0.14%)	12 (0.06%)	599 (0.14%)	8 (0.14%)
Diabetes (treated)	25 (1.34%)	111 (1.18%)	659 (1.66%)	279 (1.57%)	4194 (0.98%)	81 (1.49%)
Gallbladder disease[2,3]	10 (1.25%)	36 (0.82%)	165 (0.79%)	120 (1.51%)	2053 (1.15%)	26 (1.04%)
Hysterectomy	4 (0.49%)	25 (0.39%)	101 (0.53%)	55 (0.52%)	1524 (0.57%)	17 (0.51%)
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]	53 (4.04%)	221 (2.98%)	897 (3.25%)	479 (3.62%)	8982 (3.16%)	140 (3.56%)
Rheumatoid arthritis[3]	17 (1.83%)	28 (0.60%)	288 (1.35%)	136 (1.38%)	1279 (0.62%)	25 (0.90%)
Intestinal polyps	42 (2.30%)	149 (1.64%)	876 (2.12%)	291 (1.62%)	7486 (1.82%)	100 (1.88%)
Lupus	5 (0.26%)	4 (0.04%)	63 (0.14%)	22 (0.12%)	455 (0.10%)	7 (0.12%)
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 (3.38%)	241 (3.49%)	996 (4.30%)	552 (3.79%)	11319 (3.46%)	137 (3.65%)
COPD[5]	7 (1.23%)	13 (0.43%)	102 (0.77%)	38 (0.62%)	1283 (1.04%)	17 (0.97%)
Macular degeneration[6]	17 (0.76%)	41 (0.37%)	167 (0.34%)	101 (0.45%)	3467 (0.74%)	31 (0.47%)
Alzheimer's disease[6]	7 (0.31%)	30 (0.27%)	231 (0.47%)	95 (0.42%)	2399 (0.51%)	25 (0.38%)
Parkinson's disease[6]	0 (0.00%)	5 (0.05%)	32 (0.07%)	13 (0.06%)	437 (0.09%)	5 (0.08%)

[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 2005-2015.
[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.
[5] Data only collected during the WHI Extension Study 2010-2015.
[6] Data only collected during the WHI Extension Studies 2005-2015.

Table 5.1
Participation and Vital Status: OS Participants

Data as of: September 30, 2015
WHI Extension Study 2010-2015 Participants

	OS Participants (N = 52,068) N	%
Vital Status/Participation		
Deceased	5413	10.4
Alive: Current Participation[1]	43914	84.3
Alive: Recent Participation[2]	1327	2.5
Alive: Past/Unknown Participation[3]	30	0.1
Stopped Follow-Up[4]	729	1.4
Lost to Follow-Up[5]	655	1.3

Data as of: September 30, 2015; Status as of September 30, 2010
WHI Extension Study 2005-2010 Participants

	OS Participants (N = 63,231) N	%
Vital Status/Participation		
Deceased	4766	7.5
Alive: Current Participation[1]	57189	90.4
Alive: Recent Participation[2]	368	0.6
Alive: Past/Unknown Participation[3]	33	0.1
Stopped Follow-Up[4]	604	1.0
Lost to Follow-Up[5]	271	0.4

Data as of: September 30, 2015; Status as of April 8, 2005
WHI Participants

	OS Participants (N =93,676) N	%
Vital Status/Participation		
Deceased	6352	7.1
Alive: Current Participation[1]	78250	87.6
Alive: Recent Participation[2]	424	0.5
Alive: Past/Unknown Participation[3]	47	0.1
Stopped Follow-Up[4]	2263	2.5
Lost to Follow-Up[5]	1999	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: September 30, 2015; 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]	4224 (0.40%)	160 (0.11%)	361 (0.17%)	1780 (0.38%)	1923 (0.82%)
CHD death[2]	1575 (0.15%)	41 (0.03%)	93 (0.04%)	547 (0.12%)	894 (0.38%)
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%)	41 (0.03%)	79 (0.04%)	384 (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	3335 (0.31%)	104 (0.07%)	249 (0.12%)	1403 (0.30%)	1579 (0.67%)
PVD	840 (0.08%)	23 (0.02%)	74 (0.04%)	381 (0.08%)	362 (0.15%)
Coronary disease[4]	9135 (0.86%)	394 (0.26%)	936 (0.45%)	4073 (0.86%)	3732 (1.59%)
Total cardiovascular disease	13133 (1.23%)	540 (0.36%)	1266 (0.60%)	5761 (1.22%)	5566 (2.37%)
Cancer					
Breast cancer	6050 (0.57%)	723 (0.48%)	1087 (0.52%)	2832 (0.60%)	1408 (0.60%)
Invasive breast cancer	5024 (0.47%)	578 (0.38%)	885 (0.42%)	2348 (0.50%)	1213 (0.52%)
Non-invasive breast cancer	1091 (0.10%)	155 (0.10%)	212 (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]	6639 (0.62%)	492 (0.33%)	924 (0.44%)	3162 (0.67%)	2061 (0.88%)
Total cancer	14520 (1.36%)	1361 (0.90%)	2289 (1.09%)	6794 (1.44%)	4076 (1.73%)
Fractures					
Hip fracture	2199 (0.21%)	52 (0.03%)	131 (0.06%)	777 (0.16%)	1239 (0.53%)
Deaths					
Cardiovascular deaths	3527 (0.33%)	88 (0.06%)	213 (0.10%)	1208 (0.26%)	2018 (0.86%)
Cancer deaths	4525 (0.42%)	263 (0.17%)	520 (0.25%)	2067 (0.44%)	1675 (0.71%)
Other known cause	3090 (0.29%)	119 (0.08%)	203 (0.10%)	1183 (0.25%)	1585 (0.67%)
Unknown cause	88 (0.01%)	7 (<0.01%)	10 (<0.01%)	33 (0.01%)	38 (0.02%)
Total death	11230 (1.05%)	477 (0.32%)	946 (0.45%)	4491 (0.95%)	5316 (2.26%)
Death plus post-WHI deaths[7]	15305 (1.26%)	611 (0.36%)	1197 (0.51%)	5925 (1.11%)	7572 (2.76%)

[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 2005-2010.
[5] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[6] Only one report of "other cancer " is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.
[7] Includes deaths for non-Extension study participants after the main WHI study close-out. Annualized rates incorporate additional follow-up from the NDI search.

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

Data as of: September 30, 2015; Events through September 30, 2010

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)	120.0	121.7	118.2	113.5	140.4	127.9
Cardiovascular						
CHD[1]	23 (0.55%)	62 (0.23%)	371 (0.49%)	81 (0.24%)	3628 (0.40%)	59 (0.42%)
CHD death[2]	13 (0.31%)	25 (0.09%)	187 (0.25%)	26 (0.08%)	1302 (0.14%)	22 (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%)	39 (0.05%)	16 (0.05%)	761 (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%)	272 (0.36%)	65 (0.19%)	2853 (0.31%)	56 (0.40%)
PVD	3 (0.07%)	6 (0.02%)	88 (0.12%)	8 (0.02%)	722 (0.08%)	13 (0.09%)
Coronary disease[4]	53 (1.26%)	125 (0.46%)	784 (1.04%)	216 (0.63%)	7836 (0.86%)	121 (0.86%)
Total cardiovascular disease	67 (1.59%)	210 (0.78%)	1120 (1.49%)	295 (0.86%)	11250 (1.23%)	191 (1.35%)
Cancer						
Breast cancer	17 (0.40%)	126 (0.47%)	375 (0.50%)	138 (0.40%)	5332 (0.58%)	62 (0.44%)
Invasive breast cancer	16 (0.38%)	106 (0.39%)	303 (0.40%)	109 (0.32%)	4437 (0.49%)	53 (0.38%)
Non-invasive breast cancer	1 (0.02%)	22 (0.08%)	78 (0.10%)	31 (0.09%)	949 (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%)	377 (0.50%)	118 (0.35%)	5914 (0.65%)	91 (0.64%)
Total cancer	45 (1.07%)	274 (1.01%)	883 (1.17%)	309 (0.91%)	12834 (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	23 (0.55%)	68 (0.25%)	363 (0.48%)	71 (0.21%)	2949 (0.32%)	53 (0.38%)
Cancer deaths	13 (0.31%)	86 (0.32%)	344 (0.46%)	97 (0.28%)	3936 (0.43%)	49 (0.35%)
Other known cause	25 (0.59%)	47 (0.17%)	247 (0.33%)	90 (0.26%)	2648 (0.29%)	33 (0.23%)
Unknown cause	0 (0.00%)	2 (0.01%)	7 (0.01%)	10 (0.03%)	66 (0.01%)	3 (0.02%)
Total death	61 (1.45%)	203 (0.75%)	961 (1.28%)	268 (0.79%)	9599 (1.05%)	138 (0.98%)
Death plus post-WHI deaths[7]	97 (1.85%)	323 (0.92%)	1425 (1.48%)	432 (0.93%)	12797 (1.26%)	231 (1.36%)

[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 2005-2010.
[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: September 30, 2015; Events through September 30, 2015

Outcome	Total	Age at Enrollment 50-54	55-59	60-69	70-79
Number enrolled	93676	12381	17329	41200	22766
Mean follow-up (months)	164.4	181.2	179.6	166.1	140.8
Hospitalizations					
Ever	62931 (4.90%)	6496 (3.48%)	10345 (3.99%)	28766 (5.04%)	17324 (6.49%)
Two or more	42612 (3.32%)	3804 (2.03%)	6531 (2.52%)	19848 (3.48%)	12429 (4.65%)
Other					
DVT[1]	1703 (0.14%)	133 (0.07%)	222 (0.09%)	820 (0.15%)	528 (0.21%)
Pulmonary embolism	1409 (0.11%)	131 (0.07%)	225 (0.09%)	680 (0.12%)	373 (0.14%)
Diabetes (treated)	10678 (0.86%)	1483 (0.81%)	2118 (0.84%)	4927 (0.89%)	2150 (0.84%)
Gallbladder disease[2,3]	5652 (0.95%)	832 (0.96%)	1141 (0.98%)	2534 (0.98%)	1145 (0.85%)
Hysterectomy	4612 (0.36%)	703 (0.38%)	1064 (0.41%)	2092 (0.37%)	753 (0.28%)
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]	25086 (3.33%)	3790 (2.80%)	5172 (3.03%)	11110 (3.48%)	5014 (3.91%)
Rheumatoid arthritis[3]	4571 (0.68%)	634 (0.67%)	877 (0.68%)	1880 (0.64%)	1180 (0.76%)
Intestinal polyps	20983 (1.80%)	3039 (1.71%)	4575 (1.88%)	9556 (1.86%)	3813 (1.65%)
Lupus	1467 (0.11%)	202 (0.11%)	283 (0.11%)	665 (0.12%)	317 (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	32224 (3.44%)	4177 (2.67%)	6166 (3.01%)	14486 (3.59%)	7395 (4.32%)
COPD[5]	2980 (0.79%)	328 (0.62%)	573 (0.78%)	1546 (0.93%)	533 (0.65%)
Macular degeneration[6]	9076 (1.12%)	578 (0.50%)	1155 (0.72%)	4404 (1.23%)	2939 (1.73%)
Alzheimer's disease[6]	6382 (0.79%)	240 (0.21%)	546 (0.34%)	3105 (0.87%)	2491 (1.47%)
Parkinson's disease[6]	1281 (0.16%)	79 (0.07%)	175 (0.11%)	723 (0.20%)	304 (0.18%)

[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 2005-2015.
[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.
[5] Data only collected during the WHI Extension Study 2010-2015.
[6] Data only collected during the WHI Extension Studies 2005-2015.

Table 5.4 (continued)
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: September 30, 2015; Events through September 30, 2015

	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)	140.0	140.5	134.8	130.1	170.1	150.0
Hospitalizations						
Ever	270 (5.50%)	1152 (3.68%)	4471 (5.21%)	1712 (4.38%)	54512 (4.93%)	814 (4.92%)
Two or more	187 (3.81%)	589 (1.88%)	2782 (3.24%)	972 (2.48%)	37536 (3.39%)	546 (3.30%)
Other						
DVT[1]	7 (0.15%)	9 (0.03%)	153 (0.18%)	29 (0.08%)	1486 (0.14%)	19 (0.12%)
Pulmonary embolism	4 (0.08%)	11 (0.04%)	100 (0.12%)	15 (0.04%)	1267 (0.12%)	12 (0.07%)
Diabetes (treated)	73 (1.69%)	299 (1.00%)	1209 (1.57%)	504 (1.37%)	8431 (0.78%)	162 (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 (0.22%)	75 (0.24%)	167 (0.19%)	137 (0.35%)	4152 (0.38%)	70 (0.42%)
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]	91 (3.35%)	734 (3.31%)	1790 (3.58%)	990 (3.87%)	21121 (3.29%)	360 (3.53%)
Rheumatoid arthritis[3]	38 (1.39%)	98 (0.52%)	661 (1.33%)	382 (1.65%)	3306 (0.58%)	86 (0.95%)
Intestinal polyps	72 (1.61%)	467 (1.67%)	1542 (1.96%)	628 (1.72%)	18012 (1.80%)	262 (1.77%)
Lupus	10 (0.21%)	25 (0.08%)	138 (0.16%)	71 (0.18%)	1203 (0.11%)	20 (0.12%)
Kidney stones[3,4]	17 (0.61%)	40 (0.21%)	263 (0.50%)	125 (0.53%)	1825 (0.32%)	44 (0.47%)
Cataracts[3,4]	102 (4.20%)	683 (4.33%)	1937 (4.26%)	894 (4.11%)	23094 (4.73%)	393 (5.02%)
Hypertension treated w/pills	132 (4.11%)	774 (3.47%)	2064 (4.81%)	1145 (3.84%)	27652 (3.35%)	457 (3.84%)
COPD[5]	14 (0.85%)	29 (0.26%)	161 (0.54%)	66 (0.45%)	2681 (0.85%)	29 (0.55%)
Macular degeneration[6]	28 (0.79%)	127 (0.55%)	288 (0.46%)	189 (0.62%)	8343 (1.23%)	101 (0.90%)
Alzheimer's disease[6]	23 (0.65%)	92 (0.40%)	327 (0.52%)	141 (0.46%)	5708 (0.84%)	91 (0.82%)
Parkinson's disease[6]	4 (0.11%)	14 (0.06%)	65 (0.10%)	28 (0.09%)	1152 (0.17%)	18 (0.16%)

[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 2005-2015.
[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.
[5] Data only collected during the WHI Extension Study 2010-2015.
[6] Data only collected during the WHI Extension Studies 2005-2015.

Table 6.1
Participation and Vital Status: CT Participants

Data as of: September 30, 2015
WHI Extension Study 2010-2015 Participants

	CT Participants (N = 41,499) N	%
Vital Status/Participation		
Deceased	4167	10.0
Alive: Current Participation[1]	34932	84.2
Alive: Recent Participation[2]	1157	2.8
Alive: Past/Unknown Participation[3]	26	0.1
Stopped Follow-Up[4]	596	1.4
Lost to Follow-Up[5]	621	1.5

Data as of: September 30, 2015; Status as of September 30, 2010
WHI Extension Study 2005-2010 Participants

	CT Participants (N = 52,176) N	%
Vital Status/Participation		
Deceased	3816	7.3
Alive: Current Participation[1]	46879	89.8
Alive: Recent Participation[2]	443	0.8
Alive: Past/Unknown Participation[3]	37	0.1
Stopped Follow-Up[4]	647	1.2
Lost to Follow-Up[5]	354	0.7

Data as of: September 30, 2015; Status as of April 8, 2005
WHI Participants

	CT Participants (N = 68,132) N	%
Vital Status/Participation		
Deceased	3700	5.4
Alive: Current Participation[6]	61162	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]	727	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: September 30, 2015; 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]	3574 (0.43%)	193 (0.16%)	406 (0.22%)	1663 (0.44%)	1312 (0.91%)
CHD death[2]	1190 (0.14%)	48 (0.04%)	86 (0.05%)	503 (0.13%)	553 (0.38%)
Total MI[3]	2733 (0.33%)	155 (0.13%)	339 (0.18%)	1288 (0.34%)	951 (0.66%)
Clinical MI	2657 (0.32%)	149 (0.12%)	331 (0.18%)	1250 (0.33%)	927 (0.64%)
Angina[4]	2414 (0.43%)	129 (0.16%)	331 (0.27%)	1215 (0.48%)	739 (0.73%)
CABG/PTCA	3952 (0.48%)	217 (0.18%)	551 (0.30%)	2084 (0.55%)	1100 (0.76%)
Carotid artery disease	698 (0.08%)	27 (0.02%)	90 (0.05%)	376 (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	2701 (0.32%)	119 (0.10%)	272 (0.15%)	1267 (0.33%)	1043 (0.72%)
PVD	647 (0.08%)	29 (0.02%)	86 (0.05%)	333 (0.09%)	199 (0.14%)
Coronary disease[5]	7788 (0.94%)	442 (0.37%)	1016 (0.54%)	3795 (0.99%)	2535 (1.76%)
Total cardiovascular disease	10804 (1.30%)	587 (0.49%)	1361 (0.73%)	5231 (1.37%)	3625 (2.52%)
Cancer					
Breast cancer	4226 (0.51%)	514 (0.43%)	940 (0.50%)	2000 (0.52%)	772 (0.54%)
Invasive breast cancer	3424 (0.41%)	391 (0.33%)	768 (0.41%)	1617 (0.42%)	648 (0.45%)
Non-invasive breast cancer	857 (0.10%)	129 (0.11%)	183 (0.10%)	409 (0.11%)	136 (0.09%)
Ovary cancer	373 (0.04%)	35 (0.03%)	73 (0.04%)	192 (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]	4957 (0.60%)	406 (0.34%)	845 (0.45%)	2478 (0.65%)	1228 (0.85%)
Total cancer	10618 (1.28%)	1040 (0.87%)	2069 (1.11%)	5164 (1.35%)	2345 (1.63%)
Fractures					
Hip fracture	1639 (0.20%)	32 (0.03%)	115 (0.06%)	665 (0.17%)	827 (0.57%)
Deaths					
Cardiovascular deaths	2403 (0.29%)	86 (0.07%)	172 (0.09%)	974 (0.26%)	1171 (0.81%)
Cancer deaths	3128 (0.38%)	190 (0.16%)	432 (0.23%)	1569 (0.41%)	937 (0.65%)
Other known cause	2010 (0.24%)	83 (0.07%)	188 (0.10%)	851 (0.22%)	888 (0.62%)
Unknown cause	55 (0.01%)	2 (<0.01%	14 (0.01%)	21 (0.01%)	18 (0.01%)
Total death	7596 (0.91%)	361 (0.30%)	806 (0.43%)	3415 (0.89%)	3014 (2.09%)
Death plus post-WHI deaths[8]	9520 (1.04%)	433 (0.33%)	958 (0.47%)	4180 (1.00%)	3949 (2.46%)

[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; Q-wave MI, angina and CHF are not collected during the WHI Extension Study 2005-2010.
[6] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[7] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.
[8] Includes deaths for non-Extension study participants after the main WHI study close-out. Annualized rates incorporate additional follow-up from the NDI search.

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

Data as of: September 30, 2015; Events through September 30, 2010

Outcomes	Race/Ethnicity: American Indian/Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number enrolled	292	1519	6983	2875	55525	938
Mean follow-up (months)	135.1	140.5	139.2	131.5	148.5	137.3
Cardiovascular						
CHD[1]	8 (0.24%)	46 (0.26%)	349 (0.43%)	73 (0.23%)	3050 (0.44%)	48 (0.45%)
CHD death[2]	2 (0.06%)	13 (0.07%)	162 (0.20%)	23 (0.07%)	971 (0.14%)	19 (0.18%)
Total MI[3]	7 (0.21%)	40 (0.22%)	232 (0.29%)	56 (0.18%)	2361 (0.34%)	37 (0.34%)
Clinical MI	7 (0.21%)	39 (0.22%)	227 (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%)	3413 (0.50%)	43 (0.40%)
Carotid artery disease	3 (0.09%)	3 (0.02%)	42 (0.05%)	6 (0.02%)	635 (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%)	333 (0.41%)	64 (0.20%)	2214 (0.32%)	40 (0.37%)
PVD	5 (0.15%)	7 (0.04%)	99 (0.12%)	8 (0.03%)	520 (0.08%)	8 (0.07%)
Coronary disease[5]	26 (0.79%)	98 (0.55%)	853 (1.05%)	211 (0.67%)	6500 (0.95%)	100 (0.93%)
Total cardiovascular disease	40 (1.22%)	141 (0.79%)	1210 (1.49%)	279 (0.89%)	8996 (1.31%)	138 (1.29%)
Cancer						
Breast cancer	10 (0.30%)	95 (0.53%)	365 (0.45%)	104 (0.33%)	3609 (0.53%)	43 (0.40%)
Invasive breast cancer	7 (0.21%)	72 (0.40%)	288 (0.36%)	86 (0.27%)	2937 (0.43%)	34 (0.32%)
Non-invasive breast cancer	3 (0.09%)	25 (0.14%)	81 (0.10%)	20 (0.06%)	718 (0.10%)	10 (0.09%)
Ovarian cancer	2 (0.06%)	10 (0.06%)	27 (0.03%)	10 (0.03%)	319 (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%)	360 (0.44%)	125 (0.40%)	4323 (0.63%)	58 (0.54%)
Total cancer	29 (0.88%)	203 (1.14%)	853 (1.05%)	264 (0.84%)	9148 (1.33%)	121 (1.13%)
Fractures						
Hip fracture	5 (0.15%)	16 (0.09%)	40 (0.05%)	24 (0.08%)	1542 (0.22%)	12 (0.11%)
Deaths						
Cardiovascular deaths	9 (0.27%)	30 (0.17%)	320 (0.40%)	46 (0.15%)	1971 (0.29%)	27 (0.25%)
Cancer deaths	11 (0.33%)	50 (0.28%)	266 (0.33%)	92 (0.29%)	2668 (0.39%)	41 (0.38%)
Other known cause	13 (0.40%)	22 (0.12%)	179 (0.22%)	45 (0.14%)	1729 (0.25%)	22 (0.21%)
Unknown cause	0 (0.00%)	3 (0.02%)	8 (0.01%)	3 (0.01%)	40 (0.01%)	1 (0.01%)
Total death	33 (1.00%)	105 (0.59%)	773 (0.95%)	186 (0.59%)	6408 (0.93%)	91 (0.85%)
Death plus post-WHI deaths[8]	48 (1.25%)	148 (0.73%)	1023 (1.10%)	259 (0.66%)	7907 (1.06%)	135 (1.10%)

[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; Q-wave MI, angina and CHF are not collected during the WHI Extension Study 2005-2010.
[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: September 30, 2015; Events through September 30, 2015

Outcome	Total	Age at Enrollment 50-54	55-59	60-69	70-79
Number randomized	68132	9188	14661	31389	12894
Mean follow-up (months)	177.1	191.4	188.4	177.3	153.4
Hospitalizations					
Ever	48748 (4.85%)	5272 (3.60%)	9409 (4.09%)	23474 (5.06%)	10593 (6.43%)
Two or more	34621 (3.44%)	3270 (2.23%)	6175 (2.68%)	17048 (3.68%)	8128 (4.93%)
Other					
DVT[1]	1722 (0.18%)	126 (0.09%)	272 (0.12%)	838 (0.19%)	486 (0.31%)
Pulmonary embolism	1313 (0.13%)	110 (0.08%)	229 (0.10%)	681 (0.15%)	293 (0.18%)
Diabetes (treated)	10177 (1.05%)	1487 (1.04%)	2294 (1.03%)	4807 (1.08%)	1589 (1.01%)
Gallbladder disease[2,3]	5248 (1.15%)	746 (1.07%)	1195 (1.15%)	2463 (1.21%)	844 (1.05%)
Hysterectomy	3376 (0.57%)	496 (0.58%)	855 (0.59%)	1580 (0.59%)	445 (0.48%)
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]	20795 (3.23%)	3232 (2.81%)	4899 (2.98%)	9483 (3.39%)	3181 (3.74%)
Rheumatoid arthritis[3]	4009 (0.76%)	538 (0.70%)	866 (0.74%)	1822 (0.77%)	783 (0.84%)
Intestinal polyps	17190 (1.84%)	2498 (1.76%)	4120 (1.88%)	8178 (1.91%)	2394 (1.64%)
Lupus	1079 (0.11%)	150 (0.10%)	247 (0.11%)	505 (0.11%)	177 (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	26121 (3.64%)	3544 (2.97%)	5816 (3.29%)	12236 (3.83%)	4525 (4.42%)
COPD[5]	2582 (0.93%)	260 (0.66%)	573 (0.92%)	1391 (1.10%)	358 (0.77%)
Macular degeneration[6]	6847 (1.18%)	425 (0.51%)	1008 (0.76%)	3559 (1.33%)	1855 (1.97%)
Alzheimer's disease[6]	5046 (0.87%)	189 (0.23%)	543 (0.41%)	2590 (0.97%)	1724 (1.83%)
Parkinson's disease[6]	855 (0.15%)	62 (0.07%)	158 (0.12%)	469 (0.18%)	166 (0.18%)

[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 2005-2015.
[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.
[5] Data only collected during the WHI Extension Study 2010-2015.
[6] Data only collected during the WHI Extension Studies 2005-2015.

Table 6.4 (continued)
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: September 30, 2015; Events through September 30, 2015

	Race/Ethnicity					
Outcomes	**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)	159.9	168.9	163.1	152.7	180.6	164.1
Hospitalizations						
Ever	197 (5.06%)	833 (3.90%)	4672 (4.92%)	1579 (4.32%)	40843 (4.89%)	624 (4.86%)
Two or more	143 (3.67%)	482 (2.25%)	3234 (3.41%)	955 (2.61%)	29397 (3.52%)	410 (3.20%)
Other						
DVT[1]	7 (0.19%)	9 (0.04%)	196 (0.21%)	33 (0.09%)	1459 (0.18%)	18 (0.14%)
Pulmonary embolism	6 (0.16%)	6 (0.03%)	136 (0.14%)	22 (0.06%)	1129 (0.14%)	14 (0.11%)
Diabetes (treated)	49 (1.38%)	253 (1.25%)	1481 (1.75%)	546 (1.59%)	7700 (0.95%)	148 (1.22%)
Gallbladder disease[2,3]	22 (1.31%)	86 (0.81%)	420 (0.85%)	243 (1.45%)	4403 (1.18%)	74 (1.20%)
Hysterectomy	8 (0.47%)	51 (0.37%)	224 (0.54%)	122 (0.59%)	2939 (0.58%)	32 (0.42%)
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]	92 (3.77%)	490 (3.11%)	1962 (3.33%)	949 (3.68%)	17005 (3.19%)	297 (3.57%)
Rheumatoid arthritis[3]	32 (1.55%)	74 (0.66%)	682 (1.33%)	357 (1.70%)	2787 (0.65%)	77 (1.13%)
Intestinal polyps	78 (2.17%)	348 (1.78%)	1819 (2.06%)	599 (1.72%)	14120 (1.82%)	226 (1.91%)
Lupus	8 (0.21%)	16 (0.08%)	142 (0.15%)	51 (0.14%)	847 (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	104 (4.01%)	549 (3.72%)	2222 (4.61%)	1119 (4.07%)	21806 (3.54%)	321 (3.67%)
COPD[5]	14 (1.27%)	23 (0.36%)	196 (0.71%)	72 (0.62%)	2245 (0.99%)	32 (0.84%)
Macular degeneration[6]	25 (1.02%)	82 (0.64%)	322 (0.57%)	178 (0.79%)	6177 (1.29%)	63 (0.80%)
Alzheimer's disease[6]	17 (0.69%)	76 (0.59%)	445 (0.79%)	173 (0.77%)	4282 (0.90%)	53 (0.67%)
Parkinson's disease[6]	3 (0.12%)	15 (0.12%)	58 (0.10%)	25 (0.11%)	744 (0.16%)	10 (0.13%)

[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 2005-2015.
[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.
[5] Data only collected during the WHI Extension Study 2010-2015.
[6] Data only collected during the WHI Extension Studies 2005-2015.

Table 7.1
Verified Primary and Other Cancers (Annualized Percentages): CT and OS Participants
Data as of: September 30, 2015; Events through September 30, 2015

	CT	OS	Total
Number of participants	68132	93676	161808
Mean follow-up time (months)	177.1	164.8	170.0
Overall cancer	12927 (1.29%)	17379 (1.35%)	30306 (1.32%)
Primary cancer			
Breast cancer	5054 (0.50%)	7075 (0.55%)	12129 (0.53%)
Invasive breast cancer	4146 (0.41%)	5908 (0.46%)	10054 (0.44%)
Non-invasive breast cancer	989 (0.10%)	1252 (0.10%)	2241 (0.10%)
Ovarian cancer	454 (0.05%)	677 (0.05%)	1131 (0.05%)
Endometrial cancer[1]	698 (0.07%)	961 (0.07%)	1659 (0.07%)
Colorectal cancer	1347 (0.13%)	1614 (0.13%)	2961 (0.13%)
Other cancer			
Accessory sinus	3 (<0.01%)	7 (<0.01%)	10 (<0.01%)
Adrenal gland	6 (<0.01%)	9 (<0.01%)	15 (<0.01%)
Anus	42 (<0.01%)	61 (<0.01%)	103 (<0.01%)
Appendix	16 (<0.01%)	19 (<0.01%)	35 (<0.01%)
Biliary tract, parts of (other/unspecified)	78 (0.01%)	85 (0.01%)	163 (0.01%)
Bladder	385 (0.04%)	475 (0.04%)	860 (0.04%)
Bones/joints/articular cartilage (limbs)	5 (<0.01%)	6 (<0.01%)	11 (<0.01%)
Bones/joints/articular cartilage (other)	10 (<0.01%)	10 (<0.01%)	20 (<0.01%)
Brain	140 (0.01%)	176 (0.01%)	316 (0.01%)
Cervix	58 (0.01%)	57 (<0.01%)	115 (0.01%)
Central Nervous System (excludes brain)	1 (<0.01%)	3 (<0.01%)	4 (<0.01%)
Connective/subcutaneous/soft tissues	68 (0.01%)	87 (0.01%)	155 (0.01%)
Endocrine glands, related structures	1 (<0.01%)	2 (<0.01%)	3 (<0.01%)
Esophagus	71 (0.01%)	76 (0.01%)	147 (0.01%)
Eye and adnexa	45 (<0.01%)	30 (<0.01%)	75 (<0.01%)
Genital organs	42 (<0.01%)	68 (0.01%)	110 (<0.01%)
Kidney	297 (0.03%)	335 (0.03%)	632 (0.03%)
Larynx	27 (<0.01%)	23 (<0.01%)	50 (<0.01%)
Leukemia	405 (0.04%)	517 (0.04%)	922 (0.04%)
Liver	98 (0.01%)	138 (0.01%)	236 (0.01%)
Lung	1496 (0.15%)	1990 (0.15%)	3486 (0.15%)
Lymph nodes	2 (<0.01%)	2 (<0.01%)	4 (<0.01%)
Lymphoma, Hodgkins	24 (<0.01%)	41 (<0.01%)	65 (<0.01%)
Lymphoma, Non-Hodgkins	640 (0.06%)	925 (0.07%)	1565 (0.07%)
Melanoma of the skin	914 (0.09%)	1192 (0.09%)	2106 (0.09%)
Multiple myeloma	238 (0.02%)	291 (0.02%)	529 (0.02%)
Oral (mouth)	17 (<0.01%)	14 (<0.01%)	31 (<0.01%)
Palate	12 (<0.01%)	18 (<0.01%)	30 (<0.01%)
Pancreas	449 (0.04%)	578 (0.04%)	1027 (0.04%)
Parotid gland (Stensen's duct)	20 (<0.01%)	35 (<0.01%)	55 (<0.01%)
Peripheral nerves and autonomic nervous system	1 (<0.01%)	1 (<0.01%)	2 (<0.01%)
Pyriform sinus	0 (0.00%)	2 (<0.01%)	2 (<0.01%)
Respiratory system, intrathoracic, other	1 (<0.01%)	1 (<0.01%)	2 (<0.01%)
Salivary glands, major (other/unspecified)	5 (<0.01%)	12 (<0.01%)	17 (<0.01%)
Stomach	110 (0.01%)	148 (0.01%)	258 (0.01%)
Thyroid	195 (0.02%)	265 (0.02%)	460 (0.02%)
Tongue, part of (other/unspecified)	33 (<0.01%)	41 (<0.01%)	74 (<0.01%)
Urinary organs (other/unspecified)	12 (<0.01%)	17 (<0.01%)	29 (<0.01%)
Uterus, not otherwise specified[1]	35 (<0.01%)	49 (<0.01%)	84 (<0.01%)
Other/unknown site of cancer	626 (0.06%)	818 (0.06%)	1444 (0.06%)
Other/unknown cancers reported on death form	143 (0.01%)	271 (0.02%)	414 (0.02%)

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

Table 7.2
Verified Primary and Other Cancers (Annualized Percentages) by Race/Ethnicity: CT and OS Participants
Data as of: September 30, 2015; Events through September 30, 2015

	Race/Ethnicity					
	American Indian/Alaskan Native	**Asian/Pacific Islander**	**Black/African American**	**Hispanic/ Latino**	**White**	**Unknown**
Number of participants	713	4190	14618	6484	133541	2262
Mean follow-up time (months)	148.5	151.4	148.8	140.6	174.7	156.2
Overall cancer	98 (1.11%)	554 (1.05%)	2006 (1.11%)	679 (0.89%)	26611 (1.37%)	358 (1.22%)
Primary cancer						
Breast cancer	38 (0.43%)	256 (0.48%)	848 (0.47%)	284 (0.37%)	10576 (0.54%)	127 (0.43%)
Invasive breast cancer	32 (0.36%)	209 (0.40%)	675 (0.37%)	231 (0.30%)	8803 (0.45%)	104 (0.35%)
Non-invasive breast cancer	7 (0.08%)	51 (0.10%)	188 (0.10%)	58 (0.08%)	1912 (0.10%)	25 (0.08%)
Ovarian cancer	3 (0.03%)	17 (0.03%)	67 (0.04%)	33 (0.04%)	999 (0.05%)	12 (0.04%)
Endometrial cancer[1]	2 (0.02%)	21 (0.04%)	82 (0.05%)	29 (0.04%)	1500 (0.08%)	25 (0.08%)
Colorectal cancer	11 (0.12%)	57 (0.11%)	268 (0.15%)	73 (0.10%)	2513 (0.13%)	39 (0.13%)
Other cancer						
Accessory sinus	0 (0.00%)	0 (0.00%)	1 (<0.01%)	0 (0.00%)	9 (<0.01%)	0 (0.00%)
Adrenal gland	0 (0.00%)	0 (0.00%)	2 (<0.01%)	1 (<0.01%)	12 (<0.01%)	0 (0.00%)
Anus	1 (0.01%)	2 (<0.01%)	8 (<0.01%)	5 (0.01%)	86 (<0.01%)	1 (<0.01%)
Appendix	0 (0.00%)	0 (0.00%)	4 (<0.01%)	3 (<0.01%)	27 (<0.01%)	1 (<0.01%)
Biliary tract, parts of (other/unspecified)	2 (0.02%)	2 (<0.01%)	11 (0.01%)	9 (0.01%)	137 (0.01%)	2 (0.01%)
Bladder	2 (0.02%)	8 (0.02%)	46 (0.03%)	12 (0.02%)	784 (0.04%)	8 (0.03%)
Bones/joints/articular cartilage (limbs)	0 (0.00%)	1 (<0.01%)	0 (0.00%)	0 (0.00%)	9 (<0.01%)	1 (<0.01%)
Bones/joints/articular cartilage (other)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	19 (<0.01%)	1 (<0.01%)
Brain	1 (0.01%)	3 (0.01%)	8 (<0.01%)	5 (0.01%)	297 (0.02%)	2 (0.01%)
Cervix	0 (0.00%)	1 (<0.01%)	16 (0.01%)	5 (0.01%)	90 (<0.01%)	3 (0.01%)
Central Nervous System (excludes brain)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (<0.01%)	0 (0.00%)
Connective/subcutaneous/soft tissues	0 (0.00%)	4 (0.01%)	6 (<0.01%)	3 (<0.01%)	141 (0.01%)	1 (<0.01%)
Endocrine glands, related structures	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (<0.01%)	0 (0.00%)
Esophagus	1 (0.01%)	0 (0.00%)	9 (<0.01%)	1 (<0.01%)	133 (0.01%)	3 (0.01%)
Eye and adnexa	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (<0.01%)	71 (<0.01%)	1 (<0.01%)
Genital organs	0 (0.00%)	1 (<0.01%)	3 (<0.01%)	3 (<0.01%)	102 (0.01%)	1 (<0.01%)
Kidney	7 (0.08%)	12 (0.02%)	51 (0.03%)	19 (0.03%)	534 (0.03%)	9 (0.03%)
Larynx	0 (0.00%)	0 (0.00%)	6 (<0.01%)	0 (0.00%)	44 (<0.01%)	0 (0.00%)
Leukemia	0 (0.00%)	16 (0.03%)	56 (0.03%)	14 (0.02%)	827 (0.04%)	9 (0.03%)
Liver	1 (0.01%)	15 (0.03%)	20 (0.01%)	16 (0.02%)	179 (0.01%)	5 (0.02%)
Lung	14 (0.16%)	53 (0.10%)	234 (0.13%)	53 (0.07%)	3081 (0.16%)	51 (0.17%)
Lymph nodes	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (<0.01%)	0 (0.00%)

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

Table 7.2 (continued)
Verified Primary and Other Cancers (Annualized Percentages) by Race/Ethnicity: CT and OS Participants
Data as of: September 30, 2015; Events through September 30, 2015

	Race/Ethnicity					
	American Indian/Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Lymphoma, Hodgkins	0 (0.00%)	1 (<0.01%)	4 (<0.01%)	4 (0.01%)	55 (<0.01%)	1 (<0.01%)
Lymphoma, Non-Hodgkins	4 (0.05%)	26 (0.05%)	56 (0.03%)	43 (0.06%)	1417 (0.07%)	19 (0.06%)
Melanoma of the skin	3 (0.03%)	6 (0.01%)	8 (<0.01%)	14 (0.02%)	2058 (0.11%)	17 (0.06%)
Multiple myeloma	3 (0.03%)	1 (<0.01%)	66 (0.04%)	18 (0.02%)	435 (0.02%)	6 (0.02%)
Oral (mouth)	0 (0.00%)	0 (0.00%)	2 (<0.01%)	0 (0.00%)	29 (<0.01%)	0 (0.00%)
Palate	0 (0.00%)	1 (<0.01%)	1 (<0.01%)	0 (0.00%)	28 (<0.01%)	0 (0.00%)
Pancreas	4 (0.05%)	29 (0.05%)	85 (0.05%)	23 (0.03%)	873 (0.04%)	13 (0.04%)
Parotid gland (Stensen's duct)	0 (0.00%)	2 (<0.01%)	7 (<0.01%)	0 (0.00%)	46 (<0.01%)	0 (0.00%)
Peripheral nerves and autonomic nervous system	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (<0.01%)	0 (0.00%)
Pyriform sinus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (<0.01%)	0 (0.00%)
Respiratory system, intrathoracic, other	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (<0.01%)	0 (0.00%)
Salivary glands, major (other/ unspecified)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	17 (<0.01%)	0 (0.00%)
Stomach	1 (0.01%)	16 (0.03%)	34 (0.02%)	8 (0.01%)	195 (0.01%)	4 (0.01%)
Thyroid	1 (0.01%)	9 (0.02%)	32 (0.02%)	8 (0.01%)	403 (0.02%)	7 (0.02%)
Tongue, part of (other/unspecified)	0 (0.00%)	2 (<0.01%)	2 (<0.01%)	0 (0.00%)	68 (<0.01%)	2 (0.01%)
Urinary organs (other/unspecified)	0 (0.00%)	1 (<0.01%)	4 (<0.01%)	1 (<0.01%)	23 (<0.01%)	0 (0.00%)
Uterus, not otherwise specified[1]	0 (0.00%)	2 (<0.01%)	10 (0.01%)	4 (0.01%)	66 (<0.01%)	2 (0.01%)
Other/unknown site of cancer	5 (0.06%)	24 (0.05%)	79 (0.04%)	37 (0.05%)	1284 (0.07%)	15 (0.05%)
Other/unknown cancers reported on death form	3 (0.03%)	6 (0.01%)	41 (0.02%)	12 (0.02%)	346 (0.02%)	6 (0.02%)

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

Table 7.3
Self Reported Fractures (Annualized Percentages): CT and OS Participants

Data as of: September 30, 2015; Events through September 30, 2015

	CT		OS		Total	
Number of participants	68132		93676		161808	
Mean follow-up time (months)	177.1		164.8		170.0	
Elbow	1085	(0.11%)	1465	(0.11%)	2550	(0.11%)
Foot	3626	(0.36%)	4606	(0.36%)	8232	(0.36%)
Hand	1024	(0.10%)	1184	(0.09%)	2208	(0.10%)
Hip	2529	(0.25%)	3503	(0.27%)	6032	(0.26%)
Knee	1544	(0.15%)	2051	(0.16%)	3595	(0.16%)
Lower arm	5239	(0.52%)	6652	(0.52%)	11891	(0.52%)
Lower leg	3967	(0.39%)	4927	(0.38%)	8894	(0.39%)
Pelvis	1317	(0.13%)	2077	(0.16%)	3394	(0.15%)
Tailbone	458	(0.05%)	672	(0.05%)	1130	(0.05%)
Upper arm	3012	(0.30%)	3705	(0.29%)	6717	(0.29%)
Upper leg	1046	(0.10%)	1465	(0.11%)	2511	(0.11%)
Spine	3460	(0.34%)	5015	(0.39%)	8475	(0.37%)
Other	7694	(0.77%)	9974	(0.78%)	17668	(0.77%)
Any fracture	23539	(2.34%)	30864	(2.40%)	54403	(2.37%)

Table 7.4
Cause of Death[1] (Annualized Percentages): CT and OS Participants

Data as of: September 30, 2015; Events through September 30, 2015

	CT		OS		Total	
Number of participants	68132		93676		161808	
Mean Follow-up Time (months)	201.1		194.4		197.2	
Death plus post-WHI deaths	16260	(1.42%)	24936	(1.64%)	41196	(1.55%)
Adjudicated death	15092	(1.32%)	22940	(1.51%)	38032	(1.43%)
Centrally adjudicated death	8575	(0.75%)	4797	(0.32%)	13372	(0.50%)
Locally adjudicated death (final)	1	(<0.01%)	5573	(0.37%)	5574	(0.21%)
Identified by NDI search	6516	(0.57%)	12570	(0.83%)	19086	(0.72%)
Not yet adjudicated	298	(0.03%)	42	(<0.01%)	340	(0.01%)
Form 120 death[2]	870	(0.08%)	1954	(0.13%)	2824	(0.11%)
Cardiovascular						
Atherosclerotic cardiac	2255	(0.20%)	3231	(0.21%)	5486	(0.21%)
Definite CHD deaths after 10/99	816	(0.07%)	941	(0.06%)	1757	(0.07%)
Possible CHD deaths after 10/99	1429	(0.13%)	2254	(0.15%)	3683	(0.14%)
Cerebrovascular	1166	(0.10%)	1838	(0.12%)	3004	(0.11%)
Pulmonary embolism	108	(0.01%)	120	(0.01%)	228	(0.01%)
Other cardiovascular	1324	(0.12%)	2254	(0.15%)	3578	(0.13%)
Unknown cardiovascular	29	(<0.01%)	110	(0.01%)	139	(0.01%)
Total cardiovascular deaths	4882	(0.43%)	7553	(0.50%)	12435	(0.47%)
Cancer						
Breast cancer	427	(0.04%)	975	(0.06%)	1402	(0.05%)
Ovarian cancer	315	(0.03%)	495	(0.03%)	810	(0.03%)
Endometrial cancer	90	(0.01%)	113	(0.01%)	203	(0.01%)
Colorectal cancer	406	(0.04%)	575	(0.04%)	981	(0.04%)
Uterus cancer	48	(<0.01%)	67	(<0.01%)	115	(<0.01%)
Lung cancer	1221	(0.11%)	1603	(0.11%)	2824	(0.11%)
Pancreas cancer	450	(0.04%)	617	(0.04%)	1067	(0.04%)
Lymphoma (NHL only)	227	(0.02%)	358	(0.02%)	585	(0.02%)
Leukemia	226	(0.02%)	292	(0.02%)	518	(0.02%)
Brain cancer	144	(0.01%)	186	(0.01%)	330	(0.01%)
Multiple myeloma	161	(0.01%)	206	(0.01%)	367	(0.01%)
Other cancer	1017	(0.09%)	1395	(0.09%)	2412	(0.09%)
Unknown cancer site	229	(0.02%)	346	(0.02%)	575	(0.02%)
Total cancer deaths	4961	(0.43%)	7228	(0.48%)	12189	(0.46%)
Accident/injury						
Homicide	14	(<0.01%)	20	(<0.01%)	34	(<0.01%)
Accident	393	(0.03%)	570	(0.04%)	963	(0.04%)
Suicide	27	(<0.01%)	51	(<0.01%)	78	(<0.01%)
Other injury	16	(<0.01%)	32	(<0.01%)	48	(<0.01%)
Total accident/injury deaths	450	(0.04%)	673	(0.04%)	1123	(0.04%)
Other						
Alzheimer's disease	643	(0.06%)	1141	(0.08%)	1784	(0.07%)
COPD	652	(0.06%)	895	(0.06%)	1547	(0.06%)
Pneumonia	435	(0.04%)	682	(0.04%)	1117	(0.04%)
Pulmonary fibrosis	176	(0.02%)	223	(0.01%)	399	(0.02%)
Renal failure	234	(0.02%)	363	(0.02%)	597	(0.02%)
Sepsis	401	(0.04%)	553	(0.04%)	954	(0.04%)
Dementia, NOS	694	(0.06%)	1178	(0.08%)	1872	(0.07%)
Amyotrophic Lateral Sclerosis	94	(0.01%)	130	(0.01%)	224	(0.01%)
Parkinson's	157	(0.01%)	261	(0.02%)	418	(0.02%)
Hepatic cirrhosis	96	(0.01%)	126	(0.01%)	222	(0.01%)
Other known cause	1372	(0.12%)	2393	(0.16%)	3765	(0.14%)
Unknown cause	715	(0.06%)	1495	(0.10%)	2210	(0.08%)
Total other cause deaths	5669	(0.50%)	9440	(0.62%)	15109	(0.57%)

[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 8.1
Participation and Vital Status: WHI Participants by Extension Study Participation and Cohort

Data as of: September 30, 2015

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	2316	10.4	7264	10.2	9580	10.2
Alive: Current Participation[1]	18230	81.7	60616	85.1	78846	84.3
Alive: Recent Participation[2]	778	3.5	1706	2.4	2484	2.7
Alive: Past/Unknown Participation[3]	14	0.1	42	0.1	56	0.1
Stopped Follow-Up[4]	435	1.9	890	1.2	1325	1.4
Lost to Follow-Up[5]	543	2.4	733	1.0	1276	1.4

Data as of: September 30, 2015; 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	2368	8.1	6214	7.2	8582	7.4
Alive: Current Participation[1]	25881	88.1	78187	90.9	104068	90.2
Alive: Recent Participation[2]	320	1.1	491	0.6	811	0.7
Alive: Past/Unknown Participation[3]	31	0.1	39	<0.1	70	0.1
Stopped Follow-Up[4]	456	1.6	795	0.9	1251	1.1
Lost to Follow-Up[5]	312	1.1	313	0.4	625	0.5

Data as of: September 30, 2015; 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	2819	6.5	7233	6.3	10052	6.4
Alive: Current Participation[6]	37147	86.1	102265	89.5	139412	88.5
Alive: Recent Participation[7]	343	0.8	420	0.4	763	0.5
Alive: Past/Unknown Participation[8]	20	<0.1	37	<0.1	57	<0.1
Stopped Follow-Up[4]	1701	3.9	2756	2.4	4457	2.8
Lost to Follow-Up[5]	1125	2.6	1601	1.4	2726	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 8.2
Verified Outcomes (Annualized Percentages) by Age at Enrollment for MRC Super Cohort Participants
Data as of: September 30, 2015; Events through September 30, 2015

Outcomes	Total		Age at Enrollment 50-54		55-59		60-69		70-79	
Number randomized	44174		6788		9352		19418		8616	
Mean follow-up (months)	160.8		168.8		169.6		161.8		142.8	
Cardiovascular										
CHD[1]	2974	(0.50%)	194	(0.20%)	360	(0.27%)	1383	(0.53%)	1037	(1.01%)
CHD death[2]	1168	(0.20%)	48	(0.05%)	106	(0.08%)	484	(0.18%)	530	(0.52%)
Clinical MI	2123	(0.36%)	153	(0.16%)	284	(0.21%)	1024	(0.39%)	662	(0.65%)
Angina[3]	1625	(0.47%)	114	(0.20%)	226	(0.30%)	785	(0.52%)	500	(0.76%)
CABG/PTCA	2815	(0.48%)	220	(0.23%)	451	(0.34%)	1433	(0.55%)	711	(0.69%)
Carotid artery disease	481	(0.08%)	20	(0.02%)	67	(0.05%)	269	(0.10%)	125	(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]	2245	(0.38%)	123	(0.13%)	235	(0.18%)	1020	(0.39%)	867	(0.85%)
Stroke	2316	(0.39%)	137	(0.14%)	277	(0.21%)	1087	(0.42%)	815	(0.79%)
PVD	609	(0.10%)	39	(0.04%)	86	(0.07%)	314	(0.12%)	170	(0.17%)
DVT	933	(0.16%)	76	(0.08%)	149	(0.11%)	448	(0.17%)	260	(0.25%)
Pulmonary embolism	741	(0.13%)	62	(0.06%)	127	(0.10%)	358	(0.14%)	194	(0.19%)
DVT/PE	1340	(0.23%)	105	(0.11%)	215	(0.16%)	657	(0.25%)	363	(0.35%)
Coronary disease[5]	6532	(1.10%)	479	(0.50%)	905	(0.68%)	3054	(1.17%)	2094	(2.04%)
Aortic aneurysm[6]	42	(0.02%)	1	(<0.01%	5	(0.01%)	27	(0.03%)	9	(0.03%)
Atrial fibrillation[6]	909	(0.50%)	65	(0.22%)	128	(0.32%)	492	(0.62%)	224	(0.70%)
Valvular heart disease[6]	239	(0.13%)	15	(0.05%)	32	(0.08%)	129	(0.16%)	63	(0.20%)
Total cardiovascular disease[7]	8954	(1.51%)	629	(0.66%)	1234	(0.93%)	4199	(1.60%)	2892	(2.82%)
Cancer										
Breast cancer	2654	(0.45%)	379	(0.40%)	590	(0.45%)	1215	(0.46%)	470	(0.46%)
Invasive breast cancer	2160	(0.36%)	291	(0.30%)	479	(0.36%)	977	(0.37%)	413	(0.40%)
Non-invasive breast cancer	538	(0.09%)	92	(0.10%)	118	(0.09%)	263	(0.10%)	65	(0.06%)
Ovarian cancer	244	(0.04%)	23	(0.02%)	46	(0.03%)	128	(0.05%)	47	(0.05%)
Endometrial cancer[8]	306	(0.05%)	48	(0.05%)	80	(0.06%)	130	(0.05%)	48	(0.05%)
Colorectal cancer	851	(0.14%)	76	(0.08%)	137	(0.10%)	415	(0.16%)	223	(0.22%)
Other cancer[9]	3559	(0.60%)	314	(0.33%)	608	(0.46%)	1749	(0.67%)	888	(0.87%)
Total cancer	7125	(1.20%)	792	(0.83%)	1384	(1.05%)	3383	(1.29%)	1566	(1.53%)
Fractures										
Hip fracture	1201	(0.20%)	36	(0.04%)	88	(0.07%)	500	(0.19%)	577	(0.56%)
Deaths										
Cardiovascular deaths	2450	(0.41%)	105	(0.11%)	222	(0.17%)	993	(0.38%)	1130	(1.10%)
Cancer deaths	2551	(0.43%)	184	(0.19%)	387	(0.29%)	1241	(0.47%)	739	(0.72%)
Other known cause	2092	(0.35%)	113	(0.12%)	204	(0.15%)	938	(0.36%)	837	(0.82%)
Unknown cause	70	(0.01%)	5	(0.01%)	13	(0.01%)	30	(0.01%)	22	(0.02%)
Not yet adjudicated	340	(0.06%)	18	(0.02%)	35	(0.03%)	151	(0.06%)	136	(0.13%)
Total death	7503	(1.27%)	425	(0.45%)	861	(0.65%)	3353	(1.28%)	2864	(2.79%)
Death plus post-WHI deaths	11317	(1.58%)	614	(0.52%)	1221	(0.76%)	4966	(1.58%)	4516	(3.64%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Studies 2005-2015.
[2] "CHD death" includes definite and possible CHD death.
[3] Angina and CHF are not verified outcomes in the WHI Extension Studies 2005-2015. 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 2005-2015.
[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 8.3
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for MRC Super Cohort Participants
Data as of: September 30, 2015; Events through September 30, 2015

	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)	154.7		156.2		148.8		140.6		174.9		161.6	
Cardiovascular												
CHD[1]	10	(0.60%)	26	(0.38%)	875	(0.48%)	187	(0.25%)	1847	(0.58%)	29	(0.56%)
CHD death[2]	6	(0.36%)	10	(0.15%)	431	(0.24%)	57	(0.08%)	657	(0.20%)	7	(0.14%)
Clinical MI	6	(0.36%)	20	(0.29%)	551	(0.30%)	147	(0.19%)	1375	(0.43%)	24	(0.46%)
Angina[3]	7	(0.69%)	14	(0.34%)	548	(0.48%)	160	(0.33%)	884	(0.49%)	12	(0.40%)
CABG/PTCA	10	(0.60%)	22	(0.32%)	707	(0.39%)	250	(0.33%)	1797	(0.56%)	29	(0.56%)
Carotid artery disease	1	(0.06%)	3	(0.04%)	91	(0.05%)	22	(0.03%)	361	(0.11%)	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]	7	(0.42%)	18	(0.26%)	653	(0.36%)	113	(0.15%)	1437	(0.45%)	17	(0.33%)
Stroke	10	(0.60%)	18	(0.26%)	735	(0.41%)	166	(0.22%)	1364	(0.42%)	23	(0.44%)
PVD	3	(0.18%)	6	(0.09%)	220	(0.12%)	23	(0.03%)	353	(0.11%)	4	(0.08%)
DVT	5	(0.30%)	4	(0.06%)	161	(0.09%)	28	(0.04%)	731	(0.23%)	4	(0.08%)
Pulmonary embolism	4	(0.24%)	2	(0.03%)	151	(0.08%)	15	(0.02%)	560	(0.17%)	9	(0.17%)
DVT/PE	8	(0.48%)	4	(0.06%)	251	(0.14%)	37	(0.05%)	1029	(0.32%)	11	(0.21%)
Coronary disease[5]	20	(1.19%)	54	(0.79%)	2000	(1.10%)	499	(0.66%)	3903	(1.22%)	56	(1.08%)
Aortic aneurysm[6]	0	(0.00%)	0	(0.00%)	15	(0.03%)	3	(0.01%)	24	(0.03%)	0	(0.00%)
Atrial fibrillation[6]	0	(0.00%)	2	(0.09%)	110	(0.18%)	56	(0.21%)	731	(0.80%)	10	(0.62%)
Valvular heart disease[6]	1	(0.19%)	1	(0.05%)	37	(0.06%)	16	(0.06%)	181	(0.20%)	3	(0.19%)
Total cardiovascular disease[7]	28	(1.67%)	73	(1.06%)	2799	(1.54%)	678	(0.89%)	5304	(1.65%)	72	(1.39%)
Cancer												
Breast cancer	8	(0.48%)	32	(0.47%)	848	(0.47%)	284	(0.37%)	1464	(0.46%)	18	(0.35%)
Invasive breast cancer	7	(0.42%)	24	(0.35%)	675	(0.37%)	231	(0.30%)	1209	(0.38%)	14	(0.27%)
Non-invasive breast cancer	1	(0.06%)	9	(0.13%)	188	(0.10%)	58	(0.08%)	277	(0.09%)	5	(0.10%)
Ovarian cancer	1	(0.06%)	3	(0.04%)	67	(0.04%)	33	(0.04%)	136	(0.04%)	4	(0.08%)
Endometrial cancer[8]	1	(0.06%)	2	(0.03%)	84	(0.05%)	29	(0.04%)	188	(0.06%)	2	(0.04%)
Colorectal cancer	1	(0.06%)	17	(0.25%)	268	(0.15%)	73	(0.10%)	483	(0.15%)	9	(0.17%)
Other cancer[9]	12	(0.72%)	44	(0.64%)	877	(0.48%)	301	(0.40%)	2293	(0.71%)	32	(0.62%)
Total cancer	22	(1.31%)	95	(1.39%)	2006	(1.11%)	679	(0.89%)	4262	(1.33%)	61	(1.18%)
Fractures												
Hip fracture	4	(0.24%)	8	(0.12%)	113	(0.06%)	59	(0.08%)	1007	(0.31%)	10	(0.19%)
Deaths												
Cardiovascular deaths	11	(0.66%)	16	(0.23%)	860	(0.47%)	138	(0.18%)	1410	(0.44%)	15	(0.29%)
Cancer deaths	8	(0.48%)	34	(0.50%)	739	(0.41%)	240	(0.32%)	1508	(0.47%)	22	(0.42%)
Other known cause	7	(0.42%)	19	(0.28%)	552	(0.30%)	170	(0.22%)	1328	(0.41%)	16	(0.31%)
Unknown cause	0	(0.00%)	1	(0.01%)	20	(0.01%)	13	(0.02%)	34	(0.01%)	2	(0.04%)
Not yet adjudicated	1	(0.06%)	2	(0.03%)	81	(0.04%)	15	(0.02%)	237	(0.07%)	4	(0.08%)
Total Death	27	(1.61%)	72	(1.05%)	2252	(1.24%)	576	(0.76%)	4517	(1.41%)	59	(1.14%)
Death plus post-WHI deaths	34	(1.63%)	119	(1.39%)	3735	(1.60%)	1069	(1.00%)	6267	(1.73%)	93	(1.49%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Studies 2005-2015.
[2] "CHD death" includes definite and possible CHD death.
[3] Angina and CHF are not verified outcomes in the WHI Extension Studies 2005-2015. 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 2005-2015.
[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 8.4
Verified Outcomes (Annualized Percentages) by Age at Enrollment for SRC Super Cohort Participants

Data as of: September 30, 2015; Events through September 30, 2010 and September 30, 2015

	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]										
CHD[2]	5427	(0.39%)	201	(0.11%)	488	(0.17%)	2358	(0.37%)	2380	(0.82%)
CHD death[3]	1883	(0.13%)	49	(0.03%)	103	(0.04%)	689	(0.11%)	1042	(0.36%)
Clinical MI	4044	(0.29%)	159	(0.08%)	398	(0.14%)	1834	(0.29%)	1653	(0.57%)
Angina[4]	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	1114	(0.08%)	48	(0.03%)	117	(0.04%)	522	(0.08%)	427	(0.15%)
Congestive heart failure, WHI[4]	2797	(0.29%)	78	(0.06%)	201	(0.11%)	1096	(0.26%)	1422	(0.68%)
Stroke	4245	(0.30%)	123	(0.06%)	319	(0.11%)	1857	(0.29%)	1946	(0.67%)
PVD	984	(0.07%)	24	(0.01%)	88	(0.03%)	460	(0.07%)	412	(0.14%)
Coronary disease[5]	11764	(0.84%)	455	(0.24%)	1243	(0.43%)	5452	(0.86%)	4614	(1.60%)
Total cardiovascular disease	16744	(1.20%)	626	(0.33%)	1658	(0.58%)	7660	(1.21%)	6800	(2.36%)
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)	173.4		193.6		189.7		174.5		146.6	
Cancer										
Breast cancer	9475	(0.56%)	1173	(0.49%)	1943	(0.54%)	4447	(0.58%)	1912	(0.58%)
Invasive breast cancer	7894	(0.46%)	930	(0.39%)	1601	(0.45%)	3726	(0.48%)	1637	(0.50%)
Non-invasive breast cancer	1703	(0.10%)	260	(0.11%)	368	(0.10%)	778	(0.10%)	297	(0.09%)
Ovarian cancer	887	(0.05%)	99	(0.04%)	172	(0.05%)	415	(0.05%)	201	(0.06%)
Endometrial cancer[6]	1373	(0.08%)	144	(0.06%)	301	(0.08%)	638	(0.08%)	290	(0.09%)
Colorectal cancer	2110	(0.12%)	110	(0.05%)	266	(0.07%)	1026	(0.13%)	708	(0.21%)
Other cancer[7]	11206	(0.66%)	975	(0.41%)	1796	(0.50%)	5464	(0.71%)	2971	(0.90%)
Total cancer	23181	(1.36%)	2330	(0.98%)	4156	(1.16%)	11046	(1.43%)	5649	(1.71%)
Deaths										
Cardiovascular deaths	5803	(0.34%)	126	(0.05%)	330	(0.09%)	2153	(0.28%)	3194	(0.97%)
Cancer deaths	7293	(0.43%)	428	(0.18%)	937	(0.26%)	3470	(0.45%)	2458	(0.74%)
Other known cause	5712	(0.34%)	169	(0.07%)	388	(0.11%)	2355	(0.30%)	2800	(0.85%)
Unknown cause	1903	(0.11%)	71	(0.03%)	143	(0.04%)	866	(0.11%)	823	(0.25%)
Total death	20711	(1.22%)	794	(0.33%)	1798	(0.50%)	8844	(1.14%)	9275	(2.81%)
Death plus post-WHI deaths[8]	29879	(1.54%)	1004	(0.37%)	2326	(0.58%)	12269	(1.40%)	14280	(3.65%)

[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" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Studies 2005-2015.
[3] "CHD death" includes definite and possible CHD death.
[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; Q-wave MI, angina, and congestive heart failure are not collected in the WHI Extension Study 2005-2010.
[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 8.5
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for SRC Super Cohort Participants

Data as of: September 30, 2015; Events through September 30, 2010 and September 30, 2015

	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]				
CHD[2]	26 (0.43%)	87 (0.22%)	5233 (0.39%)	81 (0.40%)
CHD death[3]	13 (0.21%)	30 (0.08%)	1805 (0.14%)	35 (0.17%)
Clinical MI	16 (0.26%)	66 (0.17%)	3906 (0.29%)	56 (0.27%)
Angina[4]	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%)	1078 (0.08%)	19 (0.09%)
Congestive heart failure, WHI[4]	18 (0.41%)	30 (0.11%)	2702 (0.30%)	47 (0.32%)
Stroke	17 (0.28%)	101 (0.26%)	4051 (0.30%)	76 (0.37%)
PVD	6 (0.10%)	8 (0.02%)	951 (0.07%)	19 (0.09%)
Coronary disease[5]	67 (1.10%)	178 (0.46%)	11349 (0.85%)	170 (0.83%)
Total cardiovascular disease	89 (1.46%)	291 (0.75%)	16100 (1.21%)	264 (1.29%)
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)	147.1	150.7	174.6	155.1
Cancer				
Breast cancer	30 (0.42%)	224 (0.49%)	9112 (0.56%)	109 (0.45%)
Invasive breast cancer	25 (0.35%)	185 (0.40%)	7594 (0.47%)	90 (0.37%)
Non-invasive breast cancer	6 (0.08%)	42 (0.09%)	1635 (0.10%)	20 (0.08%)
Ovarian cancer	2 (0.03%)	14 (0.03%)	863 (0.05%)	8 (0.03%)
Endometrial cancer[6]	1 (0.01%)	21 (0.05%)	1327 (0.08%)	24 (0.10%)
Colorectal cancer	10 (0.14%)	40 (0.09%)	2030 (0.13%)	30 (0.12%)
Other cancer[7]	37 (0.52%)	191 (0.42%)	10828 (0.67%)	150 (0.62%)
Total cancer	76 (1.06%)	459 (1.00%)	22349 (1.38%)	297 (1.22%)
Deaths				
Cardiovascular deaths	31 (0.43%)	99 (0.22%)	5575 (0.34%)	98 (0.40%)
Cancer deaths	27 (0.38%)	140 (0.30%)	7032 (0.43%)	94 (0.39%)
Other known cause	42 (0.59%)	83 (0.18%)	5530 (0.34%)	57 (0.23%)
Unknown cause	3 (0.04%)	22 (0.05%)	1840 (0.11%)	38 (0.16%)
Total death	103 (1.44%)	344 (0.75%)	19977 (1.23%)	287 (1.18%)
Death plus post-WHI deaths[8]	171 (1.88%)	637 (1.05%)	28576 (1.55%)	495 (1.64%)

[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" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Studies 2005-2015.
[3] "CHD death" includes definite and possible CHD death.
[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; Q-wave MI, angina and congestive heart failure are not collected in the WHI Extension Study 2005-2010.
[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 8.6
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: September 30, 2015; Events through September 30, 2015

Outcome	Total	Age at Enrollment 50-54	55-59	60-69	70-79
Number randomized	44174	6788	9352	19418	8616
Mean follow-up (months)	160.6	168.5	169.4	161.6	142.6
Angina[1]	3557 (0.60%)	416 (0.44%)	599 (0.45%)	1690 (0.65%)	852 (0.83%)
Diabetes (treated)	7065 (1.20%)	1214 (1.27%)	1595 (1.21%)	3201 (1.22%)	1055 (1.03%)
Hysterectomy	1706 (0.29%)	261 (0.27%)	423 (0.32%)	778 (0.30%)	244 (0.24%)
Osteoarthritis	12374 (2.09%)	2089 (2.19%)	2796 (2.12%)	5442 (2.08%)	2047 (2.00%)
Intestinal polyps	10080 (1.71%)	1556 (1.63%)	2329 (1.76%)	4682 (1.79%)	1513 (1.48%)
Lupus	760 (0.13%)	126 (0.13%)	163 (0.12%)	346 (0.13%)	125 (0.12%)
Hypertension treated w/pills	15764 (2.67%)	2533 (2.66%)	3463 (2.62%)	6938 (2.65%)	2830 (2.76%)
COPD	1463 (0.25%)	185 (0.19%)	346 (0.26%)	721 (0.28%)	211 (0.21%)
Macular degeneration	3509 (0.59%)	253 (0.27%)	531 (0.40%)	1729 (0.66%)	996 (0.97%)
Alzheimer's disease	3015 (0.51%)	144 (0.15%)	330 (0.25%)	1491 (0.57%)	1050 (1.03%)
Parkinson's disease	464 (0.08%)	49 (0.05%)	76 (0.06%)	246 (0.09%)	93 (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)	154.7	156.2	148.3	140.1	174.9	161.5
Angina[1]	18 (1.07%)	25 (0.36%)	1242 (0.69%)	363 (0.48%)	1876 (0.58%)	33 (0.64%)
Diabetes (treated)	24 (1.43%)	83 (1.21%)	2690 (1.49%)	1050 (1.39%)	3155 (0.98%)	63 (1.22%)
Hysterectomy	4 (0.24%)	11 (0.16%)	391 (0.22%)	259 (0.34%)	1026 (0.32%)	15 (0.29%)
Osteoarthritis	46 (2.75%)	161 (2.35%)	3752 (2.08%)	1939 (2.56%)	6361 (1.98%)	115 (2.22%)
Intestinal polyps	32 (1.91%)	102 (1.49%)	3361 (1.86%)	1227 (1.62%)	5278 (1.64%)	80 (1.54%)
Lupus	3 (0.18%)	5 (0.07%)	280 (0.15%)	122 (0.16%)	346 (0.11%)	4 (0.08%)
Hypertension treated w/pills	57 (3.40%)	184 (2.68%)	4286 (2.37%)	2264 (2.99%)	8842 (2.75%)	131 (2.53%)
COPD	8 (0.48%)	8 (0.12%)	357 (0.20%)	138 (0.18%)	939 (0.29%)	13 (0.25%)
Macular degeneration	10 (0.60%)	23 (0.34%)	610 (0.34%)	367 (0.48%)	2474 (0.77%)	25 (0.48%)
Alzheimer's disease	9 (0.54%)	24 (0.35%)	772 (0.43%)	314 (0.41%)	1875 (0.58%)	21 (0.41%)
Parkinson's disease	2 (0.12%)	6 (0.09%)	123 (0.07%)	53 (0.07%)	277 (0.09%)	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 8.7
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: September 30, 2015; Events through September 30, 2015

Outcome	Total		Age at Enrollment 50-54		55-59		60-69		70-79	
Number randomized	117634		14781		22638		53171		27044	
Mean follow-up (months)	173.2		193.4		189.5		174.3		146.2	
DVT, IP/OP	3721	(0.22%)	279	(0.12%)	547	(0.15%)	1834	(0.24%)	1061	(0.32%)
PE, IP/OP	2106	(0.12%)	167	(0.07%)	335	(0.09%)	1064	(0.14%)	540	(0.16%)
PE, IP	1944	(0.11%)	156	(0.07%)	310	(0.09%)	985	(0.13%)	493	(0.15%)
PE, OP	86	(0.01%)	7	(<0.01%)	13	(<0.01%)	52	(0.01%)	14	(<0.01%)
Diabetes (treated)	13790	(0.81%)	1756	(0.74%)	2817	(0.79%)	6533	(0.85%)	2684	(0.81%)
Hysterectomy	6282	(0.37%)	938	(0.39%)	1496	(0.42%)	2894	(0.37%)	954	(0.29%)
Osteoarthritis	33507	(1.97%)	4933	(2.07%)	7275	(2.03%)	15151	(1.96%)	6148	(1.87%)
Intestinal polyps	28093	(1.65%)	3981	(1.67%)	6366	(1.78%)	13052	(1.69%)	4694	(1.42%)
Lupus	1786	(0.11%)	226	(0.09%)	367	(0.10%)	824	(0.11%)	369	(0.11%)
Pills for hypertension	42581	(2.51%)	5188	(2.18%)	8519	(2.38%)	19784	(2.56%)	9090	(2.76%)
COPD	4099	(0.24%)	403	(0.17%)	800	(0.22%)	2216	(0.29%)	680	(0.21%)
Macular degeneration	12414	(0.73%)	750	(0.31%)	1632	(0.46%)	6234	(0.81%)	3798	(1.15%)
Alzheimer's disease	8413	(0.50%)	285	(0.12%)	759	(0.21%)	4204	(0.54%)	3165	(0.96%)
Parkinson's disease	1672	(0.10%)	92	(0.04%)	257	(0.07%)	946	(0.12%)	377	(0.11%)

Outcomes	Race/Ethnicity Am Indian/ Alaskan Native		Asian/Pacific Islander		White		Unknown	
Number randomized	583		3663		111511		1877	
Mean follow-up (months)	146.7		150.1		174.4		154.7	
DVT, IP/OP	15	(0.21%)	25	(0.05%)	3627	(0.22%)	54	(0.22%)
PE, IP/OP	6	(0.08%)	16	(0.03%)	2060	(0.13%)	24	(0.10%)
PE, IP	6	(0.08%)	14	(0.03%)	1903	(0.12%)	21	(0.09%)
PE, OP	0	(0.00%)	2	(<0.01%)	83	(0.01%)	1	(<0.01%)
Diabetes (treated)	98	(1.37%)	469	(1.02%)	12976	(0.80%)	247	(1.02%)
Hysterectomy	15	(0.21%)	115	(0.25%)	6065	(0.37%)	87	(0.36%)
Osteoarthritis	137	(1.92%)	1063	(2.32%)	31765	(1.96%)	542	(2.24%)
Intestinal polyps	118	(1.66%)	713	(1.56%)	26854	(1.66%)	408	(1.69%)
Lupus	15	(0.21%)	36	(0.08%)	1704	(0.11%)	31	(0.13%)
Pills for hypertension	179	(2.51%)	1139	(2.49%)	40616	(2.51%)	647	(2.67%)
COPD	20	(0.28%)	44	(0.10%)	3987	(0.25%)	48	(0.20%)
Macular degeneration	43	(0.60%)	186	(0.41%)	12046	(0.74%)	139	(0.57%)
Alzheimer's disease	31	(0.43%)	144	(0.31%)	8115	(0.50%)	123	(0.51%)
Parkinson's disease	5	(0.07%)	23	(0.05%)	1619	(0.10%)	25	(0.10%)

IP = Inpatient; OP = Outpatient

Table 8.8
Verified Other Cancers (Annualized Percentages): MRC and SRC Super Cohort Participants
Data as of: September 30, 2015; Events through September 30, 2015

	MRC Super Cohort	SRC Super Cohort
Number of participants	44174	117634
Mean follow-up time (months)	160.8	173.4
Overall cancer	7125 (1.20%)	23181 (1.36%)
Primary cancer		
Breast cancer	2654 (0.45%)	9475 (0.56%)
Invasive breast cancer	2160 (0.36%)	7894 (0.46%)
In-situ breast cancer	538 (0.09%)	1703 (0.10%)
Ovarian cancer	244 (0.04%)	887 (0.05%)
Endometrial cancer[1]	304 (0.05%)	1355 (0.08%)
Colorectal cancer	851 (0.14%)	2110 (0.12%)
Other cancer		
Accessory sinus	1 (<0.01%)	9 (<0.01%)
Adrenal gland	4 (<0.01%)	11 (<0.01%)
Anus	23 (<0.01%)	80 (<0.01%)
Appendix	11 (<0.01%)	24 (<0.01%)
Biliary tract, parts of (other/unspecified)	49 (0.01%)	114 (0.01%)
Bladder	207 (0.03%)	653 (0.04%)
Bones/joints/articular cartilage (limbs)	1 (<0.01%)	10 (<0.01%)
Bones/joints/articular cartilage (other)	6 (<0.01%)	14 (<0.01%)
Brain	55 (0.01%)	261 (0.02%)
Cervix	39 (0.01%)	76 (<0.01%)
Central Nervous System (excludes brain)	1 (<0.01%)	3 (<0.01%)
Connective/subcutaneous/soft tissues	34 (0.01%)	121 (0.01%)
Endocrine glands, related structures	0 (0.00%)	3 (<0.01%)
Esophagus	43 (0.01%)	104 (0.01%)
Eye and adnexa	22 (<0.01%)	53 (<0.01%)
Genital organs	17 (<0.01%)	93 (0.01%)
Kidney	173 (0.03%)	459 (0.03%)
Larynx	20 (<0.01%)	30 (<0.01%)
Leukemia	216 (0.04%)	706 (0.04%)
Liver	76 (0.01%)	160 (0.01%)
Lung	971 (0.16%)	2515 (0.15%)
Lymph nodes	1 (<0.01%)	3 (<0.01%)
Lymphoma, Hodgkins	21 (<0.01%)	44 (<0.01%)
Lymphoma, Non-Hodgkins	329 (0.06%)	1236 (0.07%)
Melanoma of the skin	322 (0.05%)	1784 (0.10%)
Multiple myeloma	171 (0.03%)	358 (0.02%)
Oral (mouth)	5 (<0.01%)	26 (<0.01%)
Palate	6 (<0.01%)	24 (<0.01%)
Pancreas	269 (0.05%)	758 (0.04%)
Parotid gland (Stensen's duct)	12 (<0.01%)	43 (<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	83 (0.01%)	175 (0.01%)
Thyroid	94 (0.02%)	366 (0.02%)
Tongue, part of (other/unspecified)	15 (<0.01%)	59 (<0.01%)
Urinary organs (other/unspecified)	9 (<0.01%)	20 (<0.01%)
Uterus, not otherwise specified[1]	24 (<0.01%)	60 (<0.01%)
Other/unknown site of cancer	355 (0.06%)	1089 (0.06%)
Other/unknown cancers reported on death	90 (0.02%)	324 (0.02%)

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

Table 8.9
Self Reported Fractures (Annualized Percentages): MRC and SRC Super Cohort Participants

Data as of: September 30, 2015; Events through September 30, 2015

	MRC Super Cohort		SRC Super Cohort	
Number of participants	44174		117634	
Mean follow-up time (months)	160.8		173.4	
Elbow	586	(0.10%)	1964	(0.12%)
Foot	1794	(0.30%)	6438	(0.38%)
Hand	531	(0.09%)	1677	(0.10%)
Hip	1298	(0.22%)	4734	(0.28%)
Knee	924	(0.16%)	2671	(0.16%)
Lower arm	2857	(0.48%)	9034	(0.53%)
Lower leg	2163	(0.37%)	6731	(0.40%)
Pelvis	616	(0.10%)	2778	(0.16%)
Tailbone	223	(0.04%)	907	(0.05%)
Upper arm	1591	(0.27%)	5126	(0.30%)
Upper leg	530	(0.09%)	1981	(0.12%)
Spine	1624	(0.27%)	6851	(0.40%)
Other	3899	(0.66%)	13769	(0.81%)
Any fracture	12503	(2.11%)	41900	(2.46%)

Table 8.10
Cause of Death (Annualized Percentages): MRC and SRC Super Cohort Participants

Data as of: September 30, 2015; Events through September 30, 2015

	MRC Super Cohort		SRC Super Cohort	
Number of participants	44174		117634	
Mean Follow-up Time (months)	195.2		198.0	
Death plus post-WHI deaths	11317	(1.58%)	29879	(1.54%)
Adjudicated death	10917	(1.52%)	27115	(1.40%)
Centrally adjudicated death	5852	(0.81%)	7520	(0.39%)
Locally adjudicated death	695	(0.10%)	4879	(0.25%)
Identified by NDI search	4370	(0.61%)	14716	(0.76%)
Not yet adjudicated	340	(0.05%)	0	(0.00%)
Form 120 death[1]	60	(0.01%)	2764	(0.14%)
Cardiovascular				
Atherosclerotic cardiac	1743	(0.24%)	3743	(0.19%)
Definite CHD deaths after 10/99	598	(0.08%)	1159	(0.06%)
Possible CHD deaths after 10/99	1145	(0.16%)	2538	(0.13%)
Cerebrovascular	873	(0.12%)	2131	(0.11%)
Pulmonary embolism	75	(0.01%)	153	(0.01%)
Other cardiovascular	979	(0.14%)	2599	(0.13%)
Unknown cardiovascular	35	(<0.01%)	104	(0.01%)
Total cardiovascular deaths	3705	(0.52%)	8730	(0.45%)
Cancer				
Breast cancer	331	(0.05%)	1071	(0.06%)
Ovarian cancer	179	(0.02%)	631	(0.03%)
Endometrial cancer	38	(0.01%)	165	(0.01%)
Colorectal cancer	295	(0.04%)	686	(0.04%)
Uterus cancer	36	(0.01%)	79	(<0.01%)
Lung cancer	846	(0.12%)	1978	(0.10%)
Pancreas cancer	297	(0.04%)	770	(0.04%)
Lymphoma (NHL only)	144	(0.02%)	441	(0.02%)
Leukemia	124	(0.02%)	394	(0.02%)
Brain cancer	62	(0.01%)	268	(0.01%)
Multiple myeloma	127	(0.02%)	240	(0.01%)
Other cancer	649	(0.09%)	1763	(0.09%)
Unknown cancer site	143	(0.02%)	432	(0.02%)
Total cancer deaths	3271	(0.46%)	8918	(0.46%)
Accident/injury				
Homicide	16	(<0.01%)	18	(<0.01%)
Accident	266	(0.04%)	697	(0.04%)
Suicide	18	(<0.01%)	60	(<0.01%)
Other injury	13	(<0.01%)	35	(<0.01%)
Total accident/injury deaths	313	(0.04%)	810	(0.04%)
Other				
Alzheimer's disease	424	(0.06%)	1360	(0.07%)
COPD	420	(0.06%)	1127	(0.06%)
Pneumonia	302	(0.04%)	815	(0.04%)
Pulmonary fibrosis	115	(0.02%)	284	(0.01%)
Renal failure	233	(0.03%)	364	(0.02%)
Sepsis	315	(0.04%)	639	(0.03%)
Dementia, NOS	497	(0.07%)	1375	(0.07%)
Amyotrophic Lateral Sclerosis	42	(0.01%)	182	(0.01%)
Parkinson's	97	(0.01%)	321	(0.02%)
Hepatic cirrhosis	75	(0.01%)	147	(0.01%)
Other known cause	1024	(0.14%)	2741	(0.14%)
Unknown cause	144	(0.02%)	2066	(0.11%)
Total other cause deaths	3688	(0.51%)	11421	(0.59%)

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

Table 9.1
Agreement of the Central Adjudications with Self-Reports for Outcomes Reported in Extension Study 2010-2015

Data as of: September 30, 2015

	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	363	356	98%	220	(62%)	79	(22%)	5	(1%)	52	(15%)	0	(0%)
CABG	140	136	97%	90	(66%)	37	(27%)	3	(2%)	6	(4%)	0	(0%)
PTCA	419	413	99%	272	(66%)	85	(21%)	3	(1%)	52	(13%)	1	(0%)
Carotid artery disease	121	120	99%	62	(52%)	42	(35%)	1	(1%)	15	(13%)	0	(0%)
Stroke	636	612	96%	408	(67%)	62	(10%)	0	(0%)	138	(23%)	4	(1%)
PVD	161	154	96%	67	(44%)	24	(16%)	16	(10%)	47	(31%)	0	(0%)
DVT	425	408	96%	223	(55%)	22	(5%)	77	(19%)	86	(21%)	0	(0%)
Pulmonary embolism	227	220	97%	183	(83%)	6	(3%)	11	(5%)	20	(9%)	0	(0%)
Atrial fibrillation	1239	1207	97%	629	(52%)	169	(14%)	13	(1%)	396	(33%)	0	(0%)
Valvular heart disease	233	230	99%	161	(70%)	42	(18%)	1	(0%)	26	(11%)	0	(0%)
Cancers													
Breast cancer	1865	1833	98%	1789	(98%)	6	(0%)	0	(0%)	38	(2%)	0	(0%)
Ovarian cancer	219	216	99%	139	(64%)	58	(27%)	7	(3%)	12	(6%)	0	(0%)
Endometrial cancer	316	312	99%	250	(80%)	53	(17%)	3	(1%)	6	(2%)	0	(0%)
Cervical cancer	44	43	98%	11	(26%)	23	(53%)	2	(5%)	7	(16%)	0	(0%)
Colorectal cancer	537	523	97%	435	(83%)	56	(11%)	2	(0%)	29	(6%)	1	(0%)
Bladder cancer	215	211	98%	183	(87%)	20	(9%)	1	(0%)	7	(3%)	0	(0%)
Brain cancer	78	74	95%	22	(30%)	29	(39%)	4	(5%)	19	(26%)	0	(0%)
Esophagus cancer	38	38	100%	23	(61%)	7	(18%)	0	(0%)	8	(21%)	0	(0%)
Gallbladder/bile duct cancer	42	40	95%	16	(40%)	20	(50%)	1	(3%)	3	(8%)	0	(0%)
Kidney cancer	169	166	98%	95	(57%)	47	(28%)	3	(2%)	21	(13%)	0	(0%)
Leukemia	185	181	98%	140	(77%)	15	(8%)	3	(2%)	23	(13%)	0	(0%)
Liver cancer	159	156	98%	31	(20%)	88	(56%)	9	(6%)	28	(18%)	0	(0%)
Lung cancer	677	663	98%	556	(84%)	53	(8%)	7	(1%)	47	(7%)	0	(0%)
Lymphoma/Hodgkin's	268	264	99%	206	(78%)	42	(16%)	6	(2%)	10	(4%)	0	(0%)
Melanoma	751	739	98%	533	(72%)	30	(4%)	4	(1%)	172	(23%)	0	(0%)
Multiple myeloma	111	110	99%	92	(84%)	9	(8%)	0	(0%)	9	(8%)	0	(0%)
Pancreas cancer	222	216	97%	181	(84%)	21	(10%)	1	(0%)	13	(6%)	0	(0%)
Stomach cancer	79	78	99%	29	(37%)	31	(40%)	1	(1%)	17	(22%)	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."

Table 9.1 (continued)
Agreement of the Central Adjudications with Self-Reports for Outcomes Reported in Extension Study 2010-2015

Data as of: September 30, 2015

	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]
Thyroid cancer	105	103	98%	85	(83%)	7	(7%)	0	(0%)	11	(11%)	0	(0%)
Other genital organ cancer	71	70	99%	7	(10%)	55	(79%)	5	(7%)	3	(4%)	0	(0%)
Other cancer[4]	473	464	98%	215	(46%)	98	(21%)	17	(4%)	134	(29%)	0	(0%)
Fractures													
Hip fracture	327	304	93%	252	(83%)	0	(0%)	0	(0%)	51	(17%)	1	(0%)
Upper leg fracture[5]	192	175	91%	0	(0%)	69	(39%)	18	(10%)	87	(50%)	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."
[4] Any cancer other than those listed above, excluding non-melanoma skin cancer.
[5] Upper leg fractures are only investigated for possible occurrence of hip fracture.

Table 9.2
Source of Outcomes Identified by Central Adjudications for Outcomes Reported in Extension Study 2010-2015

Data as of: September 30, 2015

	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	421	222	53%	148	35%	51	12%
CABG	98	90	92%	8	8%	0	0%
PTCA	301	273	91%	24	8%	4	1%
Carotid artery disease	54	45	83%	5	9%	4	7%
Stroke	462	411	89%	15	3%	36	8%
PVD	106	69	65%	15	14%	22	21%
DVT	286	221	77%	20	7%	45	16%
Pulmonary embolism	228	176	77%	20	9%	32	14%
Atrial fibrillation	909	581	64%	163	18%	165	18%
Valvular heart disease	239	143	60%	78	33%	18	8%
Cancers							
Breast cancer	1807	1789	99%	12	1%	6	<1%
Ovarian cancer	144	139	97%	4	3%	1	1%
Endometrial cancer	271	250	92%	21	8%	0	0%
Cervical cancer	11	11	100%	0	0%	0	0%
Colorectal cancer	453	433	96%	15	3%	5	1%
Bladder cancer	188	181	96%	6	3%	1	1%
Brain Cancer	22	22	100%	0	0%	0	0%
Kidney cancer	98	96	98%	1	1%	1	1%
Leukemia	160	140	88%	16	10%	4	3%
Liver cancer	38	31	82%	6	16%	1	3%
Lung cancer	581	557	96%	14	2%	10	2%
Lymphoma/Hodgkin's	285	206	72%	76	27%	3	1%
Melanoma	548	533	97%	15	3%	0	0%
Multiple myeloma	103	92	89%	11	11%	0	0%
Pancreas cancer	187	181	97%	3	2%	3	2%
Thyroid cancer	85	85	100%	0	0%	0	0%
Fractures							
Hip fracture	318	251	79%	62	19%	5	2%

[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 10.1
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: September 30, 2015; Events through September 30, 2015

	Total # of Cases (N = 5,766)		# Cases by Age at Enrollment							
			50-54 (N = 323)		55-59 (N = 596)		60-69 (N = 2,637)		70-79 (N = 2,210)	
	N	%	N	%	N	%	N	%	N	%
Heart failure diagnosis										
Definite decompensated	2101	36.4	101	31.3	206	34.6	960	36.4	834	37.7
Possible decompensated	1341	23.3	78	24.1	148	24.8	606	23.0	509	23.0
Chronic stable heart failure	1128	19.6	71	22.0	116	19.5	511	19.4	430	19.5
Heart failure unlikely	789	13.7	47	14.6	84	14.1	380	14.4	278	12.6
Unclassifiable	407	7.1	26	8.0	42	7.0	180	6.8	159	7.2

	# Cases by Race/Ethnicity											
	American Indian/ Alaskan Native (N = 18)		Asian/Pacific Islander (N = 34)		Black/African American (N = 1,625)		Hispanic/ Latino (N = 290)		White (N = 3,756)		Unknown (N = 43)	
	N	%	N	%	N	%	N	%	N	%	N	%
Heart failure diagnosis												
Definite decompensated	14	77.8	14	41.2	589	36.2	95	32.8	1368	36.4	21	48.8
Possible decompensated	0	0	9	26.5	359	22.1	62	21.4	907	24.1	4	9.3
Chronic stable heart failure	3	16.7	2	5.9	357	22.0	56	19.3	699	18.6	11	25.6
Heart failure unlikely	1	5.6	7	20.6	187	11.5	49	16.9	539	14.4	6	14.0
Unclassifiable	0	0	2	5.9	133	8.2	28	9.7	243	6.5	1	2.3

[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 10.2
Comparison of WHI CHF vs. UNC HF[1] for HT, African American and Hispanic (MRC Super Cohort) Participants

Data as of: September 30, 2015; Events through April 8, 2005

	Congestive Heart Failure, WHI			
	No		Yes	
	# of Participants	%	# of Participants	%
All MRC Super Cohort participants				
Heart failure, UNC				
No	42617	99.3	263	21.1
Yes[2]	162	0.4	921	73.9
Unclassifiable[3]	149	0.3	62	5.0
HT participants				
Heart failure, UNC				
No	26310	99.1	81	10.0
Yes[2]	130	0.5	685	85.0
Unclassifiable[3]	101	0.4	40	5.0
MRC Super Cohort participants enrolled in Extension 2010-2015				
Heart failure, UNC				
No	21917	99.6	73	23.8
Yes[2]	33	0.1	214	69.7
Unclassifiable[3]	59	0.3	20	6.5

[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.

Table 10.3
Number of Participants with Definite or Possible Decompensated Heart Failure (HF)
Overall and by Race/Ethnicity

Data as of: September 30, 2015; Events through September 30, 2015

	Total # of Participants[1] (N = 2,246)		Race/Ethnicity White (N = 1,437)		Black (N = 654)		Hispanic (N = 113)	
	N	%	N	%	N	%	N	%
Total								
Definite decompensated HF	1472	65.5	932	64.9	429	65.6	76	67.3
Possible decompensated HF	774	34.5	505	35.1	225	34.4	37	32.7
Type								
Preserved ejection fraction acute decompensated HF	939	41.8	627	43.6	244	37.3	54	47.8
Recovered ejection fraction acute decompensated HF	11	0.5	4	0.3	5	0.8	2	1.8
Systolic acute decompensated HF	806	35.9	490	34.1	255	39.0	39	34.5
Unknown	490	21.8	316	22.0	150	22.9	18	15.9

[1] Refer to tables 8.2 and 8.3 for annualized rates overall, and by age and race/ethnicity.

Table 10.4
Number of UNC Cases Per Participant Adjudicated as Definite or Possible Decompensated Heart Failure (HF) by Cohort

Data as of: September 30, 2015; Events through September 30, 2015

	MRC Super Cohort participants[1]		HT participants		MRC Super Cohort participants enrolled in Extension 2010-2015	
	N	%	N	%	N	%
Total number of cases sent to UNC						
1	1988	62.0	1427	60.6	931	60.4
2	616	19.2	467	19.8	322	20.9
3	281	8.8	212	9.0	129	8.4
4	143	4.5	108	4.6	73	4.7
≥5	178	5.6	142	6.0	86	5.6
Number of confirmed HF[2] cases						
0	960	29.9	678	28.8	473	30.7
1	1574	49.1	1158	49.2	746	48.4
2	391	12.2	301	12.8	179	11.6
3	160	5.0	113	4.8	81	5.3
≥4	121	3.8	106	4.5	62	4.0

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

Table 10.5
Agreement of the UNC Heart Failure (HF) Adjudications with Self-Reports among MRC Super Cohort Participants

Data as of: September 30, 2015

	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	(%)[5]	N	(%)[5]
Overall	6641	6242	94%	5983	(96%)	4592	(77%)	795	(13%)	408	(7%)
By Self Report											
Self-reported HF	2662	2302	86%	2114	(92%)	1708	(81%)	195	(9%)	76	(4%)
No HF self-report	3979	3940	99%	3869	(98%)	2884	(75%)	600	(16%)	332	(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 11.1
Age[1] Distribution by Race/Ethnicity for Active[2] WHI Extension Study 2010-2015 Participants

Data as of: September 30, 2015

Age at start of Extension 2010-2015 (September 30, 2010)	Total (N = 78,846)		Race/Ethnicity: American Indian/ Alaskan Native (N = 263)		Asian/Pacific Islander (N = 1,660)		Black/African American (N = 4,905)		Hispanic/ Latino (N = 2,100)		White (N = 69,003)		Unknown (N = 915)	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
<65	945	1.2	10	3.8	49	3.0	150	3.1	80	3.8	642	0.9	14	1.5
65-69	14322	18.2	66	25.1	387	23.3	1175	24.0	596	28.4	11925	17.3	173	18.9
70-79	41371	52.5	127	48.3	823	49.6	2680	54.6	1062	50.6	36229	52.5	450	49.2
80-89	21121	26.8	60	22.8	375	22.6	852	17.4	353	16.8	19222	27.9	259	28.3
90+	1087	1.4	0	0.0	26	1.6	48	1.0	9	0.4	985	1.4	19	2.1

[1] Age on September 30, 2010.
[2] Vital status is alive with current participation on September 30, 2015.

Table 11.2
Distribution of Aging Indicators Collected During the WHI Extension Study 2010-2015 Stratified by Age at the Beginning of the WHI Extension Study 2010-2015 for WHI Extension Study 2010-2015 Participants

Data as of: September 30, 2015

	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	15	<0.1	1	0.1	2	<0.1	7	<0.1	5	<0.1	0	0.0
Perceived Health Status[1]												
Excellent	8887	9.5	151	14.9	2371	15.5	4597	9.9	1642	5.7	126	5.7
Very good	35412	37.9	471	46.5	6978	45.7	18653	40.2	8760	30.5	550	24.9
Good	34986	37.4	292	28.8	4676	30.6	17116	36.9	11986	41.8	916	41.5
Fair	12198	13.0	83	8.2	1091	7.1	5231	11.3	5300	18.5	493	22.3
Poor	2065	2.2	16	1.6	148	1.0	774	1.7	1005	3.5	122	5.5
Quality of Life[1]												
Worst, 0-3	2806	3.0	17	1.7	237	1.6	986	2.1	1378	4.8	188	8.5
Halfway, 4-6	17279	18.5	129	12.7	1668	10.9	7623	16.4	7167	25.0	692	31.4
Best, 7-10	73464	78.5	867	85.6	13360	87.5	37763	81.4	20147	70.2	1327	60.1
Functional Capacity, ADL Dependencies[1]												
None[2]	59950	64.1	820	80.9	12205	80.0	32756	70.6	13652	47.6	517	23.4
Eating	1479	1.6	5	0.5	75	0.5	426	0.9	830	2.9	143	6.5
Dressing	4441	4.7	13	1.3	177	1.2	1347	2.9	2449	8.5	455	20.6
Transferring	2910	3.1	8	0.8	127	0.8	872	1.9	1601	5.6	302	13.7
Bathing	7127	7.6	20	2.0	263	1.7	2002	4.3	4094	14.3	748	33.9
Grocery Shopping	17799	19.0	51	5.0	845	5.5	5869	12.7	9669	33.7	1365	61.8
Taking Medication	7901	8.4	10	1.0	262	1.7	2240	4.8	4619	16.1	770	34.9
Performance Measures, Rand-36 Scale[1]												
0-25	14063	15.0	60	5.9	807	5.3	4950	10.7	7205	25.1	1041	47.2
25-50	16627	17.8	78	7.7	1532	10.0	7528	16.2	7002	24.4	487	22.1
51-75	23082	24.7	170	16.8	2978	19.5	12036	26.0	7483	26.1	415	18.8
76-100	39755	42.5	705	69.6	9945	65.2	21852	47.1	6990	24.4	263	11.9
Independence[1]												
Supportive Services Availability	19481	20.8	75	7.4	1276	8.4	7158	15.4	9771	34.1	1201	54.5
Supportive Services Use	13033	27.8	33	9.4	454	8.2	3763	17.3	7669	43.4	1114	67.4
Need for nursing care	4285	4.6	7	0.7	257	1.7	1494	3.2	2235	7.8	292	13.2
Use of walking aid [3]	23829	25.5	78	7.7	1177	7.7	8276	17.8	12726	44.4	1572	71.3
Lives alone[4]	31605	41.4	240	27.2	4015	30.0	14864	37.7	11700	54.7	786	61.8
Falls[5]												
None	28063	30.0	364	35.9	5098	33.4	14601	31.5	7557	26.3	443	20.1
One time	18220	19.5	207	20.4	2867	18.8	9184	19.8	5598	19.5	364	16.5
Two times	13128	14.0	122	12.0	2037	13.3	6415	13.8	4211	14.7	343	15.5
Three or more times	34156	36.5	321	31.7	5265	34.5	16180	34.9	11333	39.5	1057	47.9

[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 11.3
Distribution of Aging Indicators Collected During the WHI Extension Study 2010-2015 Stratified by Race/Ethnicity for WHI Extension Study 2010-2015 Participants

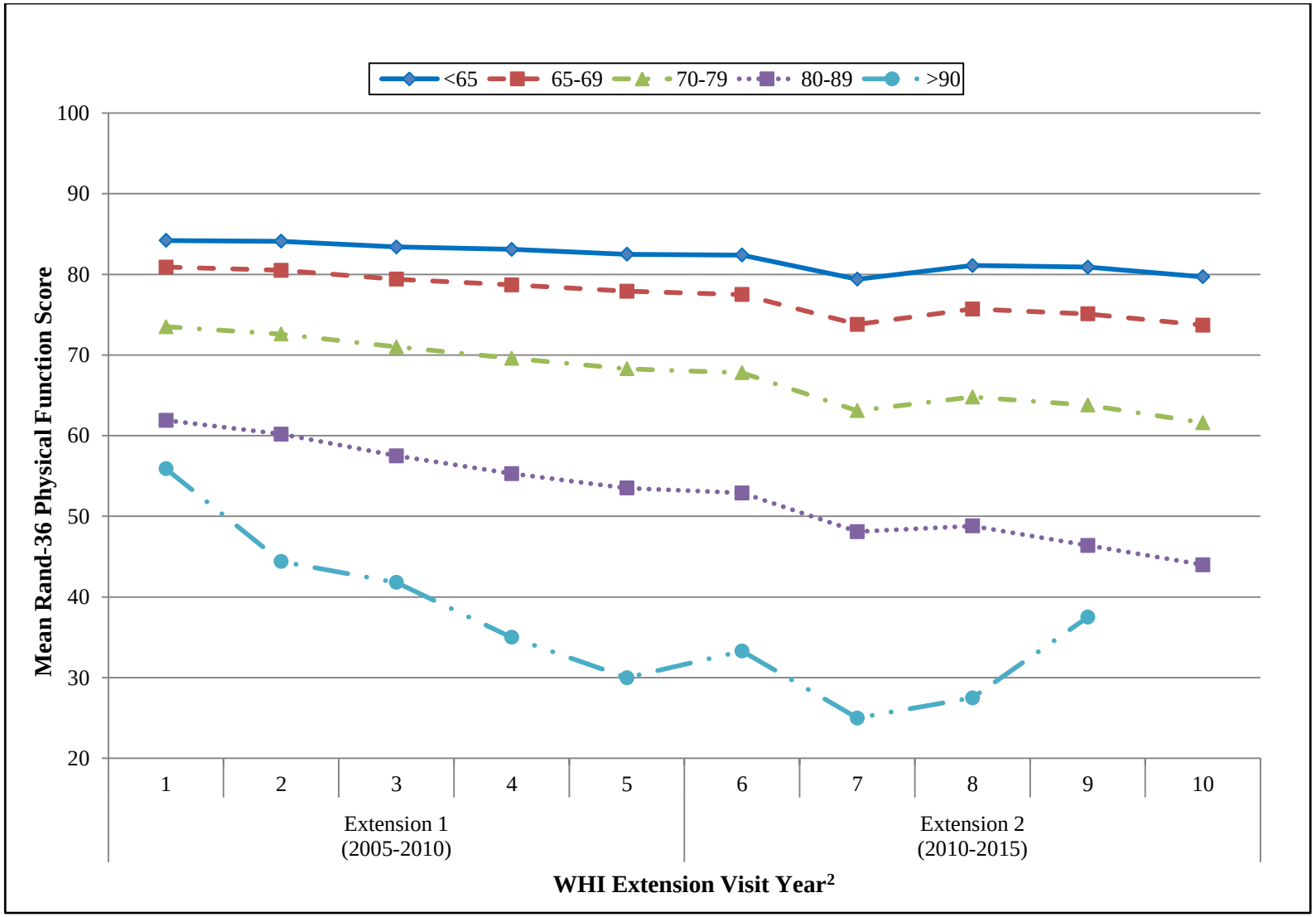
Data as of: September 30, 2015

	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	2	0.1	3	<0.1	0	0.0	9	<0.1	1	0.1
Perceived Health Status[1]												
Excellent	30	9.4	140	7.5	312	5.1	216	8.7	8111	9.9	78	7.1
Very good	117	36.8	704	37.5	1778	29.0	849	34.3	31559	38.7	405	36.8
Good	114	35.8	778	41.4	2826	46.1	950	38.4	29900	36.6	418	38.0
Fair	47	14.8	223	11.9	1087	17.7	401	16.2	10276	12.6	164	14.9
Poor	10	3.1	33	1.8	128	2.1	56	2.3	1802	2.2	36	3.3
Quality of Life[1]												
Worst, 0-3	8	2.5	26	1.4	84	1.4	50	2.0	2599	3.2	39	3.5
Halfway, 4-6	70	22.0	331	17.6	1226	20.0	506	20.5	14908	18.3	238	21.6
Best, 7-10	240	75.5	1521	81.0	4821	78.6	1916	77.5	64142	78.6	824	74.8
Functional Capacity, ADL Dependencies[1]												
None[2]	182	57.2	1305	69.5	3796	61.9	1624	65.7	52368	64.1	675	61.3
Eating	2	0.6	19	1.0	77	1.3	35	1.4	1333	1.6	13	1.2
Dressing	9	2.8	39	2.1	234	3.8	74	3.0	4033	4.9	52	4.7
Transferring	6	1.9	27	1.4	157	2.6	52	2.1	2633	3.2	35	3.2
Bathing	21	6.6	60	3.2	437	7.1	102	4.1	6427	7.9	80	7.3
Grocery Shopping	66	20.8	241	12.8	1177	19.2	373	15.1	15724	19.3	218	19.8
Taking Medication	24	7.5	81	4.3	399	6.5	144	5.8	7174	8.8	79	7.2
Performance Measures, Rand-36 Scale[1]												
0-25	53	16.7	156	8.3	963	15.7	252	10.2	12484	15.3	155	14.1
25-50	58	18.2	245	13.1	1214	19.8	375	15.2	14525	17.8	210	19.1
51-75	67	21.1	450	24.0	1485	24.2	593	24.0	20212	24.8	275	25.0
76-100	140	44.0	1025	54.6	2468	40.3	1249	50.6	34412	42.2	461	41.9
Independence[1]												
Supportive Services Availability	68	21.5	369	19.7	1054	17.2	365	14.8	17383	21.3	242	22.0
Supportive Services Use	44	22.1	186	17.2	768	23.4	236	17.5	11658	28.8	141	22.5
Need for nursing care	13	4.1	35	1.9	185	3.0	49	2.0	3963	4.9	40	3.6
Use of walking aid[3]	94	29.6	327	17.4	1862	30.4	453	18.3	20819	25.5	274	24.9
Lives alone[4]	105	43.9	451	29.0	2100	47.7	644	34.6	27979	41.5	326	37.6
Falls[5]												
None	86	27.0	777	41.3	2264	36.9	806	32.6	23762	29.1	368	33.4
One time	60	18.9	368	19.6	1257	20.5	434	17.6	15893	19.5	208	18.9
Two times	48	15.1	246	13.1	798	13.0	370	15.0	11536	14.1	130	11.8
Three or more times	124	39.0	489	26.0	1817	29.6	862	34.9	30468	37.3	396	35.9

[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 11.1
Mean Rand-36 Physical Function Score Over Time by Age[1] During the WHI Extension Studies 2005-2015

Data as of: September 30, 2015



[1] Age on April 1, 2005.
[2] Insufficient data at year 10 in the age >90 group.

Table 12.1
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 12.2

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 12.3

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 13.1
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 13.2
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 13.3
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 13.4
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 13.4 (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 13.5
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 13.5 (continued)
CBC and Biomarker Results by Race/Ethnicity for Long Life Study Participants

Data as of: September 20, 2013

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

[1] Geometric mean and SD.

Table 13.6
Verified Outcomes by Age at Visit for Long Life Study (LLS) Participants After LLS Blood Draw

Data as of: September 30, 2015; Events through September 30, 2015

		Age at Visit			
Outcomes	**Total**	**63-69**	**70-79**	**80-89**	**≥ 90**
Number randomized	7875	723	3052	3688	412
Cardiovascular					
CHD[1]	126	6	27	77	16
CHD death[2]	51	2	7	28	14
Clinical MI	103	5	25	63	10
CABG/PTCA	76	4	25	43	4
Carotid artery disease	11	0	4	7	0
Heart failure, UNC	59	0	12	41	6
Stroke	103	4	25	65	9
Non-disabling stroke[3]	37	1	8	27	1
Fatal/disabling stroke[3]	34	1	2	23	8
Unknown status from stroke[3]	0	0	0	0	0
PVD	23	0	5	15	3
DVT	70	6	23	36	5
Pulmonary embolism	52	3	18	28	3
Coronary disease	166	7	39	103	17
DVT/PE	98	8	34	51	5
Aortic aneurysm	6	1	1	3	1
Atrial fibrillation	178	4	26	126	22
Valvular heart disease	47	1	9	31	6
Total cardiovascular disease	268	10	66	166	26
Cancer					
Breast cancer	63	7	31	24	1
Invasive breast cancer	53	4	26	21	2
Non-invasive breast cancer	11	3	5	3	0
Ovarian cancer	8	0	3	5	0
Endometrial cancer	6	0	3	3	0
Colorectal cancer	25	1	8	16	0
Other cancer[4]	134	7	43	76	8
Total cancer	208	15	77	108	8
Fractures					
Hip fracture	78	0	7	59	12
Deaths					
Cardiovascular deaths	123	5	15	77	26
Cancer deaths	83	4	23	52	4
Other known cause	110	2	14	76	18
Unknown cause	0	0	0	0	0
Not yet adjudicated	106	1	18	64	23
Total death	422	12	70	269	71

[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 13.7
Verified Outcomes by Race/Ethnicity for Long Life Study (LLS) Participants After LLS Blood Draw

Data as of: September 30, 2015; Events through September 30, 2015

	Race/Ethnicity		
Outcomes	**Black/African American**	**Hispanic/Latino**	**White**
Number randomized	2651	1314	3910
Cardiovascular			
CHD[1]	25	11	90
CHD death[2]	9	2	40
Clinical MI	19	11	73
CABG/PTCA	16	6	54
Carotid artery disease	5	0	6
Heart failure, UNC	14	2	43
Stroke	25	14	64
Non-disabling stroke[3]	3	2	32
Fatal/disabling stroke[3]	1	1	32
Unknown status from stroke[3]	0	0	0
PVD	7	2	14
DVT	22	8	40
Pulmonary embolism	25	4	23
Coronary disease	33	15	118
DVT/PE	38	12	48
Aortic aneurysm	4	0	2
Atrial fibrillation	18	19	141
Valvular heart disease	3	5	39
Total cardiovascular disease	63	31	174
Cancer			
Breast cancer	20	11	32
Invasive breast cancer	13	10	30
Non-invasive breast cancer	7	1	3
Ovarian cancer	2	2	4
Endometrial cancer	1	2	3
Colorectal cancer	4	3	18
Other cancer[4]	33	23	78
Total cancer	56	37	115
Fractures			
Hip fracture	9	7	62
Deaths			
Cardiovascular deaths	21	8	94
Cancer deaths	26	11	46
Other known cause	19	8	83
Unknown cause	0	0	0
Not yet adjudicated	26	9	71
Total death	92	36	294

[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 13.8
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: September 30, 2015; Events through September 30, 2015

Outcome	Total	Age at Visit			
		63-69	70-79	80-89	≥ 90
Number randomized	7875	723	3052	3688	412
Angina	213	16	68	115	14
Diabetes (treated)	268	25	111	122	10
Hysterectomy	57	7	33	17	0
Osteoarthritis	323	37	156	115	15
Intestinal polyps	239	36	135	66	2
Lupus	19	3	10	6	0
Pills for hypertension	275	32	97	131	15
COPD	270	23	95	139	13
Macular degeneration	417	16	109	257	35
Alzheimer's disease	325	7	78	205	35
Parkinson's disease	38	5	15	17	1

Outcome	Race/Ethnicity		
	Black/African American	Hispanic/Latino	White
Number randomized	2651	1314	3910
Angina	78	27	108
Diabetes (treated)	97	43	128
Hysterectomy	17	13	27
Osteoarthritis	116	65	142
Intestinal polyps	96	59	84
Lupus	5	4	10
Pills for hypertension	53	55	167
COPD	88	39	143
Macular degeneration	79	69	269
Alzheimer's disease	85	36	204
Parkinson's disease	17	7	14

Table 14.1
Extension Study 2010-2015 Form 33 – Medical History Update Processing

Data as of September 30, 2015

	a	b	c	d	e	f	g	h	i	j	k	l	m	n	o	p
	Form 33 Collection in PMC Report Window (07-1-14 thru 06-30-15)									**F33 Collection in PMC Expanded Window** (07-01-14 thru 09-30-15)		**Total Ppts w/no F33** i-(j+k)	**Total F33 Col'd out of Windows** h+j+k		**Total F33 Never Col'd** g+l	
Regional Center	Total # of Ppts	Total Collected d+e		Col'd at CCC	Col'd at RC	RC Due			Total not Col'd in Target Window							
						Total	Never Col'd	Col'd Out of Target Window								
	b+f+i	#	%			g+h	f-h		a-b-f	CCC	RC		#	%	#	%
Boston	8,985	8,188	91.1	7,612	576	104	72	32	693	75	180	438	287	3.2	510	5.7
Buffalo	9,145	8,644	94.5	7,689	955	35	25	10	466	50	194	222	254	2.8	247	2.7
Columbus	9,457	9,052	95.7	8,358	694	43	32	11	362	35	125	202	171	1.8	234	2.5
Gainesville	7,535	6,436	85.4	6,206	230	218	145	73	881	79	32	770	184	2.4	915	12.1
Iowa	7,746	7,656	98.8	7,087	569	3	2	1	87	11	48	28	60	0.8	30	0.4
Medstar	4,130	3,818	92.4	3,383	435	25	21	4	287	26	120	141	150	3.6	162	3.9
Pittsburgh	3,771	3,336	88.5	3,131	205	31	24	7	404	29	137	238	173	4.6	262	6.9
Seattle/LaJolla	3,974	3,550	89.3	3,403	147	20	18	2	404	28	116	260	146	3.7	278	7.0
Stanford	13,979	13,405	95.9	12,393	1,012	31	26	5	543	64	215	264	284	2.0	290	2.1
Tucson	5,432	5,056	93.1	4,598	458	44	39	5	332	24	86	222	115	2.1	261	4.8
Wakeforest	8,508	7,818	91.9	7,196	622	105	77	28	585	49	112	424	189	2.2	501	5.9
All RCs	**82,662**	**76,959**	**92.4**	**71,056**	**5,903**	**659**	**481**	**178**	**5,044**	**470**	**1,365**	**3,209**	**2,013**	**2.7**	**3,690**	**4.9**

(a) Total # of Ppts = Target date in report window and follow-up status not 5, 6, or 8. [b+f+i=a]
(b) Total # Collected = Annual F33 collected by CCC or RC, for the ES2 year due. [d+e=b]
(c) Total % Collected = Percent collected of Total Due.
(d) Collected at CCC = Annual F33 collected by CCC, for the ES2 year due.
(e) Collected at RC = Annual F33 collected by RC, for the ES2 year due.
(f) Total RC Due = Target date in report window, and target window high < report window high. [g+h=f]
(g) RC Never Collected = RC due minus RC collected out of window.
(h) RC Collected out of Target Window = RC due and collected out of window; i.e. Form was counted for different ES2 year.
(i) Total not Collected in Target Window = Total Due minus Total Collected minus RC Due. [a-b-f=i]
(j,k) F33 Collection in PMC Expanded Window = Collected any F33 in the past 15 months; if more than one form is collected it is counted under RC.
(l) Total Ppts with no F33 = Totalnot Collected in Target Window minus Any F33 Collected in past 15 months (by CCC or RC). [i-(j+k)=l]
(m,n) Total F33 Collected out of Windows = F33 collected out of PMC Report and Expanded Windows. [h+j+k=m]
(o,p) Total F33 Never Collected = Total F33 never collected within or outside the Report & Expanded Windows. [g+l=o]

Definitions:
Ppt. Target Date = Anniversary of ppt randomization or enrollment date
Ppt. Target Window = Target Date -2 months to target date +12 months (1-yr period)
PMC Report Window = The 1st of this month -15 months to -3 months (1-yr period)
PMC Expanded Report Window = Report run date -15 mos (1-yr and 3-mo period)

Table 14.2
Extension Study 2010-2015 Outcomes Processing Workload

Data as of September 30, 2015

	a	b	c	d	e	f	g	h	i	j	k	l	m	n	o
	Outcomes Cases[1]	**Closed Cases**[2]				**Open Cases**[3]									
		Total Closed		Cases to Forward to CCC		Total Open		No MRs Requested[5]		No MRs Received[6]		Some MRs Received[7]		Open > 12 Mos	Open Queries[8]
Regional Center	Total #	#	%	# Cases[4]	# Not Processed at CCC	#	%	#	% of Open	#	% of Open	#	% of Open	#	#
Boston	2,982	2,885	96.7	2,467	10	97	3.3	5	5.2	50	51.5	42	43.3	10	0
Buffalo	3,937	3,824	97.1	3,437	4	113	2.9	17	15.0	63	55.8	33	29.2	0	2
Columbus	3,611	3,476	96.3	3,217	17	135	3.7	6	4.4	110	81.5	19	14.1	3	3
Gainesville	2,582	2,474	95.8	2,276	7	108	4.2	39	36.1	53	49.1	16	14.8	1	3
Iowa	2,667	2,585	96.9	2,344	34	82	3.1	34	41.5	31	37.8	17	20.7	0	2
Medstar	1,513	1,459	96.4	1,261	5	54	3.6	4	7.4	36	66.7	14	25.9	0	2
Pittsburgh	1,732	1,655	95.6	1,431	9	77	4.4	30	39.0	20	26.0	27	35.1	0	4
Seattle/LaJolla	1,528	1,512	99.0	1,286	3	16	1.0	2	12.5	9	56.3	5	31.3	0	0
Stanford	4,754	4,606	96.9	4,097	6	148	3.1	56	37.8	10	6.8	82	55.4	3	2
Tucson	1,686	1,646	97.6	1,427	22	40	2.4	0	0.0	16	40.0	24	60.0	0	0
Wakeforest	2,703	2,584	95.6	2,292	7	119	4.4	37	31.1	44	37.0	38	31.9	0	1
All RCs	**29,695**	**28,706**	**96.7**	**25,535**	**124**	**989**	**3.3**	**230**	**23.3**	**442**	**44.7**	**317**	**32.1**	**17**	**19**

[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 started for the RCs).
[3] Open cases includes all open cases for ES participants (not restricted to ES2 cases).
[4] Outcomes cases closed with code 9-forward to CCC. Not limited to Form 33 Version 11 (includes ES1 cases); 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.
[8] Open queries >30 days old.

Table 14.3
Extension Study 2010–2015 Workload for Form 33 and Outcomes

Data as of September 30, 2015

	a	b	c	d	e	f	g	h	i	j	k	l
	Historical Form 33 Status (RC only)				**Outcomes Status**			**Combined Form 33 and Outcomes Status**[6] d+g	**MRC Deaths**[7]			**# Open Cases w/ Deaths**[8]
Regional Center	Missing Forms[1] #	Incomp Forms[2] #	Avg # Forms Col'd/Mo[3] #	Est Mos Worth of Missing & Incomp Forms (a+b)/c	Open Cases[4] # Cases	Avg # Cases Closed/Mo[5] # Cases	Est Mos to Catch Up # Months	# Months	Total #	Open #	Open %	#
Boston	72	128	48	4.2	97	65	1.5	5.7	203	43	21.2	51
Buffalo	25	0	80	0.3	113	84	1.3	1.7	295	33	11.2	47
Columbus	32	5	58	0.6	135	73	1.9	2.5	281	38	13.5	56
Gainesville	145	2	19	7.7	108	65	1.7	9.3	238	23	9.7	30
Iowa	2	1	47	0.1	82	59	1.4	1.5	217	17	7.8	18
Medstar	21	1	36	0.6	54	30	1.8	2.4	117	19	16.2	21
Pittsburgh	24	4	17	1.6	77	30	2.6	4.2	106	11	10.4	24
Seattle/LaJolla	18	0	12	1.5	16	36	0.4	1.9	102	4	3.9	7
Stanford	26	10	84	0.4	148	111	1.3	1.8	366	25	6.8	46
Tucson	39	1	38	1.0	40	43	0.9	2.0	150	15	10.0	17
Wakeforest	77	0	52	1.5	119	68	1.8	3.2	235	26	11.1	43
All RCs	**481**	**152**	**45**	**1.8**	**989**	**664**	**1.5**	**3.3**	**2,310**	**254**	**11.1**	**360**

[1] Missing Form 33. From column g, table 1.
[2] Forms with incomplete/missing data in Qxs. 1-16 for MRC participants and Qxs. 1, & 8-16 for SRC participants OR Qxs. 17-end.
[3] Average # of forms collected per month within the last 12 months.
[4] Open cases includes all open cases for ES ppts (not restricted to ES2 cases). From column h, Table 2.
[5] Average # of cases closed per month in the last 12 months.
[6] Combined From 33 and outcomes status serves as a surrogate measure; a standard used by PMC to compare work across RCs.
[7] MRC deaths since Oct. 1, 2010. RCs do not follow-up on SRC deaths.
[8] Open cases with deaths. 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 14.4
Extension Study 2010-2015 Closure Codes for Closed Outcomes Cases

Data as of September 30, 2015

	a	b	c	d	e	f	g	h	i	j	k	l	m
	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)	
Regional Center	#	#	%	#	%	#	%	#	%	#	%	#	%
Boston	2,885	2,467	85.5	193	6.7	186	6.4	8	0.3	30	1.0	1	0.0
Buffalo	3,824	3,437	89.9	251	6.6	63	1.6	15	0.4	56	1.5	2	0.1
Columbus	3,476	3,217	92.5	91	2.6	110	3.2	9	0.3	49	1.4	0	0.0
Gainesville	2,474	2,276	92.0	95	3.8	53	2.1	11	0.4	38	1.5	1	0.0
Iowa	2,585	2,344	90.7	114	4.4	69	2.7	14	0.5	44	1.7	0	0.0
Medstar	1,459	1,261	86.4	109	7.5	36	2.5	27	1.9	26	1.8	0	0.0
Pittsburgh	1,655	1,431	86.5	65	3.9	105	6.3	7	0.4	47	2.8	0	0.0
Seattle/LaJolla	1,512	1,286	85.1	114	7.5	92	6.1	16	1.1	4	0.3	0	0.0
Stanford	4,606	4,097	88.9	304	6.6	139	3.0	11	0.2	55	1.2	0	0.0
Tucson	1,646	1,427	86.7	83	5.0	102	6.2	9	0.5	25	1.5	0	0.0
Wakeforest	2,584	2,292	88.7	139	5.4	90	3.5	14	0.5	47	1.8	2	0.1
All RCs	**28,706**	**25,535**	**89.0**	**1,558**	**5.4**	**1,045**	**3.6**	**141**	**0.5**	**421**	**1.5**	**6**	**0.0**

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

Table 14.5
Extension Study 2010-2015 Participant Follow-up Status[1]

Data as of September 30, 2015

	a	b	c	d	e	f	g	h	i	j	k	l	m	n	o
	# Participants	**Full** (Code 1)		**Partial/ Custom** (Code 4)		**Proxy** (Code 2)		**Lost** (Code 7)		**No Follow-up** (Code 5)		**Absolutely No Contact** (Code 8)		**Deceased** (Code 6)	
Regional Center		#	%	#	%	#	%	#	%	#	%	#	%	#	%
Boston	10,093	8,394	83.2	302	3.0	177	1.8	112	1.1	19	0.2	81	0.8	1,008	10.0
Buffalo	10,394	8,085	77.8	705	6.8	315	3.0	40	0.4	69	0.7	39	0.4	1,141	11.0
Columbus	10,825	8,655	80.0	564	5.2	154	1.4	84	0.8	19	0.2	223	2.1	1,126	10.4
Gainesville	8,478	6,413	75.6	711	8.4	73	0.9	338	4.0	44	0.5	113	1.3	786	9.3
Iowa	8,744	7,530	86.1	77	0.9	134	1.5	5	0.1	67	0.8	93	1.1	838	9.6
Medstar	4,576	3,708	81.0	326	7.1	35	0.8	61	1.3	39	0.9	44	1.0	363	7.9
Pittsburgh	4,202	3,254	77.4	343	8.2	75	1.8	99	2.4	0	0.0	26	0.6	405	9.6
Seattle/LaJolla	4,552	3,688	81.0	109	2.4	126	2.8	51	1.1	25	0.5	32	0.7	521	11.4
Stanford	15,949	12,575	78.8	979	6.1	339	2.1	86	0.5	5	0.0	185	1.2	1,780	11.2
Tucson	6,117	4,958	81.1	288	4.7	76	1.2	110	1.8	0	0.0	66	1.1	619	10.1
Wakeforest	9,637	7,733	80.2	397	4.1	88	0.9	290	3.0	46	0.5	90	0.9	993	10.3
All RCs	**93,567**	**74,993**	**80.1**	**4,801**	**5.1**	**1,592**	**1.7**	**1,276**	**1.4**	**333**	**0.4**	**992**	**1.1**	**9,580**	**10.2**

[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 14.6
Extension Study 2010-2015 Form Collection

Data as of September 30, 2015

	a	b	c	d	e	f	g	h	i	j
	Form 151 - Activities of Daily Living 06-01-14 thru 05-31-15					**Form 157- Supplemental Questionnaire** 06-01-14 thru 05-31-15				
Regional Center	**Total Collected**			**Not Collected**		**Total Collected**			**Not Collected**	
	# Due[1]	# Collected	% Collected	#	%	# Due[1]	# Collected	% Collected	#	%
Boston	9,051	8,126	89.8	925	10.2	7,338	5,730	78.1	1,608	21.9
Buffalo	9,244	8,636	93.4	608	6.6	7,371	5,516	74.8	1,855	25.2
Columbus	9,542	8,539	89.5	1,003	10.5	7,599	6,037	79.4	1,562	20.6
Gainesville	7,568	6,370	84.2	1,198	15.8	6,186	4,733	76.5	1,453	23.5
Iowa	7,807	7,522	96.3	285	3.7	6,350	5,258	82.8	1,092	17.2
Medstar	4,155	3,746	90.2	409	9.8	3,319	2,454	73.9	865	26.1
Pittsburgh	3,788	3,304	87.2	484	12.8	3,179	2,373	74.6	806	25.4
Seattle/LaJolla	3,995	3,440	86.1	555	13.9	3,315	2,535	76.5	780	23.5
Stanford	14,097	13,102	92.9	995	7.1	11,282	8,927	79.1	2,355	20.9
Tucson	5,479	5,011	91.5	468	8.5	4,416	3,376	76.4	1,040	23.6
Wakeforest	8,594	7,765	90.4	829	9.6	6,900	5,166	74.9	1,734	25.1
All RCs	**83,320**	**75,561**	**90.7**	**7,759**	**9.3**	**67,255**	**52,105**	**77.5**	**15,150**	**22.5**

[1] Excludes absolutely no contact and deceased participants
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 14.7
Extension Study 2010-2015 CCC Data Entry Volume
September 1, 2014 to August 31, 2015

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)	71,611	542	0.8	71,069	99.2	568,552	9,536	13.4
115 – Extension 2 Consent Status (1 page)	0	0	0	0	0	0	0	0
120 – Initial Report Of Death (1 page)	815	815	100	0	0	0	0	0
151 – Activities Of Daily Life (2 pages)	71,054	119	0.2	70,935	99.8	70,935	338	0.5
153 – Current Medications and Supplements	2	2	100	0	0	0	0	0
155 – Lifestyle Questionnaire (16 pages)	3	0	0	3	100	24	0	0
156 – Supplemental Questionnaire (4 pages)	3,088	3	0.4	3085	99.6	6,170	9	0.5
157 – Supplemental Questionnaire (2 pages)	67,795	79	0.2	67,716	99.8	135,432	387	0.6
Totals	**214,368**	**1,560**	**.007**	**212,805**	**99.3**	**781,113**	**10,270**	**.05**
Outcomes Data Entry								
121 – Report of Cardiovascular Outcomes (7 pages)[5]	716	1,431	100	0	0	0	0	0
123 – Report of Fracture Outcome (1 page)[5]	114	228	100	0	0	0	0	0
124 – Report of Death (Final) (3 pages)[5]	548	1,096	100	0	0	0	0	0
126 – Report of Venous Thromboembolic Disease (2 pages)[5]	145	290	100	0	0	0	0	0
130 – Report of Cancer Outcome (4 pages)[5]	1,270	2,526	100	0	0	0	0	0
132 – Report of Stroke Outcome (3 pages)[5]	1,040	2,033	100	0	0	0	0	0
Totals	**3,833**	**7,604**	**2**	**212,805**	**66.8**	**781,113**	**10,270**	**2.7**

[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 14.8
Extension Study 2010-2015 Outcomes Cases Received from RCs

Data as of 09-30-15

	Total # Cases in WHIX	Cases at RCs Not Yet Sent to CCC				Cases at CCC					
						Referred From			Cases From RCs and Referrals	QA Cases	# Cases to Adjudicate
		< 14 Days	14-29 Days	≥ 30 Days	Total (not sent)	Rec'd from RCs	From F125 Review	Other Committee			
ES 2010-2015 (ES2)[1]											
Cancers[2]	7,581	30	3	5	38	7,487	19	37	7,543	513	8,057
CVD[3]	5,022	29	3	1	33	4,421	302	266	4,989	565	5,556
Heart Failure	1,745	4		2	6	894	155	690	1,739	14	1,753
Fatal Events[4]	1,997	22	1	1	24	1,968		5	1,973	239	2,212
Stroke	1,315	3			3	1,155	100	57	1,312	119	1,432
Fracture	602	6			6	578	5	13	596	40	636
Extension Total	**18,262**	**94**	**7**	**9**	**110**	**16,503**	**581**	**1,068**	**18,152**	**1,490**	**19,646**
Form 125-Hospitalization	6,297	31			31	6,266			6,266	32	6,298
Retrospective Cases[5]											
HF (UNC)[6]	4,499					4,497			4,499		4,501
Stroke[7]	3,285					3,282			3,285		3,325

[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 aneurysm, heart valve, and atrial fibrillation (A Fib)
[4] Excludes NDI Deaths
[5] Retrospective cases identified during Extension Study 2005 and scheduled to be adjudicated during Extension Study 2010
[6] Pre-Extension-2 Cases forwarded to UNC
[7] Includes DM and OS strokes

Table 14.9
Extension Study 2010-2015 Status of Outcomes Adjudication

Data as of 09-30-15

	# 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]	7,543	7,478	66		57		9		
CVD[3]	4,989	4,896	93	3	82	3	1	2	4
Heart Failure	1,739	1,298	441	257	184				
Fatal Events[4]	1,973	1,916	57		54	2			1
Stroke	1,312	1,283	29	1	20	4	1	4	2
Fracture	596	570	26		25				1
Extension Total	**18,152**	**17,441**	**712**	**261**	**422**	**9**	**11**	**6**	**8**
Form 125-Hospitalization	6,266	6,256	10		2		6		2
Retrospective Cases[5]									
HF (UNC)[6]	4,499	4,498	1						1
Stroke[7]	3,285	2,494	791	606	174	2			8

[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 aneurysm, heart valve, and atrial fibrillation (A Fib)

[4] Excludes NDI Deaths

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

[6] Pre-Extension-2 Cases forwarded to UNC

[7] Includes DM and OS strokes prior to Sept. 12, 2005

Table 15.1
CT Outcomes Cases with Remaining Blood Sample by Estimated Volume (in ml): Baseline and AV1

				Volume of Designated Blood Components (mL)** as of 10/2015																	
Visit	**Outcome As of 9/15**	**Total *** Ppts**	**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	5054	Serum	23	0%	1	0%	6	0%	42	1%	37	1%	113	2%	176	3%	673	13%	466	9%	3517	70%
			Citrate	44	1%	1	0%	12	0%	51	1%	33	1%	293	6%	43	1%	4440	88%	7	0%	130	3%
			EDTA	76	2%	1	0%	2	0%	31	1%	26	1%	343	7%	122	2%	4307	85%	18	0%	128	3%
	Breast Cancer Invasive	4146	Serum	17	0%			5	0%	37	1%	35	1%	102	2%	157	4%	598	14%	370	9%	2825	68%
			Citrate	37	1%			9	0%	44	1%	30	1%	239	6%	37	1%	3634	88%	7	0%	109	3%
			EDTA	64	2%	1	0%	2	0%	22	1%	22	1%	283	7%	104	3%	3526	85%	15	0%	107	3%
	Colorectal Cancer	1347	Serum	4	0%			3	0%	20	1%	12	1%	56	4%	79	6%	294	22%	171	13%	708	53%
			Citrate	14	1%	2	0%	5	0%	14	1%	9	1%	83	6%	27	2%	1165	86%	1	0%	27	2%
			EDTA	25	2%	1	0%	1	0%	12	1%	7	1%	107	8%	49	4%	1112	83%	6	0%	27	2%
	Endometrial Cancer	704	Serum	6	1%	1	0%	1	0%	8	1%	4	1%	9	1%	14	2%	64	9%	53	8%	544	77%
			Citrate	8	1%			2	0%	6	1%	7	1%	40	6%	3	0%	626	89%			12	2%
			EDTA	9	1%					4	1%	7	1%	47	7%	10	1%	613	87%	3	0%	11	2%
	Ovarian Cancer	454	Serum	1	0%			2	0%	5	1%	2	0%	13	3%	8	2%	46	10%	59	13%	318	70%
			Citrate	6	1%			1	0%	7	2%	4	1%	28	6%			395	87%	1	0%	12	3%
			EDTA	3	1%					8	2%	3	1%	34	7%	7	2%	385	85%	2	0%	12	3%
	CHD	4243	Serum	23	1%	4	0%	25	1%	71	2%	99	2%	178	4%	238	6%	489	12%	535	13%	2581	61%
			Citrate	38	1%	17	0%	36	1%	193	5%	110	3%	361	9%	85	2%	3280	77%	9	0%	114	3%
			EDTA	69	2%	12	0%	29	1%	134	3%	227	5%	421	10%	344	8%	2862	67%	36	1%	109	3%
	Clinical MI	3019	Serum	19	1%	3	0%	17	1%	50	2%	80	3%	134	4%	180	6%	336	11%	387	13%	1813	60%
			Citrate	29	1%	14	0%	28	1%	150	5%	84	3%	248	8%	61	2%	2313	77%	7	0%	85	3%
			EDTA	55	2%	9	0%	22	1%	109	4%	169	6%	300	10%	246	8%	2009	67%	16	1%	84	3%
	DVT/PE	1245	Serum	4	0%	1	0%	6	0%	19	2%	20	2%	67	5%	117	9%	279	22%	224	18%	508	41%
			Citrate	12	1%	5	0%	25	2%	113	9%	112	9%	94	8%	19	2%	824	66%	2	0%	39	3%
			EDTA	15	1%	4	0%	3	0%	41	3%	32	3%	280	22%	66	5%	756	61%	8	1%	40	3%
	Stroke	3156	Serum	21	1%	4	0%	12	0%	39	1%	54	2%	142	4%	260	8%	417	13%	322	10%	1885	60%
			Citrate	48	2%	13	0%	29	1%	224	7%	102	3%	300	10%	126	4%	2241	71%	7	0%	66	2%
			EDTA	57	2%	4	0%	3	0%	58	2%	65	2%	432	14%	141	4%	2309	73%	22	1%	65	2%
	Hip Fracture	1938	Serum	10	1%	1	0%	4	0%	21	1%	21	1%	58	3%	96	5%	246	13%	284	15%	1197	62%
			Citrate	21	1%	4	0%	9	0%	45	2%	38	2%	112	6%	27	1%	1624	84%	6	0%	52	3%
			EDTA	26	1%	1	0%	5	0%	25	1%	34	2%	162	8%	107	6%	1491	77%	35	2%	52	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 15.1 (continued)
CT Outcomes Cases with Remaining Blood Sample by Estimated Volume (in ml): Baseline and AV1

				Volume of Designated Blood Components (mL)** as of 10/2015																	
Visit	**Outcome As of 9/15**	**Total *** Ppts**	**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**	**%**
AVI	Breast Cancer	4853	Serum	264	5%			2	0%	24	0%	11	0%	51	1%	76	2%	413	9%	432	9%	3580	74%
			Citrate	278	6%			4	0%	51	1%	14	0%	296	6%	35	1%	4168	86%			7	0%
			EDTA	320	7%					24	0%	16	0%	320	7%	25	1%	4140	85%	1	0%	7	0%
	Breast Cancer Invasive	3988	Serum	232	6%			2	0%	21	1%	11	0%	44	1%	70	2%	350	9%	406	10%	2852	72%
			Citrate	242	6%			2	0%	43	1%	12	0%	246	6%	27	1%	3409	85%			7	0%
			EDTA	275	7%					19	0%	13	0%	269	7%	19	0%	3385	85%	1	0%	7	0%
	Colorectal Cancer	1268	Serum	79	6%			1	0%	10	1%	5	0%	19	1%	13	1%	185	15%	49	4%	907	72%
			Citrate	84	7%	1	0%	3	0%	14	1%	7	1%	88	7%	15	1%	1055	83%			1	0%
			EDTA	93	7%			1	0%	8	1%	5	0%	96	8%	8	1%	1056	83%			1	0%
	Endometrial Cancer	664	Serum	30	5%					5	1%			9	1%	3	0%	55	8%	18	3%	544	82%
			Citrate	37	6%					9	1%	3	0%	37	6%	2	0%	575	87%			1	0%
			EDTA	35	5%			1	0%	1	0%	2	0%	47	7%	2	0%	575	87%			1	0%
	Ovarian Cancer	434	Serum	18	4%					4	1%			2	0%	1	0%	48	11%	28	6%	333	77%
			Citrate	20	5%	1	0%	1	0%	3	1%	3	1%	35	8%	2	0%	369	85%				
			EDTA	25	6%			1	0%	1	0%	3	1%	38	9%	3	1%	363	84%				
	CHD	4027	Serum	283	7%			2	0%	25	1%	7	0%	46	1%	47	1%	367	9%	239	6%	3011	75%
			Citrate	317	8%	12	0%	16	0%	127	3%	72	2%	342	8%	56	1%	3083	77%			2	0%
			EDTA	334	8%	4	0%	12	0%	56	1%	125	3%	390	10%	85	2%	3007	75%	12	0%	2	0%
	Clinical MI	2838	Serum	179	6%			2	0%	18	1%	6	0%	33	1%	34	1%	260	9%	157	6%	2149	76%
			Citrate	209	7%	10	0%	13	0%	99	3%	57	2%	231	8%	40	1%	2177	77%			2	0%
			EDTA	221	8%	4	0%	7	0%	45	2%	99	3%	273	10%	66	2%	2112	74%	9	0%	2	0%
	DVT/PE	1159	Serum	52	4%					3	0%	1	0%	12	1%	15	1%	131	11%	105	9%	840	72%
			Citrate	66	6%	4	0%	14	1%	63	5%	74	6%	105	9%	16	1%	816	70%			1	0%
			EDTA	66	6%	1	0%			29	3%	10	1%	215	19%	12	1%	825	71%			1	0%
	Stroke	3013	Serum	180	6%	2	0%	1	0%	18	1%	4	0%	27	1%	60	2%	284	9%	200	7%	2237	74%
			Citrate	199	7%	9	0%	25	1%	159	5%	69	2%	318	11%	104	3%	2129	71%			1	0%
			EDTA	218	7%	1	0%	3	0%	36	1%	28	1%	384	13%	25	1%	2312	77%	5	0%	1	0%
	Hip Fracture	1888	Serum	95	5%	1	0%			11	1%	6	0%	23	1%	28	1%	194	10%	134	7%	1396	74%
			Citrate	111	6%	3	0%	3	0%	45	2%	24	1%	113	6%	26	1%	1562	83%			1	0%
			EDTA	119	6%	1	0%	4	0%	16	1%	10	1%	151	8%	14	1%	1570	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 15.2
OS Outcomes Cases with Remaining Blood Sample by Estimated Volume (in ml): Baseline and AV3

Visit	Outcome As of 9/15	Total*** Ppts	Blood Type	Volume of Designated Blood Components (mL)** as of 10/2015																	
				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	7075	Serum	19	0%	4	0%	7	0%	39	1%	34	0%	224	3%	276	4%	677	10%	679	10%	5116	72%
			Citrate	74	1%	2	0%	5	0%	50	1%	52	1%	326	5%	642	9%	5674	80%	113	2%	137	2%
			EDTA	144	2%	2	0%	7	0%	70	1%	105	1%	480	7%	831	12%	5033	71%	264	4%	139	2%
	Breast Cancer Invasive	5908	Serum	17	0%	4	0%	5	0%	33	1%	28	0%	200	3%	261	4%	608	10%	601	10%	4151	70%
			Citrate	66	1%	2	0%	5	0%	42	1%	45	1%	274	5%	568	10%	4693	79%	97	2%	116	2%
			EDTA	121	2%	2	0%	7	0%	61	1%	91	2%	392	7%	726	12%	4134	70%	256	4%	118	2%
	Colorectal Cancer	1614	Serum	6	0%	2	0%	2	0%	17	1%	27	2%	103	6%	130	8%	301	19%	214	13%	812	50%
			Citrate	20	1%			6	0%	23	1%	34	2%	174	11%	308	19%	955	59%	50	3%	44	3%
			EDTA	41	3%	4	0%	11	1%	73	5%	97	6%	521	32%	321	20%	494	31%	11	1%	41	3%
	Endometrial Cancer	976	Serum	10	1%	5	1%	14	1%	37	4%	42	4%	150	15%	118	12%	170	17%	134	14%	296	30%
			Citrate	13	1%					6	1%	13	1%	60	6%	115	12%	736	75%	14	1%	19	2%
			EDTA	24	2%					15	2%	21	2%	61	6%	87	9%	726	74%	23	2%	19	2%
	Ovarian Cancer	677	Serum	1	0%	2	0%	4	1%	18	3%	20	3%	78	12%	68	10%	132	19%	114	17%	240	35%
			Citrate	4	1%					5	1%	2	0%	32	5%	39	6%	575	85%	5	1%	15	2%
			EDTA	11	2%	1	0%	1	0%	7	1%	13	2%	44	6%	85	13%	481	71%	20	3%	14	2%
	CHD	4668	Serum	20	0%	5	0%	18	0%	57	1%	61	1%	302	6%	179	4%	343	7%	537	12%	3146	67%
			Citrate	70	1%	10	0%	39	1%	149	3%	151	3%	524	11%	720	15%	2850	61%	39	1%	116	2%
			EDTA	112	2%	5	0%	28	1%	180	4%	273	6%	751	16%	969	21%	2032	44%	197	4%	121	3%
	Clinical MI	3148	Serum	13	0%	4	0%	13	0%	43	1%	44	1%	232	7%	126	4%	249	8%	397	13%	2027	64%
			Citrate	50	2%	7	0%	36	1%	116	4%	120	4%	413	13%	515	16%	1784	57%	30	1%	77	2%
			EDTA	82	3%	4	0%	25	1%	130	4%	215	7%	550	17%	681	22%	1246	40%	133	4%	82	3%
	Stroke	3405	Serum	6	0%	6	0%	9	0%	31	1%	40	1%	135	4%	92	3%	293	9%	506	15%	2287	67%
			Citrate	39	1%	7	0%	18	1%	116	3%	218	6%	516	15%	422	12%	1952	57%	38	1%	79	2%
			EDTA	63	2%	15	0%	53	2%	332	10 %	365	11%	491	14%	589	17%	1275	37%	138	4%	84	2%
	Hip Fracture	2218	Serum	7	0%	5	0%	20	1%	61	3%	82	4%	150	7%	184	8%	243	11%	247	11%	1219	55%
			Citrate	25	1%			2	0%	15	1%	24	1%	132	6%	173	8%	1775	80%	31	1%	41	2%
			EDTA	49	2%			2	0%	39	2%	53	2%	182	8%	266	12%	1541	69%	47	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 15.2 (continued)
OS Outcomes Cases with Remaining Blood Sample by Estimated Volume (in ml): Baseline and AV3

				Volume of Designated Blood Components (mL)** as of 10/2015																	
Visit	Outcome As of 9/15	Total*** Ppts	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	5467	Serum	644	12%					12	0%			31	1%	4	0%	74	1%	40	1%	4662	85%
			Citrate	683	12%					26	0%			59	1%	5	0%	4693	86%			1	0%
			EDTA	728	13%	1	0%	1	0%	28	1%	7	0%	120	2%	234	4%	4275	78%	71	1%	4	0%
	Breast Cancer Invasive	4566	Serum	556	12%					11	0%			27	1%	4	0%	61	1%	33	1%	3874	85%
			Citrate	584	13%					21	0%			51	1%	4	0%	3905	86%			1	0%
			EDTA	621	14%	1	0%	1	0%	26	1%	6	0%	99	2%	220	5%	3519	77%	69	2%	4	0%
	Colorectal Cancer	1280	Serum	189	15%			1	0%	3	0%	4	0%	5	0%	4	0%	25	2%	89	7%	960	75%
			Citrate	194	15%					3	0%			20	2%	10	1%	1052	82%			1	0%
			EDTA	210	16%					11	1%	1	0%	38	3%	80	6%	936	73%	3	0%	1	0%
	Endometrial Cancer	763	Serum	100	13%									5	1%			14	2%	8	1%	636	83%
			Citrate	105	14%					4	1%			10	1%			643	84%			1	0%
			EDTA	111	15%					2	0%	1	0%	13	2%	15	2%	615	81%	4	1%	1	0%
	Ovarian Cancer	540	Serum	85	16%									2	0%			17	3%	26	5%	410	76%
			Citrate	87	16%					3	1%			4	1%			446	83%				
			EDTA	87	16%					1	0%	2	0%	7	1%	27	5%	409	76%	7	1%		
	CHD	3901	Serum	668	17%					9	0%	1	0%	24	1%	5	0%	69	2%	73	2%	3052	78%
			Citrate	696	18%					10	0%			105	3%	7	0%	3081	79%			2	0%
			EDTA	726	19%	1	0%			31	1%	26	1%	327	8%	339	9%	2441	63%	9	0%	2	0%
	Clinical MI	2506	Serum	374	15%					3	0%	1	0%	17	1%	5	0%	46	2%	46	2%	2014	80%
			Citrate	392	16%					6	0%			81	3%	6	0%	2021	81%				
			EDTA	412	16%	1	0%			24	1%	22	1%	251	10%	270	11%	1523	61%	4	0%		
	Stroke	2815	Serum	469	17%					7	0%			25	1%	2	0%	40	1%	31	1%	2241	80%
			Citrate	491	17%					14	0%			47	2%	3	0%	2259	80%			1	0%
			EDTA	527	19%					15	1%	1	0%	81	3%	78	3%	2101	75%	11	0%	1	0%
	Hip Fracture	1925	Serum	295	15%					1	0%			9	0%			23	1%	19	1%	1578	82%
			Citrate	312	16%					6	0%			20	1%	17	1%	1568	81%			1	0%
			EDTA	326	17%	1	0%			9	0%	2	0%	40	2%	44	2%	1497	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 15.3
CT and OS Outcomes Cases with DNA* Available
Data as of 10/2015

		No DNA Available[1]		< 25 ug Extracted, no Buffy Coat Available for Extraction[2]		< 25 ug Extracted, with Buffy Coat Available for Extraction[3]		> 25 ug Extracted[4]	
Outcome As of 9/2015	**Ppts**	**#**	**%**	**#**	**%**	**#**	**%**	**#**	**%**
CT									
Breast Cancer	5054	74	1.5%	40	0.8%	884	17.5%	4056	80.3%
Breast Cancer Invasive	4146	57	1.4%	38	0.9%	529	12.8%	3522	84.9%
CHD	4243	84	2%	58	1.4%	446	10.5%	3655	86.1%
Clinical MI	3019	55	1.8%	47	1.6%	246	8.1%	2671	88.5%
Colorectal Cancer	1347	19	1.4%	18	1.3%	173	12.8%	1137	84.4%
Endometrial Cancer	704	12	1.7%	7	1%	124	17.6%	561	79.7%
Hip Fracture	1938	45	2.3%	48	2.5%	125	6.4%	1720	88.8%
Ovarian Cancer	454	5	1.1%	3	0.7%	71	15.6%	375	82.6%
Stroke	3156	47	1.5%	81	2.6%	255	8.1%	2773	87.9%
OS									
Breast Cancer	7075	65	0.9%	17	0.2%	1373	19.4%	5620	79.4%
Breast Cancer Invasive	5908	59	1%	15	0.3%	867	14.7%	4967	84.1%
CHD	4668	60	1.3%	27	0.6%	255	5.5%	4326	92.7%
Clinical MI	3148	33	1%	20	0.6%	80	2.5%	3015	95.8%
Colorectal Cancer	1614	22	1.4%	7	0.4%	175	10.8%	1410	87.4%
Endometrial Cancer	976	9	0.9%	1	0.1%	156	16%	810	83%
Hip Fracture	2218	24	1.1%	14	0.6%	188	8.5%	1992	89.8%
Ovarian Cancer	677	7	1%	4	0.6%	147	21.7%	519	76.7%
Stroke	3405	45	1.3%	19	0.6%	272	8%	3069	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 15.4
Number of Funded Core, BAA, and Ancillary Studies
Using Blood Sample
by Outcome[1] and Specimen Type

	Serum/Plasma Only	Both Serum/Plasma and DNA	DNA Only	GWAS[2]	Urine	RBCs	Total[3]
Cancer							
Bladder Cancer			2	1			2
Breast Cancer	11	1	10	4	4		26
Colon Cancer	1		1	1			2
Colorectal Cancer	8	4	5	1		1	17
Endometrial Cancer	3		2				5
Gastric/Esophageal Cancer	1	1		1			2
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	2	3	2	2		1	7
Ovarian Cancer	5		1				6
Cardiovascular							
CHD	16	4	6	2		1	26
Hypertension		1					1
Stroke	11	2	7	3		1	20
VTE	2	1	2	1			5
Fracture							
Elbow, Lower Humerus	1						1
Hip Fracture	5	2	2	1		1	10
Spine	2						2
Overall Fracture	1						1
Other							
Cognitive decline		1				1	2
Eye Disease	1		1				2
Frailty-disability		1					1
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 16.1
Approved Core Studies[1]

Ref #	Title	Status	Study Population	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	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; CRP; Cholesterol; 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	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	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	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 16.1 (continued)
Approved Core Studies[1]

Ref #	Title	Status	Study Population	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	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; ITGA2807CTDNA 3ug: PAI-1; PROT; FXIII val34leu; FV Leiden; PRO2; FV-HR2; MTHFR EDTA .25ml: NMR LipidsEDTA 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	DNA 2ug: Pooled GWAS	1104, 1653
W8	Nutritional biomarkers study (NBS)	Complete	DM	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); 24hr Urine 4ml: Urinary potassium; Urinary Sodium	464, 624, 646, 831, 941, 945, 2106

Table 16.1 (continued)
Approved Core Studies[1]

Ref #	Title	Status	Study Population	Analytes/Data	Publications (All time)
				DLW Spot Urine 4ml: Fluid; Total Body Water; TEE-USRQ; TEE-INTVRQ; EE3/5; O18-SU3; DE-SU4; DE-SU5; DE-SU6; O18CONST; RCO2-3/5; Fat-free mass; r-H2O; % Fat; O18-SU4; DSRATIO; Nd; RCO2-4/6; TEE-CONRQ; DE-SU3; H2CONST; No; EE4/6; O18-SU5; O18-SU6; LOT; 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	
W9	Biological markers of the effect of HT on risk of fractures in the Women's Health Initiative clinical trial	Complete	HT Fracture - Hip:750 Controls:750 *Cases=248 hip fractures + 502 non-spine fractures	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	Complete	HT Breast Cancer:755 Controls:755 *498 E+P and 260 E-Alone cases through Sept 2005; B+Y1	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 16.1 (continued)
Approved Core Studies[1]

Ref #	Title	Status	Study Population	Analytes/Data	Publications (All time)
W11	CVD biomarkers - Phase II: strokes after Feb. 2001	Complete	HT Stroke:326 Controls:326 *108 new E+P cases up to July 2002, 174 E alone cases up to March 2004; B+Y1	Citrate .35ml: TFPI activity; TFPI, total; TFPI, free 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	Complete	HT CHD:390 Stroke:270 VTE:220 Controls:880 *B, Y1	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	Serum .2ml: Vit D 25-OH	450, 451, 581, 876, 878, 910, 1121
W18	HT Hormone Pretest	Complete	HT Controls:240 *120 active + 120 placebo; B, Y1	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

Table 16.1 (continued)
Approved Core Studies[1]

Ref #	Title	Status	Study Population	Analytes/Data	Publications (All time)
W19	WHI HT Proteomic Pilot Study	Complete	HT Controls:200 *100 active, 100 control; B, AV1	Serum .1ml: Proteomics Serum .3ml: Phase II proteins	843, 921
W20	WHI-EDRN pilot study for the identification of circulating biomarkers for colon cancer in pre-clinical specimens	Complete	OS Colorectal Cancer:100 Controls:120 *Colon cancer cases 6-18 mo after Year 3	EDTA .2ml: Proteomics 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	Serum .25ml: Vit D 25-OH	
W24	Vitamin D and breast cancer in CaD trial	Complete	CaD Breast Cancer:1081 Controls:1081 *Use controls from W15 when possible	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		503, 506, 570, 591, 816, 955
W26	Food grouping in WHI by FHCRC nutrition shared resource group	Complete	DM		
W27	Nutrition and physical activity assessment study (AS218) lab work	Funded	OS *450 ppts	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

Table 16.1 (continued)
Approved Core Studies[1]

Ref #	Title	Status	Study Population	Analytes/Data	Publications (All time)
W28	Medicare claims data linkage	Complete	General population		
W30	Dietary assessment study	Complete	DM *160 ppts for 4DFR analyses, repeat 24 hr recalls, and repeat FFQs		35
W31	4DFR on DM ovarian cancers	Complete	DM Ovarian Cancer:160 *For DM Other Cancer paper		469
W33	4DFR and DM breast cancer	Complete	DM Breast Cancer:1800 *For DM Breast Cancer paper		448
W34	Extension of WHI stroke genome-wide association study (W-7)	Complete	General population Stroke:2096 Controls:2096	DNA 2ug: SNPs 5.4K	
W35	Full CMS data on all CT and OS participants aged 65 or over	Complete	General population		889, 890, 1217, 1608, 1640, 1655, 1747, 1916, 1917
W39	27-hydroxycholesterol in CVD biomarkers (W-6)	Complete	HT CHD:359 Controls:820 *CHD cases from W6-HT CVD Biomarkers	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	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		
W42	SEER code WHI and ES non-primary cancers	Complete	General population		

Table 16.1 (continued)
Approved Core Studies[1]

Ref #	Title	Status	Study Population	Analytes/Data	Publications (All time)
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	DNA 0ug: Gene seq; used residual samples from W7 and W34	
W44	Biological validation of E+P effects on the serum proteome and comparison of E+P and E-Alone effects (see W19 and W40)	Complete	HT Controls:50 *50 E+P ppts at baseline,AV1	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	Complete	OS Colon cancer:100 Controls:100	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.		
W51	Transfer of AS62-WHISE blood samples to WHI repository	Complete	General population		
W52	SHARe data clean-up	Complete	General population		
W54	CVD Biomarkers for 2010-2015 (SHARe cohort only)	Complete	General population Controls:12008 *SHARe ppts (12,008)	Serum .25ml: Glucose; CRP; Creatinine; LDLC; Cholesterol; Insulin; HDLC; Trig	1872

Table 16.1 (continued)
Approved Core Studies[1]

Ref #	Title	Status	Study Population	Analytes/Data	Publications (All time)
W57	Extend CVD Biomarker Study using HT Proteomics Study Findings on B2M and IGFBP4	Complete	General population CHD:354 Stroke:341 Controls:695	Citrate .15ml: B2M, IGFBP-4, Citrate .15ml: B2M	1065
W58	CVD, diabetes, and renal biomarkers in the EA HT Cohort	Complete	HT Controls:10254 *AS39-WHIMS (6061) + M13-GARNET (3015) + subset of HT EA aged 65 and over (279) and under 65 (899)	Serum .25ml: Cholesterol; Creatinine; Trig; Glucose; HDLC; LDLC; Insulin; CRP	2024
W59	Collaborative telomere studies pilot study (Jacques)	Complete	HT Controls:60	DNA .0625ug: TELO-LNDDCT; Baseline DNA 1ug: TELO-LNDDCT DNA .0625ug: TELO-LNDDCT; AV1	
W61	DNA Extraction of Medical Records Cohort Participants	Complete	General population Controls:12000 *~12,000 Med Records Cohort ppts who need to be extracted.		
W63	GWAS on WHIMS and subsample of HT EA women	Complete	HT Controls:5907 *Goal: Have GWAS available on a representative HT EA cohort via GARNET (M13) and W63. GWASed in W63 = Non-GARNET WHIMS (4661) + HT EA ppts aged 65+ (300) and under 65 (946)	DNA 2ug: Illumina Omn iExpress + Exome	1902, 1919, 1920, 1921, 1925, 1926, 1927, 1932, 1943, 2018, 2024, 2035, 2036, 2037, 2085, 2093

Table 16.1 (continued)
Approved Core Studies[1]

Ref #	Title	Status	Study Population	Analytes/Data	Publications (All time)
W64	Long Life Study (LLS)	Complete	General population Controls:7875 *7875 63+ year old MRC ppts with GWAS and Baseline Biomarkers	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%; CBC: Performed on the whole blood 2 ml EDTA vial within ~30 hours of draw.	
W66	Long Life Study-Phase III Biomarkers and GWAS	Complete	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.	DNA 1.5ug: Illumina Omn iExpress + Exome; GWAs + Exome Chip (Illumina Omni Express/Exome - same as W63) Serum .25ml: Insulin; Creatinine; Glucose; HDLC; Cholesterol; LDLC; Baseline Biomarker - same as W54 and W58	
286[2]	OPACH: Objective physical activity and cardiovascular health in women aged 80 and older	Funded	General population *~7060 LLS eligible (W64)		2246
M3[2]	NCI Cancer Genetic Markers of Susceptibility (CGEMS) Initiative: Replication Phase	Complete	OS Breast Cancer:2956 Controls:2956 *Caucasians only.	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	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, 2365

Table 16.1 (continued)
Approved Core Studies[1]

Ref #	Title	Status	Study Population	Analytes/Data	Publications (All time)
M5[2]	SHARe (SNP Health Association Resource) GWAS	Complete	General population Controls:12007 *Blacks, Hispanics who signed Supplemental Consent	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, 1478, 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
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)	DNA 2ug: SNPs 96 DNA 1ug: Metabochip DNA 2ug: AIMS, SNPs 384	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, 2076, 2077, 2133, 2135, 2141, 2151, 2175, 2180, 2233, 2288, 2329

Table 16.1 (continued)
Approved Core Studies[1]

Ref #	Title	Status	Study Population	Analytes/Data	Publications (All time)
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/OS 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	DNA 2ug: GWAS; GWAS in HT DNA 1ug: Exome Chip; exome chip (on residual sample from GWAS) DNA 1ug: Fluidigm Array; Phase II Validation in OS	986, 1122, 1219, 1342, 1362, 1483, 1486, 1545, 1559, 1630, 1649, 1651, 1675, 1777, 1778, 1890, 1894, 1919, 1920, 1921, 1995, 2018, 2024, 2035, 2036, 2037, 2085, 2093, 2109, 2177
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)	DNA 1ug: GWAS DNA 5ug: EXOMIC SEQ DNA 1ug: Exome Chip; Exome Chip DNA 1.05ug: Exomic Sequencing DNA 5ug: Exomic Sequencing DNA 1.5ug: Exome Chip; 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, 2286, 2398

[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 16.2
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, 1741, 1783
2	High-Dimensional Genotype in Relation to Breast Cancer and WHI Clinical Trial Interventions	Dr. Ross Prentice	Fred Hutchinson Cancer Research Center	846, 1045, 1055, 1070, 1104
3	Genome-wide Association Study to Identify Genetic Components of Hip Fracture	Dr. Rebecca Jackson	Ohio State University	
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 Diseases	Dr. Gloria Ho	Albert Einstein College of Medicine	893, 894, 922, 1025, 1029, 1061, 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. Anneclaire 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, 2206

Table 16.2 (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	2326
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	Follow-up studies of genetically determined risk factors	Dr. Rebecca Jackson	Ohio State University	1554
19	Omega-3 fatty acid biomarkers and cognitive decline in WHIMS	Dr. William Harris	Sanford Research	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, 1838, 2132
21	Understanding the role of sex hormones in colorectal cancer	Dr. Marc Gunter	Albert Einstein College of Medicine	1173, 1218, 1338
22	Predictive modeling for CVD in a multiethnic cohort in women	Dr. Nancy Cook	Brigham and Women's/Harvard University	1272, 1319, 1496, 1555, 1745
23	Integrative genomics for risk of CHD and related phenotypes in the Women's Health Initiative	Dr. Phil Tsao Dr. Tim Assimes Dr. Devin Absher Dr. Steve Horvath	Stanford University School of Medicine	2697
24	Metabolomics of CHD in the WHI	Dr. Kathryn Rexrode	Brigham and Women's/Harvard University	
25	Telomeres dynamics, cardiovascular risk and longevity in older women	Dr. Alex Reiner	Fred Hutchinson Cancer Research Institute	2394

Table 16.3
Summary of Ancillary Studies

Data as of October 2015

Current Status	Number of Studies	Led by WHI Investigator	
		Yes	No
Dropped	270	98	172
Seeking approval	41	11	30
Approved	48	13	35
Funded	45	17	28
Data analysis in progress*	84	45	39
Complete	110	65	45
Total	**598**	**249**	**349**

*Data analysis continuing after the funding end date.

Table 16.4
All Approved Ancillary Studies
(From Oct. 1, 2014)

AS #	Title	PI	WHI PI	Status	Study Dates	Case Controls	Blood Study
504	A pilot study of a novel qPCR-based measure of relative telomere length in the WHI	Assimes - Stanford University School of Medicine	Y	Funded	02/01/15-07/31/15	General population	Y
505	Validation of colon cancer early detection markers	Lampe - Fred Hutchinson Cancer Research Center	N	Approved	09/01/15-08/31/17	OS Colorectal Cancer:284 Controls:568 *Cases requested with colorectal cancer diagnosis with EDTA plasma specimen drawn up to 24 months prior.	Y
507	Microbiome of subgingival dental plaque and tumor tissue in postmenopausal women with invasive cancer: an OsteoPerio ancillary study	Mai - University of Buffalo - SUNY	N	Funded	10/01/14-12/31/15	General population	N
510	WHISH-2- Prevent Heart Failure	Eaton - Memorial Hospital of Rhode Island	Y	Approved	07/01/16-06/30/21	General population Controls:7325 *7,325 LLS with CRP, glucose, insulin, and lipids	Y
511	WHI strong and healthy silent atrial fibrillation recording (WHISH-STAR)	Perez - Stanford University	N	Approved	09/01/15-08/31/20	General population	N
514	WHISH-4-Muscle	Jackson - Ohio State University	Y	Approved	10/01/15-09/30/20	General population	Y
515	Molecular pathological epidemiology of colorectal cancer	Peters - Fred Hutchinson Cancer Research Center	N	Funded	09/01/15-08/31/19	General population Colorectal Cancer:1000 Controls:0 *PI wants as many LILAC CRC cases as possible with FFPE.	Y
516	APOL1, sickle cell trait, and chronic kidney disease in aging women	Franceschini - University of North Carolina at Chapel Hill	N	Funded	03/01/15-08/31/15	General population Controls:6304 *6,304 African American (not in PAGE 2)	Y

Table 16.4 (continued)
All Approved Ancillary Studies
(From Oct. 1, 2014)

AS #	Title	PI	WHI PI	Status	Study Dates	Case Controls	Blood Study
518	A pilot RNA-seq study among Long Life Study participants of the WHI	Assimes - Stanford University School of Medicine	Y	Analysis	03/01/15-08/31/15	General population Controls:100 *100 AA from LLS who have data from BA23 and BA25, and with no history of CVD and no incident CHD	Y
523	Feasibility study to evaluate haptoglobin phenotype and risk of CHD and stroke among older diabetic women	Donahue - University at Buffalo	N	Analysis	03/01/15-08/31/15	OS CHD:100 Stroke:100 Controls:200 *100 cases of CHD or coronary revasc AND diabetes; 100 cases cases of stroke AND diabetes; 100 diabetic cases w/o CHD, revasc, or stroke; 100 non-diabetic cases w/o the outcomes	Y
525	Assessing sodium and potassium in 24-h and spot urines: feasibility of calibrating self-reported diet for use in WHI CVD association studies	Tinker - Fred Hutchinson Cancer Research Center	Y	Analysis	03/01/15-08/31/15	General population Controls:144 *All NPAAS-FS with both 24-hour urine and first void urine (n=144)	Y
531	Feasibility study to evaluate gut microbiome and CVD-related measures in older women	LaMonte - University of Buffalo	N	Analysis	03/01/15-08/31/15	OS	Y
534	Longitudinal study of DNA methylation as a mediator between age and cardiovascular risk	Conneely - Emory University	N	Analysis	03/01/15-08/31/15	General population Controls:43 *43 AS315 participants who have previously had methylation analysis performed at two previous timepoints.	Y
536	Targeted serum metabolites profiling in early detection of pancreatic cancer	Jiao - Baylor College of Medicine	Y	Analysis	03/01/15-08/31/15	General population Pancreatic Cancer:48 Controls:48 *48 pancreatic cancer cases, 48 matched controls.	Y

Table 16.4 (continued)
All Approved Ancillary Studies
(From Oct. 1, 2014)

AS #	Title	PI	WHI PI	Status	Study Dates	Case Controls	Blood Study
537	A novel endogenous SERM and cholesterol metabolite, 27-hydroxcholesterol, and fracture risk in postmenopausal women	Lee - Stanford University School of Medicine	N	Analysis	03/01/15-08/31/15	General population Fracture - Hip:227 Fracture (general):200 Controls:400 *From BAA07/W9	Y
538	Genomic analysis of breast cancer genes in the WHI: creation of a public genomics resource	King - University of Washington	N	Funded	08/01/15-06/30/21	General population Controls:30000	Y
540	Genome studies to mitigate disparities in personalized medicine	Cox - Vanderbilt University	N	Approved	11/01/15-10/31/19	General population Controls:5000 *5000 African American or Hispanic Americans, selected on basis of hypertension or chronic kidney disease	Y
544	Iron stores in WHI HT clinical trial participants	Katz - NY University Langone Medical Center	N	Approved	04/01/16-03/31/19	General population Controls:1000 *6% subsample - HT	Y
545	Prospective identification of pre-leukemic clones in the peripheral blood of women with acute myeloid leukemia prior to the onset of overt disease	Desai - Weill Cornell Medical College, New York	N	Approved	05/01/15-04/30/16	General population Other/Unknown Cancer:239 Controls:200 *239 cases of AML, 200 age-matched controls.	Y
546	Endogenous sex hormones, inflammation, and risk of hematopoietic malignancies	Hosgood - Albert Einstein College of Medicine	N	Approved	12/01/15-11/30/19	General population Lymphoma, Non Hodgkins:822 Multiple Myeloma:275 Controls:550	Y
547	Genetic and environmental influences on optic nerve cupping	Vajaranant - University of Illinois at Chicago	N	Approved	04/16/16-04/30/18	CT	N
548	Women's Health Initiative sleep hypoxia effects on resilience (WHISPER)	Baker - Wake Forest School of Medicine	N	Approved	07/01/16-06/30/20	General population	N

Table 16.4 (continued)
All Approved Ancillary Studies
(From Oct. 1, 2014)

AS #	Title	PI	WHI PI	Status	Study Dates	Case Controls	Blood Study
551	Risk and penetrance of mutations from breast cancer testing panels in the general population	Kraft - Harvard School of Public Health	N	Approved	06/01/15-05/30/19	General population Breast Cancer:5500 Controls:5500 *5,500 breast cancer cases and 5,500 matched controls (with preference toward those cases/controls used in M18)	Y
552	Harmonized and pooled approaches in multiple cohorts to understand low concentration health impacts of air pollutants	Kaufman - University of Washington	N	Approved	02/01/16-01/31/20	General population	N
557	Comparative intra- and inter-method reliability of omega-3 fatty acids measured in different blood fractions	Brasky - The Ohio State University College of Medicine	N	Approved	07/01/16-06/30/18	CT Controls:167 *42 CT control groups only. 125 DM control groups for whom 4DFR data have been entered at BL and Y1.	Y

Table 16.5a
Recruitment to Core and Ancillary Studies Requiring Separate Consents by Field Centers[1]

Data as of September 2015

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 participants	84 Cognitive change in women	98 Bone mineral density as a predictor for periodontitis	100 Genetic, biochemical and behavioral determinants of obesity	103 Effects of HRT on cognitive aging: (WHISCA)	105 Carotenoids in age-related eye disease study (CAREDS)	117 Risk factors for dry eye syndrome in postmenopausal women	130 Randomized controlled trial of fat reduction, calcium/ vitamin D supple mentation
Atlanta					99										118
Birmingham	450			91	175										66
Bowman				36	65		11				548				67
Brigham				45	202	372									156
Buffalo		1468			157	231	21			969					76
Chapel Hill				64	252							172			119
Chicago-Rush					158							100			56
Chicago					31				546						94
Cincinnati					165		8								121
Columbus				43	290	282	19					198		217	105
Detroit			311		131	176									85
Gainesville					234							169			137
GWU-DC				57	183			442							88
Honolulu					97		9								109
Houston					118	131					249				101
Iowa City				102	395	507	13					236	631		124
Irvine					198	191									79
LA					237							159			75
La Jolla					137	323									73
Madison				35	166	260							693		128
Medlantic					179	129		293							84
Memphis				105	157	290									87
Miami					47										71
Milwaukee				42	259							198			87
Minneapolis					210							134			147
Nevada				35	232	170						113			87
Newark					329	269									149
New York					279	141						128			66
Oakland					186										82
Pawtucket					338										149
Pittsburgh				52	160	168	14								97
Portland					199								683		78
San Antonio					118										69
Seattle							2								97
Stanford					282							179			96
Stonybrook					252	136						127			120
Torrance					61										34
Tucson				94	245										101
UC Davis				56	218	304	4					135			106
Worcester					287	350						218			117
Total	**450**	**1468**	**311**	**857**	**7528**	**4430**	**101**	**735**	**546**	**969**	**797**	**2266**	**2007**	**217**	**3901**

Table 16.5a (continued)
Recruitment to Core and Ancillary Studies Requiring Separate Consents by Field Centers[1]

Data as of September 2015

Clinic	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	223 WHI cancer survivor cohort: biological, psycho-social, and behavioral predictors of survival	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 (WHI-CACS)	W30 Dietary assessment study	W47 Breast tumor tissue pilot
Atlanta		21						70	36		74	8	3
Birmingham		3	180						60		59	6	4
Bowman		24	161						36			11	7
Brigham		38							27		38	9	9
Buffalo		42							36		41	10	17
Chapel Hill		25			40			147	35		32		7
Chicago-Rush									33				4
Chicago					70			1	23		22	6	2
Cincinnati		25						117	24		47		6
Columbus		36					81	135	24		21		10
Detroit		9						63	35				5
Gainesville		49						157	50				4
GWU-DC		27						111	36		22		6
Honolulu								58	0				7
Houston		13							34				5
Iowa City		76						173	64		60	9	9
Irvine								93	40				9
LA		16						102	27		16		10
La Jolla									20		24	10	15
Madison		26			40	400		97	50		36		19
Medlantic		12						115	36		48		5
Memphis		14			40			76	23		54	10	4
Miami		6							0		49		3
Milwaukee								126	29		42		9
Minneapolis		51	224					125	41		54	7	17
Nevada		21							43				18
Newark									45		25	8	14
New York		21			40		48	165	28		26		6
Oakland		35			70			115	54		39		10
Pawtucket		34						216	50		43	9	14
Pittsburgh		20						108	39		66	8	5
Portland		27	173					130	22		47		7
San Antonio									32		58		5
Seattle					70				67	154		8	8
Stanford		42					98	194	45		28		10
Stonybrook				1300				153	22				8
Torrance									18				7
Tucson	47	9			40			108	29			9	11
UC Davis		22						119	33		46	6	8
Worcester		49			40		83		27		24		13
Total	**47**	**793**	**738**	**1300**	**450**	**400**	**310**	**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 16.5b
Recruitment to Core and Ancillary Studies Requiring Separate Consents by Regional Centers[1]

Data as of September 2015

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	223 Women's Health Initiative cancer survivor cohort: biological, psychosocial, and behavioral predictors of survival: pilot study	262[2] Women's Health Initiative memory study of younger women (WHIMS-Y)	272[2] WHI nutrition and physical activity assessment study (NPAAS)	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	355 Randomized Trial of Cocoa Extract and Multivitamins for CVD and Cancer Prevention	360 Physical activity to improve cardiovascular health in women: a pragmatic trial	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	450 Physical activity to improve cardiovascular health in women: a pragmatic trial (WHISH) DCC	W47[2] Breast tumor tissue pilot	W64 Long life study (LLS)
Midwest																		
Columbus	217		310	133		1061	108	327	2776	775	14	31	77	49		260	31	1152
Iowa		224		155		656	65	381	2266	728	12	142	61	27		161	45	718
Pittsburgh				74		412	43	150	856	291	7	27	34	19		86	10	461
Northeast																		
Boston				104		570	78	98	2670	819	15		63	27		115	36	613
Buffalo				131		1037	100	306	2774	773	21		59	57		187	45	1116
Medstar				72		661	58	173	1493	326	9		27	40		147	11	720
Southeast																		
Gainesville		180		146		871	107	276	2561	555	12		41	48		211	14	934
Wake Forest		161		160		1039	78	320	2788	649	12		57	75		228	28	1119
West																		
CCC				87	154	417	28	106	995	365	6		22	27	288	85	23	436
Stanford		173		239		1404	131	659	3124	1295	21		101	89		343	61	1476
Tucson				72		436	39	183	1558	451	7		35	42		90	36	469
TOTAL	**217**	**738**	**310**	**1373**	**154**	**8564**	**835**	**2979**	**23,861**	**6382**	**136**	**200**	**599**	**500**	**288**	**1913**	**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 16.6
Participant Enrollment in WHI Ancillary Studies Requiring Separate Consents
Data as of September 2015

CT+OS

	Ppts	%*	
CT+OS	161,808		
Not Enrolled in Ancillary Studies	107,914	66.7	
Enrolled in Ancillary Studies	53,894	33.3	
Number of Studies	**Ppts**	**%***	**Enrollments**
1	33,115	20.5	33,115
2	11,200	6.9	22,400
3	4,798	3.0	14,394
4	2,409	1.5	9,636
5	1,333	0.8	6,665
6	679	0.4	4,074
7	257	0.2	1,799
8	82	0.1	656
9	20	0.0	180
12	1	0.0	12
Total	**53,894**	**33.3**	**92,931**

Extension 1

	Ppts	%*	
Consented to Extension 1	115,407		
Not Enrolled in Ancillary Studies	65,747	57.0	
Enrolled in Ancillary Studies	49,660	43.0	
Number of Studies	**Ppts**	**%***	**Enrollments**
1	29,595	25.6	29,595
2	10,600	9.2	21,200
3	4,692	4.1	14,076
4	2,402	2.1	9,608
5	1,332	1.2	6,660
6	679	0.6	4,074
7	257	0.2	1,799
8	82	0.1	656
9	20	0.0	180
12	1	0.0	12
Total	**49,660**	**43.0**	**87,860**

Extension 1

	Ppts	%*	
Consented to Extension 2	93,567		
Not Enrolled in Ancillary Studies	47,956	51.3	
Enrolled in Ancillary Studies	45,611	48.8	
Number of Studies	**Ppts**	**%***	**Enrollments**
1	27,001	28.9	27,001
2	9,721	10.4	19,442
3	4,252	4.5	12,756
4	2,281	2.4	9,124
5	1,318	1.4	6,590
6	678	0.7	4,068
7	257	0.3	1,799
8	82	0.1	656
9	20	0.0	180
12	1	0.0	12
Total	**45,611**	**48.8**	**81,628**

*Due to rounding, the total may not add up to the sum of the individual studies.

Table 16.7
Funded BAA and Ancillary Studies PI List
(As of Oct. 2015)

Last Name	First Name	PI Institution	WHI Investigator	ANC PI for	WHI PI for	CCC PI for
Anderson	Garnet	Fred Hutchinson Cancer Research Center	Y	97, 370, 384	150, 282, 297, 311, 337, 415, 440, 538, M11, W47, W64	121, 129, 129, 129, 140, 355, BA6, BA11, BA15, BA21, M8, M9
Ascherio	Alberto	Harvard School of Public Health	N	402		
Assimes	Themistocles (Tim)	Stanford University School of Medicine	Y	332, 504, 518	BA23	
Avery	Christy	University of North Carolina at Chapel Hill	N	405		
Barnhart	Janice	Albert Einstein College of Medicine	N	127		
Bassford	Tamsen	University of Arizona	Former		113, 153, 153, 175, 191, 199	
Beasley	Jeannette	Fred Hutchinson Cancer Research Center	N	340		
Bensink	Mark	Fred Hutchinson Cancer Research Center	N	408		
Beresford	Shirley	University of Washington	Y		327	
Berndt	Sonja	National Institute of Health - NCI	N	301		
Bhatti	Parveen	Fred Hutchinson Cancer Research Center	N	311		
Bird	Chloe	Rand Corporation	N	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)	N	294		
Brinton	Louise	National Institute of Health - NCI	N	297		
Burke	Greg	Wake Forest University School of Medicine	Former		56, 139	

Table 16.7 (continued)
Funded BAA and Ancillary Studies PI List
(As of Oct. 2015)

Last Name	First Name	PI Institution	WHI Investigator	ANC PI for	WHI PI for	CCC PI for
Burrows	Beth	Fred Hutchinson Cancer Research Center	Y	50		
Caan	Bette	Kaiser Foundation Research Institute - Oakland	Y		243	
Carty	Cara	George Washington University	Y			M16
Cauley	Jane	University of Pittsburgh	Y	161, 181, BA9		
Cene	Crystal	University of North Carolina at Chapel Hill	N	414		
Chang	Shine	University of Texas MD Anderson Cancer Center	N	100		
Chanock	Stephen	National Institute of Health	N	M3, M8		
Chen	Zhao	University of Arizona	Y	82, 153, 191, 199, M2		
Chen	Jiu-Chiuan	University of Southern California Keck School of Medicine	N	226, 252		
Chlebowski	Rowan	UCLA Medical Center	Y	76, 99	108	
Cochrane	Barbara	Fred Hutchinson Cancer Research Center	Y			110, 133, 134, 146, 167, 192, 196, 214, 242, 250, 250, 262
Colditz	Graham	Washington University Saint Louis	N	207		
Conneely	Karen	Emory University	N	534		
Cook	Nancy	Brigham and Women's/Harvard University	N	BA22		
Cook	Michael	NCI, PLCO	N	482		
Cote	Michele	Wayne State University	N	400		
Coy	Christine	University of California - Irvine	N	118		
Criqui	Michael	University of California - San Diego	Former	93		
Cummings	Steve	University of California - San Francisco	Former	90, 167, BA7		

Table 16.7 (continued)
Funded BAA and Ancillary Studies PI List
(As of Oct. 2015)

Last Name	First Name	PI Institution	WHI Investigator	ANC PI for	WHI PI for	CCC PI for
Curb	David	Pacific Health Research and Education Institute	Former		25, 95, 122	
DeRoos	Anneclaire	University of Washington	N	BA13		
Donahue	Richard	SUNY University at Buffalo	N	523		
Donovan	Geoffrey	USDA Forest Service, PNW Research Station	N	386		
Dorn	Joan	University of Buffalo	N	141		
Drieling	Rebecca	Fred Hutchinson Cancer Research Center	N	449		
Driscoll	Ira	University of Wisconsin - Milwaukee	N	250		
Dunn	Julie	Tufts University	Former	84		
Eaton	Charles	Memorial Hospital of Rhode Island	Y	391	251	
Edlefsen	Kerstin	University of Washington	Y	337		
Epplein	Meira	Vanderbilt University	N	455		
Fouad	Mona	University of Alabama at Birmingham	Y	78, 102		
Franceschini	Nora	University of North Carolina at Chapel Hill	N	376, 516		
Fuchs	Charles	Dana-Farber Cancer Institute	N	146, 214		
Glanz	Karen	University of Hawaii System	N	122		
Going	Scott	University of Arizona	Y	14		
Green	Pamela	Fred Hutchinson Cancer Research Center	N	5		
Greenland	Philip	Northwestern University	Y	438		
Grimm	Richard	Berman Center for Clinical Research	Former		50	
Gunter	Marc	Albert Einstein College of Medicine	N	BA21		

Table 16.7 (continued)
Funded BAA and Ancillary Studies PI List
(As of Oct. 2015)

Last Name	First Name	PI Institution	WHI Investigator	ANC PI for	WHI PI for	CCC PI for
Haan	Mary	University of California - San Francisco	Former	62	407	
Haines	Pam	University of North Carolina	N	63		
Hakim	Iman	University of Arizona	N	113		
Han	Jiali	Brigham and Women's Hospital	N	242		
Hanash	Sam	MD Anderson Cancer Center	Y	BA17, W45		
Harris	William S.	Sanford Health	N	BA19		
Hays	Jennifer	University of Oklahoma - Tulsa	Y	163	137	
He	Ka	Indiana University Bloomington	N	187		
Heiss	Gerardo	University of North Carolina School of Medicine	Y		36, 63, 70, 140, 165, 178, 226, 236, 252, 264, 371, 376,	
Hendrix	Susan	Wayne State University Medical School	Former		34	
Hingorani	Sunil	Fred Hutchinson Cancer Research Center	N	BA16		
Ho	Gloria	Feinstein Institute for Medical Research	Y	152, 208, 266, BA10		
Hofmann	Jonathan	NCI	N	389		
Howard	Barbara	MedStar Research Institute	Y		217, 397, 403	
Hsia	Judith	George Washington University	Y	68		
Hubble	Allan	University of California - Irvine	Y		118	
Hulka	Barbara	University of North Carolina	Former	36		
Hunt	Julie	Fred Hutchinson Cancer Research Center	Y			220, 223, 226, 252, 425
Hunter	David	Harvard	N	M18		
Jackson	Rebecca	Ohio State University	Y	271, BA3, BA18, M24	117, 223, 301, W22	

Table 16.7 (continued)
Funded BAA and Ancillary Studies PI List
(As of Oct. 2015)

Last Name	First Name	PI Institution	WHI Investigator	ANC PI for	WHI PI for	CCC PI for
Jeffcoat	Marjorie	Penn Dental School	N	9		
Jiao	Li	Baylor College of Medicine	Y	292, 362, 536		
Kaufman	Joel	University of Washington	N	150		
Kerwin	Diana	Northwestern University	N	235		
King	Mary-Claire	University of Washington	N	538		
Kipnis	Victor	National Institute of Health	N	289, M12		
Klein	Liviu	University of California San Francisco	N	196		
Kleinstein	Robert	University of Alabama at Birmingham	N	31		
Kooperberg	Charles	Fred Hutchinson Cancer Research Center	Y	349, 422, 450, M6	421, 516, M13, M26	90, 126, BA10, BA12, BA18, BA19, BA20, M4, M24
Kotchen	Jane	Medical College of Wisconsin	Y		235	
Kripke	Daniel	University of California - San Diego	N	11		
Kucharska-Newton	Anna	University of North Carolina at Chapel Hill	N	371		
Kuller	Lew	University of Pittsburgh	Y	BA12	13, 121, 134, 161, 181, 189, 411, M9	
LaCroix	Andrea	Fred Hutchinson Cancer Research Center	Y	179, 286, W64	290, 321, 340, 416, 429, 449, 450, BA25, M4	83, 137, 153, 165, 181, 191, 199, 290, 340, 360, 416, 429, 449, BA3, BA7, BA9, BA13, BA14, BA22, M2
LaMonte	Michael	University of Buffalo - SUNY	N	287, 531		
Lane	Dorothy	Stony Brook University - New York	Y		216	
Langer	Robert	University of California - San Diego	Former	47	11, 24, 73, 93, 124	

Table 16.7 (continued)
Funded BAA and Ancillary Studies PI List
(As of Oct. 2015)

Last Name	First Name	PI Institution	WHI Investigator	ANC PI for	WHI PI for	CCC PI for
Lasser	Norm	University of Medicine and Dentistry of New Jersey	Former		17	
Lee	I-Minn	Brigham and Women's/Harvard University	N	BA11		
Lee	Jennifer	Stanford University School of Medicine	N	537		
Lewis	Beth	University of Alabama at Birmingham	Y		9, 111	
Li	Rongling	University of Tennessee Health Science Center	N	BA5		
Li	Christopher	Fred Hutchinson Cancer Research Center	N	316		
Lichtenstein	Alice	Tufts University	N	BA8		
Lin	Henry	UCLA - Harbor	N	108		
Liu	Simin	Brown University	Y	132, 238, 254		
Lorenz	Carol	University of North Carolina	N	165		
Lund	Bernedine	Fred Hutchinson Cancer Research Center	Y			206, 352, 427, W54, W61
Luo	Juhua	Indiana University	Y	425		
Mackey	Rachel	University of Pittsburgh	Y	189, 411		
Malone	Kathi	Fred Hutchinson Cancer Research Center	N	415		
Mann	Sue	Fred Hutchinson Cancer Research Center	Y			224, M26
Manson	JoAnn	Brigham and Women's/Harvard University	Y	352, 355, 427, W25	83, 110, 132, 133, 146, 192, 207, 214, 242, 325, 402, 458, BA11, BA24	
Mares	Julie	University of Wisconsin	Y	105, 219, 257, 471, M1		
Margolis	Karen	Health Partners Minnesota	Y	197	197, 220, 425	

Table 16.7 (continued)
Funded BAA and Ancillary Studies PI List
(As of Oct. 2015)

Last Name	First Name	PI Institution	WHI Investigator	ANC PI for	WHI PI for	CCC PI for
Masaki	Kamal	Pacific Health Research and Education Institute	Former	25		
Mayo	Charlotte	University of Alabama at Birmingham	N	33		
McGlynn	Katherine	National Institute of Health - NCI	N	296		
McIntosh	Martin	Fred Hutchinson Cancer Research Center	Y	BA15		
McTiernan	Anne	Fred Hutchinson Cancer Research Center	Y			36, 178
Melnikow	Joy	University of California - Davis	N	104		
Messina	Catherine	Stony Brook University Medical Center	Y	216		
Michael	Yvonne	Drexel University	Y	171		
Millen	Amy	University of Buffalo	Y	304		
Modugno	Francesmary	Carnegie Mellon University	N	121, 134		
Moon	Tom	University of Arizona	Former		14	
Moreland	Larry W.	University of Pittsburgh	N	BA20		
Mouton	Charles	Howard University	Former	17		
Namie	Joylin	University of California - San Diego	N	124		
Nathan	Lauren	UCLA Medical Center	Y		238, 254	
Nelson	Dorothy	Wayne State University School of Medicine	N	34		
Neuhouser	Marian	Fred Hutchinson Cancer Research Center	Y	272, 327, 440	389, 439	130, 195, 207, 236, 275, BA8
Newcomb	Polly	Fred Hutchinson Cancer Research Center	Y	290		
Nicholas	J. Skye	University of Arizona	N	175		
Nichols	Kelley	University of Houston	N	117		

Table 16.7 (continued)
Funded BAA and Ancillary Studies PI List
(As of Oct. 2015)

Last Name	First Name	PI Institution	WHI Investigator	ANC PI for	WHI PI for	CCC PI for
Nygaard	Ingrid	University of Utah Health Sciences	N	135		
O'Brien	Diane	University of Alaska Fairbanks	N	423		
Ober	Beth	University of California - Davis	Former	61		
Oberman	Albert	University of Alabama at Birmingham	Y		31, 33, 60, 78, 102	
Ockene	Judith	University of Massachusetts Medical Center	Y		75, 275	
Parks	Christine	National Institute of Environmental Health Sciences	N	403		
Paskett	Electra	Ohio State University	Y	139, 223, 370	100	
Patterson	Ruth	University of California, San Diego	Former		177	65, 108
Peters	Ulrike	Fred Hutchinson Cancer Research Center	N	206, 224, 515, M26		
Pisano	Etta	University of North Carolina - School of Medicine	N	178		
Pleuss	Joan	Wake Forest University	Former	56		
Polk	M.J.	University of Texas - San Antonio	N	86		
Prentice	Ross	Fred Hutchinson Cancer Research Center	Y	218, 343, 377, BA2, BA4	195, 206, 224, 272, 289, 294, 316, 417, 423, M12, M18, M3, W31, W33, W45, W57	84, 263, BA1, BA5, BA16, BA17, W22, W44, W58
Purdue	Mark	National Institute of Health - NCI	N	M9		
Raftery	Dan	University of Washington	N	417		
Rajaraman	Preetha	National Institute of Health	N	M14		
Rajkovic	Aleksandar	Baylor College of Medicine	Y		M8	

Table 16.7 (continued)
Funded BAA and Ancillary Studies PI List
(As of Oct. 2015)

Last Name	First Name	PI Institution	WHI Investigator	ANC PI for	WHI PI for	CCC PI for
Ramsey	Scott	Fred Hutchinson Cancer Research Center	Y		408	
Reding	Kerryn	University of Washington/Fred Hutchinson Cancer Research Center	N	321		
Reeves	Katherine	University of Massachusetts	N	458		
Reiner	Alexander	Fred Hutchinson Cancer Research Center	Y	421, BA14, BA25, M13	518	337, 516
Reis	Robert	University of Arkansas for Medical Sciences and VA Med. Center	N	416		
Rexrode	Kathryn	Brigham and Women's Hospital	Y	110, BA24		
Ridker	Paul	Partners Health Care	N	83		
Ritenbaugh	Cheryl	University of Arizona	Former	57, 73	160, 171, 82	
Robbins	John	University of California - Davis	Y		61, 62, 104, BA1	
Rodriguez	Beatriz	University of Hawaii System	Y	95		
Rohan	Tom	Albert Einstein College of Medicine	Y	65, 130, 284		
Rosal	Milagros	University of Massachusetts Medical School	Y	75		
Sangi-Haghpeykar	Haleh	Baylor College of Medicine	Y		292, 362, 536	
Sarto	Gloria	University of Wisconsin	Y		105, 219, 257, 471, M1	
Schenken	Robert	University of Texas - San Antonio	Former		86	
Schlecht	Nicolas	Albert Einstein College of Medicine	N	374		
Schneider	Diane	University of California - San Diego	N	24		
Seguin	Rebecca	Cornell University	N	429		
Seldin	Michael	University of California - Davis	N	BA1		

Table 16.7 (continued)
Funded BAA and Ancillary Studies PI List
(As of Oct. 2015)

Last Name	First Name	PI Institution	WHI Investigator	ANC PI for	WHI PI for	CCC PI for
Sesso	Howard	Brigham and Women's Hospital	Y	133, 355		
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	Y	39, 103, 183, 233, 244, 262	250, 373, 413, 414	
Siega-Riz	Anna Maria	University of North Carolina	N	236		
Simon	Michael	Wayne State University Medical School	Y	464	400, 482	
Smith-Warner	Stephanie	Harvard School of Public Health	N	383		
Smoller	Sylvia	Albert Einstein College of Medicine	Y	40, 48, 126, M16	40, 48, 127, 129, 130, 152, 208, 266, 284, 374, 455, BA10, M16	
Song	Yiqing	Brigham and Women's Hospital	N	325		
Stefanick	Marcia	Stanford University	Y	360	332, 346, 504, 537	
Sternfeld	Barbara	Kaiser Permanente Division of Research	N	243		
Stolzenberg-Solomon	Rachael	National Institute of Health - NCI	N	M4		
Stone	Katie	Research Institute, California Pacific Medical Center	N	413		
Strickler	Howard	Albert Einstein College of Medicine	N	129		
Sturgeon	Susan	University of Massachusetts	N	275		
Subar	Amy	National Institute of Health	N	177		
Sun	Jielin	Wake Forest University	N	263		
Tang	Jean	Stanford University	Y	346		
Taylor	Phil	National Institute of Health	N	M11		

Table 16.7 (continued)
Funded BAA and Ancillary Studies PI List
(As of Oct. 2015)

Last Name	First Name	PI Institution	WHI Investigator	ANC PI for	WHI PI for	CCC PI for
Thomson	Cynthia	University of Arizona	Y		383, M14	
Tindle	Hilary	University of Pittsburgh	Y	373		
Tinker	Lesley	Fred Hutchinson Cancer Research Center	Y	398, 439, 525		105, 111, 132, 152, 187, 189, 208, 218, 219, 238, 251, 254, 257, 264, 266, 271, 272, 284, 292, 296, 301, 311, 315, 321, 325, 332, 346, 362, 374, 376, 383, 391, 402, 403, 411, 438, 455, 458, 471, 482, 504, 518, 523, 534, 536, 537, BA23, BA24, M1, M12, M14
Trevisan	Maurizio	State University of New York - Buffalo	Y		15, 74, 98, 141	
Tsao	Phil	Stanford University School of Medicine	N	BA23		
Ulrich	Cornelia		N	195		
Urban	Nicole	Fred Hutchinson Cancer Research Center	Y	282		
Vajaranant	Thasarat	University of Illinois at Chicago	N	407		
Valanis	Barbara	Kaiser Permanente Center for Health Research, Portland	Former	160		
Van Horn	Linda	Northwestern University	Y		84, 187, 196, 315, 438	
Vitolins	Mara	Wake Forest University	Y		263	
Vogt	Molly	University of Pittsburgh	N	13		
Wactawski-Wende	Jean	University of Buffalo	Y	15, 98, 303, M25	287, 296, 304, 523, 531, M25	
Walitt	Brian	MedStar Research Institute	Y	217, 397		
Wallace	Robert	University of Iowa	Y		135, 308	

Table 16.7 (continued)
Funded BAA and Ancillary Studies PI List
(As of Oct. 2015)

Last Name	First Name	PI Institution	WHI Investigator	ANC PI for	WHI PI for	CCC PI for
Wang	C.Y.	Fred Hutchinson Cancer Research Center	Former			9
Wellenius	Greg	Brown University	N	251		
Whitsel	Eric	University of North Carolina	Y	140, 264, 315	386, 405, 534	
Wilson	Robin	Penn State University College of Medicine	N	308		
Wodarski	Lois	State University of New York - Buffalo	N	74		
Xu	Jianfeng	Wake Forest University School of Medicine	N	BA6		
Zhang	Shumin	Brigham and Women's Hospital	Y	192		

Table 17.1
WHI Manuscript Stages through September 2015

Stage #	Definition	Number
12*	Published	1189
11	In press / accepted by journal	19
10	Submitted to journal	29
9	Final manuscript approved by P&P Committee	202
8	Final manuscript submitted to P&P Committee	45
7	Draft manuscript	28
6	Analysis completed	39
5	Analysis in progress	66
4	Analysis proposed	5
3	Manuscript proposal and writing group approved	658
2	Approved/Writing group nominations open	69
Total		**2349**

*Only Stage 12 papers are included in Table 17.2

Table 17.2
Publications since October 2014

MS#	Title	Authors	Focus	Reference	Study #
466	Low-fat dietary pattern intervention and health-related quality of life: The Women's Health Initiative Randomized Controlled Dietary Modification Trial	Assaf, Beresford, Risica, Aragaki, Brunner, Bowen, Naughton, Rosal, Snetselaar, Wenger	CT	J Acad Nutr Diet. 2015 Sep 16. pii: S2212-2672(15)01225-3. doi: 10.1016/j.jand.2015.07.016.	
670	Sleep duration, cognitive decline, and dementia risk in older women	Chen, Espeland, Brunner, Lovato, Wallace, Phillips, Robinson, Kotchen, Johnson, Manson, Stefanick, Sarto, Mysiw	WHIMS	Alzheimers Dement. 2015 Jun 15. pii: S1552-5260(15)00195-8. doi: 10.1016/j.jalz.2015.03.004.	AS39
699	Lipoprotein particles and size, total and high molecular weight adiponectin, and leptin in relation to incident coronary heart disease among severely obese postmenopausal women: The Women's Health Initiative Observational Study	Mackey, McTigue, Chang, Barinas-Mitchell, Evans, Tinker, Lewis, Manson, Stefanick, Howard, Phillips, Liu, Kulick, Kuller	OS	BBA Clin. 2015 Jun;3:243-250	AS189
834	Hormone use, reproductive history and risk of lung cancer: the Women’s Health Initiative studies	Schwartz, Ray, Cote, Abrams, Sokol, Hendrix, Chen, Chlebowski, Hubbell, Kooperberg, Manson, O'Sullivan, Rohan, Stefanick, Wactawski-Wende, Wakelee, et al.	Gen	J Thorac Oncol. 2015 Jul;10(7):1004-13. doi: 10.1097/JTO.0000000000000558	
870	Prevalence and correlates of body image dissatisfaction in postmenopausal women	Ginsberg, Tinker, Liu, Gray, Sangi-Haghpeykar, Manson, Margolis	OS	Women Health. 2015 Jul 28:1-27.	
995	Genetic variation predicts serum lycopene concentrations in a multiethnic population of postmenopausal women	Zubair, Kooperberg, Liu, Di, Peters, Neuhouser	Gen	J Nutr. 2015 Feb;145(2):187-92. doi: 10.3945/jn.114.202150.	M5
1016	Meta-analysis of genome-wide association studies identifies genetic risk factors for stroke in African-Americans	Carty, Keene, Cheng, Meschia, Chen, Nalls, Bis, Kittner, Rich, Tajuddin	Gen	Stroke. 2015 Aug;46(8):2063-8. doi: 10.1161/STROKEAHA.115.009044.	M5
1024	Shared molecular pathways and gene networks for cardiovascular disease and type 2 diabetes mellitus in women across diverse ethnicities	Chan, Zhou, Horvath, Liu, Kooperberg, Reiner, Kuller, Manson, Eaton, Curb, Papanicolaou	Gen	Circ Cardiovasc Genet. 2014 Dec;7(6):911-9. doi: 10.1161/CIRCGENETICS.114.000676.	AS132, M5

Table 17.2
Publications since October 2014

MS#	Title	Authors	Focus	Reference	Study #
1050	Genetic variations in magnesium-related ion channels may affect diabetes risk among African American and Hispanic American women	Chan, Chacko, Song, Cho, Eaton, Wu, Liu	OS	J Nutr. 2015 Mar;145(3):418-24. doi: 10.3945/jn.114.203489.	AS132, M5
1061	Circulating adipokines and inflammatory markers and postmenopausal breast cancer risk	Gunter, Wang, Cushman, Xue, Wassertheil-Smoller, Strickler, Rohan, Manson, McTiernan, Kaplan, Scherer, Chlebowski, Snetselaar, Wang, Ho	OS	J Natl Cancer Inst. 2015 Jul 16;107(9). pii: djv169. doi: 10.1093/jnci/djv169.	AS126, AS129, BAA10
1107	Effects of bilateral salpingo-oophorectomy at the time of hysterectomy on pelvic organ prolapse: results from the Women's Health Initiative trial	Shveiky, Kudish, Iglesia, Park, Sokol, Lehman, Shara, Howard	CT	Menopause. 2015 May;22(5):483-8. doi: 10.1097/GME.0000000000000375	
1282	Insecticide exposure and farm history in relation to risk of lymphomas and leukemias in the Women's Health Initiative observational study cohort	Schinasi, De Roos, Ray, Edlefsen, Parks, Howard, Meliker, Bonner, Wallace, LaCroix	OS	Ann Epidemiol. 2015 Aug 19. pii: S1047-2797(15)00344-0. doi: 10.1016/j.annepidem.2015.08 .002.	
1306	Anticholinergic medication use and fractures in postmenopausal women: Findings from the Women's Health Initiative	Marcum, Wirtz, Pettinger, LaCroix, Carnahan, Cauley, Bea, Gray	Gen	Drugs Aging. 2015 Sep;32(9):755-63. doi: 10.1007/s40266-015-0298-1	
1338	A prospective evaluation of endogenous sex hormone levels and colorectal cancer risk in postmenopausal women	Murphy, Strickler, Stanczyk, Xue, Wassertheil-Smoller, Rohan, Ho, Anderson, Potter, Gunter	CT	J Natl Cancer Inst. 2015 Aug 1;107(10). pii: djv210. doi: 10.1093/jnci/djv210.	BAA21
1376	Effects of self-reported age at nonsurgical menopause on time to first fracture and bone mineral density in the Women's Health Initiative Observational Study	Sullivan, Lehman, Thomas, Johnson, Jackson, Wactawski-Wende, Ko, Chen, Curb, Howard	OS	Menopause. 2015 Oct;22(10):1035-44. doi: 10.1097/GME.0000000000000451.	
1379	Menopausal hormone therapy and cancer: changing clinical observations of target site specificity	Chlebowski, Anderson	N/A	Steroids. 2014 Nov;90:53-9. doi: 10.1016/j.steroids.2014.06.001.	

Table 17.2
Publications since October 2014

MS#	Title	Authors	Focus	Reference	Study #
1404	Associations of menopausal vasomotor symptoms with fracture incidence	Crandall, Aragaki, Cauley, Manson, LeBlanc, Wallace, Wactawski-Wende, LaCroix, O'Sullivan, Vitolins, Watts	OS	J Clin Endocrinol Metab. 2015 Feb;100(2):524-34. doi: 10.1210/jc.2014-3062.	
1418	Non-steroidal anti-inflammatory drug and aspirin use in relation to lung cancer risk among postmenopausal women	Baik, Brasky, Pettinger, Luo, Gong, Wactawski-Wende, Prentice	Gen	Cancer Epidemiol Biomarkers Prev. 2015 May;24(5):790-7. doi: 10.1158/1055-9965.EPI-14-1322.	
1419	The association between dietary inflammatory index and risk of colorectal cancer among postmenopausal women: results from the Women's Health Initiative	Tabung, Steck, Ma, Liese, Zhang, Caan, Hou, Johnson, Mossavar-Rahmani, Shivappa, Wactawski-Wende, Ockene, Hebert	Gen	Cancer Causes Control. 2015 Mar;26(3):399-408. doi: 10.1007/s10552-014-0515-y.	
1421	Construct validation of the dietary inflammatory index among postmenopausal women	Tabung, Steck, Zhang, Ma, Liese, Agalliu, Hingle, Hou, Hurley, Jiao, Martin, Millen, Park, Rosal, Shikany, Shivappa, et al.	OS	Ann Epidemiol. 2015 Jun;25(6):398-405. doi: 10.1016/ j.annepidem.2015.03 .009.	
1451	Statin use and risk of hemorrhagic stroke in a community-based cohort of postmenopausal women: an observational study from the Women's Health Initiative	Salmoirago-Blotcher, Hovey, Andrews, Robinson, Johnson, Wassertheil-Smoller, Crawford, Qi, Martin, Ockene, Manson	OS	BMJ Open. 2015 Feb 25;5(2):e007075. doi: 10.1136/bmjopen-2014-007075	
1454	Postmenopausal weight change and incidence of fracture: post hoc findings from Women’s Health Initiative Observational Study and Clinical Trials	Crandall, Yildiz, Wactawski-Wende, Johnson, Chen, Going, Wright, Cauley	Gen	BMJ. 2015 Jan 27;350:h25. doi: 10.1136/bmj.h25	
1478	Genome-wide meta-analysis identifies six novel loci associated with habitual coffee consumption	Coffee and Caffeine Genetics Consortium, Cornelis, Byrne, Esko, Nalls, Ganna, Paynter, Monda, Amin, Fischer	Gen	Mol Psychiatry. 2015 May;20(5):647-56. doi: 10.1038/mp.2014.107.	M5
1481	Calcium and Vitamin D supplementation do not influence menopause-related symptoms: Results of the Women’s Health Initiative Trial	LeBlanc, Hedlin, Qin, Desai, Wactawski-Wende, Perrin, Manson, Johnson, Masaki, Tylavsky, Stefanick	CT	Maturitas. 2015 Jul;81(3):377-83. doi: 10.1016/j.maturitas.2015.04.007.	

Table 17.2
Publications since October 2014

MS#	Title	Authors	Focus	Reference	Study #
1487	Risk factors for endometrial cancer in black and white women: a pooled analysis from the Epidemiology of Endometrial Cancer Consortium (E2C2)	Cote, Alhajj, Ruterbusch, Bernstein, Brinton, Blot, Chen, Gass, Gaussoin, Henderson	Gen	Cancer Causes Control. 2015 Feb;26(2):287-96. doi: 10.1007/s10552-014-0510-3.	
1504	Identifying post-menopausal women at elevated risk for epithelial ovarian cancer	Urban, Hawley, Janes, Karlan, Berg, Drescher, Manson, Palomares, Daly, Wactawski-Wende, O'Sullivan, Thorpe, Robinson, Lane, Li, Anderson, et al.	OS	Gynecol Oncol. 2015 Sep 3. pii: S0090-8258(15)30115-3. doi: 10.1016/ j.ygyno.2015.08.024 .	AS282, AS97
1522	Risk of mortality according to body mass index and body composition among postmenopausal women	Bea, Thomson, Wertheim, Nicholas, Ernst, Hu, Jackson, Cauley, Lewis, Caan, Roe, Chen	Gen	Am J Epidemiol. 2015 Oct 1;182(7):585-96. doi: 10.1093/aje/kwv103.	AS153
1539	Menopausal estrogen therapy and non-Hodgkin's lymphoma: a post- hoc analysis of Women's Health Initiative Randomized Clinical Trial	Kato, Chlebowski, Hou, Wactawski-Wende, Ray, Abrams, Bock, Desai, Simon	CT	Int J Cancer. 2015 Aug 27. doi: 10.1002/ijc.29819.	
1555	B-type natriuretic peptides improve cardiovascular disease risk prediction in a multiethnic cohort of women	Everett, Berger, Manson, Ridker, Cook	OS	J Am Coll Cardiol. 2014 Oct 28;64(17):1789-97. doi: 10.1016/j.jacc.2014.04.089.	BAA22
1565	Smoking behavior and risk of melanoma and non-melanoma skin cancer in the Women's Health Initiative	Henderson, Kubo, Desai, David, Tindle, Sinha, Seiffert, Hou, Messina, Saquib, Stefanick, Tang	OS	J Am Acad Dermatol. 2015 Jan;72(1):190-191.e3. doi: 10.1016/j.jaad.2014.09.024	
1580	Electric blanket (EB) use and risk of thyroid cancer in the Women's Health Initiative (WHI) observational cohort	Kato, Young, Liu, Abrams, Bock, Simon	OS	Women Health. 2015 Oct;55(7):829-41. doi: 10.1080/03630242.2015.1050545.	
1587	Active and passive smoking in relation to lung cancer incidence in the Women's Health Initiative Observational Study prospective cohort	Wang, Kubo, Luo, Desai, Hedlin, Henderson, Chlebowski, Tindle, Chen, Gomez, Manson, Schwartz, Wactawski-Wende, Cote, Patel,	OS	Ann Oncol. 2015 Jan;26(1):221-30. doi: 10.1093/annonc/mdu470.	
1597	Urinary tract stones and osteoporosis: findings From the Women's Health Initiative	Carbone, Hovey, Andrews, Thomas, Sorensen, Crandall, Watts, Bethel, Johnson	Gen	J Bone Miner Res. 2015 May 19. doi: 10.1002/jbmr.2553.	

Table 17.2
Publications since October 2014

MS#	Title	Authors	Focus	Reference	Study #
1614	Breast cancer risk in metabolically healthy but overweight postmenopausal women	Gunter, Xie, Xue, Kabat, Rohan, Wassertheil-Smoller, Ho, Wylie-Rosette, Greco, Yu, Beasley, Strickler	Gen	Cancer Res. 2015 Jan 15;75(2):270-4. doi: 10.1158/0008-5472.CAN-14-2317	AS129
1616	The effect of calcium plus vitamin D supplementation on the risk of venous thromboembolism in the Women's Health Initiative Randomized Controlled Trial	Blondon, Rodabough, Budrys, Johnson, Berger, Shikany, Raiesdana, Heckbert, Manson, LaCroix, Siscovick, Kestenbaum, Smith, de Boer	Gen	Thromb Haemost. 2015 May;113(5):999-1009. doi: 10.1160/TH14-05-0478.	
1646	Estrogen and colorectal cancer incidence and mortality	Lavasani, Chlebowski, Prentice, Kato, Wactawski-Wende, Johnson, Young, Rodabough, Hubbell, Mahinbakht, Simon	Gen	Cancer. 2015 Sep 15;121(18):3261-71. doi: 10.1002/cncr.29464.	
1664	Dietary polyamine intake and colorectal cancer risk in post-menopausal women	Vargas, Ashbeck, Wertheim, Wallace, Neuhouser, Thomson, Thompson	OS	Am J Clin Nutr. 2015 Aug;102(2):411-9. doi: 10.3945/ajcn.114.103895.	
1667	Familial clustering of breast and prostate cancer and risk of postmenopausal breast cancer in the Women's Health Initiative Study	Beebe-Dimmer, Yee, Cote, Petrucelli, Palmer, Bock, Lane, Agalliu, Stefanick, Simon	OS	Cancer. 2015 Apr 15;121(8):1265-72. doi: 10.1002/cncr.29075.	
1670	Healthy lifestyle and decreasing risk of heart failure in wome: The Women's Health Initiative Observational Study	Agha, Loucks, Tinker, Waring, Michaud, Foraker, Li, Martin, Greenland, Manson, Eaton	OS	J Am Coll Cardiol. 2014 Oct 28;64(17):1777-85. doi: 10.1016/j.jacc.2014.07.981.	
1677	Risk of heart failure among postmenopausal women: a secondary analysis of the randomized trial of Vitamin D plus calcium of the Women's Health Initiative	Donneyong, Hornung, Taylor, Baumgartner, Myers, Eaton, Gorodeski, Klein, Martin, Shikany, Song, Li, Manson	CT	Circ Heart Fail. 2015 Jan;8(1):49-56. doi: 10.1161/CIRCHEARTFAILURE.114.001738.	
1688	Factors associated with nursing home admission after stroke in older women	Bell, LaCroix, Desai, Hedlin, Rapp, Cene, Savla, Shippee, Wassertheil-Smoller, Stefanick, Masaki	Gen	J Stroke Cerebrovasc Dis. 2015 Oct;24(10):2329-37. doi: 10.1016/j.jstrokecerebrovasdis.2015.06.013.	

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1693	Red meat intake, NAT2, and risk of colorectal cancer: a pooled analysis of 11 studies	Ananthakrishnan, Du, Berndt, Brenner, Caan, Casey, Chang-Claude, Duggan, Fuchs, Gallinger	Gen	Cancer Epidemiol Biomarkers Prev. 2015 Jan;24(1):198-205. doi: 10.1158/1055-9965.EPI-14-0897.	AS224
1703	Kidney function and cardiovascular events in postmenopausal women: the impact of race and ethnicity in the Women's Health Initiative	Arce, Rhee, Cheung, Hedlin, Kapphahn, Franceschini, Kalil, Martin, Qi, Shara, Desai, Stefanick, Winklemayer	Gen	Am J Kidney Dis. 2015 Sep 1. pii: S0272-6386(15)01043-4. doi: 10.1053/j.ajkd.2015.07.020.	
1734	Folate-mediated one-carbon metabolism genes and interactions with nutritional factors on colorectal cancer risk: Women's Health Initiative Observational Study	Cheng, Makar, Neuhouser, Miller, Song, Brown, Beresford, Zheng, Poole, Galbraith, Duggan, Habermann, Bailey, Maneval Jr, Caudill, Toriola, et al.	OS	Cancer. 2015 Oct 15;121(20):3684-91. doi: 10.1002/cncr.29465.	AS195
1741	Relationship of pain and ancestry in African American women	Robbins, Qi, Garcia, Younger, Seldin	Gen	Eur J Pain. 2015 May;19(5):601-10. doi: 10.1002/ejp.680.	BAA1
1748	Driving with mild cognitive impairment or dementia: cognitive test performance and proxy report of daily life function in older women	Vaughan, Hogan, Rapp, Dugan, Marottoli, Snively, Shumaker, Sink	OS	J Am Geriatr Soc. 2015 Sep;63(9):1774-1782. doi: 10.1111/jgs.13634.	AS244
1753	Adiposity patterns and the risk for ESRD in postmenopausal women	Franceschini, Gouskova, Reiner, Bosom, Howard, Pettinger, Pettinger, Umans, Kooperberg, Winklemayer, Eaton, Heiss, Fine	N/A	Clin J Am Soc Nephrol. 2015 Feb 6;10(2):241-50. doi: 10.2215/CJN.02860314.	M5
1763	Baseline age and time to major fracture in younger postmenopausal women	Gourlay, Overman, Fine, Ensrud, Crandall, Gass, Robbins, Johnson, LeBlanc, Womack, Schousboe, LaCroix	Gen	Menopause. 2015 Jun;22(6):589-97. doi: 10.1097/GME.0000000000000356.	
1773	Menopausal symptoms in women with chronic kidney disease	Cheung, Stefanick, Allison, LeBlanc, Vitolins, Shara, Chertow, Winklemayer, Tamura	OS	Menopause. 2015 Sep;22(9):1006-11. doi: 10.1097/GME.0000000000000416.	

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MS#	Title	Authors	Focus	Reference	Study #
1776	Residential proximity to major roadways and incident hypertension in post-menopausal women	Kingsley, Eliot, Whitsel, Wang, Coull, Hou, Margolis, Margolis, Mu, Wu, Johnson, Allison, Manson, Eaton, Wellenius	CT	Environ Res. 2015 Aug 14;142:ER15803. doi: 10.1016/ j.envres.2015.08.002 .	
1783	Relationship between glaucoma and admixture in postmenopausal African-American women	Garcia, Qi, Singh, Kosoy, Nassir, Fijalkowski, Haan, Robbins, Seldin	Gen	Ethn Dis. 2014 Autumn;24(4):399-405	BAA1
1790	The effect of hormone therapy on mean blood pressure and visit-to-visit blood pressure variability in postmenopausal women: results from the Women's Health Initiative randomized controlled trials	Shimbo, Wang, LaMonte, Allison, Wellenius, Bavry, Martin, Aragaki, Newman, Swica, Rossouw, Manson, Wassertheil-Smoller	CT	J Hypertens. 2014 Oct;32(10):2071-81. doi: 10.1097/HJH.0000000000000287	
1797	Association of aspirin and NSAID use with risk of colorectal cancer according to genetic variants	Nan, Hutter, Lin, Jacobs, Ulrich, White, Baron, Berndt, Brenner, Butterbach, Caan	OS	JAMA. 2015 Mar 17;313(11):1133-42. doi: 10.1001/jama.2015.1815	AS224
1838	Rheumatoid arthritis, anti-CCP positivity, and cardiovascular disease risk in the Women's Health Initiative	Mackey, Kuller, Deane, Walitt, Chang, Holers, Robinson, Tracy, Hlatky, Eaton, Liu, Freiberg, Talabi, Schelbert, Moreland	Gen	Arthritis Rheumatol. 2015 Sep;67(9):2311-22. doi: 10.1002/art.39198.	BAA20
1850	Prospective analysis of health and mortality risk in veteran and non-veteran participants in the Women's Health Initiative	Weitlauf, LaCroix, Bird, Woods, Washington, Katon, LaMonte, Goldstein, Bassuk, Sarto, Stefanick	Gen	Womens Health Issues. 2015 Sep 25. pii: S1049-3867(15)00131-0. doi: 10.1016/j.whi.2015.08.006.	
1872	Leveraging population admixture to characterize the heritability of complex traits	Zaitlen, Pasaniuc, Sankararam, Bhatia, Zhang, Gusev, Young, Tandon, Pollack, Vilhjalmsson	Gen	Nat Genet. 2014 Dec;46(12):1356-62. doi: 10.1038/ng.3139.	M5, W54
1882	Statins and breast cancer stage and mortality in the Women's Health Initiative	Desai, Lehman, Chlebowski, Kwan, Arun, Manson, Lavsani, Wassertheil-Smoller, Sarto, LeBoff, Cauley, Cote, Beebe-Dimmer, Jay, Simon	Gen	Cancer Causes Control. 2015 Apr;26(4):529-39. doi: 10.1007/s10552-015-0530-7.	

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MS#	Title	Authors	Focus	Reference	Study #
1895	Overweight, obesity, and postmenopausal invasive breast cancer risk: a secondary analysis of the Women's Health Initiative Randomized Clinical Trials	Neuhouser, Aragaki, Prentice, Manson, Chlebowski, Carty, Ochs-Balcom, Thomson, Caan, Tinker, Urrutia, Knudtson, Anderson	CT	JAMA Oncol. 2015 Aug 1;1(5):611-21. doi: 10.1001/jamaoncol.2015.1546.	
1917	Lean body mass and risk of incident atrial fibrillation in post-menopausal women	Azarbal, Stefanick, Assimes, Manson, Bea, Li, Hlatky, Larson, LeBlanc, Albert, Nassir, Martin, Perez	CT	Eur Heart J. 2015 Sep 14. pii: ehv423.	W35
1918	Analyses of 7,635 patients with colorectal cancer using independent training and validation cohorts show that rs9929218 in CDH1 is a prognostic marker of survival	Smith, Fisher, Harris, Maughan, Phipps, Richman, Seymour, Tomlinson, Rosmarin, Kerr, Chan, Peters, Newcomb	Gen	Clin Cancer Res. 2015 Aug 1;21(15):3453-61. doi: 10.1158/1078-0432.CCR-14-3136.	M24
1944	Chocolate-candy consumption and 3-year weight gain among postmenopausal U.S. women	Greenberg, Manson, Buijsse, Wang, Allison, Neuhouser, Tinker, Waring, Isasi, Martin, Thomson	OS	Obesity (Silver Spring). 2015 Mar;23(3):677-83. doi: 10.1002/oby.20983.	
1951	Plasma choline metabolites and colorectal cancer risk in the Women's Health Initiative Observational Study	Bae, Ulrich, Neuhouser, Malysheva, Bailey, Xiao, Brown, Cushing-Haugen, Zheng, Cheng, Miller, Green, Lane, Beresford, Caudill	OS	Cancer Res. 2014 Dec 15;74(24):7442-52. doi: 10.1158/0008-5472.CAN-14-1835.	AS195
1964	Is tree loss associated with cardiovascular-disease risk in the Women's Health Initiative? A natural experiment	Donovan, Michael, Gatziolis, Prestemon, Whitsel	Gen	Health Place. 2015 Aug 31;36:1-7. doi: 10.1016/j.healthplace.2015.08.007.	AS386
1976	Optimal cutoffs of obesity measures in relation to cancer risk in postmenopausal women in the Women's Health Initiative Study	Heo, Kabat, Strickler, Lin, Hou, Stefanick, Anderson, Rohan	Gen	J Womens Health (Larchmt). 2015 Mar;24(3):218-27. doi: 10.1089/jwh.2014.4977.	
1989	Diet drink consumption and the risk of cardiovascular events: a report from the Women's Health Initiative	Vyas, Rubenstein, Robinson, Seguin, Vitolins, Kazlauskaite, Shikany, Johnson, Snetselaar, Wallace	OS	J Gen Intern Med. 2015 Apr;30(4):462-8. doi: 10.1007/s11606-014-3098-0.	

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2014	Antioxidant micronutrients and risk of renal cell carcinoma in the Women's Health Initiative Cohort	Ho, Simon, Yildiz, Shikany, Kato, Beebe-Dimmer, Cetnar, Bock	Gen	Cancer. 2015 Feb 15;121(4):580-8. doi: 10.1002/cncr.29091.	
2056	Genetic variants of adiponectin and risk of colorectal cancer	Song, Gong, Giovannucci, Berndt, Brenner, Chang-Claude, Curtis, Harrison, Hoffmeister, Hsu	Gen	Int J Cancer. 2015 Jul 1;137(1):154-64. doi: 10.1002/ijc.29360.	AS224
2074	Hypertension, dietary sodium and cognitive decline: Results from the Women's Health Initiative Memory Study	Haring, Wu, Coker, Seth, Snetselaar, Manson, Rossouw, Wassertheil-Smoller	OS	Am J Hypertens. 2015 Jul 2.	AS39
2080	Diet quality and survival after ovarian cancer: Results from the Women's Health Initiative	Thomson, Crane, Wertheim, Neuhouser, Li, Snetselaar, Basen-Engquist, Zhou, Irwin	Gen	J Natl Cancer Inst. 2014 Oct 21;106(11). pii: dju314. doi: 10.1093/jnci/dju314.	
2107	Urinary cadmium and estimated dietary cadmium in the Women's Health Initiative	Quraishi, Adams, Shafer, Meliker, Li, Luo, Neuhouser, Newcomb	Gen	J Expo Sci Environ Epidemiol. 2015 May 27. doi: 10.1038/jes.2015.40.	AS290
2108	Long-chain ω-3 fatty acid intake and endometrial cancer risk in the Women's Health Initiative	Brasky, Rodabough, Liu, Kurta, Wise, Orchard, Cohn, Belury, White, Manson, Neuhouser	Gen	Am J Clin Nutr. 2015 Apr;101(4):824-34. doi: 10.3945/ajcn.114.098988.	
2114	Longitudinal changes in insomnia status and incidence of physical, emotional, or mixed impairment in postmenopausal women participating in the Women's Health Initiative (WHI) study	Zaslavsky, LaCroix, Hale, Tindle, Shochat	CT	Sleep Med. 2015 Mar;16(3):364-71. doi: 10.1016/j.sleep.2014.11.008.	
2130	Stroke in the Women's Health Initiative	Wassertheil-Smoller, Kaplan, Salazar	Gen	Semin Reprod Med. 2014 Nov;32(6):438-46. doi: 10.1055/s-0034-1384627.	

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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, Okin, Perez, Psaty, Soliman, et al.	Gen	Epidemiology. 2014 Nov;25(6):790-8. doi: 10.1097/EDE.0000000000000168	M6
2148	Longitudinal association of measures of adiposity with serum antioxidant concentrations in postmenopausal women	Kabat, Heo, Ochs-Balcom, LeBoff, Mossavar-Rahmani, Adams-Campbell, Nassir, Ard, Zaslavsky, Rohan	Gen	Eur J Clin Nutr. 2015 May 27. doi: 10.1038/ejcn.2015.74.	
2150	Longitudinal association of anthropometric measures of adiposity with cardiometabolic risk factors in postmenopausal women	Kabat, Heo, Van Horn, Kazlauskaite, Getaneh, Ard, Vitolins, Waring, Zaslavsky, Wassertheil-Smoller, Rohan	Gen	Ann Epidemiol. 2014 Oct 15;24(12):896-902. doi: 10.1016/ j.annepidem.2014.10 .007.	
2156	Insulin resistance and risk of cardiovascular disease in postmenopausal women: a cohort study from the Women's Health Initiative	Schmiegelow, Hedlin, Stefanick, Mackey, Allison, Martin, Robinson, Hlatky	Gen	Circ Cardiovasc Qual Outcomes. 2015 May;8(3):309-16. doi: 10.1161/CIRCOUTCOMES.114.001563.	
2157	Race and ethnicity, obesity, metabolic health, and risk of cardiovascular disease in postmenopausal women	Schmiegelow, Hedlin, Mackey, Martin, Vitolins, Stefanick, Perez, Allison, Hlatky	Gen	J Am Heart Assoc. 2015 May 20;4(5). pii: e001695. doi: 10.1161/JAHA.114.001695.	
2163	Reconciling the divergent findings from clinical trials and observational studies of menopausal hormone therapy for prevention of coronary heart disease	Rossouw	Gen	Semin Reprod Med. 2014 Nov;32(6):426-32. doi: 10.1055/s-0034-1384625.	
2178	Breast cancer after use of estrogen plus progestin and estrogen alone: analyses of data from 2 Women's Health Initiative randomized clinical trials	Chlebowski, Rohan, Manson, Aragaki, Kaunitz, Stefanick, Simon, Johnson, Wactawski-Wende, O'Sullivan, Adams-Campbell, Nassir, Lessin, Prentice	CT	JAMA Oncol. 2015 Jun 1;1(3):296-305. doi: 10.1001/jamaoncol.2015.0494	
2183	Global cognitive function before, surrounding, and after ischemic stroke: the role of risk and protective factors varies with time among ischemic stroke survivors	Vaughan, Bushnell, Bell, Espeland	CT	J Am Geriatr Soc. 2015 Sep;63(9):1774-82. doi: 10.1111/jgs.13634.	AS39

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2217	The evolution of the WHI 80+ cohort	Beavers, Pettinger, Espeland, Snively, Leng, Hunt, Tindle, Shumaker	Gen	J Gerontol A Biol Sci Med Sci. 2015 Apr 28. pii: glv050.	
2238	Reproductive factors, exogenous hormone use and risk of hepatocellular carcinoma among U.S. women: Results from the Liver Cancer Pooling Project	McGlynn, Sahasrabuddhe, Campbell, Graubard, Chen, Schwartz, Petrick, Alavanja, Andreotti, Boggs	OS	Br J Cancer. 2015 Mar 31;112 Suppl:1266-72. doi: 10.1038/bjc.2015.58	
2241	Association of sickle cell trait with chronic kidney disease and albuminuria in African-Americans	Naik, Derebail, Grams, Franceschini, Auer, Peloso, Young, Lettre, Peralta, Katz	Gen	JAMA. 2014 Nov 26;312(20):2115-25. doi: 10.1001/jama.2014.15063	
2248	High glycemic index diet as a risk factor for depression: Analyses from the Women's Health Initiative	Gangwisch, Hale, Garcia, Malaspina, Opler, Payne, Rossom, Lane	OS	Am J Clin Nutr. 2015 Aug;102(2):454-63. doi: 10.3945/ajcn.114.103846.	
2252	Joint associations of diet, lifestyle, and genes with age-related macular degeneration	Meyers, Liu, Millen, Iyengar, Blodi, Johnson, Snodderly, Klein, Gehrs, Tinker, Sarto, Robinson, Wallace, Mares	OS	Ophthalmology. 2015 Sep 6. pii: S0161-6420(15)00767-8. doi: 10.1016/j.ophtha.2015.07.029.	AS105, AS257
2254	Powerful set-based gene-environment interaction testing framework for complex diseases	Jiao, Peters, Berndt, Bezieau, Brenner, Campbell, Chan, Chang-Claude, Lemire, Newcomb, Potter, Slattery, Woods, Hsu	Gen	Genet Epidemiol. 2015 Jun 10. doi: 10.1002/gepi.21908.	AS224
2265	Defining the role of common variation in the genomic and biological architecture of adult human height	Wood, Esko, Yang, Vedantam, Pers, Gustafsson, Chu, Estrada, Luan, Kutalik	Gen	Nat Genet. 2014 Nov;46(11):1173-86. doi: 10.1038/ng.3097.	M6
2274	Risk of breast, endometrial, colorectal, and renal cancers in postmenopausal women in association with a body shape index and other anthropometric measures	Kabat, Xue, Kamensky, Lane, Bea, Chen, Qi, Stefanick, Chlebowski, Wactawski-Wende, Wassertheil-Smoller, Rohan	OS	Cancer Causes Control. 2015 Feb;26(2):219-29. doi: 10.1007/s10552-014-0501-4.	

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2287	Within-person variability of urinary Bisphenol-A in postmenopausal women	Reeves, Luo, Hankinson, Hendryx, Margolis, Manson, Franke	Gen	Environ Res. 2014 Nov;135:285-8. doi: 10.1016/ j.envres.2014.09.016 .	AS425
2288	New genetic loci link adipocyte and insulin biology to body fat distribution	Shungin, Winkler, Croteau-Chonka, Ferreira, Locke, Mägi, Strawbridge, Pers, Fischer, Justice	Gen	Nature. 2015 Feb 12;518(7538):187-96. doi: 10.1038/nature14132	M6
2290	Relationships between dog ownership and physical activity in postmenopausal women	Garcia, Wertheim, Manson, Chlebowski, Volpe, Howard, Stefanick, Thomson	Gen	Prev Med. 2015 Jan;70:33-8. doi: 10.1016/ j.ypmed.2014.10.030 .	
2326	Cross-species antibody microarray interrogation identifies a 3-protein panel of plasma biomarkers for the early detection of pancreas cancer	Mirus, Zhang, Li, Lokshin, Prentice, Lampe, Hingorani	OS	Clin Cancer Res. 2015 Apr 1;21(7):1764-71. doi: 10.1158/1078-0432.CCR-13-3474.	BAA16
2327	Genome-wide association study of colorectal cancer identifies six new susceptibility loci	Schumacher, Schmit, Jiao, Edlund, Wang, Zhang, Hsu, Huang, Fischer, Harju, Aragaki, Caan, Jackson, Kooperberg, LaCroix, Newcomb, et al.		Nat Commun. 2015 Jul 7;6:7138. doi: 10.1038/ncomms8138	AS224
2329	Prospective associations of coronary heart disease loci in African Americans using the MetaboChip: the PAGE study	Franceschini, Hu, Reiner, Buyske, Nalls, Yanek, Li, Hindorff, Cole, Howard	Gen	PLoS One. 2014 Dec 26;9(12):e113203. doi: 10.1371/journal.pone.011320 3. eCollection 2014.	M6
2334	Depression and quality of life before and after breast cancer diagnosis in older women from the Women's Health Initiative	Jones, LaCroix, Li, Zaslavsky, Wassertheil-Smoller, Weitlauf, Brenes, Nassir, Ockene, Caire-Juvera, Danhauer	Gen	J Cancer Surviv. 2015 Feb 24.	
2335	Prospective data from the Women's Health Initiative on depression, stress, and inflammation	Jones, Weitlauf, Danhauer, Qi, Zaslavsky, Wassertheil-Smoller, Brenes, LaCroix	Gen	J Health Psychol. 2015 Sep 8. pii: 1359105315603701.	
2337	Association of obstructive sleep apnea risk factors with nocturnal enuresis in postmenopausal women	Koo, McCool, Hale, Stone, Eaton	Gen	Menopause. 2015 Aug 31.	

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2349	Ambient air pollution and neurotoxicity on brain structure: Evidence from Women's Health Initiative Memory Study	Chen, Wang, Wellenius, Serre, Driscoll, Casanova, McArdle, Manson, Chui, Espeland	CT	Ann Neurol. 2015 Sep;78(3):466-76. doi: 10.1002/ana.24460.	AS252
2351	Incidence of endometrial spotting or bleeding during continuous-combined estrogen-progestin therapy in postmenopausal women with and without hypertension	Sriprasert, Baydoun, Barnabei, Nassir, LaCroix, Archer	CT	Menopause. 2015 Oct;22(10):1067-75. doi: 10.1097/GME.0000000000000436.	
2352	Association between magnesium intake and risk of colorectal cancer among postmenopausal women	Gorczyca (Gabbard), He, Xun, Margolis, Wallace, Lane, Thomson, Ho, Shikany, Luo	OS	Cancer Causes Control. 2015 Sep 21.	
2356	Assessing potentially time-dependent treatment effect from clinical trials and observational studies for survival data, with applications to the Women's Health Initiative combined hormone therapy trial	Yang, Prentice	CT	Stat Med. 2015 May 20;34(11):1801-17. doi: 10.1002/sim.6453.	
2357	Integrative analysis of sequencing and array genotype data for discovering disease associations with rare mutations	Hu, Li, Auer, Lin	Gen	Proc Natl Acad Sci U S A. 2015 Jan 27;112(4):1019-24. doi: 10.1073/pnas.1406143112.	
2367	Development and application of an automated algorithm to identify a window of consecutive days of accelerometer wear for large‐scale studies	Rillamas-Sun, Buchner, Di, Evenson, LaCroix	Gen	BMC Res Notes. 2015 Jun 26;8:270. doi: 10.1186/s13104-015-1229-2	AS286
2379	Risk profiles for weight gain among postmenopausal women: a classification and regression tree analysis approach	Jung, Vitolins, Fenton, Frazier-Wood, Hursting, Chang	OS	PLoS One. 2015 Mar 30;10(3):e0121430. doi: 10.1371/journal.pone.0121430. eCollection 2015	AS100
2387	A prospective analysis of diet quality and endometrial cancer among 84,415 postmenopausal women in The Women's Health Initiative	George, Ballard-Barbash, Shikany, Crane, Neuhouser	Gen	Ann Epidemiol. 2015 Oct;25(10):788-93. doi: 10.1016/ j.annepidem.2015.05 .009.	

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2394	Leukocyte telomere length and risks of incident coronary heart disease and mortality in a racially diverse population of postmenopausal women	Carty, Kooperberg, Liu, Herndon, Assimes, Hou, Kroenke, LaCroix, Kimura, Aviv, Reiner	Gen	Arterioscler Thromb Vasc Biol. 2015 Oct;35(10):2225-31. doi: 10.1161/ATVBAHA.115.305838.	BAA25
2400	Comparison of fracture risk prediction by the U.S. Preventive services task force strategy and two alternative strategies in women 50-64 years old in the Women's Health Initiative	Crandall, Larson, Watts, Gourlay, Donaldson, LaCroix, Cauley, Wactawski-Wende, Gass, Robbins, Ensrud	Gen	J Clin Endocrinol Metab. 2014 Dec;99(12):4514-22. doi: 10.1210/jc.2014-2332.	
2419	Genome-wide association study identifies new follicular lymphoma outside the HLA region	Skibola, Berndt, Vijai, Conde, Wang, Yeager, de Bakker, Birmann, Vajdic, Foo	Gen	Am J Hum Genet. 2014 Oct 2;95(4):462-71. doi: 10.1016/j.ajhg.2014.09.004	AS301
2428	Postmenopausal hormone therapy, type 2 diabetes mellitus, and brain volumes	Espeland, Brinton, Manson, Yaffe, Hugenschmidt, Vaughan, Craft, Edwards, Casanova, Masaki, Resnick, WHIMS-MRI2 Study Group	CT	Neurology. 2015 Sep 29;85(13):1131-8. doi: 10.1212/WNL.0000000000001816.	AS183
2442	Serum IGFBP-2 and risk of atypical hyperplasia of the breast	Catsburg, Gunter, Tinker, Chlebowski, Pollak, Strickler, Cote, Page, Rohan	CT	J Cancer Epidemiol. 2015;2015:203284. doi: 10.1155/2015/203284.	
2444	Dispositional optimism and terminal decline in global quality of life	Zaslavsky, Palgi, Rillamas-Sun, LaCroix, Schnall, Woods, Cochrane, Garcia, Hingle, Post, Seguin, Tindle, Shrira	CT	Dev Psychol. 2015 Jun;51(6):856-63. doi: 10.1037/dev0000018.	
2445	Global quality of life modifies terminal change in physical functioning among older adult women	Shrira, Zaslavsky, LaCroix, Seguin, Post, Tindle, Hingle, Woods, Cochrane, Garcia, Schnall, Rillamas-Sun, Palgi	Gen	Age Ageing. 2015 May;44(3):520-4. doi: 10.1093/ageing/afu176.	
2459	Vasomotor symptoms and quality of life among veteran and non-veteran postmenopausal women	Katon, Gray, Gerber, Harrington, Woods, Weitlauf, Bean-Mayberry, Goldstein, Hunt, Katon, Haskell, McCutcheon, Gass, Gibson, Zephyrin	OS	Gerontologist. 2015 Jul 28. pii: gnv104.	

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2473	Longitudinal association of hemostatic factors with risk for cancers of the breast, colorectum, and lung among postmenopausal women	Kabat, Salazar, Zaslavsky, Lane, Rohan	Gen	Eur J Cancer Prev. 2015 Aug 27.	
2530	Association of serum 17β-estradiol concentration, hormone therapy and alveolar crestal height in postmenopausal women	Wang, LaMonte, Hovey, Mai, Tezal, Millen, Ochs-Balcom, Genco, Barnabei, Wactawski-Wende	OS	J Periodontol. 2015 Apr;86(4):595-605. doi: 10.1902/jop.2015.140533.	AS15
2536	The dietary patterns methods project:synthesis of findings across cohorts and relevance to dietary guidance	Liese, Krebs-Smith, Subar, George, Harmon, Neuhouser, Boushey, Schap, Reedy	OS	J Nutr. 2015 Mar;145(3):393-402. doi: 10.3945/jn.114.205336.	
2541	Residential proximity to major roadways and prevalent hypertension among post-menopausal women: results from the Women's Health Initiative San Diego cohort	Kirwa, Eliot, Wang, Adams, Morgan, Kerr, Norman, Eaton, Allison, Wellenius	Gen	J Am Heart Assoc. 2014 Oct 1;3(5). pii: e000727. doi: 10.1161/JAHA.113.000727	
2552	Occupational physical demand and risk of hip fracture in older women	Palumbo, Michael, Burstyn, Lee, Wallace	OS	Occup Environ Med. 2015 Aug;72(8):567-72. doi: 10.1136/oemed-2014-102670.	
2592	Wrist fracture and risk of subsequent fracture: findings from the Women’s Health Initiative Study	Crandall, Hovey, Cauley, Andrews, Curtis, Wactawski-Wende, Wright, Li, LeBoff	Gen	J Bone Miner Res. 2015 May 19. doi: 10.1002/jbmr.2559.	
2593	Bone mineral density as a predictor of subsequent wrist fractures: findings from the Women’s Health Initiative Study	Crandall, Hovey, Andrews, Cauley, Manson, Wactawski-Wende, Wright, Li, Beavers, Curtis, LeBoff	Gen	J Clin Endocrinol Metab. 2015 Sep 14:jc20152568.	
2682	Of conflicts, conspiracies, red herrings, and black swans	Wactawski-Wende, Anderson	N/A	Climacteric. 2015 Jun;18(3):343-5. doi: 10.3109/13697137.2015.1019244.	
2697	DNA methylation age of blood predicts future onset of lung cancer in the Women's Health Initiative	Levine, Hosgood, Chen, Absher, Assimes, Horvath	Gen	Aging (Albany NY). 2015 Sep;7(9):690-700	BAA23

Table 17.2
Publications since October 2014

MS#	Title	Authors	Focus	Reference	Study #
2717	Pre-existing diabetes and breast cancer prognosis among elderly women	Luo, Hendryx, Virnig, Wen, Chlebowski, Chen, Rohan, Tinker, Wactawski-Wende, Lessin, Margolis	Gen	Br J Cancer. 2015 Sep 1;113(5):827-32. doi: 10.1038/bjc.2015.249.	W35
2730	Reliable evidence from placebo-controlled, randomized, clinical trials for menopausal hormone therapy's influence on incidence and deaths from breast cancer	Chlebowski, Anderson, Prentice, Rossouw, Aragaki, Manson	N/A	Climacteric. 2015 Jun;18(3):336-8. doi: 10.3109/13697137.2015.1038770	
2733	Menopausal hormone therapy and breast cancer mortality: Clinical implications	Chlebowski, Anderson	N/A	Ther Adv Drug Saf. 2015 Apr;6(2):45-56. doi: 10.1177/2042098614568300	
2800	Association of cardiometabolic multimorbidity with mortality	Emerging Risk Factors Collaboration	OS	JAMA. 2015 Jul 7;314(1):52-60. doi: 10.1001/jama.2015.7008	

Women's Health Initiative Memory Suite of Studies

2015 Annual Progress Report

Report Date: October 26, 2015

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.

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Section 1.

Introduction

Introduction

This report has been prepared to support the Data Safety 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 Department of Social Sciences and Health Policy in the Division of Public Health Sciences at Wake Forest School of Medicine.

Materials are drawn from study databases and records from October 2015 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 26, 2015

Section 2.

Overview of Suite of Studies

The Women's Health Initiative Memory Study (WHIMS)

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

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

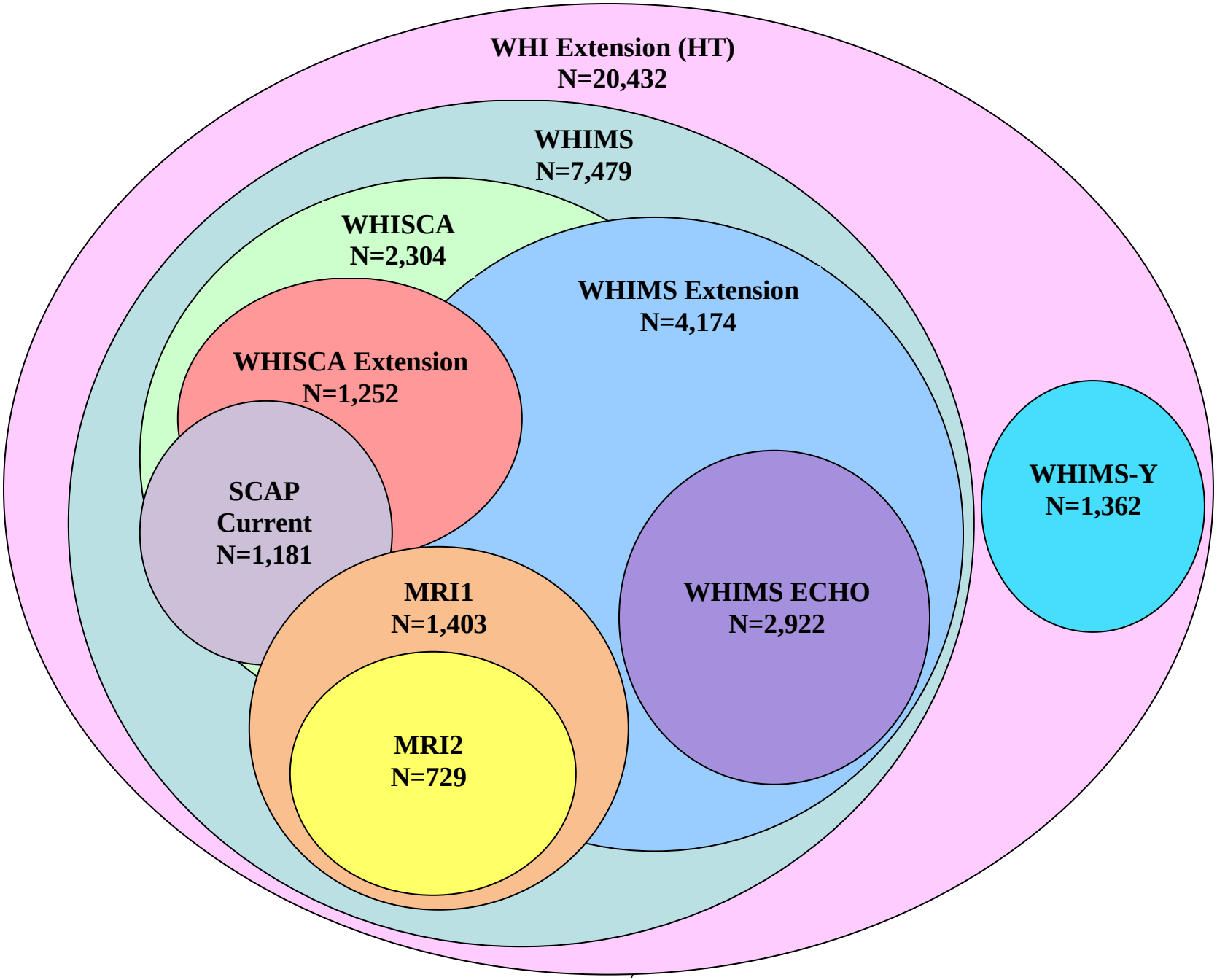
The Women's Health Initiative Memory Study of Younger Women (WHIMS-Y)

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

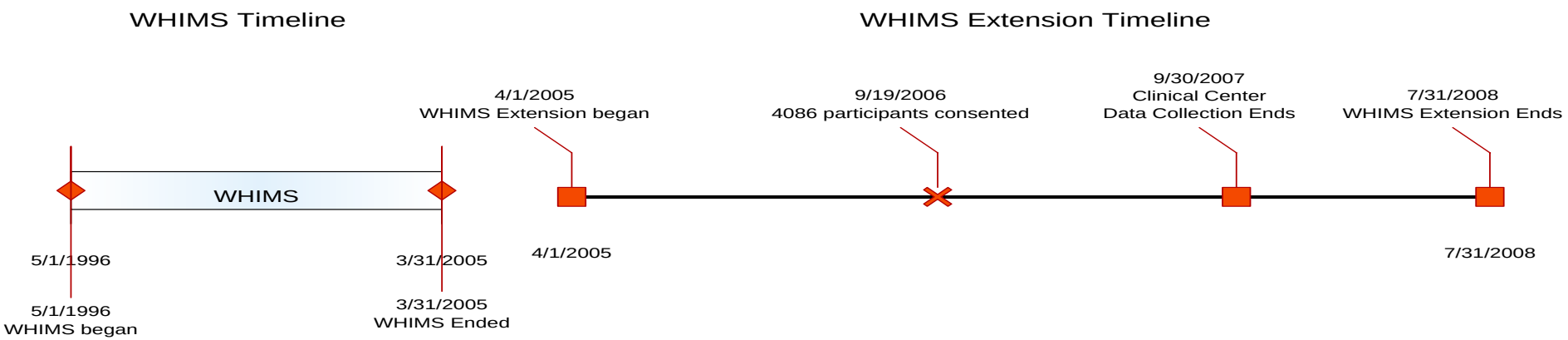
The Women's Health Initiative Study of Cognitive Aging (WHISCA) Extension

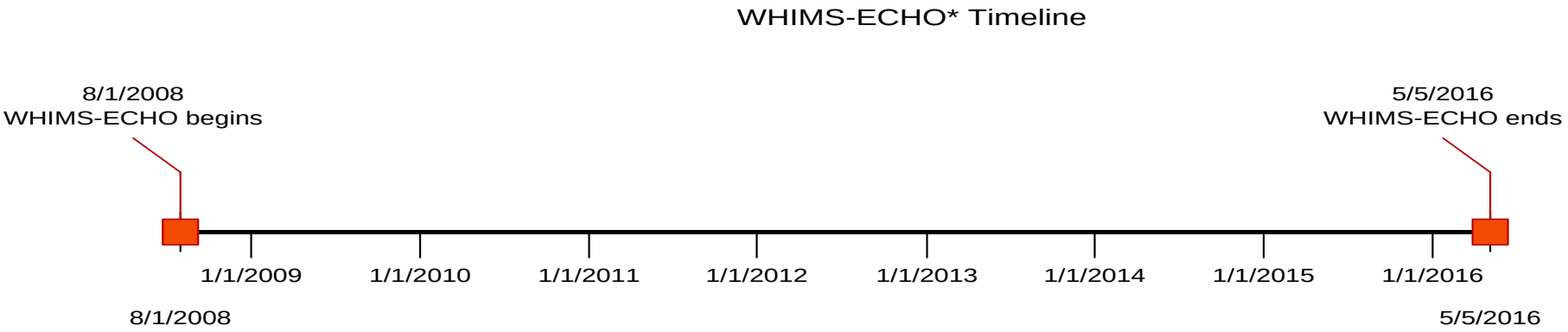
The Women's Health Initiative Memory Study of Cerebral Magnetic Resonance Imaging (WHIMS-MRI-1+2)

2.1 Relationships Among Study Cohorts



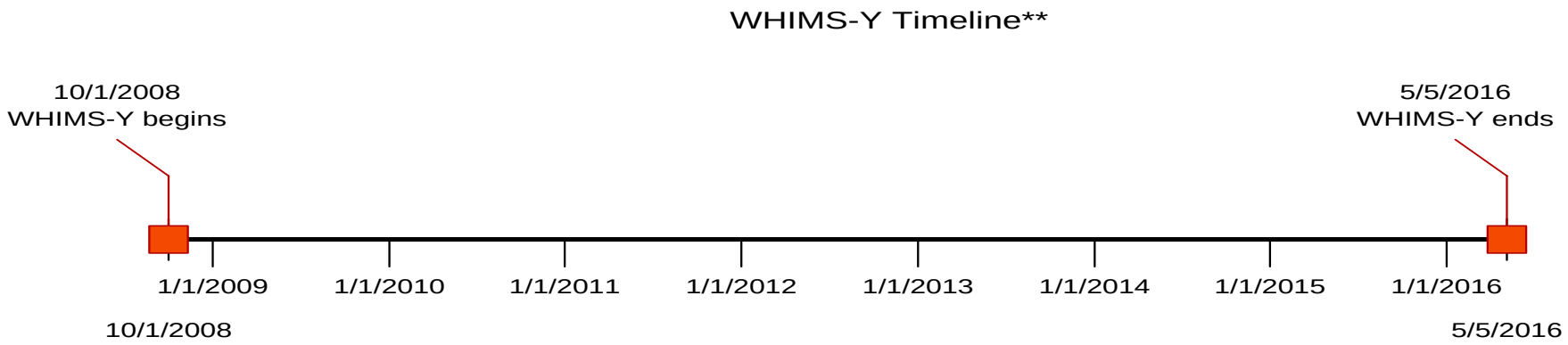
2.2 Timelines for the WHIMS, WHIMS Extension, WHIMS-ECHO, WHIMS-MRI, WHIMS-MRI2, WHISCA, WHISCA Extension, and WHIMS-Y Studies



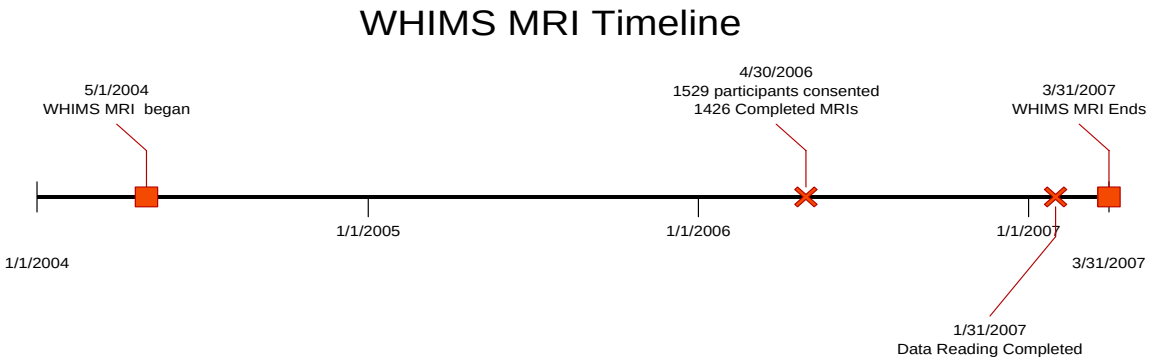


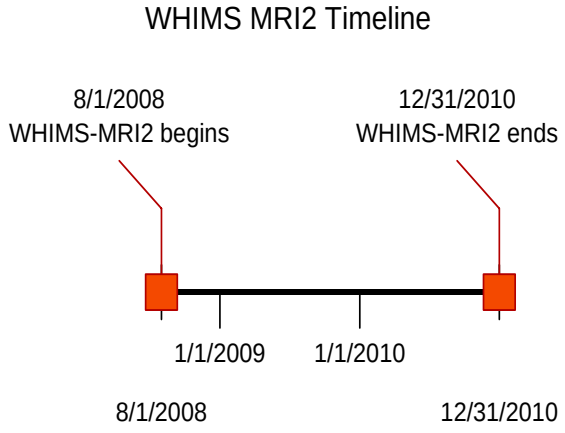
**Funding for WHIMS-ECHO: 8/1/2008-5/5/2011 – NHLBI
5/5/2011-5/6/2016 – NIA

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

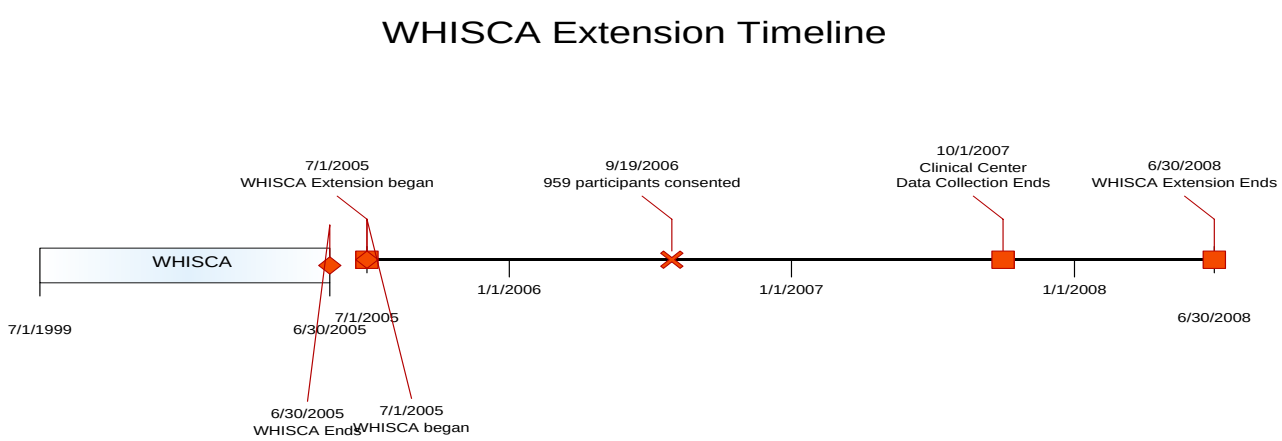


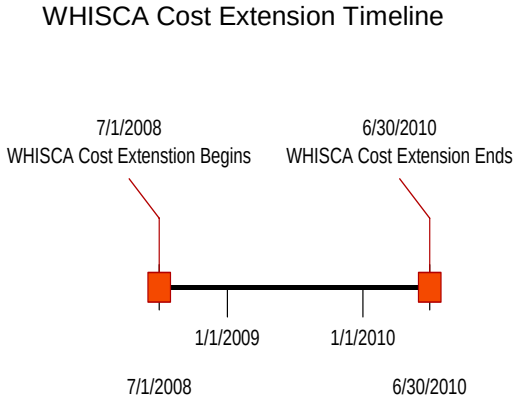
**Funding for WHIMS-Y: 10/1/2008-5/5/2011 – NHLBI
5/6/2011-5/6/2016 – NIA





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





2.3 Studies Objectives

2.3.1 Women's Health Initiative Memory Study (WHIMS)

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

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

Corresponding to an extension for WHI, a concomitant extension for safety monitoring in the WHIMS E-alone and the E+P trials (WHIMS Extension) was funded in March 2004 by the NHLBI. The goal of the WHIMS Extension was to provide post-trial follow-up and surveillance of participants from the completed E+P and E-alone trials to determine whether an increased risk of dementia was sustained following study drug termination. By continuing the ascertainment of PD, MCI, and global cognitive functioning, we increased the power in the surveillance component. The WHIMS Epidemiology of Cognitive Health Outcomes (WHIMS-ECHO) continues the follow-up of this cohort with telephone-based assessments rather than the previous face-to face assessments (see Section 3). In May, 2011 the WHIMS-ECHO Extension was funded by NIA for an additional five years. Early in 2015, discussions with the NIA began regarding a subsequent 5-year extension to begin in May 2016 and extend into 2021. Presently we are awaiting the release of the RFA.

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.

> 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, 8 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 971(23%) declined to release contact information. Of those, 2,922 (91%) 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 26, 2015

	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***	***83***	***2***	***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**	**6**	**5.5**	**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**	**5**	**4.6**	**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**	**2**	**1.7**	**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**	**3**	**1.8**	**5**	**4.5**	**9**	**8.0**	**98**	**87.5**
50=Columbus	**139**	**111**	**79.9**	**2**	**1.4**	**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**	**3**	**2.7**	**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**	**2**	**5.3**	**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**	**4**	**4.2**	**2**	**2.7**	**2**	**2.7**	**69**	**94.5**
70=Pauline	**28**	**15**	**53.6**	**1**	**3.6**	**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

	Year 1		Year 2		Year 3		Year 4		Year 5		Year 6		Year 7		Year 8	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%
Agreed to participate	2663		238		21		0		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	2922	100.0
Lost to follow-up																
---- Deceased	0		63		94		116		83		91		89		18	
---- Withdrew	0		6		78		122		91		95		77		44	
---- Attempts to locate exhausted	0		0		0		0		0		0		0		0	
Due for telephone contact	2663	100.0	2832	97.6	2681	91.8	2443	83.6	2269	77.7	2083	71.3	1917	65.6	1855	63.5
Completed test battery	2615	98.2	2469	87.2	2258	84.2	1998	81.8	1726	76.1	1577	75.7	1215	63.5	86	4.7
Failed after 8 attempts	2	0.1	105	3.7	170	6.3	164	6.7	201	8.9	201	9.7	141	7.4	3	0.2

Table 3-2 WHIMS ECHO Overall Status of Last Call Attempt by Year																
	Year 1		Year 2		Year 3		Year 4		Year 5		Year 6		Year 7		Year 8	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%
Declined	2	0.1	88	3.1	169	6.3	180	7.4	194	8.6	156	7.5	87	4.6	6	0.3
Phone disconnected	0	0.0	66	2.3	43	1.6	72	2.9	100	4.4	103	4.9	114	6.0	18	1.0
Unable to locate	0	0.0	10	0.4	8	0.3	4	0.2	3	0.1	0	0.0	0	0.0	0	0.0
Recontact	2	0.1	29	1.0	0	0.0	0	0.0	0	0.0	1	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	16	0.8	15	0.8	3	0.2
Discontinued	15	0.6	22	0.8	11	0.4	11	0.5	22	1.0	16	0.8	4	0.2	1	0.1
No answer	1	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	0.1	8	0.4	6	0.3
Left message	0	0.0	1	0.0	1	0.0	0	0.0	0	0.0	0	0.0	25	1.3	15	0.8
Scheduled	0	0.0	1	0.0	0	0.0	0	0.0	1	0.0	7	0.3	30	1.6	10	0.5
Busy	0	0.0	1	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.1
No message	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	14	0.7	8	0.4
Other	0	0.0	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	0	0.0	3	0.1	259	13.5	1680	91.5

3.5 Characteristics of Enrollees

Table 3-3 WHIMS-ECHO Characteristics of Enrollees (N=2922)

Characteristic	N (%)
WHI Treatment Assignment	
E-Alone Placebo	543 (18.6)
E-Alone	530 (18.1)
E+P	894 (30.6)
E+P Placebo	955 (32.7)
Age at WHI Enrollment	
64-69	1531 (52.4)
70-74	1028 (35.2)
75+	363 (12.4)
Age as of October 1, 2015	
80-84	539 (18.5)
85-89	1444 (49.4)
90+	939 (32.1)
Baseline WHIMS 3MS	
Less than 90	100 (3.5)
90-94	435 (15.2)
95-100	2329 (81.3)
Race/Ethnicity	
American Indian/Alaskan native	6 (0.2)
Asian/Pacific Islander	42 (1.4)
Black/African American	188 (6.4)
Hispanic/Latino	47 (1.6)
White	2595 (88.8)
Other	43 (1.5)

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.

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.

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 and WHIMS ECHO data.

From WHIMS ECHO currently, 2,777 women were eligible for the DQ based on their TICSm scores which were below the study cut-point. Of these, 2,558 progressed to administration of the DQ.

Table 3-4 Dementia Questionnaire Progressions in WHIMS-ECHO as of October 26, 2015

	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	TOTAL
TICS Administrations	**2624**	**2468**	**2262**	**2006**	**1750**	**1592**	**1207**	**73**	**13982**
DQ Progressions	**442 (16.8%)**	**460 (18.6%)**	**426 (18.8%)**	**394 (19.6%)**	**361 (20.6%)**	**372 (23.4%)**	**304 (25.2%)**	**18 (24.7%)**	**2777 (19.9%)**
Withdrawals	**45 (10.2%)**	**45 (9.8%)**	**28 (6.6%)**	**27 (6.9%)**	**22 (6.1%)**	**6 (1.6%)**	**0 (0%)**	**0 (0%)**	**173 (6.2%)**
Missing Proxy information	**7 (1.6%)**	**12 (2.6%)**	**9 (2.1%)**	**7 (1.8%)**	**7 (1.9%)**	**3 (0.8%)**	**1 (0.3%)**	**0 (0%)**	**46 (1.7%)**
Total Eligible DQ Progressions	**390 (88.2%)**	**403 (87.6%)**	**389 (91.3%)**	**360 (91.4%)**	**332 (92.0%)**	**363 (97.6%)**	**303 (99.7%)**	**18 (100%)**	**2558 (92.1%)**

Table 3.5 Dementia Questionnaire Administration in WHIMS-ECHO as of October 26, 2015									
Outcome	**Visit 1**	**Visit 2**	**Visit 3**	**Visit 4**	**Visit 5**	**Visit 6**	**Visit 7**	**Visit 8**	**TOTAL**
DQ's completed^^	242 (62.1%)	202 (50.1%)	250 (64.3%)	226 (62.8%)	167 (50.5%)	173 (47.9%)	140 (46.4%)	3 (16.7%)	1403 (54.9%)
DQ's in process	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.6%)	19 (6.3%)	5 (27.8%)	26 (1.0%)
Phone Disconnected/Unable to locate/Hearing Impaired	23 (5.9%)	26 (6.5%)	27 (6.9%)	17 (4.7%)	11 (3.3%)	14 (3.9%)	17 (5.6%)	0 (0.0%)	135 (5.3%)
Proxy Refused DQ	43 (11.0%)	41 (10.2%)	26 (6.7%)	11 (3.1%)	10 (3.0%)	7 (1.9%)	9 (3.0%)	1 (5.6%)	148 (5.8%)
PD	19 (4.9%)	48 (11.9%)	35 (9.0%)	56 (15.6%)	76 (23.0%)	73 (20.2%)	67 (22.2%)	8 (44.4%)	382 (15.0%)
4th attempt	55 (14.1%)	45 (11.2%)	50 (12.9%)	50 (13.9%)	67 (20.2%)	92 (25.5%)	50 (16.6%)	1 (5.6%)	410 (16.1%)
Permanently Missing	8 (2.1%)	41 (10.2%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	50 (2.0%)
TOTAL	390	403	389	360	331	361	302	18	2554

There are 57 (2.3%) eligible adjudication cases in process. 1,025 (41.1%) adjudication cases are complete and 1409 (56.6%) were not selected to further adjudication based on algorithm.

Table 3-6 Cases Eligible to be Reviewed by Adjudication Committee as of October 26, 2015

	N (%)								
^	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Total
Adjudication in process	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	2 (0.7%)	51 (26.7%)	3 (75.0%)	57 (2.3%)
Adjudication complete	157 (35.0%)	134 (28.0%)	210 (51.6%)	183 (52.0%)	134 (43.9%)	144 (47.4%)	63 (33.0%)	0 (0.0%)	1025 (41.1%)
- - - - ND	30 (19.1%)	35 (26.1%)	50 (23.8%)	52 (28.4%)	30 (22.4%)	29 (20.1%)	4 (6.3%)	0 (0.0%)	230 (22.4%)
- - - - MCI	73 (46.5%)	48 (35.8%)	85 (40.5%)	75 (41.0%)	65 (48.5%)	57 (39.6%)	23 (36.5%)	0 (0.0%)	426 (41.6%)
- - - - PD	54 (34.4%)	47 (35.1%)	75 (35.7%)	55 (30.1%)	39 (29.1%)	55 (38.2%)	36 (57.1%)	0 (0.0%)	361 (35.2%)
- - - - UTC-CI	0 (0.0%)	3 (2.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.4%)	0 (0.0%)	0 (0.0%)	5 (0.5%)
- - - - UTC-FI	0 (0.0%)	1 (0.7%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	1 (0.7%)	0 (0.0%)	0 (0.0%)	3 (0.3%)
Not Adjudicated (ND)	85 (18.9%)	70 (14.6%)	40 (9.8%)	44 (12.5%)	32 (10.5%)	27 (8.9%)	26 (13.6%)	0 (0.0%)	324 (13.0%)
Not Adjudicated (UTC-CI)	84 (18.7%)	147 (30.7%)	88 (21.6%)	67 (19.0%)	84 (27.5%)	73 (24.0%)	27 (14.1%)	1 (25.0%)	571 (22.9%)
Not Adjudicated (UTC-No CI+No DQ)	123 (27.4%)	128 (26.7%)	69 (17.0%)	58 (16.5%)	54 (17.7%)	58 (19.1%)	24 (12.6%)	0 (0.0%)	514 (20.6%)
TOTAL	449	479	407	352	305	304	191	4	2491

Note: ND=No Dementia, MCI=Mid Cognitive Impairment, PD=probable dementia, UTC-CI=Unable to Classify-Cognitive Impairment, UTC-FI=Unable to Classify-Functional Impairment, UTC-No CI+No DQ=Unable to Classify-No Cognitive Impairment+No Dementia Questionnaire

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, across the WHIMS studies, 1,181 participants who have either the status of proxy or are deceased, have become SCAP-eligible. Of the 1,181 SCAP-eligible, 1023 proxies have been contacted by the WHIMS CoC.

Table 4-1 shows the current progress as outlined as of October 26, 2015.

Call Outcome	N	%
Attempts at DQ completion ended		
-----Call Completed	**498**	**48.68**
-----Declined	**55**	**5.38**
-----Phone Disconnected	**75**	**7.33**
-----Unable to locate	**10**	**0.98**
-----Hearing Impaired	**0**	**0.00**
-----Discontinued	**0**	**0.00**
-----Deceased	**3**	**0.29**
-----No Proxy provided	**54**	**5.28**
-----No Answer - 4th and final attempt	**134**	**13.10**
DQ completion possible		
-----Other		
-----Left a Message	**184**	**17.99**
-----Scheduled	**0**	**0.00**
-----Re-Contact	**0**	**0.00**
-----Busy	**0**	**0.00**
-----No Message	**5**	**0.49**
-----No Answer - 1st attempt	**4**	**0.39**
-----No Answer - 2nd attempt	**1**	**0.10**
-----No Answer - 3rd attempt	**0**	**0.00**

4.3 SCAP Adjudication

With SCAP adjudication,

- Each participant is classified as either "ND", "MCI" or "PD" as in the WHIMS ECHO protocol 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 1077 cases of SCAP protocols for adjudication. Of those, 383 (35.6%) have been adjudicated and 13 (1.2%) are under review. There are 182 (16.9%) protocols that were not adjudicated because the algorithm pre-classified them as ND.

Additionally, 499 cases where attempts to complete the DQ have ceased because the proxy declined, the phone was disconnected, 4^{th} and final attempt was reached, or we are unable to locate the proxy were classified as Probable No Dementia (PND) without full adjudication based on test scores falling within the normal range.

The overall classification of SCAP protocols (Adjudicated + Not Adjudicated) includes 1,064 cases. Of those, 375 (35.2%) were classified as ND, 471 (44.3%) as PND, 34 (3.2%) were MCI 80 (7.5%) were PD, 23 (2.2%) were Unable to Classify-Cognitive Impairment, 15 (1.4%) were Unable to Classify-Functional Impairment and 66 (6.2%) were Cannot Classify.

Table 4-2 SCAP Protocols		
	Subtotal	
	N	%
SCAP Protocols	1077	
- - - - Adjudicated Protocols	383	35.6
- - - - Protocols Under Review by Adjudicators	13	1.2
- - - - Protocols Not Adjudicated (ND or MCI)	182	16.9
- - - - Protocols Classified Without Full Adjudication (PND)	471	43.7
- - - - Protocols Classified Without Full Adjudication (CC)	28	2.6

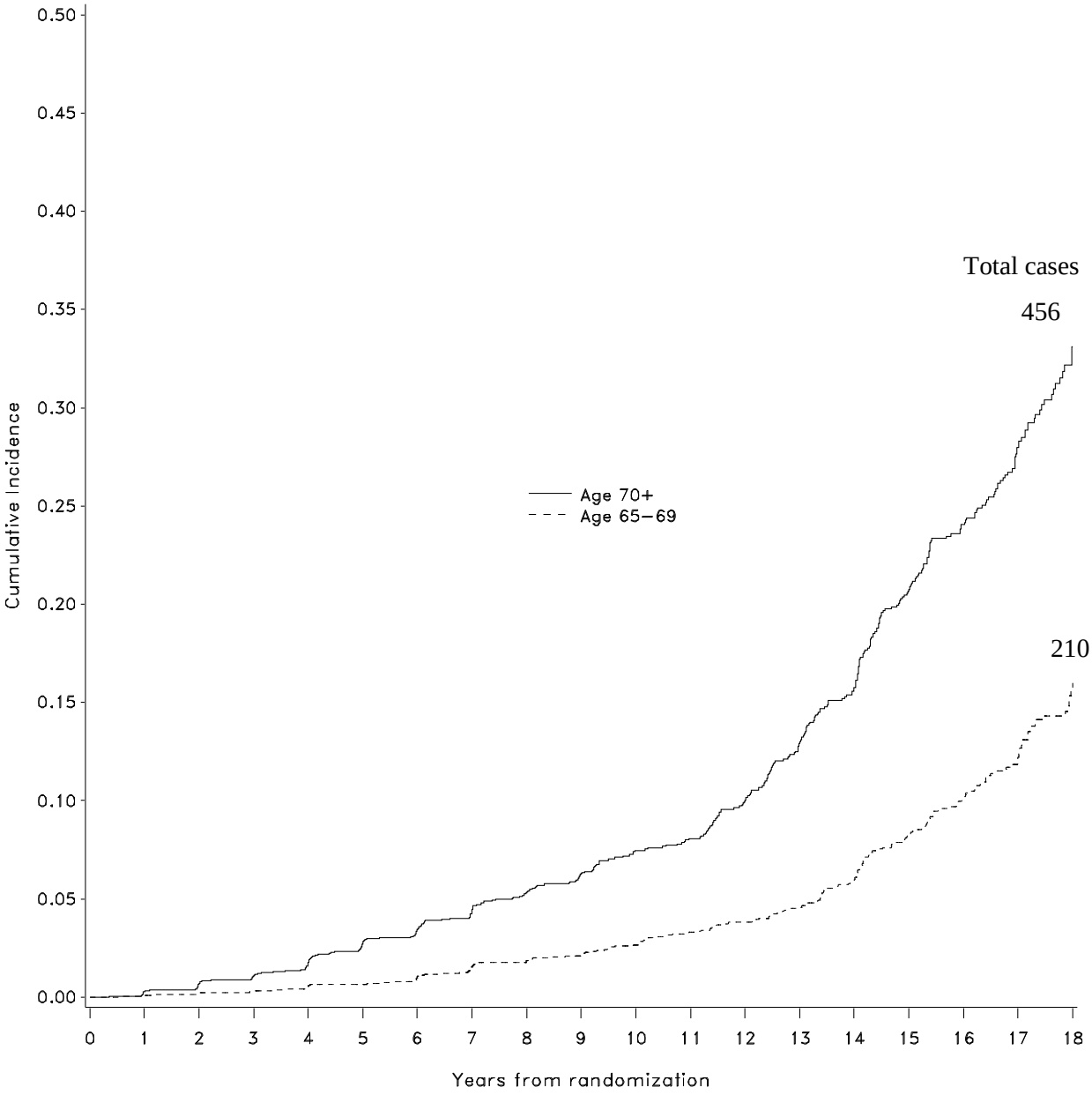
Table 4-3 Overall Classification of SCAP Protocols		
	Subtotal	
	N	%
Overall Classification of Protocols	1064	
----ND	375	35.2
----PND	471	44.3
----MCI	34	3.2
----PD	80	7.5
----UC-CI	23	2.2
----UC-FI	15	1.4
----CC	66	6.2

Note: ND=No Dementia, MCI=Mid Cognitive Impairment, PD=probable dementia, UTC-CI=Unable to Classify-Cognitive Impairment, UTC-FI=Unable to Classify-Functional Impairment, CC=Cannot Classify

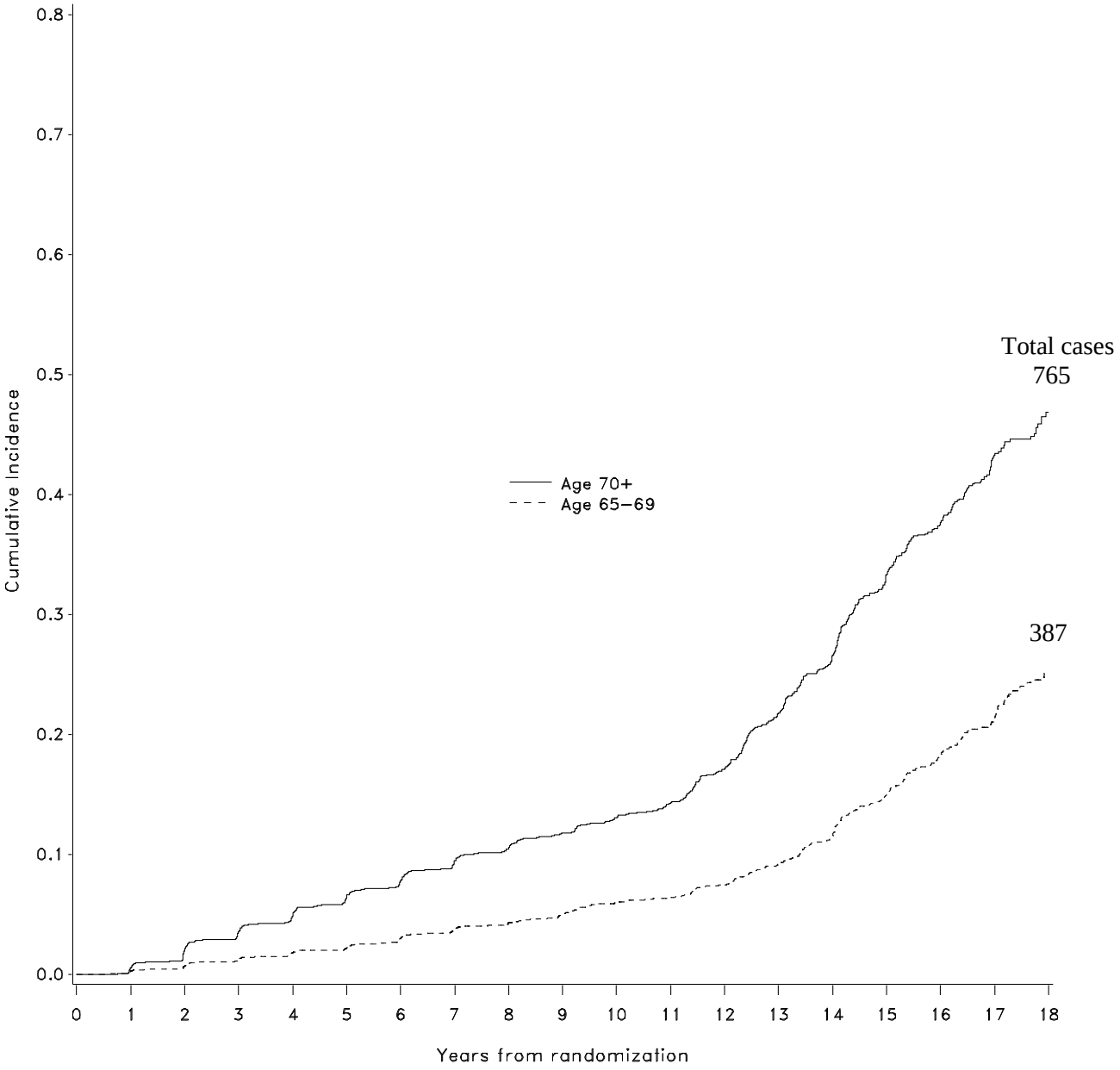
Section 5.

WHIMS Cohort

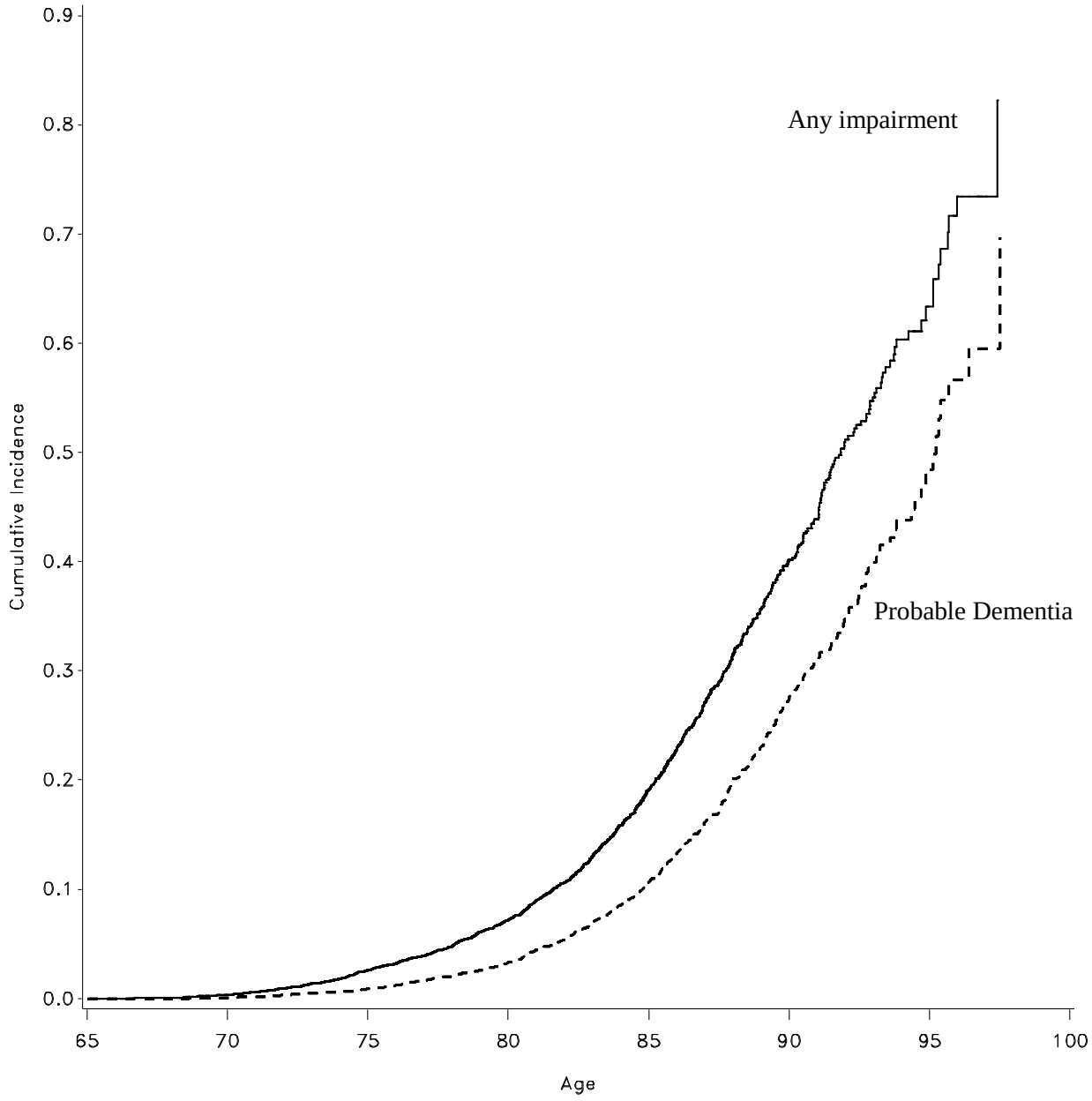
5.1 Incidence of Probable Dementia by Age at Enrollment



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

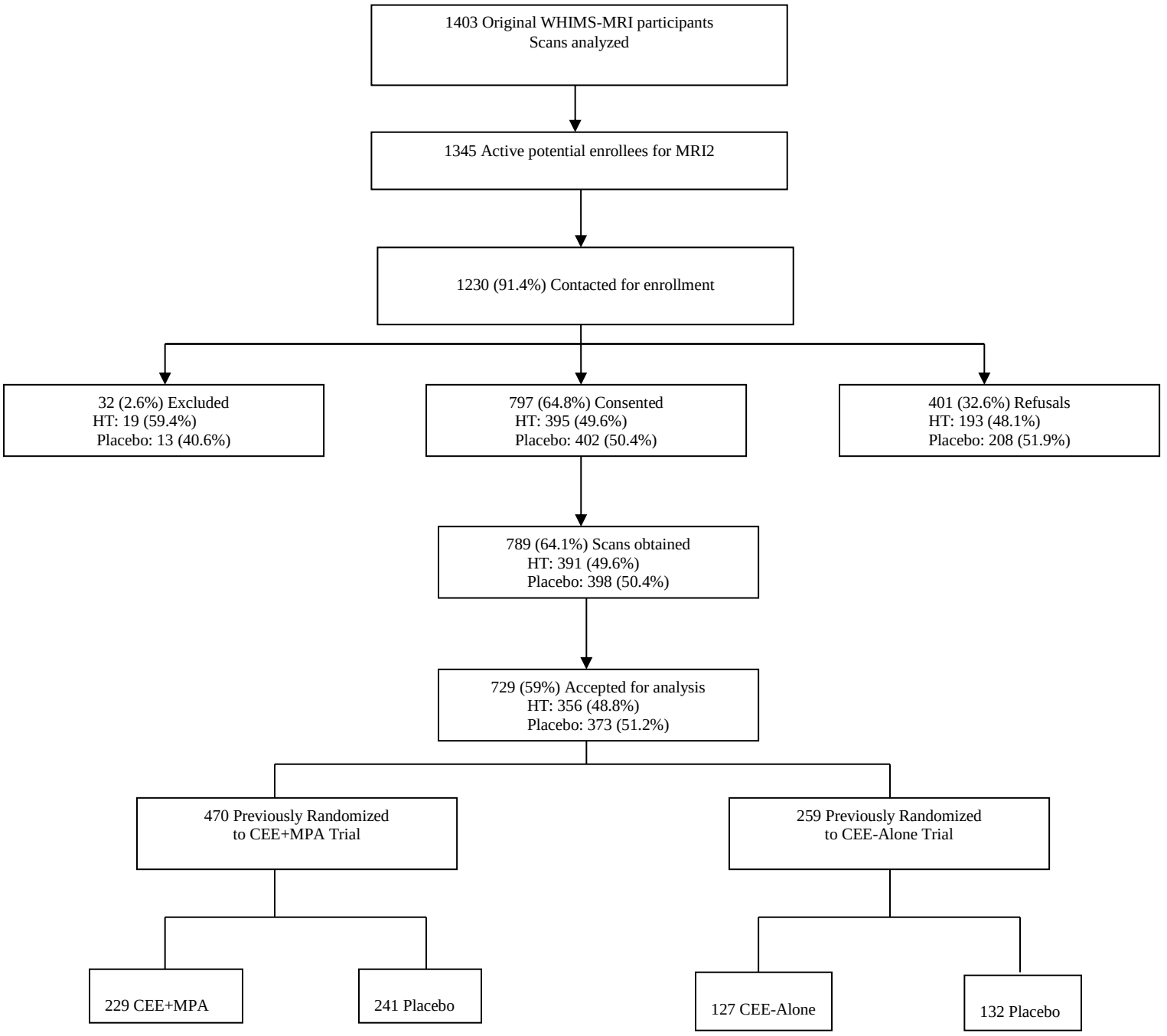
Approximately 4.7 years following the initial WHIMS MRI study, the WHIMS-MRI-2 study was initiated to collect a second MRI brain scan to assess incident neuropathology and the annual rates of change in brain volumes and lesions.

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



6.2.3 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.

6.2.4 WHIMS MRI2 Bibliography

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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 July 1, 2015												
	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		7		4	
---- Withdrew	2		5		31		26		31		33	
---- Attempts to locate exhausted	0		0		0		0		0		0	
Due for telephone contact	1359	99.8	1349	99.0	1308	96.0	1274	93.5	1236	90.7	1199	88.0
Completed test battery	1267	93.2	1175	87.1	1051	80.4	976	76.6	933	75.5	588	49.0
Failed after 8 attempts	65	4.8	113	8.4	190	14.5	203	15.9	211	17.1	90	7.5
Declined	4	0.3	45	3.3	52	4.0	67	5.3	63	5.1	29	2.4
Phone disconnected	18	1.3	11	0.8	13	1.0	26	2.0	18	1.5	14	1.2
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	3	0.2	0	0.0
Discontinued	0	0.0	1	0.1	0	0.0	0	0.0	1	0.1	0	0.0
No answer	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	0.3

Table 7-2 WHIMS-Y Overall Status of Last Call Attempts by Year as of July 1, 2015												
	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	1	0.1	18	1.5
Scheduled	0	0.0	0	0.0	0	0.0	0	0.0	2	0.2	3	0.3
Busy	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.1
No message	0	0.0	0	0.0	0	0.0	0	0.0	2	0.2	39	3.3
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	2	0.2	413	34.4

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

Table 7-3 Characteristics of Enrollees	
Characteristic	N (%)
WHI Treatment Assignment	
E-Alone	271 (19.9)
E-Alone Placebo	255 (18.7)
E+P	446 (32.8)
E+P Placebo	390 (28.6)
Age at WHI Enrollment	
50-54	1362 (100)
Age as of October 1, 2013	
65-69	83 (6.1)
70-74	1190 (87.4)
80+	89 (6.5)
Race/Ethnicity	
American Indian/Alaskan native	5 (0.4)
Asian/Pacific Islander	16 (1.2)
Black/African American	169 (12.4)
Hispanic/Latino	60 (4.4)
White	1093 (80.4)
Other	16 (1.2)

7.5 WHIMS-Y Adjudication

The WHIMS-Y adjudication process is identical to the one utilized in WHIMS-ECHO. A total of 252 WHIMS-Y women were eligible for the DQ based on their TICSm scores which were below the study cut-points. Of these, 232 progressed to administration of the DQ.

Table 7-4 Dementia Questionnaire Progressions in WHIMS-Y as of October 26, 2015

	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	TOTAL
TICS Administrations	**1265**	**1174**	**1051**	**977**	**935**	**586**	**5988**
DQ Progressions	**61 (4.8%)**	**77 (6.6%)**	**43 (4.1%)**	**32 (3.3%)**	**20 (2.1%)**	**19 (3.2%)**	**252 (4.2%)**
Withdrawals	**2 (3.3%)**	**1 (1.3%)**	**1 (2.3%)**	**1 (3.1%)**	**0 (0.0%)**	**0 (0%)**	**5 (2.0%)**
Missing Proxy information	**5 (8.2%)**	**5 (6.5%)**	**1 (2.3%)**	**2 (6.3%)**	**2 (10.0%)**	**0 (0%)**	**15 (6.0%)**
Total Eligible DQ Progressions	**54 (88.5%)**	**71 (92.2%)**	**41 (95.3%)**	**29 (90.6%)**	**18 (90.0%)**	**19 (100%)**	**232 (92.1%)**

	Table 7-5 Dementia Questionnaire Administration in WHIMS-Y as of October 26, 2015						
	Visit 1	**Visit 2**	**Visit 3**	**Visit 4**	**Visit 5**	**Visit 6**	**TOTAL**
DQ's ready and completed for adjudication^^	**30 (55.6%)**	**38 (53.5%)**	**25 (61.0%)**	**12 (41.4%)**	**6 (33.3%)**	**3 (15.8%)**	**114 (49.1%)**
DQ's in process	**0 (0.0%)**	**0 (0.0%)**	**0 (0.0%)**	**0 (0.0%)**	**1 (5.6%)**	**11 (57.9%)**	**12 (5.2%)**
Phone Disconnected/Unable to locate/Hearing Impaired	**3 (5.6%)**	**3 (4.2%)**	**1 (2.4%)**	**1 (3.4%)**	**0 (0.0%)**	**0 (0.0%)**	**8 (3.4%)**
Proxy Refused DQ	**8 (14.8%)**	**8 (11.3%)**	**3 (7.3%)**	**2 (6.9%)**	**1 (5.6%)**	**0 (0.0%)**	**22 (9.5%)**
PD	**0 (0.0%)**	**0 (0.0%)**	**0 (0.0%)**	**1 (3.4%)**	**0 (0.0%)**	**0 (0.0%)**	**1 (0.4%)**
4th attempt	**13 (24.1%)**	**22 (31.0%)**	**12 (29.3%)**	**13 (44.8%)**	**10 (55.6%)**	**5 (26.3%)**	**75 (32.3%)**
TOTAL	**54**	**71**	**41**	**29**	**18**	**19 (26.3%)**	**232**

There is one (0.9%) eligible adjudication case in process. 45 (39.8%) adjudication complete and 67 (59.3%) 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	Year 6	Total
Adjudication in process	**0 (0.0%)**	**0 (0.0%)**	**0 (0.0%)**	**0 (0.0%)**	**0 (0.0%)**	**1 (50.0%)**	**1 (0.9%)**
Adjudication complete	**12 (40.0%)**	**14 (36.8%)**	**11 (44.0%)**	**5 (41.7%)**	**3 (50.0%)**	**0 (0.0%)**	**45 (39.8%)**
- - - - ND	**7 (58.3%)**	**7 (50.0%)**	**2 (18.2%)**	**3 (60.0%)**	**1 (33.3%)**	**0 (0.0%)**	**20 (44.4%)**
- - - - MCI	**5 (41.7%)**	**5 (35.7%)**	**6 (54.5%)**	**2 (40.0%)**	**1 (33.3%)**	**0 (0.0%)**	**19 (42.2%)**
- - - - PD	**0 (0.0%)**	**2 (14.3%)**	**3 (27.3%)**	**0 (0.0%)**	**1 (33.3%)**	**0 (0.0%)**	**6 (13.3%)**
Not Adjudicated (ND)	**18 (60.0%)**	**24 (63.2%)**	**14 (56.0%)**	**7 (58.3%)**	**3 (50.0%)**	**1 (50.0%)**	**67 (59.3%)**
TOTAL	**30**	**38**	**25**	**12**	**6**	**2**	**112**

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 October 2015			
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 Iris Leng
881	Change in cognitive function in cancer patients among WHIMS participants	Michelle Naughton	Mark Espeland Sarah Gaussoin
884	Effects on dementia and cognitive functioning 3 years after stopping estrogen with and without progestin: the WHIMS	Sally Shumaker	Daniel Beavers Leslie Vaughan
909	Spatial distribution of ischemic lesions in WHIMS-MRI and effects of postmenopausal hormone therapy	Christos Davatzikos	Ramon Casanova 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
947	Weight cycling and cancer risk in postmenopausal women: The Women's Health Initiative	Mara Vitolins	Daniel Beavers
1042	Relationships that cognitive function and changes in cognitive function have with incident cardiovascular disease: the WHIMS	Sally Shumaker	Mark Espeland Iris Leng
1115	Obesity and brain volume in post-menopausal women: the WHIMS-MRI Study	Ira Driscoll	Ramon Casanova Mark Espeland Sarah Gaussoin Leslie Vaughan
1260	Omega-3 fatty acid biomarkers, global cognitive function, and cognitive impairment	Jennifer Robinson	Eric Amman 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 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 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 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 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
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 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 Beverly Snively
2217	Evolution of the WHI 80+ Cohort	Daniel Beavers	Mary Pettinger
2219	Predictors of optimal cognitive aging in 80+ women: the WHIMS	Joseph Goveas	Mark Espeland 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 Leslie Vaughan
2344	Home environmental modifications and functional status in WHI women	Leslie Vaughan	Daniel Beavers 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 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 Leslie Vaughan
2431	Geographic disparities in cognitive decline and dementia risks in older women	Jiu-Chiuan Chen	Ramon Casanova 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 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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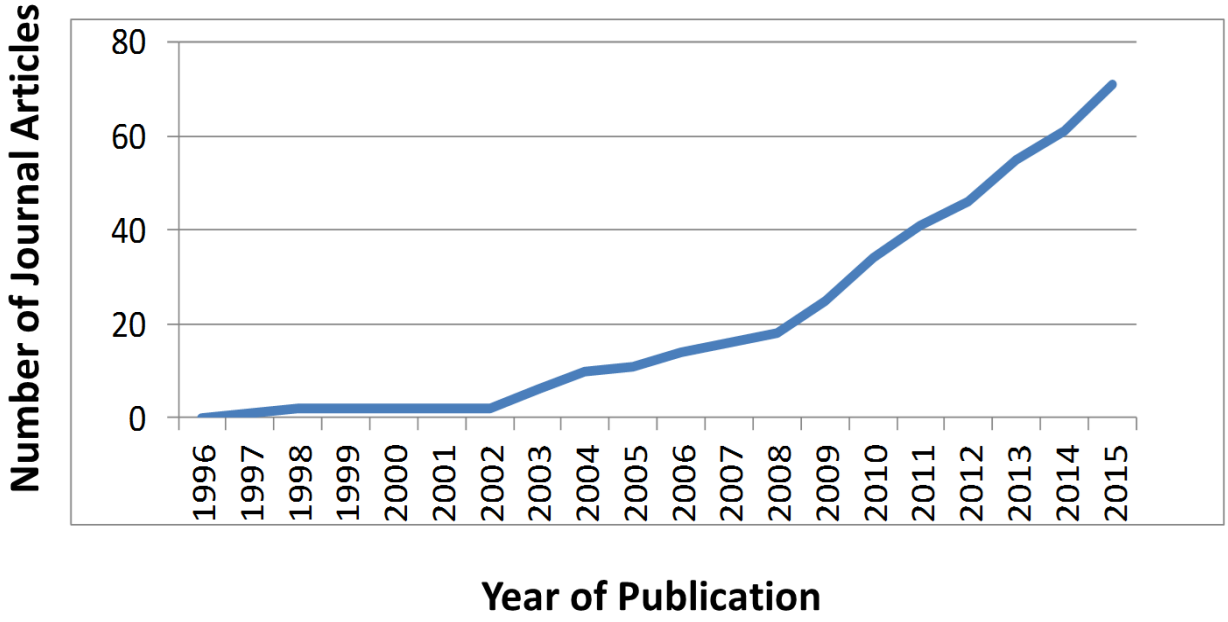
WHI Cognition Program Publications

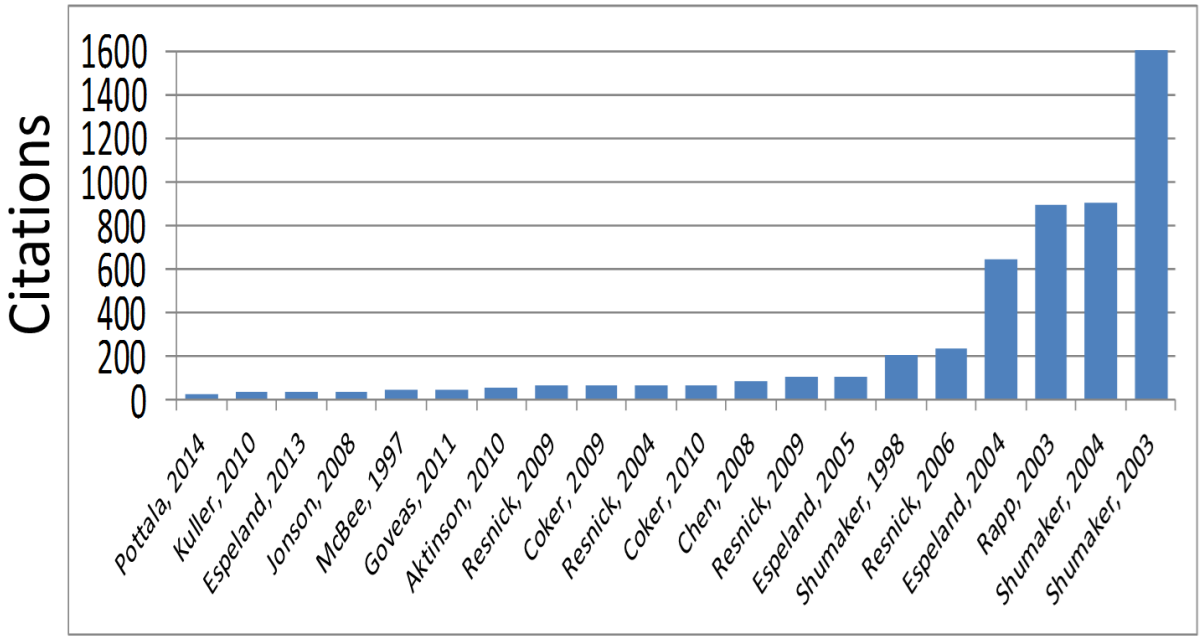
September, 2015: 71 Journal Articles



Most Highly Cited WHI Cognition Articles

Source: Google Scholar September 25, 2015

>6100 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 Baker (WFUHS) **Sally Shumaker** (WFUHS) **Steve Rapp**, (WFUHS) **Katie Stone** (Research Institute, California Pacific Medical Center)	Women's Health Initiative Sleep Hypoxia Effects on Resilience (WHISPER)	WHISPER will obtain Nonin, Actigraphy and cognitive data from 5,000 WHI participants The cognitive protocol for WHISPER is based directly on the cost efficient WHIMS ECHO telephone cognitive assessment protocol. All the preliminary data for this proposal came from WHIMS. The R01 proposal was submited to NHLBI on 09/30/15.	ACFS
Laura Baker (WFUHS) **Mark Espeland (WFUHS)** **Sally Shumaker (WFUHS)** **Steve Rapp (WFUHS)**	COSMOS-Mind	COSMOS-Mind will enroll 2,000 participants from COSMOS (50% men, aged ≥65 years), and conduct standardized telephone cognitive assessments pre-randomization and annually for 3 years to examine longitudinal effects of cocoa flavanols on a cognitive composite outcome. We will also establish whether administration of a multivitamin benefits cognition, explore whether cocoa flavanols reduce risk of dementia including AD, and examine intervention effects on key cognitive domains (e.g., executive function, short-term memory). The cognitive protocol for COSMOS-Mind is based directly on the cost efficient WHIMS ECHO telephone cognitive assessment protocol. Preliminary data analyses were based on WHIMS ECHO. The R01 proposal submitted to NIA was recently reviewed and received an excellent score of 20 (8^{th} percentile).	ACFS
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
Crystal Cene (University of North Carolina-Chapel Hill)**, 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	

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:

Vaughan L, Hogan PE, Rapp SR, Dugan E, Marottoli RA, Snively BA, Shumaker SA, Sink KM. Driving with mild cognitive impairment or dementia: cognitive test performance and proxy report of daily life function in older women. J Am Geriatr Soc. 2015 Sep;63(9):1774-82. PMID: 26338449

OBJECTIVES: To investigate associations between proxy report of cognitive and functional limitations and cognitive performance and current or former driving status in older women with mild cognitive impairment (MCI) and all-cause dementia.
DESIGN: Cross-sectional data analysis of retrospectively identified older women with adjudicated MCI and all-cause dementia in the Women's Health Initiative Memory Study-Epidemiology of Cognitive Health Outcomes (WHIMS-ECHO).
SETTING: Academic medical center.
PARTICIPANTS: Women (mean age ± standard deviation 83.7 ± 3.5) adjudicated with MCI or dementia during Year 1, 2, 3, or 4 of the WHIMS-ECHO follow-up period (N = 385).
MEASUREMENTS: The telephone-administered cognitive battery included tests of attention, verbal learning and memory, verbal fluency, executive function, working memory, and global cognitive function plus self-report measures of depressive symptomatology. The Dementia Questionnaire (DQ) was administered to a knowledgeable proxy (family member, friend).
RESULTS: Sixty percent of women with MCI and 40% of those with dementia are current drivers. Proxy reports of functional limitations in instrumental activities of daily living (IADLs) are associated with current driving status in women with MCI, whereas performance-based cognitive tests are not. In women with dementia, proxy reports of functional limitations in IADLs and performance-based cognitive tests are associated with current driving status, as expected.
CONCLUSION: These findings have clinical implications for the importance of evaluating driving concurrently with other instrumental functional abilities in MCI and dementia. Additional work is needed to determine whether proxy report of cognitive and functional impairments should help guide referrals for driving assessment and rehabilitation or counseling for driving transition.

Espeland MA, Brinton RD, Manson JE, Yaffe K, Hugenschmidt C, Vaughan L, Craft S, Edwards BJ, Casanova R, Masaki K, Resnick SM; WHIMS-MRI2 Study Group. Postmenopausal hormone therapy, type 2 diabetes mellitus, and brain volumes. Neurology. 2015 Jul 10. pii: 10.1212/WNL.0000000000001816. [Epub ahead of print]. PMID: 26163429.

OBJECTIVE: To examine whether the effect of postmenopausal hormone therapy (HT) on brain volumes in women aged 65-79 years differs depending on type 2 diabetes status during postintervention follow-up of a randomized controlled clinical trial.
METHODS: The Women's Health Initiative randomized clinical trials assigned women to HT (0.625 mg/day conjugated equine estrogens with or without 2.5 mg/day medroxyprogesterone acetate) or placebo for an average of 5.6 years. A total of 1,402 trial participants underwent brain

MRI 2.4 years after the trials; these were repeated in 699 women 4.7 years later. General linear models were used to assess the interaction between diabetes status and HT assignment on brain volumes.
RESULTS: Women with diabetes at baseline or during follow-up who had been assigned to HT compared to placebo had mean decrement in total brain volume of -18.6 mL (95% confidence interval [CI] -29.6, -7.6). For women without diabetes, this mean decrement was -0.4 (95% CI -3.8, 3.0) (interaction $p = 0.002$). This interaction was evident for total gray matter ($p < 0.001$) and hippocampal ($p = 0.006$) volumes. It was not evident for changes in brain volumes over follow-up or for ischemic lesion volumes and was not influenced by diabetes duration or oral medications.
CONCLUSIONS: For women aged 65 years or older who are at increased risk for brain atrophy due to type 2 diabetes, prescription of postmenopausal HT is associated with lower gray matter (total and hippocampal) volumes. Interactions with diabetes and insulin resistance may explain divergent findings on how estrogen influences brain volume among older women.

Haring B, Wu C, Coker LH, Seth A, Snetselaar L, Manson JE, Rossouw JE, Wassertheil-Smoller S. Hypertension, dietary sodium, and cognitive decline: Results from the Women's Health Initiative Memory Study. Am J Hypertens. 2015 Jul 1. pii: hpv081. [Epub ahead of print]. PMID: 26137952.

BACKGROUND: To investigate the relationships of hypertension, antihypertensive treatment, and sodium intake on cognitive decline in older women.
METHODS: Prospective follow-up of 6,426 cognitively intact women aged 65-79 years enrolled in the Women's Health Initiative Memory Study (WHIMS) with a median follow-up of 9.1 years. Dietary sodium intake was determined by food frequency questionnaires. Hypertension was defined as self-report of current drug therapy for hypertension. Blood pressure (BP) control was assessed by treatment for hypertension and clinic measurement of systolic BP $\geq$ 140mm Hg or diastolic BP $\geq$ 90mm Hg at baseline. Cognitive functioning was assessed annually by global cognitive screening, neurocognitive, and neuropsychiatric evaluations. Cognitive decline was identified by the incidence of mild cognitive impairment (MCI) or probable dementia (PD). Cox proportional hazards analyses were used to calculate hazard ratios (HRs).
RESULTS: Hypertension was associated with an increased risk for cognitive decline (HR 1.20; 95% confidence interval (CI) 1.04, 1.39; P = 0.02). Among women with antihypertensive medication, those with BP $\geq$140/90mm Hg (uncontrolled BP) were at highest risk for developing cognitive decline (HR 1.30; 95% CI 1.05, 1.60) compared to women without treatment and BP <140/90mm Hg (controlled BP). Sodium intake >1,500mg/day did not alter the risk for cognitive decline in hypertensive women or women with antihypertensive treatment (P for interaction = 0.96 or 0.97).
CONCLUSIONS: Women with antihypertensive treatment and uncontrolled BP showed highest risk estimates for developing cognitive decline compared to non-hypertensive women. Sodium intake did not modify the risk for cognitive decline in women with hypertension or receiving antihypertensive medication.

Vaughan L, Bushnell C, Bell CL, Espeland MA. Global cognitive function before, surrounding, and after ischemic stroke: the role of risk and protective factors varies with time among ischemic stroke survivors. Neuropsychol Dev Cogn B Aging Neuropsychol Cogn. 2015 Jun 15:1-15. PMID: 26073439

An estimated 65% of individuals demonstrate multidomain cognitive impairment poststroke, although little is known about the varying role of cognitive risk and protective factors in preischemic, peri-ischemic, and postischemic stroke phases. Longitudinal changes in global cognitive function after ischemic stroke are not well characterized, especially in older adults over age 80. We examined global cognitive function trajectories in these three phases across a mean follow-up of 8.12 (2.30) years in 159 female stroke survivors aged 65-79 at baseline using linear mixed models with change points. In separate models controlling for demographic variables, we tested the interaction of baseline risk and protective factors with stroke phase on global cognitive function. None of the prestroke global cognitive function means or trajectories differed significantly. At the time of ischemic stroke, higher body mass index (BMI), the presence of hypertension (HTN), low optimism, and higher physical function were all associated with significantly greater mean decreases in global cognition (all p's <.0.0001), but were not significantly different from the contrasting level (all p's >0.05). Higher BMI, the presence of HTN, low optimism, and higher physical function were in turn protective of global cognitive decline postischemic stroke (all contrasting p values <.01). Baseline factors may play either a risk or a protective role in global cognitive function depending on the phase of ischemic stroke.

Chen JC, Wang X, Wellenius GA, Serre ML, Driscoll I, Casanova R, McArdle JJ, Manson JE, Chui HC, Espeland MA. Ambient air pollution and neurotoxicity on brain structure: Evidence from Women's Health Initiative Memory Study. Ann Neurol. 2015 Jun 15. doi: 10.1002/ana.24460. [Epub ahead of print]. PMID: 26075655

OBJECTIVE: The aim of this study was to examine the putative adverse effects of ambient fine particulate matter (PM2.5 : PM with aerodynamic diameters <2.5μm) on brain volumes in older women.
METHODS: We conducted a prospective study of 1,403 community-dwelling older women without dementia enrolled in the Women's Health Initiative Memory Study, 1996-1998. Structural brain magnetic resonance imaging scans were performed at the age of 71-89 years in 2005-2006 to obtain volumetric measures of gray matter (GM) and normal-appearing white matter (WM). Given residential histories and air monitoring data, we used a spatiotemporal model to estimate cumulative PM2.5 exposure in 1999-2006. Multiple linear regression was employed to evaluate the associations between PM2.5 and brain volumes, adjusting for intracranial volumes and potential confounders.
RESULTS: Older women with greater PM2.5 exposures had significantly smaller WM, but not GM, volumes, independent of geographical region, demographics, socioeconomic status, lifestyles, and clinical characteristics, including cardiovascular risk factors. For each interquartile increment (3.49μg/m(3)) of cumulative PM2.5 exposure, the average WM volume (WMV; 95% confidence interval) was 6.23cm(3) (3.72-8.74) smaller in the total brain and 4.47cm(3) (2.27-6.67) lower in the association areas, equivalent to 1 to 2 years of brain aging. The adverse PM2.5 effects on smaller WMVs were present in frontal and temporal lobes and corpus callosum (all p values <0.01). Hippocampal volumes did not differ by PM2.5 exposure.

INTERPRETATION: PM2.5 exposure may contribute to WM loss in older women. Future studies are needed to determine whether exposures result in myelination disturbance, disruption of axonal integrity, damages to oligodendrocytes, or other WM neuropathologies.

Chen JC, Espeland MA, Brunner RL, Lovato LC, Wallace RB, Leng X, Phillips LS, Robinson JG, Kotchen JM, Johnson KC, Manson JE, Stefanick ML, Sarto GE, Mysiw WJ. Sleep duration, cognitive decline, and dementia risk in older women. Alzheimers Dement. 2015 Jun 15. pii: S1552-5260(15)00195-8. doi: 10.1016/j.jalz.2015.03.004. [Epub ahead of print]. PMID: 26086180.

BACKGROUND: Consistent evidence linking habitual sleep duration with risks of mild cognitive impairment (MCI) and dementia is lacking.
METHODS: We conducted a prospective study on 7444 community-dwelling women (aged 65-80 y) with self-reported sleep duration, within the Women's Health Initiative Memory Study in 1995-2008. Incident MCI/dementia cases were ascertained by validated protocols. Cox models were used to adjust for multiple sociodemographic and lifestyle factors, depression, cardiovascular disease (CVD), and other clinical characteristics.
RESULTS: We found a statistically significant (P = .03) V-shaped association with a higher MCI/dementia risk in women with either short (≤6 hours/night) or long (≥8 hours/night) sleep duration (vs. 7 hours/night). The multicovariate-adjusted hazard for MCI/dementia was increased by 36% in short sleepers irrespective of CVD, and by 35% in long sleepers without CVD. A similar V-shaped association was found with cognitive decline.
CONCLUSIONS: In older women, habitual sleep duration predicts the future risk for cognitive impairments including dementia, independent of vascular risk factors.

Agnew-Blais JC, Wassertheil-Smoller S, Kang JH, Hogan PE, Coker LH, Snetselaar LG, Smoller JW. Folate, Vitamin B-6, and vitamin B-12 intake and mild cognitive impairment and probable dementia in the Women's Health Initiative Memory Study. J Acad Nutr Diet. 2015 Feb;115(2):231-41. doi: 10.1016/j.jand.2014.07.006. Epub 2014 Sep 8. PMID: 25201007. PMCID: PMC4312724.

BACKGROUND: Whether higher B vitamin intake (ie, B-6, B-12, and folate) is protective against cognitive decline in later life remains uncertain. Several prospective, observational studies find higher B vitamin intake to be associated with lower risk of dementia; other studies, including most trials of B vitamin supplementation, have observed no effect on cognition. We examined this question in a large population of older women carefully monitored for development of mild cognitive impairment (MCI) and probable dementia.
OBJECTIVE: To determine whether baseline folate, vitamin B-6, and/or vitamin B-12 intake, alone or in combination, are associated with incident MCI/probable dementia among older women.
DESIGN: Prospective, longitudinal cohort study. Participants were enrolled between 1993 and 1998, and B vitamin intake was self-reported using a food frequency questionnaire administered at baseline.
PARTICIPANTS/SETTING: Postmenopausal women (N=7,030) free of MCI/probable dementia at baseline in the Women's Health Initiative Memory Study.

MAIN OUTCOME MEASURES: Over a mean follow-up of 5.0 years, 238 cases of incident MCI and 69 cases of probable dementia were identified through rigorous screening and expert adjudication.
STATISTICAL ANALYSES: Cox proportional hazard models adjusting for sociodemographic and lifestyle factors examined the association of B vitamin intake above and below the Recommended Daily Allowance and incident MCI/probable dementia.
RESULTS: Folate intake below the Recommended Daily Allowance at study baseline was associated with increased risk of incident MCI/probable dementia (hazard ratio 2.0, 95% CI 1.3 to 2.9), after controlling for multiple confounders. There were no significant associations between vitamins B-6 or B-12 and MCI/probable dementia, nor any evidence of an interaction between these vitamins and folate intake.
CONCLUSIONS: Folate intake below the Recommended Daily Allowance may increase risk for MCI/probable dementia in later life. Future research should include long-term trials of folic acid supplementation to examine whether folate may impart a protective effect on cognition in later life.

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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