Women's Health Initiative

2012 Annual Progress Report

Data as of: September 2012

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

2012 Annual Progress Report

Data as of: September 2012

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1. Overview

1.0 Background

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

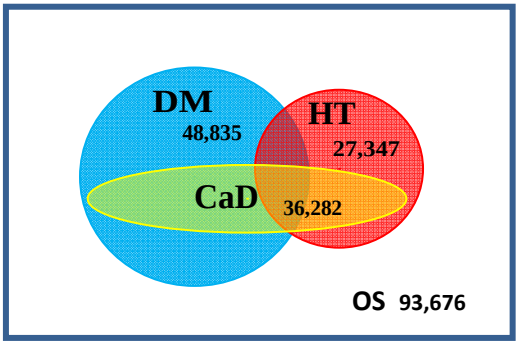


Figure 1: Original design of the WHI partial factorial trial and observational study of 161,808 postmenopausal women.

1.1 Changes associated with the 2010-2015 Extension Study

The follow-up protocol for 2010-2015 is derived from the previous phases but incorporates noteworthy streamlining. As before, 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 participants and all African American and Hispanic participants, regardless of their previous enrollment status. Active outcome data collection for the remaining participants (the Self-Report Cohort or SRC) is limited to self-report with the exception of cancer, for which NCI is supporting the documentation and coding of all incident primary cancers.

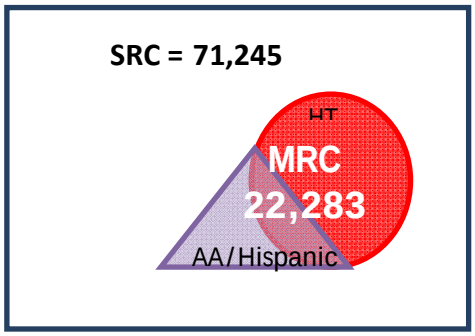


Figure 2: 2010-2015 Extension Study design reflecting differing levels of outcomes ascertainment: Medical Records Cohort (MRC) and the Self-Report Cohort (SRC). Total enrollment = 93,558.

This reduction in data collection prompted streamlining of the operational infrastructure. The 40 Field Centers were consolidated into 4 Regional Centers (RC) plus the Clinical Coordinating Center (CCC). Each RC has subcontracted with one or two former sites 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 Clinical Centers (Seattle and LaJolla).

1.2 Progress on primary study objectives

This report provides an update on study status through September 2012, 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, 91.7% responded to mailings and 78% of the remaining responded to RC contacts, yielding an overall 97.1% response rate. Year 2 results are not yet final but suggest only slight reductions in response rates. We observe a somewhat lower response rate among MRC participants than SRC participants but no noteworthy differences by original CT/OS enrollment status or centers.

For the designated WHI outcomes, clinical event rates using the fully adjudicated outcomes through the end of the first Extension Study (September 2010) are presented by original study component, age and race. Using the new study components, fully adjudicated events available through September 2012 are provided for the MRC (Table 7.2 and 7.3). For the SRC, fully adjudicated events are provided for the interval from enrollment to September 2010 (Table 7.4 and 7.5). Self-reported events for the subsequent interval (September 2010 to September 2012) are shown in Tables 7.6 and 7.7. A brief summary of other outcomes is also provided.

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

In recognition of the growing emphasis on studies of aging, a brief summary of the current age distribution and health characteristics are included (Section 9). We also provide a brief summary of the recently collected medication inventory data in Section 10. Two-thirds of the women report no barriers to taking prescription medications. The most commonly reported medication/supplement being consumed regularly by these women was calcium combinations, followed closely by multivitamins with minerals (both over 58%). Salicylates, statins, NSAIDS, and vitamin D form the next most commonly used classes.

Regional Center performance in follow-up and outcomes documentation is summarized in Section 11. Although there is some variability in specific items monitored across sites, we find that all centers are performing adequately in outcomes processing.

Information on the status of the WHI biorepository is presented in Section 12. Section 13 lists core, BAA and ancillary studies activities and Section 14 addresses publications. To streamline this report, we now include only those ancillary studies approved and manuscripts published in the last year. A full listing and status of all proposed ancillary studies and manuscripts is available on the WHI website (www.whi.org). At this point WHI has reviewed 429 ancillary study proposals, over 60% of which were lead by non-WHI investigators. Over 1600 manuscript proposals have been approved and 747 are published or in press.

1.3 WHI Long-Life Study (LLS)

During the past year we have implemented the WHI Long Life Study protocol which consists of an in-person visit among 8,000 of the oldest women in the MRC. As part of its recent renewal, the CCC contracted with a national-based organization, Examination Management Services, Inc (EMSI) to conduct home visits among consenting MRC participants to obtain clinical measures (blood pressure, pulse, height, weight), basic physical function measures, and a new blood collection. Women were preferentially sampled based on availability of GWAS data, CVD biomarkers and older ages. An ancillary study entitled "Objective Physical Activity and Cardiac Health [OPACH] (PI: Andrea LaCroix) supports the collection of an objective measure of physical activity using actigraphy in conjunction with this visit. A separate ancillary study (PI: Jeanette Beasley) funds the collection of a food frequency questionnaire after the visit.

Currently 7,566 women have consented (53.7% of participants contacted) and 4,857 visits have been conducted, including 4,538 for OPACH. Visits are scheduled in the near term for 507 women. Over 96% of visits have resulted in a successful blood collection. The final phase of consent mailings was sent on October 18, 2012. We project a completion of the remaining visits by May 1, 2013.

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
Ross Prentice, PhD	Fred Hutchinson Cancer Research Center	Seattle, WA

Regional Centers

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

Former Field Centers

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

Table 1.1 (continued)
WHI Centers and Principal Investigators

Former Field Centers

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

Table 1.2
Consent Status by Study Component and Arm

Data as of: September 17, 2012

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

WHI Enrollment	Enrolled in extension 2005-2010	Eligible for extension 2010-2015[1]	Consented N	Consented %
Hormone Therapy	20433	18794	15583	82.9
With Uterus	12788	11789	9891	83.9
E+P	6545	6048	5047	83.4
Placebo	6243	5741	4844	84.4
Without Uterus	7645	7005	5692	81.3
E-alone	3778	3479	2833	81.4
Placebo	3867	3526	2859	81.1
Dietary Modification	37858	35594	30687	86.2
Intervention	14769	13922	12013	86.3
Comparison	23089	21672	18674	86.2
Calcium and Vitamin D	29862	27975	24230	86.6
Active	15025	14083	12241	86.9
Placebo	14837	13892	11989	86.3
Clinical Trial Total	52176	48697	41495	85.2
Observational Study	63231	59009	52063	88.2
Total	115407	107706	93558	86.9

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

Table 1.3
Consent Status by Age and Race/Ethnicity

Data as of: September 17, 2012

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

	Clinical Trial				Observational Study			
			Consented				Consented	
WHI Enrollment	Enrolled in extension 2005-2010	Eligible for extension 2010-2015[1]	N	%	Enrolled in extension 2005-2010	Eligible for extension 2010-2015[1]	N	%
Total	52176	48697	41495	85.2	63231	59009	52063	88.2
Age								
50-54	7237	7068	6248	88.4	8996	8802	8224	93.4
55-59	11724	11329	10053	88.7	12732	12400	11479	92.6
60-69	24528	22940	19642	85.6	28582	26820	23716	88.4
70-79	8687	7360	5552	75.4	12921	10987	8644	78.7
Race/Ethnicity								
American Indian	185	174	146	83.9	217	204	171	83.8
Asian/Pacific Islander	1105	1050	845	80.5	1291	1224	1035	84.6
Black	4769	4459	3419	76.7	3585	3358	2715	80.9
Hispanic	1791	1701	1226	72.1	1598	1527	1246	81.6
White	43680	40704	35361	86.9	55767	51969	46292	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 17, 2012

	Enrolled in Extension 2005-2010	Eligible for Extension 2010-2015[2]	Consented	
			N	%
Total	115407	107706	93558	86.9
Age on 9/17/2012				
<80	61922	59866	54028	90.2
≥80	53485	47840	39530	82.6
80-84	26317	24481	21193	86.6
85-89	18726	16584	13434	81.0
90-94	7768	6310	4585	72.7
95-99	674	465	318	68.4
Race/Ethnicity				
American Indian	402	378	317	83.9
Asian/Pacific Islander	2396	2274	1880	82.7
Black	8354	7817	6134	78.5
Hispanic	3389	3228	2472	76.6
White	99447	92673	81653	88.1
Unknown	1419	1336	1102	82.5
Medical Record Cohort	29368	27221	22313	82.0
Age on 9/17/2012				
<80	16429	15724	13338	84.8
≥80	12939	11497	8975	78.1
80-84	6431	5953	4848	81.4
85-89	4498	3931	3042	77.4
90-94	1859	1510	1022	67.7
95-99	151	103	63	61.2
Race/Ethnicity				
American Indian	79	75	64	85.3
Asian/Pacific Islander	363	328	240	73.2
Black	8354	7817	6134	78.5
Hispanic	3389	3228	2472	76.6
White	16919	15525	13203	85.0
Unknown	264	248	200	80.6
Self Report Cohort	86039	80485	71245	88.5
Age on 9/17/2012				
<80	45493	44142	40690	92.2
≥80	40546	36343	30555	84.1
80-84	19886	18528	16345	88.2
85-89	14228	12653	10392	82.1
90-94	5909	4800	3563	74.2
95-99	523	362	255	70.4
Race/Ethnicity				
American Indian	323	303	253	83.5
Asian/Pacific Islander	2033	1946	1640	84.3
White	82528	77148	68450	88.7
Unknown	1155	1088	902	82.9

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

Table 1.5
Extension 2010-2015 Consent Summary by Field Center

Data as of: September 17, 2012

	DM			HT			CaD			CT			OS		
	Eligible	**Consent**	**%**	**Eligible**	**Consent**	**%**	**Eligible**	**Consent**	**%**	**Eligible**	**Consent**	**%**	**Eligible**	**Consent**	**%**
Atlanta	1015	825	81.3	415	318	76.6	690	574	83.2	1233	986	80.0	1717	1482	86.3
Bettendorf	369	319	86.4	575	494	85.9	556	485	87.2	855	737	86.2	1044	910	87.2
Birmingham	892	673	75.4	529	389	73.5	707	560	79.2	1233	932	75.6	1238	1000	80.8
Bowman	763	648	84.9	397	332	83.6	511	442	86.5	1024	864	84.4	1466	1249	85.2
Brigham	1358	1178	86.7	629	540	85.9	898	798	88.9	1811	1567	86.5	2215	2023	91.3
Buffalo	918	831	90.5	502	453	90.2	805	734	91.2	1260	1139	90.4	1561	1432	91.7
Chapel Hill	892	785	88.0	452	383	84.7	618	542	87.7	1187	1033	87.0	1485	1351	91.0
Chi-Rush	575	467	81.2	320	244	76.3	544	433	79.6	800	633	79.1	967	847	87.6
Chicago	892	772	86.5	393	337	85.8	627	546	87.1	1173	1007	85.8	1257	1113	88.5
Cincinnati	833	713	85.6	410	328	80.0	752	649	86.3	1104	928	84.1	1536	1356	88.3
Columbus	835	778	93.2	417	384	92.1	674	633	93.9	1109	1032	93.1	1581	1461	92.4
Des Moines	383	345	90.1	579	501	86.5	602	536	89.0	879	776	88.3	1031	912	88.5
Detroit	679	596	87.8	332	286	86.1	615	547	88.9	886	773	87.2	1327	1189	89.6
Gainesville	1130	906	80.2	746	575	77.1	760	622	81.8	1680	1323	78.8	2024	1664	82.2
GWU-DC	882	777	88.1	422	361	85.5	701	621	88.6	1173	1024	87.3	1601	1472	91.9
Honolulu	775	648	83.6	265	197	74.3	500	425	85.0	960	784	81.7	932	780	83.7
Houston	602	522	86.7	255	214	83.9	418	369	88.3	783	669	85.4	1323	1161	87.8
Irvine	886	800	90.3	407	357	87.7	726	655	90.2	1187	1060	89.3	1559	1396	89.5
L.A.	857	779	90.9	368	325	88.3	747	674	90.2	1125	1018	90.5	1484	1361	91.7
La Jolla	924	832	90.0	313	271	86.6	683	621	90.9	1129	1006	89.1	1737	1519	87.4
Madison	879	814	92.6	524	471	89.9	759	698	92.0	1262	1154	91.4	1321	1225	92.7
Medlantic	839	682	81.3	415	329	79.3	663	546	82.4	1097	888	80.9	1376	1192	86.6
Memphis	792	624	78.8	425	319	75.1	602	488	81.1	1038	809	77.9	1127	952	84.5
Miami	692	548	79.2	374	272	72.7	363	284	78.2	941	727	77.3	657	580	88.3

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

Data as of: September 17, 2012

	DM			HT			CaD			CT			OS		
	Eligible	Consent	%	Eligible	Consent	%	Eligible	Consent	%	Eligible	Consent	%	Eligible	Consent	%
Milwaukee	918	808	88.0	545	464	85.1	825	739	89.6	1266	1103	87.1	1492	1345	90.1
Minneapolis	1047	936	89.4	620	550	88.7	912	808	88.6	1530	1363	89.1	1847	1667	90.3
Nevada	790	676	85.6	440	365	83.0	749	650	86.8	1073	906	84.4	1399	1213	86.7
Newark	962	828	86.1	367	306	83.4	678	597	88.1	1208	1033	85.5	1590	1402	88.2
New Brunswick	306	253	82.7	298	228	76.5	371	299	80.6	535	423	79.1	600	527	87.8
NY-City	939	785	83.6	516	393	76.2	678	540	79.6	1337	1082	80.9	1444	1262	87.4
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	750	83.1
Seattle	851	774	91.0	502	442	88.0	635	574	90.4	1268	1140	89.9	984	886	90.0
Stanford	1003	896	89.3	508	449	88.4	808	732	90.6	1342	1192	88.8	1903	1676	88.1
Stonybrook	753	656	87.1	373	309	82.8	482	423	87.8	1016	872	85.8	1368	1219	89.1
Torrance	530	449	84.7	194	161	83.0	385	327	84.9	641	542	84.6	817	724	88.6
Tucson	983	862	87.7	448	363	81.0	737	631	85.6	1320	1128	85.5	1524	1306	85.7
UC Davis	1058	900	85.1	492	406	82.5	842	712	84.6	1371	1159	84.5	1287	1107	86.0
Worcester	988	876	88.7	466	392	84.1	735	654	89.0	1315	1144	87.0	1667	1475	88.5
Total	35594	30687	86.2	18794	15583	82.9	27975	24230	86.6	48697	41495	85.2	59009	52063	88.2

Table 1.6
Extension 2010-2015 Consent Summary by Regional Center

Data as of: September 17, 2012

	DM			HT			CaD			CT			OS		
	Eligible	**Consent**	**%**	**Eligible**	**Consent**	**%**	**Eligible**	**Consent**	**%**	**Eligible**	**Consent**	**%**	**Eligible**	**Consent**	**%**
Boston	3903	3370	86.3	1821	1523	83.6	2772	2425	87.5	5157	4409	85.5	6377	5683	89.1
Buffalo	3878	3353	86.5	2056	1689	82.1	3014	2593	86.0	5356	4549	84.9	6563	5842	89.0
Seattle	1775	1606	90.5	815	713	87.5	1318	1195	90.7	2397	2146	89.5	2721	2405	88.4
Columbus	4053	3538	87.3	2085	1757	84.3	3422	3000	87.7	5452	4703	86.3	6833	6122	89.6
Gainesville	3557	2835	79.7	1902	1465	77.0	2390	1960	82.0	4809	3795	78.9	5574	4682	84.0
Iowa	2678	2414	90.1	2298	2016	87.7	2829	2527	89.3	4526	4030	89.0	5243	4714	89.9
Medstar	1721	1459	84.8	837	690	82.4	1364	1167	85.6	2270	1912	84.2	2977	2664	89.5
Pittsburgh	1613	1427	88.5	808	691	85.5	1298	1144	88.1	2160	1886	87.3	2608	2315	88.8
Stanford	6060	5365	88.5	2913	2513	86.3	4759	4204	88.3	8089	7118	88.0	9892	8830	89.3
Tucson	2548	2186	85.8	1153	925	80.2	1986	1706	85.9	3353	2818	84.0	3855	3299	85.6
Wake Forest	3808	3134	82.3	2106	1601	76.0	2823	2309	81.8	5128	4129	80.5	6366	5507	86.5
Total	35594	30687	86.2	18794	15583	82.9	27975	24230	86.6	48697	41495	85.2	59009	52063	88.2

Table 1.7
Response Rates to CCC Annual Mailings, Extension Study 2010-2015 Year 1

Data as of: September 17, 2012

	1st Mailing Period				2nd Mailing Period					
Study	Form	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%
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%

Table 1.7 (continued for Year 2)
Response Rates to CCC Annual Mailings, Extension Study 2010-2015 Year 2

Data as of: September 17, 2012

	1st Mailing Period				2nd Mailing Period					
Study	Form	Sent Mail 1	Response		Past 2nd mailing period	Sent Mail 2		Response		Cumulative Response
Total	33	73966	61131	82.7%	64735	10653	16.5%	4234	39.7%	90.1%
	151	73820	60934	82.5%	64611	10743	16.6%	4255	39.6%	90.1%
HT	33	12114	9660	79.7%	10836	1985	18.3%	782	39.4%	88.2%
	151	12079	9629	79.7%	10809	1998	18.5%	776	38.8%	88.2%
DM	33	23828	19509	81.9%	21371	3609	16.9%	1402	38.9%	89.6%
	151	23787	19451	81.8%	21336	3637	17.1%	1405	38.6%	89.5%
CaD	33	18867	15511	82.2%	16932	2828	16.7%	1115	39.4%	89.8%
	151	18827	15459	82.1%	16900	2857	16.9%	1118	39.1%	89.8%
OS	33	41706	34872	83.6%	35811	5660	15.8%	2291	40.5%	90.8%
	151	41627	34752	83.5%	35742	5716	16.0%	2317	40.5%	90.8%

Table 1.8
Response Rates to Regional Center Follow-up and Cumulative Response--Extension Study 2010-2015 Follow-up Year 1

Data as of: September 17, 2012

Study	Form	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%
HT	33	1597	1374	86.0%	97.0%
	151	1710	941	55.0%	94.1%
DM	33	2732	2185	80.0%	97.1%
	151	2863	1626	56.8%	95.1%
CaD	33	2090	1703	81.5%	97.2%
	151	2213	1241	56.1%	95.1%
OS	33	3774	2809	74.4%	97.2%
	151	3935	2093	53.2%	95.7%

Table 1.8 (continued for year 2)
Response Rates to Regional Center Follow-up and Cumulative Response--Extension Study 2010-2015 Follow-up Year 2

Data as of: September 17, 2012

Study	Form	Eligible for RC Follow-up	Respondents		Total Estimated Response Rate
Total	33	1783	1486	83.3%	96.9%
	151	1871	417	22.3%	88.9%
HT	33	413	350	84.8%	96.3%
	151	426	86	20.2%	85.8%
DM	33	687	562	81.8%	96.5%
	151	725	156	21.5%	88.0%
CaD	33	545	452	82.9%	96.7%
	151	565	125	22.1%	88.2%
OS	33	830	695	83.7%	97.2%
	151	871	198	22.7%	90.0%

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

Data as of: September 17, 2012

	1st Mailing Period				2nd Mailing Period					
Cohort	Form	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%

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

Data as of: September 17, 2012

	1st Mailing Period				2nd Mailing Period					
Cohort	**Form**	**Sent Mail 1**	**Response**		**Past 2nd mailing period**	**Sent Mail 2**		**Response**		**Cumulative Response**
Total	33	73966	61131	82.7%	64735	10653	16.5%	4234	39.7%	90.1%
	151	73820	60934	82.5%	64611	10743	16.6%	4255	39.6%	90.1%
Medical Record	33	17124	13331	77.9%	15229	3038	20.0%	1126	37.1%	86.7%
Cohort	151	17089	13294	77.8%	15202	3063	20.2%	1123	36.7%	86.7%
Self Report	33	56842	47800	84.1%	49506	7615	15.4%	3108	40.8%	91.2%
Cohort	151	56731	47640	84.0%	49409	7680	15.5%	3132	40.8%	91.1%
Regional Center										
Boston	33	8280	6910	83.5%	7084	1147	16.2%	485	42.3%	90.7%
	151	8266	6894	83.4%	7073	1156	16.3%	477	41.3%	90.6%
Buffalo	33	7932	6467	81.5%	6880	1153	16.8%	480	41.6%	89.7%
	151	7902	6450	81.6%	6855	1155	16.9%	479	41.5%	89.9%
Columbus	33	8590	7229	84.2%	7494	1163	15.5%	470	40.4%	90.9%
	151	8578	7209	84.0%	7482	1178	15.7%	475	40.3%	90.9%
Gainesville	33	6850	5438	79.4%	6075	1176	19.4%	428	36.4%	88.0%
	151	6847	5423	79.2%	6073	1210	19.9%	435	36.0%	87.9%
Iowa	33	7045	5995	85.1%	6275	938	15.0%	411	43.8%	92.4%
	151	7019	5959	84.9%	6252	940	15.0%	412	43.8%	92.2%
Medstar	33	3525	2822	80.1%	3067	566	18.5%	221	39.1%	88.4%
	151	3520	2811	79.9%	3062	577	18.8%	228	39.5%	88.6%
Pittsburgh	33	3320	2631	79.3%	3038	532	17.5%	218	41.0%	87.0%
	151	3309	2625	79.3%	3029	529	17.5%	214	40.5%	87.2%
Seattle	33	3630	3039	83.7%	3227	504	15.6%	186	36.9%	90.2%
	151	3614	3023	83.7%	3216	505	15.7%	191	37.8%	90.3%
Stanford	33	12494	10609	84.9%	10844	1589	14.7%	628	39.5%	91.7%
	151	12486	10572	84.7%	10839	1598	14.7%	638	39.9%	91.7%
Tucson	33	4866	3915	80.5%	4297	788	18.3%	288	36.6%	88.2%
	151	4859	3905	80.4%	4290	795	18.5%	282	35.5%	87.9%
Wake Forest	33	7434	6076	81.7%	6454	1097	17.0%	419	38.2%	89.5%
	151	7420	6063	81.7%	6440	1100	17.1%	424	38.6%	89.6%

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

Data as of: September 17, 2012

Cohort	Form	Eligible for RC Follow-up	Respondents		Total Estimated Response Rate
Total	33	7574	5911	78.0%	97.1%
	151	7946	4344	54.7%	95.3%
Medical Record Cohort	33	2604	2227	85.5%	96.4%
	151	2753	1633	59.3%	93.6%
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%	96.8%
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%

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

Data as of: September 17, 2012

Cohort	Form	Eligible for RC Follow-up	Respondents		Total Estimated Response Rate
Total	33	1783	1486	83.3%	96.9%
	151	1871	417	22.3%	88.9%
Medical Record Cohort	33	634	546	86.1%	96.0%
	151	668	139	20.8%	84.2%
Self Report Cohort	33	1149	940	81.8%	97.1%
	151	1203	278	23.1%	90.5%
Regional Center					
Boston	33	196	194	99.0%	98.1%
	151	215	54	25.1%	87.6%
Buffalo	33	240	233	97.1%	97.6%
	151	255	121	47.5%	90.7%
Columbus	33	182	169	92.9%	98.1%
	151	191	25	13.1%	88.8%
Gainesville	33	171	132	77.2%	95.4%
	151	179	82	45.8%	90.6%
Iowa	33	138	60	43.5%	94.5%
	151	146	56	38.4%	93.8%
Medstar	33	103	96	93.2%	97.9%
	151	107	16	15.0%	85.4%
Pittsburgh	33	110	103	93.6%	97.8%
	151	115	31	27.0%	87.3%
Seattle	33	57	40	70.2%	96.0%
	151	57	3	5.3%	89.4%
Stanford	33	221	197	89.1%	98.6%
	151	224	20	8.9%	90.7%
Tucson	33	125	88	70.4%	95.0%
	151	138	1	0.7%	85.3%
Wake Forest	33	240	174	72.5%	95.1%
	151	244	8	3.3%	83.6%

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

Data as of: September 17, 2012
WHI Extension Study 2010-2015 Participants

	Without Uterus (N = 5,692)		With Uterus (N = 9,891)		HT Participants (N = 15,583)	
	N	%	N	%	N	%
Vital Status/Participation						
Deceased	191	3.4	303	3.1	494	3.2
Alive: Current Participation[1]	5282	92.8	9265	93.7	14547	93.4
Alive: Recent Participation[2]	122	2.1	188	1.9	310	2.0
Alive: Past/Unknown Participation[3]	34	0.6	41	0.4	75	0.5
Stopped Follow-Up[4]	31	0.5	54	0.5	85	0.5
Lost to Follow-Up[5]	32	0.6	40	0.4	72	0.5

Data as of: September 17, 2012; 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	678	8.9	1043	8.2	1721	8.4
Alive: Current Participation[1]	6643	86.9	11272	88.1	17915	87.7
Alive: Recent Participation[2]	94	1.2	119	0.9	213	1.0
Alive: Past/Unknown Participation[3]	10	0.1	13	0.1	23	0.1
Stopped Follow-Up[4]	132	1.7	226	1.8	358	1.8
Lost to Follow-Up[5]	88	1.2	115	0.9	203	1.0

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

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

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

Table 2.2
Verified Outcomes (Annualized Percentages) by Age for Hormone Therapy

Data as of: September 17, 2012; Events through September 17, 2012

Outcomes	Total	Age 50-54	55-59	60-69	70-79
Number randomized	27347	3420	5413	12360	6154
Mean follow-up (months)	152.3	162.0	159.6	153.1	138.8
Cardiovascular					
CHD[1]	1738 (0.50%)	87 (0.19%)	189 (0.26%)	800 (0.51%)	662 (0.93%)
CHD death[2]	577 (0.17%)	18 (0.04%)	43 (0.06%)	235 (0.15%)	281 (0.39%)
Total MI[3]	1337 (0.39%)	72 (0.16%)	161 (0.22%)	626 (0.40%)	478 (0.67%)
Clinical MI	1304 (0.38%)	71 (0.15%)	159 (0.22%)	609 (0.39%)	465 (0.65%)
CABG/PTCA	1701 (0.49%)	96 (0.21%)	244 (0.34%)	864 (0.55%)	497 (0.70%)
Carotid artery disease	357 (0.10%)	10 (0.02%)	46 (0.06%)	196 (0.12%)	105 (0.15%)
Stroke	1300 (0.37%)	51 (0.11%)	117 (0.16%)	600 (0.38%)	532 (0.75%)
Non-disabling stroke[4]	711 (0.20%)	39 (0.08%)	83 (0.12%)	321 (0.20%)	268 (0.38%)
Fatal/disabling stroke[4]	522 (0.15%)	9 (0.02%)	27 (0.04%)	244 (0.15%)	242 (0.34%)
Unknown status from stroke[4]	67 (0.02%)	3 (0.01%)	7 (0.01%)	35 (0.02%)	22 (0.03%)
PVD	359 (0.10%)	18 (0.04%)	44 (0.06%)	185 (0.12%)	112 (0.16%)
DVT	674 (0.19%)	48 (0.10%)	102 (0.14%)	318 (0.20%)	206 (0.29%)
Pulmonary embolism	521 (0.15%)	35 (0.08%)	75 (0.10%)	251 (0.16%)	160 (0.22%)
Coronary disease[5]	3667 (1.06%)	205 (0.44%)	457 (0.63%)	1731 (1.10%)	1274 (1.79%)
DVT/PE	953 (0.27%)	61 (0.13%)	136 (0.19%)	466 (0.30%)	290 (0.41%)
Abdominal aortic aneurysm (AAA)[6]	3 (0.01%)	0 (0.00%)	1 (0.01%)	2 (0.01%)	0 (0.00%)
Aortic aneurysm[6]	5 (0.01%)	0 (0.00%)	1 (0.01%)	3 (0.02%)	1 (0.01%)
Atrial fibrillation[6]	169 (0.45%)	9 (0.19%)	21 (0.28%)	92 (0.55%)	47 (0.59%)
Valvular heart disease[6]	22 (0.06%)	1 (0.02%)	2 (0.03%)	12 (0.07%)	7 (0.09%)
Total cardiovascular disease[7]	5759 (1.66%)	323 (0.70%)	714 (0.99%)	2727 (1.73%)	1995 (2.80%)
Cancer					
Breast cancer	1449 (0.42%)	156 (0.34%)	276 (0.38%)	695 (0.44%)	322 (0.45%)
Invasive breast cancer	1177 (0.34%)	118 (0.26%)	227 (0.32%)	554 (0.35%)	278 (0.39%)
Non-invasive breast cancer	289 (0.08%)	39 (0.08%)	53 (0.07%)	150 (0.10%)	47 (0.07%)
Ovarian cancer	125 (0.04%)	9 (0.02%)	24 (0.03%)	66 (0.04%)	26 (0.04%)
Endometrial cancer[8]	169 (0.05%)	20 (0.04%)	37 (0.05%)	77 (0.05%)	35 (0.05%)
Colorectal cancer	468 (0.13%)	30 (0.06%)	56 (0.08%)	228 (0.14%)	154 (0.22%)
Other cancer[9]	2153 (0.62%)	161 (0.35%)	326 (0.45%)	1052 (0.67%)	614 (0.86%)
Total cancer	4137 (1.19%)	360 (0.78%)	697 (0.97%)	1994 (1.26%)	1086 (1.53%)
Fractures					
Hip fracture	850 (0.24%)	16 (0.03%)	56 (0.08%)	331 (0.21%)	447 (0.63%)
Deaths					
Cardiovascular deaths	1149 (0.33%)	37 (0.08%)	78 (0.11%)	452 (0.29%)	582 (0.82%)
Cancer deaths	1428 (0.41%)	80 (0.17%)	178 (0.25%)	707 (0.45%)	463 (0.65%)
Other known cause	972 (0.28%)	38 (0.08%)	94 (0.13%)	397 (0.25%)	443 (0.62%)
Unknown cause	86 (0.02%)	6 (0.01%)	17 (0.02%)	28 (0.02%)	35 (0.05%)
Not yet adjudicated	232 (0.07%)	11 (0.02%)	18 (0.03%)	97 (0.06%)	106 (0.15%)
Total death	3867 (1.11%)	172 (0.37%)	385 (0.53%)	1681 (1.07%)	1629 (2.29%)
Death plus post-WHI deaths[10]	4462 (1.21%)	191 (0.38%)	426 (0.56%)	1911 (1.15%)	1934 (2.54%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Studies.
[2] "CHD death" includes definite and possible CHD death.
[3] "Total MI' includes clinical MI and evolving Q-wave MI; Q-wave MI is not collected in the WHI Extension Studies.
[4] Non-disabling stroke includes Glasgow scales 1 and 2; fatal/disabling includes Glasgow scales 3-5 and death within 1 month of stroke; and unknown status includes Glasgow scale 6 and status not yet known.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA; Q-wave MI and angina are not collected in the WHI Extension Studies. Congestive heart failure is not collected in the WHI Extension Study 2005-2010.
[6] AAA, 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 AAA, aortic aneurysm, atrial fibrillation or valvular heart disease.
[8] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[9] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.
[10] Includes deaths for non-Extension study participants after the main WHI study close-out.

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

Data as of: September 17, 2012; Events through September 17, 2012

	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)	138.7	140.6	145.6	135.5	154.8	144.1
Cardiovascular						
CHD[1]	7 (0.47%)	22 (0.36%)	160 (0.48%)	44 (0.25%)	1478 (0.52%)	27 (0.58%)
CHD death[2]	4 (0.27%)	9 (0.15%)	75 (0.23%)	11 (0.06%)	472 (0.17%)	6 (0.13%)
Total MI[3]	5 (0.33%)	18 (0.29%)	102 (0.31%)	35 (0.20%)	1153 (0.41%)	24 (0.52%)
Clinical MI	5 (0.33%)	17 (0.28%)	101 (0.30%)	33 (0.19%)	1125 (0.40%)	23 (0.50%)
CABG/PTCA	7 (0.47%)	20 (0.32%)	119 (0.36%)	57 (0.33%)	1474 (0.52%)	24 (0.52%)
Carotid artery disease	1 (0.07%)	2 (0.03%)	13 (0.04%)	4 (0.02%)	334 (0.12%)	3 (0.06%)
Stroke	7 (0.47%)	15 (0.24%)	152 (0.46%)	31 (0.18%)	1076 (0.38%)	19 (0.41%)
Non-disabling stroke[4]	4 (0.27%)	8 (0.13%)	87 (0.26%)	19 (0.11%)	585 (0.21%)	8 (0.17%)
Fatal/disabling stroke[4]	3 (0.20%)	7 (0.11%)	54 (0.16%)	8 (0.05%)	442 (0.16%)	8 (0.17%)
Unknown status from stroke[4]	0 (0.00%)	0 (0.00%)	11 (0.03%)	4 (0.02%)	49 (0.02%)	3 (0.06%)
PVD	2 (0.13%)	6 (0.10%)	37 (0.11%)	4 (0.02%)	308 (0.11%)	2 (0.04%)
DVT	4 (0.27%)	4 (0.06%)	70 (0.21%)	11 (0.06%)	581 (0.20%)	4 (0.09%)
Pulmonary embolism	4 (0.27%)	2 (0.03%)	63 (0.19%)	5 (0.03%)	440 (0.15%)	7 (0.15%)
Coronary disease[5]	14 (0.93%)	46 (0.75%)	365 (1.10%)	123 (0.71%)	3066 (1.08%)	53 (1.15%)
DVT/PE	7 (0.47%)	4 (0.06%)	102 (0.31%)	13 (0.07%)	818 (0.29%)	9 (0.19%)
Abdominal aortic aneurysm (AAA)[6]	0 (0.00%)	0 (0.00%)	1 (0.03%)	0 (0.00%)	2 (0.01%)	0 (0.00%)
Aortic aneurysm[6]	0 (0.00%)	0 (0.00%)	1 (0.03%)	0 (0.00%)	4 (0.01%)	0 (0.00%)
Atrial fibrillation[6]	0 (0.00%)	1 (0.14%)	4 (0.11%)	4 (0.20%)	159 (0.53%)	1 (0.19%)
Valvular heart disease[6]	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.05%)	21 (0.07%)	0 (0.00%)
Total cardiovascular disease[7]	26 (1.73%)	66 (1.07%)	592 (1.78%)	163 (0.94%)	4842 (1.70%)	70 (1.51%)
Cancer						
Breast cancer	4 (0.27%)	29 (0.47%)	126 (0.38%)	45 (0.26%)	1230 (0.43%)	15 (0.32%)
Invasive breast cancer	3 (0.20%)	22 (0.36%)	104 (0.31%)	36 (0.21%)	1001 (0.35%)	11 (0.24%)
Non-invasive breast cancer	1 (0.07%)	8 (0.13%)	23 (0.07%)	10 (0.06%)	242 (0.09%)	5 (0.11%)
Ovarian cancer	1 (0.07%)	3 (0.05%)	9 (0.03%)	0 (0.00%)	110 (0.04%)	2 (0.04%)
Endometrial cancer[8]	1 (0.07%)	2 (0.03%)	12 (0.04%)	6 (0.03%)	146 (0.05%)	2 (0.04%)
Colorectal cancer	1 (0.07%)	13 (0.21%)	37 (0.11%)	17 (0.10%)	391 (0.14%)	9 (0.19%)
Other cancer[9]	8 (0.53%)	35 (0.57%)	150 (0.45%)	71 (0.41%)	1863 (0.66%)	26 (0.56%)
Total cancer	15 (1.00%)	80 (1.30%)	318 (0.96%)	132 (0.76%)	3542 (1.25%)	50 (1.08%)
Fractures						
Hip fracture	4 (0.27%)	8 (0.13%)	20 (0.06%)	16 (0.09%)	795 (0.28%)	7 (0.15%)
Deaths						
Cardiovascular deaths	7 (0.47%)	15 (0.24%)	142 (0.43%)	20 (0.12%)	954 (0.34%)	11 (0.24%)
Cancer deaths	6 (0.40%)	27 (0.44%)	113 (0.34%)	53 (0.31%)	1213 (0.43%)	16 (0.35%)
Other known cause	5 (0.33%)	12 (0.19%)	70 (0.21%)	19 (0.11%)	855 (0.30%)	11 (0.24%)
Unknown cause	0 (0.00%)	2 (0.03%)	15 (0.05%)	5 (0.03%)	61 (0.02%)	3 (0.06%)
Not yet adjudicated	0 (0.00%)	1 (0.02%)	12 (0.04%)	4 (0.02%)	211 (0.07%)	4 (0.09%)
Total Death	18 (1.20%)	57 (0.92%)	352 (1.06%)	101 (0.58%)	3294 (1.16%)	45 (0.97%)
Death plus post-WHI deaths[10]	20 (1.20%)	68 (1.00%)	419 (1.17%)	122 (0.61%)	3776 (1.26%)	57 (1.13%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Studies.
[2] "CHD death" includes definite and possible CHD death.
[3] "Total MI" includes clinical MI and evolving Q-wave MI; Q-wave MI is not collected in the WHI Extension Studies.
[4] Non-disabling stroke includes Glasgow scales 1 and 2; fatal/disabling includes Glasgow scales 3-5 and death within 1 month of stroke; and unknown status includes Glasgow scale 6 and status not yet known.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA; Q-wave MI and angina are not collected in the WHI Extension Studies. Congestive heart failure is not collected in the WHI Extension Study 2005-2010.
[6] AAA, 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 AAA, aortic aneurysm, atrial fibrillation or valvular heart disease.
[8] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[9] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.
[10] Includes deaths for non-Extension study participants after the main WHI study close-out.

Table 2.4
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for HT Participants Who Did Not Report a Prevalent Condition at Baseline

Data as of: September 17, 2012; Events through September 17, 2012

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	27347	3420	5413	12360	6154
Mean follow-up (months)	152.3	162.0	159.6	153.1	138.8
Hospitalizations					
Ever	18292 (5.27%)	1711 (3.71%)	3089 (4.29%)	8604 (5.46%)	4888 (6.87%)
Two or more	11877 (3.42%)	894 (1.94%)	1805 (2.51%)	5650 (3.58%)	3528 (4.96%)
Other					
Diabetes (treated)	3790 (1.15%)	561 (1.26%)	772 (1.13%)	1770 (1.18%)	687 (1.02%)
Gallbladder disease[1,2]	2117 (1.15%)	282 (1.11%)	443 (1.15%)	988 (1.20%)	404 (1.04%)
Hysterectomy	1088 (0.51%)	118 (0.43%)	252 (0.53%)	521 (0.54%)	197 (0.47%)
Glaucoma[2]	3201 (1.51%)	286 (0.99%)	548 (1.25%)	1519 (1.60%)	848 (1.92%)
Osteoporosis[2]	6111 (2.91%)	475 (1.65%)	962 (2.19%)	2954 (3.14%)	1720 (3.99%)
Osteoarthritis[3]	7327 (3.29%)	998 (2.73%)	1569 (3.02%)	3342 (3.44%)	1418 (3.85%)
Rheumatoid arthritis[2]	1696 (0.80%)	211 (0.75%)	341 (0.79%)	763 (0.81%)	381 (0.85%)
Intestinal polyps	6044 (1.87%)	729 (1.63%)	1257 (1.83%)	2961 (2.02%)	1097 (1.74%)
Lupus	403 (0.12%)	45 (0.10%)	82 (0.11%)	191 (0.12%)	85 (0.12%)
Kidney stones[2,3]	769 (0.36%)	94 (0.33%)	143 (0.33%)	346 (0.36%)	186 (0.40%)
Cataracts[2,3]	8648 (4.57%)	505 (1.75%)	1344 (3.11%)	4577 (5.35%)	2222 (7.03%)
Pills for hypertension	10119 (4.06%)	1257 (3.35%)	2061 (3.68%)	4634 (4.20%)	2167 (4.77%)
COPD[4]	577 (1.55%)	54 (1.14%)	116 (1.53%)	309 (1.83%)	98 (1.24%)
Macular degeneration[4]	549 (1.47%)	25 (0.53%)	81 (1.07%)	275 (1.63%)	168 (2.12%)
Alzheimer's disease[4]	405 (1.09%)	18 (0.38%)	30 (0.40%)	219 (1.30%)	138 (1.74%)
Parkinson's disease[4]	44 (0.12%)	4 (0.08%)	7 (0.09%)	24 (0.14%)	9 (0.11%)

Outcomes	Race/Ethnicity: Am Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	130	527	2738	1537	22030	385
Mean follow-up (months)	138.7	140.6	145.6	135.5	154.8	144.1
Hospitalizations						
Ever	85 (5.66%)	263 (4.26%)	1772 (5.33%)	764 (4.40%)	15166 (5.34%)	242 (5.23%)
Two or more	61 (4.06%)	141 (2.28%)	1149 (3.46%)	397 (2.29%)	9974 (3.51%)	155 (3.35%)
Other						
Diabetes (treated)	22 (1.66%)	76 (1.32%)	538 (1.84%)	297 (1.85%)	2802 (1.03%)	55 (1.28%)
Gallbladder disease[1,2]	13 (1.68%)	32 (0.87%)	187 (0.95%)	129 (1.43%)	1730 (1.16%)	26 (1.05%)
Hysterectomy	4 (0.65%)	11 (0.25%)	71 (0.51%)	50 (0.49%)	938 (0.51%)	14 (0.49%)
Glaucoma[2]	16 (1.69%)	60 (1.53%)	408 (2.02%)	190 (1.64%)	2480 (1.44%)	47 (1.69%)
Osteoporosis[2]	32 (3.33%)	141 (3.61%)	348 (1.65%)	338 (3.01%)	5159 (3.04%)	93 (3.28%)
Osteoarthritis[3]	45 (4.31%)	151 (3.40%)	703 (3.38%)	497 (4.01%)	5825 (3.22%)	106 (3.47%)
Rheumatoid arthritis[2]	15 (1.67%)	30 (0.77%)	272 (1.36%)	219 (1.92%)	1125 (0.65%)	35 (1.24%)
Intestinal polyps	31 (2.23%)	99 (1.78%)	645 (2.08%)	274 (1.65%)	4922 (1.86%)	73 (1.72%)
Lupus	3 (0.20%)	5 (0.08%)	44 (0.13%)	28 (0.16%)	319 (0.11%)	4 (0.09%)
Kidney stones[2,3]	9 (0.98%)	25 (0.64%)	82 (0.38%)	62 (0.55%)	583 (0.34%)	8 (0.28%)
Cataracts[2,3]	44 (4.91%)	143 (4.16%)	790 (4.13%)	450 (4.06%)	7108 (4.67%)	113 (4.50%)
Pills for hypertension	57 (5.29%)	177 (4.07%)	847 (5.05%)	584 (4.45%)	8332 (3.95%)	122 (3.93%)
COPD[4]	9 (5.44%)	4 (0.58%)	42 (1.13%)	17 (0.83%)	497 (1.65%)	8 (1.51%)
Macular degeneration[4]	4 (2.42%)	7 (1.01%)	41 (1.10%)	13 (0.64%)	478 (1.59%)	6 (1.13%)
Alzheimer's disease[4]	1 (0.60%)	4 (0.58%)	37 (1.00%)	19 (0.93%)	340 (1.13%)	4 (0.76%)
Parkinson's disease[4]	0 (0.00%)	0 (0.00%)	2 (0.05%)	2 (0.10%)	39 (0.13%)	1 (0.19%)

[1] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[2] Data not collected for WHI Extension Studies.
[3] These outcomes have not been self-reported on all versions of Form 33 during WHI follow-up. The annualized percentages are corrected for the different amounts of follow-up.
[4] Data only collected during the WHI Extension Study 2010-2015.

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

Data as of: September 17, 2012
WHI Extension Study 2010-2015 Participants

	DM Participants (N = 30,687)	
	N	%
Vital Status/Participation		
Deceased	753	2.5
Alive: Current Participation[1]	29088	94.8
Alive: Recent Participation[2]	506	1.6
Alive: Past/Unknown Participation[3]	124	0.4
Stopped Follow-Up[4]	110	0.4
Lost to Follow-Up[5]	106	0.3

Data as of: September 17, 2012; Status as of September 30, 2010
WHI Extension Study 2005-2010 Participants

	DM Participants (N = 37,858)	
	N	%
Vital Status/Participation		
Deceased	2471	6.5
Alive: Current Participation[1]	34402	90.9
Alive: Recent Participation[2]	315	0.8
Alive: Past/Unknown Participation[3]	21	0.1
Stopped Follow-Up[4]	419	1.1
Lost to Follow-Up[5]	230	0.6

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

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

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

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

Data as of: September 17, 2012; **Events through September 30, 2010**

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	48835		6961		11037		22715		8122	
Mean follow-up (months)	148.2		157.5		154.0		147.2		134.9	
Cancer										
Breast cancer	3170	(0.53%)	404	(0.44%)	740	(0.52%)	1503	(0.54%)	523	(0.57%)
Invasive breast cancer	2563	(0.43%)	302	(0.33%)	602	(0.42%)	1224	(0.44%)	435	(0.48%)
Non-invasive breast cancer	652	(0.11%)	107	(0.12%)	148	(0.10%)	299	(0.11%)	98	(0.11%)
Ovarian cancer	274	(0.05%)	30	(0.03%)	52	(0.04%)	138	(0.05%)	54	(0.06%)
Endometrial cancer[1]	454	(0.07%)	56	(0.06%)	113	(0.08%)	219	(0.08%)	66	(0.07%)
Colorectal cancer	767	(0.13%)	51	(0.06%)	135	(0.10%)	377	(0.14%)	204	(0.22%)
Other cancer[2]	3350	(0.56%)	298	(0.33%)	607	(0.43%)	1706	(0.61%)	739	(0.81%)
Total cancer	7566	(1.25%)	800	(0.88%)	1552	(1.10%)	3717	(1.33%)	1497	(1.64%)
Cardiovascular										
CHD[3]	2278	(0.38%)	129	(0.14%)	276	(0.19%)	1098	(0.39%)	775	(0.85%)
CHD death[4]	721	(0.12%)	36	(0.04%)	56	(0.04%)	329	(0.12%)	300	(0.33%)
Total MI[5]	1781	(0.30%)	101	(0.11%)	233	(0.16%)	859	(0.31%)	588	(0.64%)
Clinical MI	1729	(0.29%)	95	(0.10%)	226	(0.16%)	833	(0.30%)	575	(0.63%)
CABG/PTCA	2486	(0.41%)	138	(0.15%)	353	(0.25%)	1370	(0.49%)	625	(0.68%)
Carotid artery disease	439	(0.07%)	23	(0.03%)	59	(0.04%)	235	(0.08%)	122	(0.13%)
Stroke	1861	(0.31%)	93	(0.10%)	209	(0.15%)	892	(0.32%)	667	(0.73%)
PVD	396	(0.07%)	17	(0.02%)	52	(0.04%)	209	(0.08%)	118	(0.13%)
Coronary disease[6]	5169	(0.86%)	301	(0.33%)	705	(0.50%)	2627	(0.94%)	1536	(1.68%)
Total cardiovascular disease	7191	(1.19%)	411	(0.45%)	963	(0.68%)	3605	(1.29%)	2212	(2.42%)
Fractures										
Hip fracture	1047	(0.17%)	22	(0.02%)	74	(0.05%)	458	(0.16%)	493	(0.54%)
Deaths										
Cardiovascular deaths	1459	(0.24%)	61	(0.07%)	114	(0.08%)	622	(0.22%)	662	(0.72%)
Cancer deaths	2049	(0.34%)	133	(0.15%)	299	(0.21%)	1039	(0.37%)	578	(0.63%)
Other known cause	1282	(0.21%)	54	(0.06%)	129	(0.09%)	564	(0.20%)	535	(0.59%)
Unknown cause	104	(0.02%)	5	(0.01%)	12	(0.01%)	60	(0.02%)	27	(0.03%)
Not yet adjudicated	40	(0.01%)	1	(<0.01%)	5	(<0.01%)	22	(0.01%)	12	(0.01%)
Total death	4934	(0.82%)	254	(0.28%)	559	(0.39%)	2307	(0.83%)	1814	(1.99%)
Death plus post-WHI deaths[7]	5663	(0.88%)	282	(0.29%)	617	(0.41%)	2606	(0.88%)	2158	(2.20%)

[1] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[2] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.
[3] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Studies.
[4] "CHD death" includes definite and possible CHD death.
[5] "Total MI" includes clinical MI and evolving Q-wave MI is not collected in the WHI Extension Study.
[6] "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.
[7] Includes deaths for non-Extension study participants after the main WHI study close-out.

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

Data as of: Data as of September 17, 2012; **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)	138.4	143.4	140.1	133.0	150.3	138.4
Cancer						
Breast cancer	7 (0.30%)	71 (0.54%)	273 (0.44%)	75 (0.37%)	2709 (0.54%)	35 (0.46%)
Invasive breast cancer	5 (0.21%)	55 (0.42%)	206 (0.34%)	60 (0.29%)	2208 (0.44%)	29 (0.38%)
Non-invasive breast cancer	2 (0.09%)	17 (0.13%)	71 (0.12%)	17 (0.08%)	538 (0.11%)	7 (0.09%)
Ovarian cancer	1 (0.04%)	7 (0.05%)	20 (0.03%)	9 (0.04%)	234 (0.05%)	3 (0.04%)
Endometrial cancer[1]	0 (0.00%)	5 (0.04%)	28 (0.05%)	9 (0.04%)	406 (0.08%)	6 (0.08%)
Colorectal cancer	5 (0.21%)	12 (0.09%)	87 (0.14%)	22 (0.11%)	632 (0.13%)	9 (0.12%)
Other cancer[2]	7 (0.30%)	47 (0.36%)	261 (0.42%)	68 (0.33%)	2926 (0.59%)	41 (0.54%)
Total cancer	18 (0.77%)	134 (1.01%)	628 (1.02%)	170 (0.83%)	6530 (1.31%)	86 (1.13%)
Cardiovascular						
CHD[3]	4 (0.17%)	28 (0.21%)	239 (0.39%)	41 (0.20%)	1936 (0.39%)	30 (0.39%)
CHD death[4]	0 (0.00%)	6 (0.05%)	104 (0.17%)	14 (0.07%)	583 (0.12%)	14 (0.18%)
Total MI[5]	4 (0.17%)	25 (0.19%)	164 (0.27%)	32 (0.16%)	1534 (0.31%)	22 (0.29%)
Clinical MI	4 (0.17%)	25 (0.19%)	159 (0.26%)	31 (0.15%)	1489 (0.30%)	21 (0.28%)
CABG/PTCA	8 (0.34%)	22 (0.17%)	224 (0.36%)	57 (0.28%)	2151 (0.43%)	24 (0.32%)
Carotid artery disease	2 (0.09%)	1 (0.01%)	31 (0.05%)	4 (0.02%)	395 (0.08%)	6 (0.08%)
Stroke	6 (0.26%)	28 (0.21%)	250 (0.41%)	45 (0.22%)	1506 (0.30%)	26 (0.34%)
PVD	3 (0.13%)	3 (0.02%)	75 (0.12%)	6 (0.03%)	303 (0.06%)	6 (0.08%)
Coronary disease[6]	17 (0.73%)	61 (0.46%)	614 (1.00%)	126 (0.62%)	4288 (0.86%)	63 (0.83%)
Total cardiovascular disease	27 (1.16%)	91 (0.69%)	868 (1.41%)	176 (0.86%)	5939 (1.19%)	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%)	209 (0.34%)	25 (0.12%)	1185 (0.24%)	18 (0.24%)
Cancer deaths	8 (0.34%)	27 (0.20%)	177 (0.29%)	51 (0.25%)	1757 (0.35%)	29 (0.38%)
Other known cause	11 (0.47%)	11 (0.08%)	131 (0.21%)	27 (0.13%)	1087 (0.22%)	15 (0.20%)
Unknown cause	0 (0.00%)	3 (0.02%)	19 (0.03%)	6 (0.03%)	74 (0.01%)	2 (0.03%)
Not yet adjudicated	0 (0.00%)	0 (0.00%)	2 (<0.01%)	0 (0.00%)	38 (0.01%)	0 (0.00%)
Total death	23 (0.99%)	59 (0.45%)	538 (0.88%)	109 (0.53%)	4141 (0.83%)	64 (0.84%)
Death plus post-WHI deaths[7]	31 (1.22%)	76 (0.53%)	639 (0.95%)	126 (0.54%)	4713 (0.90%)	78 (0.94%)

[1] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[2] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.
[3] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Study.
[4] "CHD death" includes definite and possible CHD death.
[5] "Total MI" includes clinical MI and evolving Q-wave MI; Q-wave MI is not collected in the WHI Extension Studies.
[6] "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.
[7] Includes deaths for non-Extension study participants after the main WHI study close-out.

Table 3.4
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for DM Participants Who Did Not Report a Prevalent Condition at Baseline

Data as of: September 17, 2012; Events through September 17, 2012

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	48835	6961	11037	22715	8122
Mean follow-up (months)	158.6	169.3	165.9	157.8	141.8
Hospitalizations					
Ever	32511 (5.04%)	3645 (3.71%)	6479 (4.25%)	15925 (5.33%)	6462 (6.74%)
Two or more	20735 (3.21%)	1895 (1.93%)	3755 (2.46%)	10457 (3.50%)	4628 (4.82%)
Other					
DVT[1]	974 (0.16%)	71 (0.07%)	147 (0.10%)	504 (0.18%)	252 (0.28%)
Pulmonary embolism	748 (0.12%)	57 (0.06%)	126 (0.08%)	396 (0.13%)	169 (0.18%)
Diabetes (treated)	6587 (1.06%)	1003 (1.05%)	1529 (1.04%)	3095 (1.08%)	960 (1.05%)
Gallbladder disease[2,3]	3830 (1.13%)	573 (1.04%)	902 (1.12%)	1802 (1.18%)	553 (1.07%)
Hysterectomy	2282 (0.62%)	347 (0.62%)	573 (0.62%)	1081 (0.65%)	281 (0.54%)
Glaucoma[3]	5315 (1.36%)	567 (0.93%)	1098 (1.19%)	2587 (1.46%)	1063 (1.78%)
Osteoporosis[3]	10217 (2.67%)	1128 (1.86%)	1968 (2.15%)	5020 (2.89%)	2101 (3.65%)
Osteoarthritis[4]	14057 (3.39%)	2259 (2.93%)	3409 (3.14%)	6425 (3.58%)	1964 (3.97%)
Rheumatoid arthritis[3]	2848 (0.73%)	399 (0.66%)	631 (0.69%)	1319 (0.74%)	499 (0.82%)
Intestinal polyps	11757 (1.96%)	1735 (1.82%)	2878 (1.99%)	5626 (2.05%)	1518 (1.78%)
Lupus	700 (0.11%)	101 (0.10%)	164 (0.11%)	338 (0.11%)	97 (0.10%)
Kidney stones[3,4]	1319 (0.34%)	175 (0.29%)	281 (0.31%)	654 (0.37%)	209 (0.34%)
Cataracts[3,4]	15480 (4.33%)	1157 (1.90%)	2858 (3.15%)	8460 (5.24%)	3005 (6.84%)
Pills for hypertension	17508 (3.85%)	2457 (3.10%)	4065 (3.51%)	8287 (4.10%)	2699 (4.69%)

Outcomes	Race/Ethnicity: Am Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	202	1105	5262	1845	39762	659
Mean follow-up (months)	147.0	153.2	148.3	140.3	161.2	147.2
Hospitalizations						
Ever	125 (5.05%)	554 (3.93%)	3294 (5.06%)	961 (4.46%)	27178 (5.09%)	399 (4.94%)
Two or more	77 (3.11%)	276 (1.96%)	2100 (3.23%)	534 (2.48%)	17504 (3.28%)	244 (3.02%)
Other						
DVT[1]	3 (0.13%)	5 (0.04%)	111 (0.18%)	18 (0.09%)	824 (0.16%)	13 (0.17%)
Pulmonary embolism	4 (0.16%)	2 (0.01%)	80 (0.12%)	13 (0.06%)	639 (0.12%)	10 (0.12%)
Diabetes (treated)	33 (1.43%)	163 (1.22%)	1066 (1.84%)	308 (1.52%)	4924 (0.95%)	93 (1.21%)
Gallbladder disease[2,3]	14 (1.19%)	60 (0.75%)	304 (0.79%)	152 (1.39%)	3250 (1.17%)	50 (1.11%)
Hysterectomy	6 (0.52%)	38 (0.42%)	154 (0.53%)	69 (0.60%)	1996 (0.64%)	19 (0.41%)
Glaucoma[3]	30 (1.91%)	108 (1.26%)	762 (1.90%)	201 (1.43%)	4150 (1.29%)	64 (1.30%)
Osteoporosis[3]	43 (2.74%)	272 (3.24%)	678 (1.64%)	409 (3.03%)	8675 (2.77%)	140 (2.88%)
Osteoarthritis[4]	54 (3.59%)	326 (3.13%)	1398 (3.47%)	560 (3.70%)	11520 (3.36%)	199 (3.86%)
Rheumatoid arthritis[3]	23 (1.56%)	49 (0.57%)	505 (1.26%)	222 (1.61%)	1998 (0.62%)	51 (1.03%)
Intestinal polyps	58 (2.51%)	251 (1.94%)	1310 (2.16%)	379 (1.84%)	9605 (1.94%)	154 (2.07%)
Lupus	5 (0.21%)	10 (0.07%)	100 (0.15%)	23 (0.11%)	549 (0.10%)	13 (0.16%)
Kidney stones[3,4]	9 (0.59%)	27 (0.32%)	137 (0.33%)	58 (0.42%)	1071 (0.33%)	17 (0.34%)
Cataracts[3,4]	61 (4.35%)	306 (3.94%)	1509 (3.95%)	537 (4.04%)	12863 (4.41%)	204 (4.49%)
Pills for hypertension	64 (3.95%)	375 (3.92%)	1636 (4.97%)	691 (4.31%)	14529 (3.73%)	213 (3.87%)

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

Table 4.1
Lost-to-Follow-up and Vital Status: CaD Participants

Data as of: September 17, 2012
WHI Extension Study 2010-2015 Participants

	CaD Participants (N = 24,230)	
	N	%
Vital Status/Participation		
Deceased	600	2.5
Alive: Current Participation[1]	22944	94.7
Alive: Recent Participation[2]	395	1.6
Alive: Past/Unknown Participation[3]	95	0.4
Stopped Follow-Up[4]	94	0.4
Lost to Follow-Up[5]	102	0.4

Data as of: September 17, 2012; Status as of September 30, 2010
WHI Extension Study 2005-2010 Participants

	CaD Participants (N = 29,862)	
	N	%
Vital Status/Participation		
Deceased	2042	6.8
Alive: Current Participation[1]	26979	90.3
Alive: Recent Participation[2]	248	0.8
Alive: Past/Unknown Participation[3]	18	0.1
Stopped Follow-Up[4]	369	1.2
Lost to Follow-Up[5]	206	0.7

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

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

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

Table 4.2
Verified Outcomes (Annualized Percentages) by Age for Calcium and Vitamin D

Data as of: September 17, 2012; **Events through September 30, 2010**

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	36282	5153	8269	16519	6341
Mean follow-up (months)	138.7	146.5	144.2	137.9	127.1
Fractures					
Hip fracture	810 (0.19%)	18 (0.03%)	74 (0.07%)	325 (0.17%)	393 (0.59%)
Cancer					
Colorectal cancer	543 (0.13%)	39 (0.06%)	83 (0.08%)	267 (0.14%)	154 (0.23%)
Breast cancer	2127 (0.51%)	267 (0.42%)	505 (0.51%)	1001 (0.53%)	354 (0.53%)
Invasive breast cancer	1707 (0.41%)	200 (0.32%)	408 (0.41%)	805 (0.42%)	294 (0.44%)
Non-invasive breast cancer	450 (0.11%)	68 (0.11%)	102 (0.10%)	210 (0.11%)	70 (0.10%)
Ovarian cancer	186 (0.04%)	21 (0.03%)	44 (0.04%)	88 (0.05%)	33 (0.05%)
Endometrial cancer[1]	293 (0.07%)	38 (0.06%)	74 (0.07%)	131 (0.07%)	50 (0.07%)
Other cancer[2]	2419 (0.58%)	207 (0.33%)	419 (0.42%)	1231 (0.65%)	562 (0.84%)
Total cancer	5281 (1.26%)	552 (0.88%)	1076 (1.08%)	2566 (1.35%)	1087 (1.62%)
Cardiovascular					
CHD[3]	1747 (0.42%)	92 (0.15%)	215 (0.22%)	834 (0.44%)	606 (0.90%)
CHD death[4]	536 (0.13%)	22 (0.03%)	47 (0.05%)	218 (0.11%)	249 (0.37%)
Total MI[5]	1368 (0.33%)	75 (0.12%)	175 (0.18%)	680 (0.36%)	438 (0.65%)
Clinical MI	1319 (0.31%)	71 (0.11%)	170 (0.17%)	656 (0.35%)	422 (0.63%)
CABG/PTCA	1884 (0.45%)	108 (0.17%)	274 (0.28%)	1013 (0.53%)	489 (0.73%)
Carotid artery disease	355 (0.08%)	16 (0.03%)	50 (0.05%)	199 (0.10%)	90 (0.13%)
Stroke	1372 (0.33%)	70 (0.11%)	156 (0.16%)	639 (0.34%)	507 (0.76%)
PVD	328 (0.08%)	11 (0.02%)	48 (0.05%)	164 (0.09%)	105 (0.16%)
Coronary disease[6]	3840 (0.92%)	221 (0.35%)	543 (0.55%)	1910 (1.01%)	1166 (1.74%)
Total cardiovascular disease	5377 (1.28%)	306 (0.49%)	745 (0.75%)	2639 (1.39%)	1687 (2.51%)
Deaths					
Cardiovascular deaths	1079 (0.26%)	42 (0.07%)	89 (0.09%)	440 (0.23%)	508 (0.76%)
Cancer deaths	1493 (0.36%)	104 (0.17%)	215 (0.22%)	763 (0.40%)	411 (0.61%)
Other known cause	958 (0.23%)	41 (0.07%)	102 (0.10%)	418 (0.22%)	397 (0.59%)
Unknown cause	71 (0.02%)	3 (<0.01%)	13 (0.01%)	35 (0.02%)	20 (0.03%)
Not yet adjudicated	25 (0.01%)	2 (<0.01%)	1 (<0.01%)	12 (0.01%)	10 (0.01%)
Total death	3626 (0.86%)	192 (0.31%)	420 (0.42%)	1668 (0.88%)	1346 (2.00%)
Death plus post-WHI deaths[7]	4058 (0.93%)	212 (0.32%)	457 (0.44%)	1840 (0.94%)	1549 (2.21%)

[1] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[2] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.
[3] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Study.
[4] "CHD death" includes definite and possible CHD death.
[5] "Total MI" includes clinical MI and evolving Q-wave MI; Q-wave MI is not collected in the WHI Extension Studies.
[6] "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.
[7] Includes deaths for non-Extension study participants after the main WHI study close-out.

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

Data as of: September 17, 2012; **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)	130.9		132.5		132.1		126.1		140.3		128.6	
Fractures												
Hip fracture	3	(0.18%)	10	(0.13%)	14	(0.04%)	10	(0.06%)	771	(0.22%)	2	(0.04%)
Cancer												
Colorectal cancer	2	(0.12%)	9	(0.11%)	54	(0.15%)	15	(0.10%)	456	(0.13%)	7	(0.15%)
Breast cancer	5	(0.31%)	41	(0.52%)	167	(0.46%)	52	(0.33%)	1841	(0.52%)	21	(0.45%)
Invasive breast cancer	3	(0.18%)	30	(0.38%)	128	(0.35%)	42	(0.27%)	1485	(0.42%)	19	(0.40%)
Non-invasive breast cancer	2	(0.12%)	13	(0.16%)	42	(0.12%)	12	(0.08%)	378	(0.11%)	3	(0.06%)
Ovarian cancer	0	(0.00%)	7	(0.09%)	12	(0.03%)	6	(0.04%)	159	(0.05%)	2	(0.04%)
Endometrial cancer[1]	1	(0.06%)	4	(0.05%)	14	(0.04%)	6	(0.04%)	264	(0.07%)	4	(0.08%)
Other cancer[2]	6	(0.37%)	35	(0.44%)	160	(0.44%)	55	(0.35%)	2140	(0.61%)	23	(0.49%)
Total cancer	13	(0.80%)	92	(1.16%)	387	(1.06%)	126	(0.80%)	4608	(1.31%)	55	(1.17%)
Cardiovascular												
CHD[3]	5	(0.31%)	14	(0.18%)	155	(0.42%)	36	(0.23%)	1514	(0.43%)	23	(0.49%)
CHD death[4]	1	(0.06%)	3	(0.04%)	63	(0.17%)	10	(0.06%)	449	(0.13%)	10	(0.21%)
Total MI[5]	5	(0.31%)	13	(0.16%)	104	(0.29%)	30	(0.19%)	1197	(0.34%)	19	(0.40%)
Clinical MI	5	(0.31%)	13	(0.16%)	101	(0.28%)	29	(0.18%)	1153	(0.33%)	18	(0.38%)
CABG/PTCA	5	(0.31%)	17	(0.21%)	142	(0.39%)	58	(0.37%)	1637	(0.46%)	25	(0.53%)
Carotid artery disease	1	(0.06%)	1	(0.01%)	21	(0.06%)	4	(0.03%)	323	(0.09%)	5	(0.11%)
Stroke	8	(0.49%)	23	(0.29%)	142	(0.39%)	32	(0.20%)	1147	(0.33%)	20	(0.42%)
PVD	2	(0.12%)	5	(0.06%)	46	(0.13%)	3	(0.02%)	269	(0.08%)	3	(0.06%)
Coronary disease[6]	11	(0.68%)	38	(0.48%)	378	(1.04%)	111	(0.70%)	3255	(0.92%)	47	(1.00%)
Total cardiovascular disease	19	(1.17%)	62	(0.78%)	536	(1.47%)	147	(0.93%)	4546	(1.29%)	67	(1.42%)
Deaths												
Cardiovascular deaths	3	(0.18%)	13	(0.16%)	129	(0.35%)	22	(0.14%)	898	(0.25%)	14	(0.30%)
Cancer deaths	2	(0.12%)	25	(0.31%)	110	(0.30%)	43	(0.27%)	1295	(0.37%)	18	(0.38%)
Other known cause	8	(0.49%)	9	(0.11%)	77	(0.21%)	15	(0.10%)	841	(0.24%)	8	(0.17%)
Unknown cause	0	(0.00%)	4	(0.05%)	11	(0.03%)	5	(0.03%)	50	(0.01%)	1	(0.02%)
Not yet adjudicated	0	(0.00%)	0	(0.00%)	1	(<0.01%)	0	(0.00%)	24	(0.01%)	0	(0.00%)
Total death	13	(0.80%)	51	(0.64%)	328	(0.90%)	85	(0.54%)	3108	(0.88%)	41	(0.87%)
Death plus post-WHI deaths[7]	16	(0.94%)	59	(0.70%)	380	(0.99%)	99	(0.58%)	3452	(0.95%)	52	(1.04%)

[1] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[2] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.
[3] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Study.
[4] "CHD death" includes definite and possible CHD death.
[5] "Total MI" includes clinical MI and evolving Q-wave MI; Q-wave MI is not collected in the WHI Extension Studies.
[6] "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.
[7] Includes deaths for non-Extension study participants after the main WHI study close-out.

Table 4.4
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for CaD Participants Who Did Not Report a Prevalent Condition at Baseline

Data as of: September 17, 2012; Events through September 17, 2012

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	36282	5153	8269	16519	6341
Mean follow-up (months)	149.7	158.8	156.7	149.1	134.7
Hospitalizations					
Ever	23755 (5.25%)	2599 (3.81%)	4754 (4.40%)	11396 (5.55%)	5006 (7.03%)
Two or more	14635 (3.23%)	1260 (1.85%)	2672 (2.47%)	7234 (3.52%)	3469 (4.87%)
Other					
DVT[1]	718 (0.16%)	51 (0.08%)	111 (0.11%)	356 (0.18%)	200 (0.29%)
Pulmonary embolism	546 (0.12%)	42 (0.06%)	97 (0.09%)	291 (0.14%)	116 (0.16%)
Diabetes (treated)	4676 (1.07%)	731 (1.10%)	1062 (1.02%)	2190 (1.11%)	693 (1.02%)
Gallbladder disease[2,3]	2410 (1.12%)	355 (1.03%)	591 (1.14%)	1116 (1.18%)	348 (1.00%)
Hysterectomy	1542 (0.58%)	220 (0.56%)	412 (0.62%)	712 (0.59%)	198 (0.49%)
Glaucoma[3]	3570 (1.45%)	389 (1.01%)	751 (1.28%)	1702 (1.55%)	728 (1.83%)
Osteoporosis[3]	6835 (2.80%)	717 (1.87%)	1333 (2.28%)	3299 (3.05%)	1486 (3.83%)
Osteoarthritis[4]	9757 (3.33%)	1574 (2.95%)	2385 (3.10%)	4385 (3.50%)	1413 (3.78%)
Rheumatoid arthritis[3]	1773 (0.72%)	257 (0.68%)	405 (0.70%)	798 (0.73%)	313 (0.77%)
Intestinal polyps	8172 (1.94%)	1231 (1.86%)	1999 (1.94%)	3817 (2.01%)	1125 (1.77%)
Lupus	509 (0.11%)	71 (0.10%)	116 (0.11%)	230 (0.11%)	92 (0.13%)
Kidney stones[3,4]	818 (0.32%)	111 (0.29%)	180 (0.30%)	383 (0.34%)	144 (0.34%)
Cataracts[3,4]	10522 (4.69%)	809 (2.11%)	2040 (3.53%)	5602 (5.63%)	2071 (7.13%)
Pills for hypertension	12361 (3.79%)	1749 (3.13%)	2897 (3.47%)	5740 (4.04%)	1975 (4.45%)

Outcomes	Race/Ethnicity: American Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	149	721	3315	1502	30155	440
Mean follow-up (months)	139.8	142.6	141.1	133.8	151.8	138.1
Hospitalizations						
Ever	91 (5.24%)	366 (4.27%)	2066 (5.30%)	742 (4.43%)	20216 (5.30%)	274 (5.41%)
Two or more	59 (3.40%)	185 (2.16%)	1272 (3.26%)	375 (2.24%)	12571 (3.29%)	173 (3.42%)
Other						
DVT[1]	6 (0.36%)	2 (0.02%)	76 (0.20%)	15 (0.09%)	611 (0.16%)	8 (0.16%)
Pulmonary embolism	4 (0.23%)	0 (0.00%)	49 (0.13%)	10 (0.06%)	475 (0.13%)	8 (0.16%)
Diabetes (treated)	23 (1.41%)	93 (1.15%)	597 (1.71%)	257 (1.63%)	3637 (0.98%)	69 (1.45%)
Gallbladder disease[2,3]	10 (1.25%)	36 (0.82%)	165 (0.79%)	120 (1.51%)	2053 (1.15%)	26 (1.04%)
Hysterectomy	4 (0.56%)	24 (0.43%)	89 (0.53%)	45 (0.48%)	1363 (0.59%)	17 (0.59%)
Glaucoma[3]	20 (2.00%)	56 (1.20%)	443 (2.05%)	171 (1.70%)	2850 (1.38%)	30 (1.06%)
Osteoporosis[3]	27 (2.70%)	148 (3.16%)	394 (1.77%)	282 (2.91%)	5907 (2.90%)	77 (2.77%)
Osteoarthritis[4]	47 (4.11%)	195 (3.05%)	834 (3.43%)	449 (3.80%)	8103 (3.30%)	129 (3.75%)
Rheumatoid arthritis[3]	17 (1.82%)	28 (0.60%)	288 (1.35%)	136 (1.38%)	1279 (0.62%)	25 (0.90%)
Intestinal polyps	40 (2.49%)	140 (1.78%)	802 (2.20%)	264 (1.65%)	6836 (1.92%)	90 (1.93%)
Lupus	5 (0.29%)	4 (0.05%)	58 (0.15%)	19 (0.11%)	416 (0.11%)	7 (0.14%)
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 (4.76%)	126 (4.82%)
Pills for hypertension	42 (3.78%)	225 (3.77%)	955 (4.69%)	518 (4.00%)	10498 (3.72%)	123 (3.78%)

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

Table 5.1
Lost-to-Follow-up and Vital Status: OS Participants

Data as of: September 17, 2012
WHI Extension Study 2010-2015 Participants

	OS Participants (N = 52,063)	
	N	%
Vital Status/Participation		
Deceased	1413	2.7
Alive: Current Participation[1]	49300	94.7
Alive: Recent Participation[2]	805	1.5
Alive: Past/Unknown Participation[3]	133	0.3
Stopped Follow-Up[4]	240	0.5
Lost to Follow-Up[5]	172	0.3

Data as of: September 17, 2012; Status as of September 30, 2010
WHI Extension Study 2005-2010 Participants

	OS Participants (N = 63,231)	
	N	%
Vital Status/Participation		
Deceased	4677	7.4
Alive: Current Participation[1]	57194	90.5
Alive: Recent Participation[2]	396	0.6
Alive: Past/Unknown Participation[3]	36	0.1
Stopped Follow-Up[4]	648	1.0
Lost to Follow-Up[5]	280	0.4

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

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

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

Table 5.2
Verified Outcomes (Annualized Percentages) by Age for OS Participants

Data as of: September 17, 2012; **Events through September 30, 2010**

Outcome	Total	Age 50-54	Age 55-59	Age 60-69	Age 70-79
Number enrolled	93676	12381	17329	41200	22766
Mean follow-up (months)	136.2	145.8	144.7	136.9	123.4
Cardiovascular					
CHD[1]	4125 (0.39%)	155 (0.10%)	351 (0.17%)	1751 (0.37%)	1868 (0.80%)
CHD death[2]	1470 (0.14%)	37 (0.02%)	82 (0.04%)	515 (0.11%)	836 (0.36%)
Clinical MI	3086 (0.29%)	124 (0.08%)	286 (0.14%)	1384 (0.29%)	1292 (0.55%)
Angina[3]	2834 (0.39%)	124 (0.12%)	318 (0.23%)	1319 (0.41%)	1073 (0.63%)
CABG/PTCA	4250 (0.40%)	194 (0.13%)	511 (0.24%)	2134 (0.45%)	1411 (0.60%)
Carotid artery disease	846 (0.08%)	42 (0.03%)	79 (0.04%)	385 (0.08%)	340 (0.15%)
Congestive heart failure[3]	2295 (0.31%)	81 (0.08%)	174 (0.12%)	882 (0.27%)	1158 (0.68%)
Stroke	3255 (0.31%)	99 (0.07%)	245 (0.12%)	1378 (0.29%)	1533 (0.65%)
PVD	840 (0.08%)	23 (0.02%)	74 (0.04%)	381 (0.08%)	362 (0.15%)
Coronary disease[4]	9044 (0.85%)	389 (0.26%)	927 (0.44%)	4046 (0.86%)	3682 (1.57%)
Total cardiovascular disease	12891 (1.21%)	528 (0.35%)	1250 (0.60%)	5680 (1.21%)	5433 (2.32%)
Cancer					
Breast cancer	5943 (0.56%)	706 (0.47%)	1064 (0.51%)	2777 (0.59%)	1396 (0.60%)
Invasive breast cancer	4934 (0.46%)	566 (0.38%)	868 (0.42%)	2299 (0.49%)	1201 (0.51%)
Non-invasive breast cancer	1069 (0.10%)	150 (0.10%)	205 (0.10%)	507 (0.11%)	207 (0.09%)
Ovarian cancer	546 (0.05%)	61 (0.04%)	102 (0.05%)	243 (0.05%)	140 (0.06%)
Endometrial cancer[5]	816 (0.08%)	76 (0.05%)	151 (0.07%)	376 (0.08%)	213 (0.09%)
Colorectal cancer	1317 (0.12%)	78 (0.05%)	139 (0.07%)	605 (0.13%)	495 (0.21%)
Other cancer[6]	6458 (0.61%)	479 (0.32%)	897 (0.43%)	3069 (0.65%)	2013 (0.86%)
Total cancer	14212 (1.34%)	1333 (0.89%)	2233 (1.07%)	6633 (1.41%)	4013 (1.71%)
Fractures					
Hip fracture	2199 (0.21%)	52 (0.03%)	131 (0.06%)	777 (0.17%)	1239 (0.53%)
Deaths					
Cardiovascular deaths	3209 (0.30%)	77 (0.05%)	188 (0.09%)	1103 (0.23%)	1841 (0.79%)
Cancer deaths	4339 (0.41%)	259 (0.17%)	506 (0.24%)	1965 (0.42%)	1609 (0.69%)
Other known cause	2960 (0.28%)	113 (0.08%)	201 (0.10%)	1134 (0.24%)	1512 (0.65%)
Unknown cause	376 (0.04%)	19 (0.01%)	31 (0.01%)	143 (0.03%)	183 (0.08%)
Not yet adjudicated	127 (0.01%)	5 (<0.01%)	11 (0.01%)	55 (0.01%)	56 (0.02%)
Total death	11011 (1.04%)	473 (0.31%)	937 (0.45%)	4400 (0.94%)	5201 (2.22%)
Death plus post-WHI deaths[7]	13657 (1.16%)	557 (0.34%)	1103 (0.48%)	5309 (1.03%)	6688 (2.53%)

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

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

Data as of: September 17, 2012; **Events through September 30, 2010**

	Race/Ethnicity					
Outcomes	**American Indian/Alaskan Native**	**Asian/Pacific Islander**	**Black/African American**	**Hispanic/ Latino**	**White**	**Unknown**
Number enrolled	421	2671	7635	3609	78016	1324
Mean follow-up (months)	119.4	120.5	117.0	112.4	140.0	127.2
Cardiovascular						
CHD[1]	23 (0.55%)	59 (0.22%)	355 (0.48%)	79 (0.23%)	3550 (0.39%)	59 (0.42%)
CHD death[2]	12 (0.29%)	22 (0.08%)	169 (0.23%)	24 (0.07%)	1222 (0.13%)	21 (0.15%)
Clinical MI	13 (0.31%)	44 (0.16%)	225 (0.30%)	63 (0.19%)	2698 (0.30%)	43 (0.31%)
Angina[3]	18 (0.59%)	40 (0.20%)	250 (0.45%)	80 (0.31%)	2412 (0.39%)	34 (0.34%)
CABG/PTCA	21 (0.50%)	50 (0.19%)	261 (0.35%)	115 (0.34%)	3744 (0.41%)	59 (0.42%)
Carotid artery disease	5 (0.12%)	9 (0.03%)	38 (0.05%)	17 (0.05%)	764 (0.08%)	13 (0.09%)
Congestive heart failure[3]	16 (0.52%)	22 (0.11%)	233 (0.42%)	42 (0.16%)	1948 (0.31%)	34 (0.34%)
Stroke	14 (0.33%)	73 (0.27%)	262 (0.35%)	64 (0.19%)	2786 (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 (1.27%)	122 (0.45%)	771 (1.04%)	213 (0.63%)	7764 (0.85%)	121 (0.86%)
Total cardiovascular disease	66 (1.58%)	201 (0.75%)	1085 (1.46%)	288 (0.85%)	11060 (1.22%)	191 (1.36%)
Cancer						
Breast cancer	17 (0.41%)	124 (0.46%)	365 (0.49%)	134 (0.40%)	5243 (0.58%)	60 (0.43%)
Invasive breast cancer	16 (0.38%)	104 (0.39%)	294 (0.39%)	106 (0.31%)	4362 (0.48%)	52 (0.37%)
Non-invasive breast cancer	1 (0.02%)	22 (0.08%)	77 (0.10%)	30 (0.09%)	930 (0.10%)	9 (0.06%)
Ovarian cancer	1 (0.02%)	6 (0.02%)	26 (0.03%)	18 (0.05%)	492 (0.05%)	3 (0.02%)
Endometrial cancer[5]	1 (0.02%)	12 (0.04%)	27 (0.04%)	12 (0.04%)	749 (0.08%)	15 (0.11%)
Colorectal cancer	4 (0.10%)	28 (0.10%)	121 (0.16%)	28 (0.08%)	1122 (0.12%)	14 (0.10%)
Other cancer[6]	22 (0.53%)	114 (0.42%)	367 (0.49%)	112 (0.33%)	5756 (0.63%)	87 (0.62%)
Total cancer	45 (1.07%)	271 (1.01%)	858 (1.15%)	298 (0.88%)	12570 (1.38%)	170 (1.21%)
Fractures						
Hip fracture	5 (0.12%)	21 (0.08%)	47 (0.06%)	19 (0.06%)	2086 (0.23%)	21 (0.15%)
Deaths						
Cardiovascular deaths	21 (0.50%)	57 (0.21%)	320 (0.43%)	64 (0.19%)	2700 (0.30%)	47 (0.33%)
Cancer deaths	13 (0.31%)	82 (0.31%)	328 (0.44%)	93 (0.28%)	3777 (0.42%)	46 (0.33%)
Other known cause	26 (0.62%)	48 (0.18%)	222 (0.30%)	89 (0.26%)	2540 (0.28%)	35 (0.25%)
Unknown cause	1 (0.02%)	9 (0.03%)	55 (0.07%)	15 (0.04%)	292 (0.03%)	4 (0.03%)
Not yet adjudicated	0 (0.00%)	2 (0.01%)	7 (0.01%)	2 (0.01%)	114 (0.01%)	2 (0.01%)
Total death	61 (1.46%)	198 (0.74%)	932 (1.25%)	263 (0.78%)	9423 (1.04%)	134 (0.95%)
Death plus post-WHI deaths[7]	83 (1.66%)	269 (0.82%)	1226 (1.35%)	365 (0.84%)	11512 (1.16%)	202 (1.24%)

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

Table 5.4
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for OS Participants Who Did Not Report a Prevalent Condition at Baseline

Data as of: September 17, 2012; Events through September 17, 2012

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number enrolled	93676	12381	17329	41200	22766
Mean follow-up (months)	145.6	157.3	156.1	146.5	129.4
Hospitalizations					
Ever	58649 (5.16%)	5772 (3.56%)	9300 (4.13%)	26846 (5.34%)	16731 (6.81%)
Two or more	35907 (3.16%)	2883 (1.78%)	5116 (2.27%)	16582 (3.30%)	11326 (4.61%)
Other					
DVT[1]	1390 (0.13%)	104 (0.07%)	181 (0.08%)	660 (0.14%)	445 (0.19%)
Pulmonary embolism	1113 (0.10%)	103 (0.06%)	170 (0.08%)	527 (0.11%)	313 (0.13%)
Diabetes (treated)	9291 (0.85%)	1281 (0.81%)	1785 (0.81%)	4273 (0.88%)	1952 (0.83%)
Gallbladder disease[2,3]	5652 (0.91%)	832 (0.92%)	1141 (0.94%)	2534 (0.95%)	1145 (0.82%)
Hysterectomy	4266 (0.38%)	631 (0.39%)	945 (0.42%)	1956 (0.39%)	734 (0.30%)
Glaucoma[3]	8452 (1.21%)	843 (0.84%)	1364 (0.99%)	3886 (1.27%)	2359 (1.51%)
Osteoporosis[3]	20667 (3.07%)	2090 (2.12%)	3364 (2.51%)	9501 (3.25%)	5712 (3.88%)
Osteoarthritis[4]	23120 (3.48%)	3359 (2.86%)	4643 (3.14%)	10289 (3.66%)	4829 (4.09%)
Rheumatoid arthritis[3]	4571 (0.66%)	634 (0.64%)	877 (0.65%)	1880 (0.62%)	1180 (0.74%)
Intestinal polyps	19463 (1.89%)	2648 (1.71%)	4101 (1.94%)	8982 (1.99%)	3732 (1.76%)
Lupus	1389 (0.12%)	185 (0.11%)	269 (0.12%)	628 (0.13%)	307 (0.13%)
Kidney stones[3,4]	2314 (0.33%)	292 (0.30%)	433 (0.32%)	994 (0.32%)	595 (0.36%)
Cataracts[3,4]	27103 (4.48%)	1726 (1.73%)	4088 (3.07%)	14045 (5.26%)	7244 (6.90%)
Pills for hypertension	30286 (3.68%)	3801 (2.80%)	5694 (3.21%)	13603 (3.84%)	7188 (4.59%)

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)	126.3	126.9	123.0	118.0	150.0	134.7
Hospitalizations						
Ever	259 (5.85%)	1079 (3.82%)	4255 (5.44%)	1615 (4.55%)	50672 (5.20%)	769 (5.17%)
Two or more	163 (3.68%)	499 (1.77%)	2420 (3.09%)	825 (2.32%)	31529 (3.23%)	471 (3.17%)
Other						
DVT[1]	4 (0.10%)	7 (0.02%)	121 (0.16%)	22 (0.06%)	1221 (0.13%)	15 (0.11%)
Pulmonary embolism	3 (0.07%)	7 (0.02%)	78 (0.10%)	13 (0.04%)	1005 (0.10%)	7 (0.05%)
Diabetes (treated)	70 (1.81%)	268 (0.99%)	1118 (1.60%)	468 (1.41%)	7223 (0.76%)	144 (1.01%)
Gallbladder disease[2,3]	31 (1.28%)	81 (0.44%)	374 (0.75%)	230 (1.15%)	4860 (0.93%)	76 (0.91%)
Hysterectomy	11 (0.25%)	71 (0.25%)	159 (0.20%)	133 (0.37%)	3826 (0.39%)	66 (0.44%)
Glaucoma[3]	45 (1.59%)	253 (1.32%)	987 (1.92%)	308 (1.27%)	6737 (1.14%)	122 (1.28%)
Osteoporosis[3]	90 (3.20%)	625 (3.40%)	1069 (2.01%)	735 (3.13%)	17825 (3.15%)	323 (3.52%)
Osteoarthritis[4]	86 (3.52%)	682 (3.42%)	1700 (3.73%)	945 (4.06%)	19369 (3.43%)	338 (3.71%)
Rheumatoid arthritis[3]	38 (1.35%)	98 (0.51%)	661 (1.30%)	382 (1.61%)	3306 (0.56%)	86 (0.92%)
Intestinal polyps	65 (1.61%)	443 (1.75%)	1448 (2.02%)	582 (1.76%)	16685 (1.89%)	240 (1.80%)
Lupus	9 (0.21%)	25 (0.09%)	134 (0.17%)	66 (0.19%)	1136 (0.12%)	19 (0.13%)
Kidney stones[3,4]	17 (0.59%)	40 (0.21%)	263 (0.48%)	125 (0.52%)	1825 (0.31%)	44 (0.46%)
Cataracts[3,4]	102 (4.07%)	683 (4.21%)	1937 (4.14%)	894 (4.00%)	23094 (4.54%)	393 (4.85%)
Pills for hypertension	125 (4.36%)	745 (3.72%)	2003 (5.15%)	1105 (4.10%)	25868 (3.57%)	440 (4.14%)

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

Table 6.1
Lost-to-Follow-up and Vital Status: CT Participants

Data as of: September 17, 2012
WHI Extension Study 2010-2015 Participants

	CT Participants (N = 41,495)	
	N	%
Vital Status/Participation		
Deceased	1105	2.7
Alive: Current Participation[1]	39152	94.4
Alive: Recent Participation[2]	726	1.7
Alive: Past/Unknown Participation[3]	175	0.4
Stopped Follow-Up[4]	177	0.4
Lost to Follow-Up[5]	160	0.4

Data as of: September 17, 2012; Status as of September 30, 2010
WHI Extension Study 2005-2010 Participants

	CT Participants (N = 52,176)	
	N	%
Vital Status/Participation		
Deceased	3746	7.2
Alive: Current Participation[1]	46880	89.8
Alive: Recent Participation[2]	454	0.9
Alive: Past/Unknown Participation[3]	38	0.1
Stopped Follow-Up[4]	691	1.3
Lost to Follow-Up[5]	367	0.7

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

	CT Participants (N = 68,132)	
	N	%
Vital Status/Participation		
Deceased	3605	5.3
Alive: Current Participation[6]	61177	89.8
Alive: Recent Participation[7]	348	0.5
Alive: Past/Unknown Participation[8]	13	<0.1
Stopped Follow-Up[4]	2246	3.3
Lost to Follow-Up[5]	743	1.1

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

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

Data as of: September 17, 2012; **Events through September 30, 2010**

Outcome	Total	Age 50-54	Age 55-59	Age 60-69	Age 70-79
Number randomized	68132	9188	14661	31389	12894
Mean follow-up (months)	146.3	155.7	152.6	145.8	133.8
Cardiovascular					
CHD[1]	3516 (0.42%)	191 (0.16%)	402 (0.22%)	1638 (0.43%)	1285 (0.89%)
CHD death[2]	1139 (0.14%)	47 (0.04%)	82 (0.04%)	484 (0.13%)	526 (0.37%)
Total MI[3]	2720 (0.33%)	154 (0.13%)	338 (0.18%)	1279 (0.34%)	949 (0.66%)
Clinical MI	2644 (0.32%)	148 (0.12%)	330 (0.18%)	1241 (0.33%)	925 (0.64%)
Angina[4]	2414 (0.43%)	129 (0.16%)	331 (0.27%)	1215 (0.48%)	739 (0.73%)
CABG/PTCA	3667 (0.44%)	202 (0.17%)	513 (0.28%)	1945 (0.51%)	1007 (0.70%)
Carotid artery disease	693 (0.08%)	27 (0.02%)	91 (0.05%)	370 (0.10%)	205 (0.14%)
Congestive heart failure[4]	1748 (0.31%)	81 (0.10%)	172 (0.14%)	745 (0.29%)	750 (0.74%)
Stroke	2719 (0.33%)	116 (0.10%)	271 (0.15%)	1276 (0.33%)	1056 (0.73%)
PVD	645 (0.08%)	29 (0.02%)	86 (0.05%)	332 (0.09%)	198 (0.14%)
Coronary disease[5]	7742 (0.93%)	440 (0.37%)	1012 (0.54%)	3775 (0.99%)	2515 (1.75%)
Total cardiovascular disease	10717 (1.29%)	582 (0.49%)	1353 (0.73%)	5190 (1.36%)	3592 (2.50%)
Cancer					
Breast cancer	4133 (0.50%)	500 (0.42%)	914 (0.49%)	1955 (0.51%)	764 (0.53%)
Invasive breast cancer	3343 (0.40%)	379 (0.32%)	746 (0.40%)	1576 (0.41%)	642 (0.45%)
Non-invasive breast cancer	845 (0.10%)	127 (0.11%)	179 (0.10%)	405 (0.11%)	134 (0.09%)
Ovary cancer	363 (0.04%)	33 (0.03%)	73 (0.04%)	185 (0.05%)	72 (0.05%)
Endometrial cancer[6]	562 (0.07%)	63 (0.05%)	135 (0.07%)	269 (0.07%)	95 (0.07%)
Colorectal cancer	1085 (0.13%)	68 (0.06%)	172 (0.09%)	531 (0.14%)	314 (0.22%)
Other cancer[7]	4831 (0.58%)	397 (0.33%)	819 (0.44%)	2413 (0.63%)	1202 (0.84%)
Total cancer	10375 (1.25%)	101 (0.85%)	2009 (1.08%)	5046 (1.32%)	2307 (1.60%)
Fractures					
Hip fracture	1638 (0.20%)	32 (0.03%)	115 (0.06%)	665 (0.17%)	826 (0.57%)
Deaths					
Cardiovascular deaths	2262 (0.27%)	82 (0.07%)	162 (0.09%)	919 (0.24%)	1099 (0.76%)
Cancer deaths	3020 (0.36%)	181 (0.15%)	414 (0.22%)	1515 (0.40%)	910 (0.63%)
Other known cause	1939 (0.23%)	79 (0.07%)	188 (0.10%)	824 (0.22%)	848 (0.59%)
Unknown cause	165 (0.02%)	9 (0.01%)	25 (0.01%)	78 (0.02%)	53 (0.04%)
Not yet adjudicated	53 (0.01%)	3 (<0.01%)	5 (<0.01%)	25 (0.01%)	20 (0.01%)
Total death	7439 (0.90%)	354 (0.30%)	794 (0.43%)	3361 (0.88%)	2930 (2.04%)
Death plus post-WHI deaths[8]	8602 (0.97%)	395 (0.31%)	883 (0.45%)	3825 (0.95%)	3499 (2.27%)

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

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

Data as of: September 17, 2012; **Events through September 30, 2010**

	Race/Ethnicity					
Outcomes	**American Indian/Alaskan Native**	**Asian/Pacific Islander**	**Black/African American**	**Hispanic/ Latino**	**White**	**Unknown**
Number enrolled	292	1519	6983	2875	55525	938
Mean follow-up (months)	134.9	140.4	139.0	131.3	148.4	137.1
Cardiovascular						
CHD[1]	8 (0.24%)	46 (0.26%)	340 (0.42%)	71 (0.23%)	3003 (0.44%)	48 (0.45%)
CHD death[2]	2 (0.06%)	13 (0.07%)	155 (0.19%)	21 (0.07%)	929 (0.14%)	19 (0.18%)
Total MI[3]	7 (0.21%)	40 (0.23%)	227 (0.28%)	56 (0.18%)	2353 (0.34%)	37 (0.35%)
Clinical MI	7 (0.21%)	39 (0.22%)	222 (0.27%)	54 (0.17%)	2287 (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%)	38 (0.21%)	306 (0.38%)	97 (0.31%)	3172 (0.46%)	41 (0.38%)
Carotid artery disease	3 (0.09%)	3 (0.02%)	42 (0.05%)	6 (0.02%)	630 (0.09%)	9 (0.08%)
Congestive heart failure[4]	5 (0.21%)	17 (0.14%)	244 (0.43%)	49 (0.22%)	1409 (0.31%)	24 (0.32%)
Stroke	10 (0.30%)	40 (0.23%)	338 (0.42%)	65 (0.21%)	2227 (0.32%)	39 (0.36%)
PVD	5 (0.15%)	7 (0.04%)	98 (0.12%)	8 (0.03%)	519 (0.08%)	8 (0.07%)
Coronary disease[5]	26 (0.79%)	98 (0.55%)	845 (1.04%)	209 (0.66%)	6464 (0.94%)	100 (0.93%)
Total cardiovascular disease	40 (1.22%)	141 (0.79%)	1197 (1.48%)	277 (0.88%)	8925 (1.30%)	137 (1.28%)
Cancer						
Breast cancer	10 (0.30%)	92 (0.52%)	355 (0.44%)	100 (0.32%)	3533 (0.51%)	43 (0.40%)
Invasive breast cancer	7 (0.21%)	71 (0.40%)	278 (0.34%)	82 (0.26%)	2871 (0.42%)	34 (0.32%)
Non-invasive breast cancer	3 (0.09%)	23 (0.13%)	81 (0.10%)	20 (0.06%)	708 (0.10%)	10 (0.09%)
Ovarian cancer	2 (0.06%)	10 (0.06%)	25 (0.03%)	9 (0.03%)	312 (0.05%)	5 (0.05%)
Endometrial cancer[6]	1 (0.03%)	7 (0.04%)	36 (0.04%)	13 (0.04%)	497 (0.07%)	8 (0.07%)
Colorectal cancer	6 (0.18%)	22 (0.12%)	110 (0.14%)	31 (0.10%)	900 (0.13%)	16 (0.15%)
Other cancer[7]	12 (0.37%)	75 (0.42%)	352 (0.44%)	122 (0.39%)	4214 (0.61%)	56 (0.52%)
Total cancer	29 (0.88%)	196 (1.10%)	830 (1.03%)	258 (0.82%)	8944 (1.30%)	118 (1.10%)
Fractures						
Hip fracture	5 (0.15%)	16 (0.09%)	40 (0.05%)	24 (0.08%)	1541 (0.22%)	12 (0.11%)
Deaths						
Cardiovascular deaths	9 (0.27%)	30 (0.17%)	300 (0.37%)	39 (0.12%)	1858 (0.27%)	26 (0.24%)
Cancer deaths	11 (0.34%)	49 (0.28%)	250 (0.31%)	87 (0.28%)	2584 (0.38%)	39 (0.36%)
Other known cause	13 (0.40%)	21 (0.12%)	174 (0.22%)	39 (0.12%)	1670 (0.24%)	22 (0.21%)
Unknown cause	0 (0.00%)	5 (0.03%)	28 (0.03%)	10 (0.03%)	118 (0.02%)	4 (0.04%)
Not yet adjudicated	0 (0.00%)	0 (0.00%)	4 (<0.01%)	0 (0.00%)	49 (0.01%)	0 (0.00%)
Total death	33 (1.01%)	105 (0.59%)	756 (0.93%)	175 (0.56%)	6279 (0.91%)	91 (0.85%)
Death plus post-WHI deaths[8]	43 (1.19%)	131 (0.68%)	904 (1.02%)	210 (0.58%)	7198 (0.99%)	116 (0.99%)

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

Table 6.4
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for CT Participants Who Did Not Report a Prevalent Condition at Baseline

Data as of: September 17, 2012; Events through September 17, 2012

Outcome	Total	Age			
		50-54	55-59	60-69	70-79
Number randomized	68132	9188	14661	31389	12894
Mean follow-up (months)	156.4	167.2	164.2	156.1	140.5
Hospitalizations					
Ever	45431 (5.12%)	4739 (3.70%)	8538 (4.26%)	21912 (5.37%)	10242 (6.79%)
Two or more	29073 (3.27%)	2471 (1.93%)	4937 (2.46%)	14317 (3.51%)	7348 (4.87%)
Other					
DVT[1]	1432 (0.17%)	103 (0.08%)	206 (0.11%)	709 (0.18%)	414 (0.28%)
Pulmonary embolism	1050 (0.12%)	79 (0.06%)	168 (0.08%)	544 (0.13%)	259 (0.17%)
Diabetes (treated)	9031 (1.06%)	1324 (1.06%)	1988 (1.03%)	4252 (1.09%)	1467 (1.02%)
Gallbladder disease[2,3]	5248 (1.12%)	746 (1.04%)	1195 (1.12%)	2463 (1.17%)	844 (1.03%)
Hysterectomy	3060 (0.59%)	410 (0.55%)	753 (0.60%)	1464 (0.62%)	433 (0.51%)
Glaucoma[3]	7565 (1.40%)	744 (0.93%)	1457 (1.20%)	3662 (1.50%)	1702 (1.82%)
Osteoporosis[3]	14695 (2.78%)	1450 (1.83%)	2635 (2.19%)	7142 (2.99%)	3468 (3.83%)
Osteoarthritis[4]	19111 (3.36%)	2893 (2.88%)	4445 (3.10%)	8716 (3.54%)	3057 (3.92%)
Rheumatoid arthritis[3]	4009 (0.74%)	538 (0.68%)	866 (0.72%)	1822 (0.75%)	783 (0.82%)
Intestinal polyps	15922 (1.93%)	2202 (1.78%)	3696 (1.94%)	7674 (2.04%)	2350 (1.76%)
Lupus	1002 (0.11%)	136 (0.11%)	225 (0.11%)	475 (0.12%)	166 (0.11%)
Kidney stones[3,4]	1877 (0.35%)	241 (0.31%)	379 (0.32%)	898 (0.37%)	359 (0.37%)
Cataracts[3,4]	21570 (4.42%)	1468 (1.85%)	3731 (3.12%)	11649 (5.28%)	4722 (6.93%)
Pills for hypertension	24596 (3.90%)	3271 (3.15%)	5423 (3.53%)	11517 (4.11%)	4385 (4.70%)

Outcomes	Race/Ethnicity					
	Am Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	292	1519	6983	2875	55525	938
Mean follow-up (months)	142.8	149.4	146.9	138.1	158.9	145.8
Hospitalizations						
Ever	184 (5.30%)	763 (4.03%)	4428 (5.18%)	1469 (4.44%)	38014 (5.17%)	573 (5.03%)
Two or more	123 (3.54%)	388 (2.05%)	2809 (3.29%)	794 (2.40%)	24602 (3.35%)	357 (3.13%)
Other						
DVT[1]	6 (0.18%)	8 (0.04%)	161 (0.19%)	26 (0.08%)	1216 (0.17%)	15 (0.13%)
Pulmonary embolism	6 (0.17%)	5 (0.03%)	104 (0.12%)	16 (0.05%)	906 (0.12%)	13 (0.11%)
Diabetes (treated)	45 (1.42%)	223 (1.25%)	1383 (1.81%)	508 (1.64%)	6748 (0.95%)	124 (1.16%)
Gallbladder disease[2,3]	22 (1.28%)	86 (0.79%)	420 (0.83%)	243 (1.42%)	4403 (1.15%)	74 (1.17%)
Hysterectomy	8 (0.53%)	48 (0.39%)	202 (0.54%)	104 (0.56%)	2668 (0.60%)	30 (0.45%)
Glaucoma[3]	40 (1.81%)	153 (1.32%)	1005 (1.91%)	338 (1.56%)	5930 (1.34%)	99 (1.43%)
Osteoporosis[3]	66 (2.97%)	389 (3.40%)	909 (1.67%)	639 (3.05%)	12483 (2.88%)	209 (3.03%)
Osteoarthritis[4]	84 (3.88%)	447 (3.21%)	1822 (3.43%)	893 (3.82%)	15589 (3.33%)	276 (3.73%)
Rheumatoid arthritis[3]	32 (1.52%)	74 (0.64%)	682 (1.30%)	357 (1.67%)	2787 (0.63%)	77 (1.10%)
Intestinal polyps	74 (2.31%)	326 (1.89%)	1707 (2.14%)	553 (1.75%)	13056 (1.91%)	206 (1.96%)
Lupus	8 (0.23%)	15 (0.08%)	133 (0.16%)	46 (0.14%)	785 (0.11%)	15 (0.13%)
Kidney stones[3,4]	15 (0.69%)	47 (0.41%)	190 (0.35%)	100 (0.47%)	1501 (0.34%)	24 (0.34%)
Cataracts[3,4]	92 (4.58%)	428 (4.10%)	2002 (4.01%)	828 (4.01%)	17927 (4.50%)	293 (4.60%)
Pills for hypertension	101 (4.38%)	519 (3.99%)	2160 (5.00%)	1067 (4.30%)	20451 (3.79%)	298 (3.87%)

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

Table 6.5
Verified Other Cancers (Annualized Percentages): CT and OS Participants

Data as of: September 17, 2012; Events through September 17, 2012

	CT		OS	
Number of participants	68132		93676	
Mean follow-up time (months)	156.4		145.6	
Ppts with other cancer	5060	(0.57%)	6749	(0.59%)
Accessory sinus	1	(<0.01%)	4	(<0.01%)
Adrenal gland	2	(<0.01%)	6	(<0.01%)
Anus	26	(<0.01%)	37	(<0.01%)
Appendix	13	(<0.01%)	10	(<0.01%)
Biliary tract, parts of (other/unspecified)	43	(<0.01%)	45	(<0.01%)
Bladder	271	(0.03%)	347	(0.03%)
Bones/joints/articular cartilage (limbs)	4	(<0.01%)	6	(<0.01%)
Bones/joints/articular cartilage (other)	7	(<0.01%)	3	(<0.01%)
Brain	92	(0.01%)	111	(0.01%)
Cervix	52	(0.01%)	45	(<0.01%)
Central Nervous System (excludes brain)	0	(0.00%)	2	(<0.01%)
Connective/subcutaneous/soft tissues	48	(0.01%)	53	(<0.01%)
Endocrine glands, related structures	1	(<0.01%)	1	(<0.01%)
Esophagus	40	(<0.01%)	42	(<0.01%)
Eye and adnexa	37	(<0.01%)	26	(<0.01%)
Genital organs	31	(<0.01%)	39	(<0.01%)
Kidney	225	(0.03%)	256	(0.02%)
Larynx	23	(<0.01%)	20	(<0.01%)
Leukemia	278	(0.03%)	352	(0.03%)
Liver	51	(0.01%)	79	(0.01%)
Lung	1088	(0.12%)	1403	(0.12%)
Lymph nodes	1	(<0.01%)	0	(0.00%)
Lymphoma, Hodgkins	22	(<0.01%)	29	(<0.01%)
Lymphoma, Non-Hodgkins	463	(0.05%)	632	(0.06%)
Melanoma of the skin	688	(0.08%)	919	(0.08%)
Multiple myeloma	183	(0.02%)	192	(0.02%)
Oral (mouth)	10	(<0.01%)	9	(<0.01%)
Palate	8	(<0.01%)	16	(<0.01%)
Pancreas	280	(0.03%)	345	(0.03%)
Parotid gland (Stensen's duct)	14	(<0.01%)	32	(<0.01%)
Peripheral nerves and autonomic nervous system	1	(<0.01%)	1	(<0.01%)
Pyriform sinus	0	(0.00%)	2	(<0.01%)
Respiratory system, intrathoracic, other	1	(<0.01%)	1	(<0.01%)
Salivary glands, major (other/unspecified)	4	(<0.01%)	7	(<0.01%)
Stomach	80	(0.01%)	107	(0.01%)
Thyroid	154	(0.02%)	202	(0.02%)
Tongue, part of (other/unspecified)	14	(<0.01%)	20	(<0.01%)
Urinary organs (other/unspecified)	6	(<0.01%)	11	(<0.01%)
Uterus, not otherwise specified	3	(<0.01%)	1	(<0.01%)
Other/unknown site of cancer	477	(0.05%)	642	(0.06%)
Other/unknown cancers reported on death form	471	(0.05%)	885	(0.08%)

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

Data as of: September 17, 2012

	CT		OS	
Number of participants	68132		93676	
Mean follow-up time (months)	156.4		145.6	
Elbow	932	(0.10%)	1269	(0.11%)
Foot	3246	(0.37%)	4053	(0.36%)
Hand	862	(0.10%)	981	(0.09%)
Hip	1945	(0.22%)	2742	(0.24%)
Knee	1307	(0.15%)	1735	(0.15%)
Lower arm	4569	(0.51%)	5746	(0.51%)
Lower leg	3544	(0.40%)	4407	(0.39%)
Pelvis	1016	(0.11%)	1640	(0.14%)
Tailbone	368	(0.04%)	515	(0.05%)
Upper arm	2440	(0.27%)	3039	(0.27%)
Upper leg	784	(0.09%)	1082	(0.10%)
Spine	2845	(0.32%)	4132	(0.36%)
Other	5251	(0.59%)	6654	(0.59%)
Total fracture	20806	(2.34%)	27168	(2.39%)

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

Data as of: September 17, 2012; Events through September 17, 2012

	CT		OS	
Number of participants	68132		93676	
Mean Follow-up Time (months)	165.8		160.2	
Death plus post-WHI deaths	9719	(1.03%)	15054	(1.20%)
Adjudicated death	8633	(0.92%)	13150	(1.05%)
Centrally adjudicated death	7438	(0.79%)	4780	(0.38%)
Locally adjudicated death (final)	1	(<0.01%)	5616	(0.45%)
Temporary adjudicated death	0	(0.00%)	0	(0.00%)
Identified by NDI search	1194	(0.13%)	2754	(0.22%)
Form 120 death	547	(0.06%)	1327	(0.11%)
Cardiovascular				
Atherosclerotic cardiac	1325	(0.14%)	1846	(0.15%)
CHD deaths locally adjudicated before 10/99	0	(0.00%)	0	(0.00%)
Definite CHD deaths	520	(0.06%)	647	(0.05%)
Possible CHD deaths	784	(0.08%)	1149	(0.09%)
Cerebrovascular	685	(0.07%)	1076	(0.09%)
Pulmonary embolism	81	(0.01%)	80	(0.01%)
Other cardiovascular	570	(0.06%)	1029	(0.08%)
Unknown cardiovascular	31	(<0.01%)	120	(0.01%)
Total cardiovascular deaths	2692	(0.29%)	4151	(0.33%)
Cancer				
Breast cancer	264	(0.03%)	720	(0.06%)
Ovarian cancer	221	(0.02%)	365	(0.03%)
Endometrial cancer	59	(0.01%)	85	(0.01%)
Colorectal cancer	304	(0.03%)	400	(0.03%)
Other cancer	2424	(0.26%)	3266	(0.26%)
Unknown cancer site	175	(0.02%)	260	(0.02%)
Total cancer deaths	3447	(0.37%)	5096	(0.41%)
Accident/injury				
Homicide	12	(<0.01%)	18	(<0.01%)
Accident	254	(0.03%)	334	(0.03%)
Suicide	23	(<0.01%)	50	(<0.01%)
Other injury	12	(<0.01%)	34	(<0.01%)
Total accidental deaths	301	(0.03%)	436	(0.03%)
Other				
Other known cause	2222	(0.24%)	3665	(0.29%)
Unknown cause	1057	(0.11%)	1706	(0.14%)
Total deaths – other causes	3279	(0.35%)	5371	(0.43%)

[1] Includes deaths for non-Extension study participants after the main WHI study close-out

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

Data as of: September 17, 2012

	MRC (N = 22,313)		SRC (N = 71,245)		Total Participants (N = 93,558)	
	N	%	N	%	N	%
Vital Status/Participation						
Deceased	644	2.9	1874	2.6	2518	2.7
Alive: Current Participation[1]	20819	93.3	67633	94.9	88452	94.5
Alive: Recent Participation[2]	455	2.0	1076	1.5	1531	1.6
Alive: Past/Unknown Participation[3]	152	0.7	156	0.2	308	0.3
Stopped Follow-Up[4]	125	0.6	292	0.4	417	0.4
Lost to Follow-Up[5]	118	0.5	214	0.3	332	0.4

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

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

Data as of: September 17, 2012; Events through September 17, 2012

Outcomes	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	22313		3727		5291		10112		3183	
Mean follow-up (months)	183.6		188.4		186.0		182.0		179.1	
Cardiovascular										
CHD[1]	841	(0.25%)	75	(0.13%)	123	(0.15%)	427	(0.28%)	216	(0.45%)
CHD death[2]	36	(0.01%)	0	(0.00%)	4	(<0.01%)	14	(0.01%)	18	(0.04%)
Clinical MI	800	(0.23%)	73	(0.12%)	121	(0.15%)	411	(0.27%)	195	(0.41%)
Angina[3]	692	(0.37%)	57	(0.17%)	113	(0.25%)	374	(0.44%)	148	(0.57%)
CABG/PTCA	1283	(0.38%)	120	(0.21%)	225	(0.27%)	691	(0.45%)	247	(0.52%)
Carotid artery disease	237	(0.07%)	10	(0.02%)	29	(0.04%)	145	(0.09%)	53	(0.11%)
Congestive heart failure[4]	379	(0.17%)	36	(0.09%)	50	(0.09%)	200	(0.20%)	93	(0.31%)
Stroke	655	(0.19%)	49	(0.08%)	96	(0.12%)	350	(0.23%)	160	(0.34%)
PVD	235	(0.07%)	20	(0.03%)	37	(0.05%)	126	(0.08%)	52	(0.11%)
Coronary disease[5]	2203	(0.65%)	211	(0.36%)	374	(0.46%)	1134	(0.74%)	484	(1.02%)
Abdominal aortic aneurysm (AAA)[6]	3	(0.01%)	0	(0.00%)	1	(0.01%)	2	(0.01%)	0	(0.00%)
Aortic aneurysm[6]	7	(0.02%)	0	(0.00%)	1	(0.01%)	3	(0.02%)	3	(0.07%)
Atrial fibrillation[6]	189	(0.62%)	10	(0.19%)	24	(0.32%)	101	(0.73%)	54	(1.32%)
Valvular heart disease[6]	25	(0.08%)	1	(0.02%)	2	(0.03%)	14	(0.10%)	8	(0.19%)
Total cardiovascular disease[7]	2978	(0.87%)	269	(0.46%)	493	(0.60%)	1534	(1.00%)	682	(1.44%)
Cancer										
Breast cancer	1361	(0.40%)	205	(0.35%)	323	(0.39%)	632	(0.41%)	201	(0.42%)
Invasive breast cancer	1071	(0.31%)	152	(0.26%)	255	(0.31%)	492	(0.32%)	172	(0.36%)
Non-invasive breast cancer	313	(0.09%)	56	(0.10%)	72	(0.09%)	153	(0.10%)	32	(0.07%)
Ovarian cancer	69	(0.02%)	10	(0.02%)	17	(0.02%)	32	(0.02%)	10	(0.02%)
Endometrial cancer[8]	137	(0.04%)	23	(0.04%)	35	(0.04%)	60	(0.04%)	19	(0.04%)
Colorectal cancer	292	(0.09%)	34	(0.06%)	51	(0.06%)	150	(0.10%)	57	(0.12%)
Other cancer[9]	925	(0.27%)	118	(0.20%)	216	(0.26%)	440	(0.29%)	151	(0.32%)
Total cancer	2652	(0.78%)	375	(0.64%)	624	(0.76%)	1244	(0.81%)	409	(0.86%)
Fractures										
Hip fracture	471	(0.14%)	18	(0.03%)	36	(0.04%)	222	(0.14%)	195	(0.41%)
Deaths										
Cardiovascular deaths	96	(0.03%)	1	(<0.01%)	9	(0.01%)	32	(0.02%)	54	(0.11%)
Cancer deaths	124	(0.04%)	14	(0.02%)	24	(0.03%)	60	(0.04%)	26	(0.05%)
Other known cause	107	(0.03%)	5	(0.01%)	4	(<0.01%)	44	(0.03%)	54	(0.11%)
Unknown cause	12	(<0.01%)	0	(0.00%)	1	(<0.01%)	3	(<0.01%)	8	(0.02%)
Not yet adjudicated	305	(0.09%)	17	(0.03%)	34	(0.04%)	132	(0.09%)	122	(0.26%)
Total death	644	(0.19%)	37	(0.06%)	72	(0.09%)	271	(0.18%)	264	(0.56%)

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

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

Data as of: September 17, 2012; Events through September 17, 2012

	Race/Ethnicity					
Outcomes	**American Indian/ Alaskan Native**	**Asian/Pacific Islander**	**Black/African American**	**Hispanic/ Latino**	**White**	**Unknown**
Number randomized	64	240	6134	2472	13203	200
Mean follow-up (months)	183.1	180.7	183.0	181.1	184.5	180.4
Cardiovascular						
CHD[1]	4 (0.41%)	6 (0.17%)	167 (0.18%)	60 (0.16%)	599 (0.30%)	5 (0.17%)
CHD death[2]	2 (0.20%)	1 (0.03%)	7 (0.01%)	1 (<0.01%)	25 (0.01%)	0 (0.00%)
Clinical MI	3 (0.31%)	4 (0.11%)	160 (0.17%)	59 (0.16%)	569 (0.28%)	5 (0.17%)
Angina[3]	3 (0.55%)	2 (0.10%)	206 (0.40%)	59 (0.29%)	416 (0.37%)	6 (0.37%)
CABG/PTCA	4 (0.41%)	10 (0.28%)	287 (0.31%)	108 (0.29%)	862 (0.42%)	12 (0.40%)
Carotid artery disease	0 (0.00%)	1 (0.03%)	36 (0.04%)	9 (0.02%)	190 (0.09%)	1 (0.03%)
Congestive heart failure[4]	1 (0.16%)	1 (0.04%)	109 (0.18%)	25 (0.11%)	240 (0.18%)	3 (0.16%)
Stroke	4 (0.41%)	2 (0.06%)	195 (0.21%)	35 (0.09%)	411 (0.20%)	8 (0.27%)
PVD	0 (0.00%)	1 (0.03%)	65 (0.07%)	9 (0.02%)	158 (0.08%)	2 (0.07%)
Coronary disease[5]	7 (0.72%)	16 (0.44%)	543 (0.58%)	172 (0.46%)	1445 (0.71%)	20 (0.67%)
Abdominal aortic aneurysm (AAA)[6]	0 (0.00%)	0 (0.00%)	1 (0.01%)	0 (0.00%)	2 (0.01%)	0 (0.00%)
Aortic aneurysm[6]	0 (0.00%)	0 (0.00%)	3 (0.04%)	0 (0.00%)	4 (0.02%)	0 (0.00%)
Atrial fibrillation[6]	0 (0.00%)	1 (0.32%)	17 (0.20%)	11 (0.33%)	159 (0.88%)	1 (0.36%)
Valvular heart disease[6]	0 (0.00%)	0 (0.00%)	2 (0.02%)	2 (0.06%)	21 (0.12%)	0 (0.00%)
Total cardiovascular disease[7]	10 (1.02%)	18 (0.50%)	763 (0.82%)	214 (0.57%)	1946 (0.96%)	27 (0.90%)
Cancer						
Breast cancer	4 (0.41%)	19 (0.53%)	397 (0.42%)	128 (0.34%)	803 (0.40%)	10 (0.33%)
Invasive breast cancer	3 (0.31%)	13 (0.36%)	302 (0.32%)	104 (0.28%)	641 (0.32%)	8 (0.27%)
Non-invasive breast cancer	1 (0.10%)	6 (0.17%)	106 (0.11%)	25 (0.07%)	172 (0.08%)	3 (0.10%)
Ovarian cancer	1 (0.10%)	1 (0.03%)	17 (0.02%)	7 (0.02%)	43 (0.02%)	0 (0.00%)
Endometrial cancer[8]	1 (0.10%)	2 (0.06%)	27 (0.03%)	9 (0.02%)	97 (0.05%)	1 (0.03%)
Colorectal cancer	1 (0.10%)	4 (0.11%)	73 (0.08%)	21 (0.06%)	190 (0.09%)	3 (0.10%)
Other cancer[9]	2 (0.20%)	5 (0.14%)	186 (0.20%)	68 (0.18%)	655 (0.32%)	9 (0.30%)
Total cancer	9 (0.92%)	30 (0.83%)	663 (0.71%)	227 (0.61%)	1700 (0.84%)	23 (0.76%)
Fractures						
Hip fracture	3 (0.31%)	2 (0.06%)	32 (0.03%)	21 (0.06%)	408 (0.20%)	5 (0.17%)
Deaths						
Cardiovascular deaths	2 (0.20%)	1 (0.03%)	20 (0.02%)	1 (<0.01%)	71 (0.03%)	1 (0.03%)
Cancer deaths	1 (0.10%)	0 (0.00%)	23 (0.02%)	14 (0.04%)	86 (0.04%)	0 (0.00%)
Other known cause	0 (0.00%)	1 (0.03%)	19 (0.02%)	6 (0.02%)	81 (0.04%)	0 (0.00%)
Unknown cause	0 (0.00%)	0 (0.00%)	2 (<0.01%)	1 (<0.01%)	9 (<0.01%)	0 (0.00%)
Not yet adjudicated	0 (0.00%)	1 (0.03%)	75 (0.08%)	19 (0.05%)	206 (0.10%)	4 (0.13%)
Total Death	3 (0.31%)	3 (0.08%)	139 (0.15%)	41 (0.11%)	453 (0.22%)	5 (0.17%)

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

Table 7.4
Verified Outcomes (Annualized Percentages) by Age for SRC Participants

Data as of: September 17, 2012; Events through September 30, 2010

Outcomes	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	71245		10749		16244		33247		11005	
Mean follow-up (months)	167.7		173.3		170.4		165.7		164.5	
Cardiovascular										
Clinical MI	1978	(0.20%)	109	(0.07%)	273	(0.12%)	1015	(0.22%)	581	(0.39%)
Angina[1]	1748	(0.29%)	87	(0.09%)	276	(0.19%)	914	(0.33%)	471	(0.52%)
CABG/PTCA	3416	(0.34%)	168	(0.11%)	508	(0.22%)	1902	(0.41%)	838	(0.56%)
Carotid artery disease	567	(0.06%)	28	(0.02%)	73	(0.03%)	306	(0.07%)	160	(0.11%)
Congestive heart failure[1]	675	(0.11%)	31	(0.03%)	81	(0.06%)	322	(0.12%)	241	(0.27%)
Stroke	1491	(0.15%)	69	(0.04%)	174	(0.08%)	775	(0.17%)	473	(0.31%)
PVD	426	(0.04%)	19	(0.01%)	48	(0.02%)	228	(0.05%)	131	(0.09%)
Coronary disease[2]	5300	(0.53%)	284	(0.18%)	796	(0.35%)	2820	(0.61%)	1400	(0.93%)
Total cardiovascular disease	7098	(0.71%)	380	(0.24%)	1012	(0.44%)	3757	(0.82%)	1949	(1.29%)
Cancer										
Breast cancer	5199	(0.52%)	706	(0.45%)	1178	(0.51%)	2531	(0.55%)	784	(0.52%)
Invasive breast cancer	4165	(0.42%)	541	(0.35%)	945	(0.41%)	2023	(0.44%)	656	(0.43%)
Non-invasive breast cancer	1092	(0.11%)	175	(0.11%)	248	(0.11%)	532	(0.12%)	137	(0.09%)
Ovarian cancer	219	(0.02%)	42	(0.03%)	52	(0.02%)	94	(0.02%)	31	(0.02%)
Endometrial cancer[3]	735	(0.07%)	95	(0.06%)	179	(0.08%)	352	(0.08%)	109	(0.07%)
Colorectal cancer	832	(0.08%)	56	(0.04%)	116	(0.05%)	440	(0.10%)	220	(0.15%)
Other cancer[4]	3316	(0.33%)	384	(0.25%)	694	(0.30%)	1682	(0.37%)	556	(0.37%)
Total cancer	9730	(0.98%)	121	(0.78%)	2104	(0.91%)	4797	(1.05%)	1612	(1.07%)
Fractures										
Hip fracture	1449	(0.15%)	51	(0.03%)	128	(0.06%)	661	(0.14%)	609	(0.40%)

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

Table 7.5
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for SRC Participants

Data as of: September 17, 2012; Events through September 30, 2010

	Race/Ethnicity							
Outcomes	**American Indian/ Alaskan Native**		**Asian/Pacific Islander**		**White**		**Unknown**	
Number randomized	253		1640		68450		902	
Mean follow-up (months)	167.2		165.7		167.8		165.2	
Cardiovascular								
Clinical MI	5	(0.14%)	19	(0.08%)	1931	(0.20%)	23	(0.19%)
Angina[1]	10	(0.47%)	27	(0.20%)	1694	(0.29%)	17	(0.23%)
CABG/PTCA	17	(0.48%)	37	(0.16%)	3321	(0.35%)	41	(0.33%)
Carotid artery disease	2	(0.06%)	4	(0.02%)	552	(0.06%)	9	(0.07%)
Congestive heart failure[1]	1	(0.05%)	3	(0.02%)	666	(0.11%)	5	(0.07%)
Stroke	2	(0.06%)	26	(0.11%)	1439	(0.15%)	24	(0.19%)
PVD	0	(0.00%)	2	(0.01%)	417	(0.04%)	7	(0.06%)
Coronary disease[2]	21	(0.60%)	63	(0.28%)	5158	(0.54%)	58	(0.47%)
Total cardiovascular disease	24	(0.68%)	90	(0.40%)	6892	(0.72%)	92	(0.74%)
Cancer								
Breast cancer	12	(0.34%)	115	(0.51%)	5018	(0.52%)	54	(0.43%)
Invasive breast cancer	9	(0.26%)	93	(0.41%)	4019	(0.42%)	44	(0.35%)
Non-invasive breast cancer	3	(0.09%)	24	(0.11%)	1054	(0.11%)	11	(0.09%)
Ovarian cancer	0	(0.00%)	4	(0.02%)	214	(0.02%)	1	(0.01%)
Endometrial cancer[3]	1	(0.03%)	9	(0.04%)	712	(0.07%)	13	(0.11%)
Colorectal cancer	4	(0.11%)	18	(0.08%)	799	(0.08%)	11	(0.09%)
Other cancer[4]	8	(0.23%)	52	(0.23%)	3216	(0.34%)	40	(0.32%)
Total cancer	24	(0.68%)	186	(0.82%)	9406	(0.98%)	114	(0.92%)
Fractures								
Hip fracture	4	(0.11%)	12	(0.05%)	1425	(0.15%)	8	(0.06%)

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

Table 7.6
Verified Cancer and Self Reported Outcomes (Annualized Percentages) by Age for SRC Participants
During the WHI Extension Study 2010-2015

Data as of: September 17, 2012; Events through September 17, 2012

Outcomes	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	71245		10749		16244		33247		11005	
Mean follow-up (months)	16.7		17.2		17.1		16.7		15.7	
Cardiovascular										
CHD[1]	540	(0.54%)	34	(0.22%)	79	(0.34%)	258	(0.56%)	169	(1.17%)
CHD death[2]	78	(0.08%)	1	(0.01%)	4	(0.02%)	33	(0.07%)	40	(0.28%)
MI, IP/OP	503	(0.51%)	37	(0.24%)	84	(0.36%)	246	(0.53%)	136	(0.94%)
MI, IP	465	(0.47%)	33	(0.21%)	75	(0.32%)	226	(0.49%)	131	(0.91%)
MI, OP	39	(0.04%)	4	(0.03%)	9	(0.04%)	21	(0.05%)	5	(0.03%)
Angina	1193	(1.20%)	95	(0.62%)	219	(0.94%)	601	(1.30%)	278	(1.93%)
CABG/PTCA, IP/OP	700	(0.71%)	63	(0.41%)	112	(0.48%)	395	(0.85%)	130	(0.90%)
CABG/PTCA, IP	653	(0.66%)	57	(0.37%)	105	(0.45%)	366	(0.79%)	125	(0.87%)
CABG/PTCA, OP	53	(0.05%)	7	(0.05%)	9	(0.04%)	30	(0.06%)	7	(0.05%)
Carotid artery disease, IP/OP	214	(0.22%)	18	(0.12%)	33	(0.14%)	117	(0.25%)	46	(0.32%)
Carotid artery disease, IP	190	(0.19%)	16	(0.10%)	31	(0.13%)	103	(0.22%)	40	(0.28%)
Carotid artery disease, OP	26	(0.03%)	2	(0.01%)	2	(0.01%)	16	(0.03%)	6	(0.04%)
Congestive heart failure, IP/OP	859	(0.87%)	31	(0.20%)	82	(0.35%)	449	(0.97%)	297	(2.06%)
Congestive heart failure, IP	671	(0.68%)	24	(0.16%)	64	(0.28%)	357	(0.77%)	226	(1.57%)
Congestive heart failure, OP	198	(0.20%)	7	(0.05%)	18	(0.08%)	100	(0.22%)	73	(0.51%)
Stroke, IP/OP	784	(0.79%)	50	(0.32%)	115	(0.50%)	415	(0.90%)	204	(1.42%)
Stroke, IP	705	(0.71%)	41	(0.27%)	96	(0.41%)	376	(0.81%)	192	(1.33%)
Stroke, OP	152	(0.15%)	13	(0.08%)	28	(0.12%)	77	(0.17%)	34	(0.24%)
PVD, IP/OP	493	(0.50%)	32	(0.21%)	58	(0.25%)	269	(0.58%)	134	(0.93%)
PVD, IP	175	(0.18%)	6	(0.04%)	16	(0.07%)	98	(0.21%)	55	(0.38%)
PVD, OP	326	(0.33%)	27	(0.18%)	42	(0.18%)	176	(0.38%)	81	(0.56%)
Coronary disease[3]	2333	(2.35%)	162	(1.05%)	344	(1.48%)	1208	(2.61%)	619	(4.29%)
Abdominal aortic aneurysm (AAA)	192	(0.19%)	12	(0.08%)	32	(0.14%)	103	(0.22%)	45	(0.31%)
Atrial fibrillation	2149	(2.16%)	156	(1.01%)	321	(1.38%)	1139	(2.46%)	533	(3.70%)
Valvular heart disease	385	(0.39%)	24	(0.16%)	61	(0.26%)	211	(0.46%)	89	(0.62%)
Cancer[4]										
Breast cancer	221	(0.22%)	35	(0.23%)	52	(0.22%)	110	(0.24%)	24	(0.17%)
Invasive breast cancer	181	(0.18%)	27	(0.18%)	36	(0.16%)	98	(0.21%)	20	(0.14%)
Non-invasive breast cancer	40	(0.04%)	8	(0.05%)	16	(0.07%)	12	(0.03%)	4	(0.03%)
Ovarian cancer	15	(0.02%)	1	(0.01%)	4	(0.02%)	5	(0.01%)	5	(0.03%)
Endometrial cancer[5]	28	(0.03%)	5	(0.03%)	8	(0.03%)	12	(0.03%)	3	(0.02%)
Colorectal cancer	28	(0.03%)	1	(0.01%)	6	(0.03%)	15	(0.03%)	6	(0.04%)
Other cancer[6]	525	(0.53%)	60	(0.39%)	90	(0.39%)	250	(0.54%)	125	(0.87%)
Total cancer	813	(0.82%)	102	(0.66%)	159	(0.69%)	389	(0.84%)	163	(1.13%)
Fractures										
Hip fracture	1449	(1.46%)	51	(0.33%)	128	(0.55%)	661	(1.43%)	609	(4.22%)
Deaths										
Cardiovascular deaths	245	(0.25%)	5	(0.03%)	11	(0.05%)	97	(0.21%)	132	(0.92%)
Cancer deaths	342	(0.34%)	20	(0.13%)	51	(0.22%)	161	(0.35%)	110	(0.76%)
Other known cause	284	(0.29%)	6	(0.04%)	25	(0.11%)	132	(0.29%)	121	(0.84%)
Unknown cause	1003	(1.01%)	30	(0.19%)	84	(0.36%)	415	(0.90%)	474	(3.29%)
Total death	1874	(1.89%)	61	(0.40%)	171	(0.74%)	805	(1.74%)	837	(5.81%)

IP = Inpatient; OP = Outpatient.

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

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

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

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

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

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

Table 7.7
Verified Cancer and Self Reported Outcomes (Annualized Percentages) by Race/Ethnicity for SRC Participants During the WHI Extension Study 2010-2015

Data as of: September 17, 2012; Events through September 17, 2012

	Race/Ethnicity			
Outcomes	**American Indian/Alaskan Native**	**Asian/Pacific Islander**	**White**	**Other/Unspecified**
Number randomized	253	1640	68450	902
Mean follow-up (months)	16.6	16.4	16.7	16.3
Cardiovascular				
CHD[1]	2 (0.57%)	11 (0.49%)	523 (0.55%)	4 (0.33%)
CHD death[2]	0 (0.00%)	1 (0.04%)	77 (0.08%)	0 (0.00%)
MI, IP/OP	2 (0.57%)	10 (0.45%)	487 (0.51%)	4 (0.33%)
MI, IP	2 (0.57%)	10 (0.45%)	449 (0.47%)	4 (0.33%)
MI, OP	0 (0.00%)	0 (0.00%)	39 (0.04%)	0 (0.00%)
Angina	10 (2.85%)	14 (0.62%)	1156 (1.21%)	13 (1.06%)
CABG/PTCA, IP/OP	6 (1.71%)	8 (0.36%)	681 (0.71%)	5 (0.41%)
CABG/PTCA, IP	6 (1.71%)	7 (0.31%)	635 (0.67%)	5 (0.41%)
CABG/PTCA, OP	0 (0.00%)	1 (0.04%)	52 (0.05%)	0 (0.00%)
Carotid artery disease, IP/OP	0 (0.00%)	0 (0.00%)	208 (0.22%)	6 (0.49%)
Carotid artery disease, IP	0 (0.00%)	0 (0.00%)	185 (0.19%)	5 (0.41%)
Carotid artery disease, OP	0 (0.00%)	0 (0.00%)	25 (0.03%)	1 (0.08%)
Congestive heart failure, IP/OP	2 (0.57%)	7 (0.31%)	843 (0.88%)	7 (0.57%)
Congestive heart failure, IP	1 (0.28%)	6 (0.27%)	662 (0.69%)	2 (0.16%)
Congestive heart failure, OP	1 (0.28%)	1 (0.04%)	191 (0.20%)	5 (0.41%)
Stroke, IP/OP	3 (0.85%)	15 (0.67%)	756 (0.79%)	10 (0.82%)
Stroke, IP	3 (0.85%)	9 (0.40%)	682 (0.71%)	11 (0.90%)
Stroke, OP	0 (0.00%)	6 (0.27%)	146 (0.15%)	0 (0.00%)
PVD, IP/OP	2 (0.57%)	5 (0.22%)	479 (0.50%)	7 (0.57%)
PVD, IP	1 (0.28%)	3 (0.13%)	170 (0.18%)	1 (0.08%)
PVD, OP	1 (0.28%)	2 (0.09%)	317 (0.33%)	6 (0.49%)
Coronary disease[3]	12 (3.42%)	30 (1.34%)	2272 (2.38%)	19 (1.55%)
Abdominal aortic aneurysm (AAA)	2 (0.57%)	5 (0.22%)	182 (0.19%)	3 (0.24%)
Atrial fibrillation	4 (1.14%)	30 (1.34%)	2091 (2.19%)	24 (1.96%)
Valvular heart disease	0 (0.00%)	5 (0.22%)	377 (0.39%)	3 (0.24%)
Cancer[4]				
Breast cancer	1 (0.28%)	1 (0.04%)	215 (0.23%)	4 (0.33%)
Invasive breast cancer	0 (0.00%)	1 (0.04%)	176 (0.18%)	4 (0.33%)
Non-invasive breast cancer	1 (0.28%)	0 (0.00%)	39 (0.04%)	0 (0.00%)
Ovarian cancer	1 (0.28%)	0 (0.00%)	14 (0.01%)	0 (0.00%)
Endometrial cancer[5]	0 (0.00%)	1 (0.04%)	27 (0.03%)	0 (0.00%)
Colorectal cancer	0 (0.00%)	0 (0.00%)	27 (0.03%)	1 (0.08%)
Other cancer[6]	1 (0.28%)	5 (0.22%)	512 (0.54%)	7 (0.57%)
Total cancer	3 (0.85%)	7 (0.31%)	791 (0.83%)	12 (0.98%)
Fractures				
Hip fracture	4 (1.14%)	12 (0.53%)	1425 (1.49%)	8 (0.65%)
Deaths				
Cardiovascular deaths	0 (0.00%)	4 (0.18%)	240 (0.25%)	1 (0.08%)
Cancer deaths	2 (0.57%)	5 (0.22%)	330 (0.35%)	5 (0.41%)
Other known cause	2 (0.57%)	7 (0.31%)	273 (0.29%)	2 (0.16%)
Unknown cause	2 (0.57%)	12 (0.53%)	974 (1.02%)	15 (1.22%)
Total death	6 (1.71%)	28 (1.25%)	1817 (1.90%)	23 (1.88%)

IP = Inpatient; OP = Outpatient.
[1] CHD" includes MI and CHD death.
[2] "CHD death" includes definite and possible CHD death.
[3] "Coronary disease" includes MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[4] All cancers are adjudicated in the WHI Extension Study 2010-2015.
[5] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[6] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.

Table 7.8
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes During WHI Extension Study 2010-2015 by Age and Race/Ethnicity for MRC Participants Without a Prior Event[1]

Data as of: September 17, 2012; Events through September 17, 2012

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	22313	3727	5291	10112	3183
Mean follow-up (months)	16.3	16.5	16.7	16.2	15.3
DVT, IP/OP	155 (0.51%)	18 (0.35%)	32 (0.44%)	79 (0.58%)	26 (0.64%)
DVT, IP	101 (0.33%)	10 (0.20%)	20 (0.27%)	53 (0.39%)	18 (0.44%)
DVT, OP	59 (0.20%)	9 (0.18%)	12 (0.16%)	28 (0.20%)	10 (0.25%)
PE, IP/OP	71 (0.23%)	9 (0.18%)	25 (0.34%)	27 (0.20%)	10 (0.25%)
PE, IP	64 (0.21%)	9 (0.18%)	21 (0.29%)	25 (0.18%)	9 (0.22%)
PE, OP	7 (0.02%)	0 (0.00%)	4 (0.05%)	2 (0.01%)	1 (0.02%)
Diabetes (treated)	613 (2.03%)	126 (2.46%)	130 (1.77%)	284 (2.08%)	73 (1.79%)
Hysterectomy	118 (0.39%)	27 (0.53%)	45 (0.61%)	40 (0.29%)	6 (0.15%)
Osteoarthritis	851 (2.82%)	180 (3.52%)	218 (2.96%)	361 (2.64%)	92 (2.26%)
Intestinal polyps	638 (2.11%)	130 (2.54%)	206 (2.80%)	261 (1.91%)	41 (1.01%)
Lupus	27 (0.09%)	3 (0.06%)	4 (0.05%)	19 (0.14%)	1 (0.02%)
Pills for hypertension	749 (2.48%)	165 (3.23%)	191 (2.60%)	311 (2.27%)	82 (2.02%)
COPD	778 (2.57%)	98 (1.92%)	164 (2.23%)	394 (2.88%)	122 (3.00%)
Macular degeneration	718 (2.38%)	54 (1.06%)	127 (1.73%)	349 (2.55%)	188 (4.62%)
Alzheimer's disease	524 (1.73%)	26 (0.51%)	50 (0.68%)	282 (2.06%)	166 (4.08%)
Parkinson's disease	64 (0.21%)	8 (0.16%)	9 (0.12%)	33 (0.24%)	14 (0.34%)

Outcomes	Race/Ethnicity: Am Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	64	240	6134	2472	13203	200
Mean follow-up (months)	15.1	15.6	16.3	15.9	16.3	16.5
DVT, IP/OP	0 (0.00%)	2 (0.64%)	57 (0.68%)	8 (0.24%)	88 (0.49%)	0 (0.00%)
DVT, IP	0 (0.00%)	0 (0.00%)	36 (0.43%)	3 (0.09%)	62 (0.35%)	0 (0.00%)
DVT, OP	0 (0.00%)	2 (0.64%)	22 (0.26%)	6 (0.18%)	29 (0.16%)	0 (0.00%)
PE, IP/OP	0 (0.00%)	0 (0.00%)	22 (0.26%)	6 (0.18%)	42 (0.23%)	1 (0.36%)
PE, IP	0 (0.00%)	0 (0.00%)	21 (0.25%)	6 (0.18%)	37 (0.21%)	0 (0.00%)
PE, OP	0 (0.00%)	0 (0.00%)	1 (0.01%)	0 (0.00%)	5 (0.03%)	1 (0.36%)
Diabetes (treated)	5 (6.19%)	8 (2.56%)	203 (2.43%)	67 (2.04%)	325 (1.81%)	5 (1.82%)
Hysterectomy	0 (0.00%)	1 (0.32%)	26 (0.31%)	10 (0.30%)	80 (0.45%)	1 (0.36%)
Osteoarthritis	3 (3.72%)	15 (4.80%)	218 (2.61%)	110 (3.35%)	500 (2.79%)	5 (1.82%)
Intestinal polyps	2 (2.48%)	11 (3.52%)	212 (2.54%)	77 (2.35%)	331 (1.85%)	5 (1.82%)
Lupus	1 (1.24%)	1 (0.32%)	11 (0.13%)	0 (0.00%)	14 (0.08%)	0 (0.00%)
Pills for hypertension	3 (3.72%)	8 (2.56%)	135 (1.62%)	97 (2.96%)	498 (2.78%)	8 (2.91%)
COPD	9 (11.15%)	4 (1.28%)	189 (2.26%)	71 (2.17%)	497 (2.77%)	8 (2.91%)
Macular degeneration	4 (4.95%)	7 (2.24%)	148 (1.77%)	75 (2.29%)	478 (2.67%)	6 (2.18%)
Alzheimer's disease	1 (1.24%)	4 (1.28%)	121 (1.45%)	54 (1.65%)	340 (1.90%)	4 (1.45%)
Parkinson's disease	0 (0.00%)	0 (0.00%)	17 (0.20%)	7 (0.21%)	39 (0.22%)	1 (0.36%)

IP = Inpatient; OP = Outpatient

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

Table 7.9
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes During WHI Extension Study 2010-2015 by Age and Race/Ethnicity for SRC Participants Without a Prior Event[1]

Data as of: September 17, 2012; Events through September 17, 2012

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	71245	10749	16244	33247	11005
Mean follow-up (months)	16.7	17.2	17.1	16.7	15.7
DVT, IP/OP	528 (0.53%)	57 (0.37%)	83 (0.36%)	282 (0.61%)	106 (0.74%)
DVT, IP	291 (0.29%)	37 (0.24%)	37 (0.16%)	171 (0.37%)	46 (0.32%)
DVT, OP	247 (0.25%)	17 (0.11%)	48 (0.21%)	125 (0.27%)	57 (0.40%)
PE, IP/OP	287 (0.29%)	26 (0.17%)	53 (0.23%)	163 (0.35%)	45 (0.31%)
PE, IP	263 (0.26%)	25 (0.16%)	47 (0.20%)	149 (0.32%)	42 (0.29%)
PE, OP	27 (0.03%)	1 (0.01%)	6 (0.03%)	16 (0.03%)	4 (0.03%)
Diabetes (treated)	1708 (1.72%)	258 (1.67%)	383 (1.65%)	819 (1.77%)	248 (1.72%)
Hysterectomy	423 (0.43%)	80 (0.52%)	134 (0.58%)	181 (0.39%)	28 (0.19%)
Osteoarthritis	2513 (2.53%)	444 (2.88%)	627 (2.70%)	1164 (2.52%)	278 (1.93%)
Intestinal polyps	1727 (1.74%)	351 (2.28%)	506 (2.18%)	734 (1.59%)	136 (0.94%)
Lupus	72 (0.07%)	6 (0.04%)	21 (0.09%)	31 (0.07%)	14 (0.10%)
Pills for hypertension	2570 (2.59%)	423 (2.75%)	597 (2.57%)	1229 (2.66%)	321 (2.23%)
COPD	2163 (2.18%)	206 (1.34%)	403 (1.74%)	1151 (2.49%)	403 (2.80%)
Macular degeneration	2443 (2.46%)	140 (0.91%)	385 (1.66%)	1281 (2.77%)	637 (4.42%)
Alzheimer's disease	1444 (1.45%)	54 (0.35%)	124 (0.53%)	761 (1.65%)	505 (3.50%)
Parkinson's disease	253 (0.25%)	22 (0.14%)	37 (0.16%)	148 (0.32%)	46 (0.32%)

Outcomes	Race/Ethnicity: Am Indian/ Alaskan Native	Asian/Pacific Islander	White	Unknown
Number randomized	253	1640	68450	902
Mean follow-up (months)	16.6	16.4	16.7	16.3
DVT, IP/OP	1 (0.28%)	9 (0.40%)	510 (0.53%)	8 (0.65%)
DVT, IP	0 (0.00%)	5 (0.22%)	284 (0.30%)	2 (0.16%)
DVT, OP	1 (0.28%)	3 (0.13%)	237 (0.25%)	6 (0.49%)
PE, IP/OP	0 (0.00%)	5 (0.22%)	279 (0.29%)	3 (0.24%)
PE, IP	0 (0.00%)	4 (0.18%)	256 (0.27%)	3 (0.24%)
PE, OP	0 (0.00%)	1 (0.04%)	26 (0.03%)	0 (0.00%)
Diabetes (treated)	7 (1.99%)	51 (2.27%)	1629 (1.71%)	21 (1.71%)
Hysterectomy	0 (0.00%)	6 (0.27%)	408 (0.43%)	9 (0.73%)
Osteoarthritis	9 (2.56%)	53 (2.36%)	2409 (2.52%)	42 (3.43%)
Intestinal polyps	1 (0.28%)	39 (1.74%)	1662 (1.74%)	25 (2.04%)
Lupus	0 (0.00%)	1 (0.04%)	67 (0.07%)	4 (0.33%)
Pills for hypertension	8 (2.28%)	70 (3.12%)	2463 (2.58%)	29 (2.37%)
COPD	11 (3.13%)	27 (1.20%)	2102 (2.20%)	23 (1.88%)
Macular degeneration	10 (2.85%)	42 (1.87%)	2363 (2.48%)	28 (2.28%)
Alzheimer's disease	4 (1.14%)	29 (1.29%)	1392 (1.46%)	19 (1.55%)
Parkinson's disease	2 (0.57%)	4 (0.18%)	245 (0.26%)	2 (0.16%)

IP = Inpatient; OP = Outpatient

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

Table 7.10
Verified Other Cancers (Annualized Percentages): MRC and SRC Participants

Data as of: September 17, 2012; Events through September 17, 2012

	MRC		SRC	
Number of participants	22313		71245	
Mean follow-up time (months)	183.6		184.5	
Ppts with other cancer	918	(0.27%)	3733	(0.34%)
Accessory sinus	1	(<0.01%)	3	(<0.01%)
Adrenal gland	0	(0.00%)	0	(0.00%)
Anus	5	(<0.01%)	27	(<0.01%)
Appendix	5	(<0.01%)	10	(<0.01%)
Biliary tract, parts of (other/unspecified)	3	(<0.01%)	13	(<0.01%)
Bladder	74	(0.02%)	269	(0.02%)
Bones/joints/articular cartilage (limbs)	0	(0.00%)	3	(<0.01%)
Bones/joints/articular cartilage (other)	1	(<0.01%)	3	(<0.01%)
Brain	0	(0.00%)	12	(<0.01%)
Cervix	18	(0.01%)	35	(<0.01%)
Central Nervous System (excludes brain)	0	(0.00%)	0	(0.00%)
Connective/subcutaneous/soft tissues	6	(<0.01%)	34	(<0.01%)
Endocrine glands, related structures	0	(0.00%)	0	(0.00%)
Esophagus	6	(<0.01%)	5	(<0.01%)
Eye and adnexa	6	(<0.01%)	30	(<0.01%)
Genital organs	6	(<0.01%)	32	(<0.01%)
Kidney	59	(0.02%)	188	(0.02%)
Larynx	8	(<0.01%)	12	(<0.01%)
Leukemia	49	(0.01%)	232	(0.02%)
Liver	6	(<0.01%)	12	(<0.01%)
Lung	169	(0.05%)	541	(0.05%)
Lymph nodes	0	(0.00%)	0	(0.00%)
Lymphoma, Hodgkins	5	(<0.01%)	14	(<0.01%)
Lymphoma, Non-Hodgkins	107	(0.03%)	442	(0.04%)
Melanoma of the skin	188	(0.06%)	1057	(0.10%)
Multiple myeloma	35	(0.01%)	91	(0.01%)
Oral (mouth)	3	(<0.01%)	11	(<0.01%)
Palate	0	(0.00%)	12	(<0.01%)
Pancreas	24	(0.01%)	87	(0.01%)
Parotid gland (Stensen's duct)	5	(<0.01%)	24	(<0.01%)
Peripheral nerves and autonomic nervous system	0	(0.00%)	1	(<0.01%)
Pyriform sinus	0	(0.00%)	1	(<0.01%)
Respiratory system, intrathoracic, other	0	(0.00%)	0	(0.00%)
Salivary glands, major (other/unspecified)	2	(<0.01%)	3	(<0.01%)
Stomach	13	(<0.01%)	36	(<0.01%)
Thyroid	50	(0.01%)	212	(0.02%)
Tongue, part of (other/unspecified)	3	(<0.01%)	15	(<0.01%)
Urinary organs (other/unspecified)	2	(<0.01%)	4	(<0.01%)
Uterus, not otherwise specified	3	(<0.01%)	0	(0.00%)
Other/unknown site of cancer	66	(0.02%)	273	(0.02%)
Other/unknown cancers reported on death form	20	(0.01%)	118	(0.01%)

Table 7.11
Self Reported Fractures (Annualized Percentages): MRC and SRC Participants

Data as of: September 17, 2012

	MRC		SRC	
Number of participants	22313		71245	
Mean follow-up time (months)	183.6		184.5	
Elbow	345	(0.10%)	1243	(0.11%)
Foot	1149	(0.34%)	4320	(0.39%)
Hand	306	(0.09%)	1039	(0.09%)
Hip	508	(0.15%)	2101	(0.19%)
Knee	535	(0.16%)	1639	(0.15%)
Lower arm	1630	(0.48%)	5611	(0.51%)
Lower leg	1294	(0.38%)	4311	(0.39%)
Pelvis	299	(0.09%)	1490	(0.14%)
Tailbone	126	(0.04%)	513	(0.05%)
Upper arm	871	(0.26%)	2866	(0.26%)
Upper leg	248	(0.07%)	1027	(0.09%)
Spine	889	(0.26%)	3861	(0.35%)
Other	1715	(0.50%)	6508	(0.59%)
Total fracture	7176	(2.10%)	25897	(2.36%)

Table 7.12
Cause of Death (Annualized Percentages): MRC and SRC Participants

Data as of: September 17, 2012; Events through September 17, 2012

	MRC		SRC	
Number of participants	22313		71245	
Mean Follow-up Time (months)	183.6		184.5	
Total death	644	(0.19%)	1874	(0.17%)
Centrally adjudicated death	339	(0.10%)	0	(0.00%)
Form 120 death	0	(0.00%)	1874	(0.17%)
Cardiovascular				
Atherosclerotic cardiac	36	(0.01%)	78	(0.01%)
Definite CHD deaths	16	(<0.01%)	0	(0.00%)
Possible CHD deaths	20	(0.01%)	7	(<0.01%)
Cerebrovascular	25	(0.01%)	59	(0.01%)
Pulmonary embolism	3	(<0.01%)	4	(<0.01%)
Other cardiovascular	30	(0.01%)	87	(0.01%)
Unknown cardiovascular	2	(<0.01%)	17	(<0.01%)
Total cardiovascular deaths	96	(0.03%)	245	(0.02%)
Cancer				
Breast cancer	13	(<0.01%)	29	(<0.01%)
Ovarian cancer	12	(<0.01%)	27	(<0.01%)
Endometrial cancer	1	(<0.01%)	4	(<0.01%)
Colorectal cancer	11	(<0.01%)	21	(<0.01%)
Other cancer	81	(0.02%)	224	(0.02%)
Unknown cancer site	6	(<0.01%)	37	(<0.01%)
Total cancer deaths	124	(0.04%)	342	(0.03%)
Accident/injury				
Homicide	0	(0.00%)	1	(<0.01%)
Accident	10	(<0.01%)	16	(<0.01%)
Suicide	0	(0.00%)	0	(0.00%)
Other injury	0	(0.00%)	5	(<0.01%)
Total accidental deaths	10	(<0.01%)	22	(<0.01%)
Other				
Other known cause	97	(0.03%)	262	(0.02%)
Unknown cause	317	(0.09%)	1003	(0.09%)
Total deaths – other causes	414	(0.12%)	1265	(0.12%)

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

Data as of: September 17, 2012

	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	113	70	62%	37	(53%)	17	(24%)	1	(1%)	15	(21%)	0	(0%)
CABG	50	29	58%	19	(66%)	7	(24%)	0	(0%)	3	(10%)	0	(0%)
PTCA	153	83	54%	50	(60%)	16	(19%)	1	(1%)	16	(19%)	0	(0%)
Carotid artery disease	48	42	88%	18	(43%)	4	(10%)	0	(0%)	20	(48%)	0	(0%)
Stroke/TIA[4]	199	165	83%	92	(56%)	24	(15%)	0	(0%)	47	(28%)	2	(1%)
PVD	67	44	66%	20	(45%)	6	(14%)	4	(9%)	14	(32%)	0	(0%)
AAA	44	26	59%	4	(15%)	17	(65%)	0	(0%)	5	(19%)	0	(0%)
CHF	240	83	35%	47	(57%)	19	(23%)	1	(1%)	16	(19%)	0	(0%)
DVT	137	87	64%	39	(45%)	2	(2%)	25	(29%)	21	(24%)	0	(0%)
Pulmonary embolism	65	38	58%	27	(71%)	3	(8%)	2	(5%)	6	(16%)	0	(0%)
Atrial fibrillation	418	264	63%	123	(47%)	35	(13%)	6	(2%)	100	(38%)	0	(0%)
Valvular heart disease	56	31	55%	16	(52%)	9	(29%)	0	(0%)	6	(19%)	0	(0%)
Cancers													
Breast cancer	759	276	36%	267	(97%)	0	(0%)	0	(0%)	9	(3%)	0	(0%)
Ovarian cancer	90	10	11%	3	(30%)	6	(60%)	0	(0%)	1	(10%)	0	(0%)
Endometrial cancer	130	39	30%	31	(79%)	6	(15%)	1	(3%)	1	(3%)	0	(0%)
Cervical cancer	16	11	69%	3	(27%)	7	(64%)	0	(0%)	1	(9%)	0	(0%)
Colorectal cancer	221	13	6%	7	(54%)	3	(23%)	0	(0%)	3	(23%)	0	(0%)
Bladder cancer	87	12	14%	7	(58%)	4	(33%)	0	(0%)	1	(8%)	0	(0%)
Brain cancer	32	7	22%	0	(0%)	4	(57%)	1	(14%)	2	(29%)	0	(0%)
Esophagus cancer	15	3	20%	1	(33%)	1	(33%)	0	(0%)	1	(33%)	0	(0%)
Ballbladder/bile duct cancer	10	3	30%	2	(67%)	1	(33%)	0	(0%)	0	(0%)	0	(0%)
Kidney cancer	72	7	10%	4	(57%)	3	(43%)	0	(0%)	0	(0%)	0	(0%)
Leukemia	61	42	69%	31	(74%)	5	(12%)	0	(0%)	6	(14%)	0	(0%)
Liver cancer	60	22	37%	1	(5%)	13	(59%)	1	(5%)	7	(32%)	0	(0%)
Lung cancer	231	187	81%	150	(80%)	16	(9%)	0	(0%)	21	(11%)	0	(0%)
Lymphoma/Hodgkin's	120	8	7%	3	(38%)	3	(38%)	1	(13%)	1	(13%)	0	(0%)
Melanoma	262	212	81%	120	(57%)	8	(4%)	1	(0%)	83	(39%)	0	(0%)
Multiple myeloma	35	21	60%	13	(62%)	4	(19%)	0	(0%)	4	(19%)	0	(0%)
Pancreas cancer	64	52	81%	40	(77%)	9	(17%)	0	(0%)	3	(6%)	0	(0%)
Stomach cancer	32	2	6%	0	(0%)	2	(0%)	0	(0%)	0	(0%)	0	(0%)

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

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

Data as of: September 17, 2012

	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	48	6	13%	3	(50%)	0	(0%)	0	(0%)	2	(33%)	1	(17%)
Other genital organ cancer	35	6	17%	1	(17%)	5	(83%)	0	(0%)	0	(0%)	0	(0%)
Other cancer[4]	183	30	16%	5	(17%)	12	(40%)	3	(10%)	9	(30%)	1	(3%)
Fractures													
Hip fracture	76	68	89%	44	(65%)	0	(0%)	0	(0%)	23	(34%)	1	(1%)
Upper leg fracture[5]	73	69	95%	0	(0%)	30	(43%)	0	(0%)	38	(55%)	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 8.2
Source of Outcomes Identified by Central Adjudications for Outcomes Reported in Extension Study 2010-2015

Data as of: September 17, 2012

	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	63	37	59%	23	37%	3	5%
CABG	13	13	100%	0	0%	0	0%
PTCA	54	50	93%	4	7%	0	0%
Carotid artery disease	18	15	83%	2	11%	1	6%
Stroke	95	92	97%	1	1%	2	2%
PVD	27	20	74%	2	7%	5	19%
AAA	3	3	100%	0	0%	0	0%
CHF	72	34	47%	31	43%	7	10%
DVT	32	27	84%	2	6%	3	9%
Pulmonary embolism	17	14	82%	3	18%	0	0%
Atrial fibrillation	189	129	68%	36	19%	24	13%
Valvular heart disease	25	16	64%	9	36%	0	0%
Cancers							
Breast cancer	268	267	100%	1	<1%	0	0%
Ovarian cancer	4	3	75%	1	25%	0	0%
Endometrial cancer	32	31	97%	1	3%	0	0%
Cervical cancer	3	3	100%	0	0%	0	0%
Colorectal cancer	8	7	88%	0	0%	1	13%
Bladder cancer	6	6	100%	0	0%	0	0%
Kidney cancer	4	4	100%	0	0%	0	0%
Leukemia	32	31	97%	1	3%	0	0%
Liver cancer	2	1	50%	1	50%	0	0%
Lung cancer	151	151	100%	0	0%	0	0%
Lymphoma/Hodgkin's	5	3	60%	2	40%	0	0%
Melanoma	123	120	98%	3	2%	0	0%
Multiple myeloma	17	13	76%	4	24%	0	0%
Pancreas cancer	40	40	100%	0	0%	0	0%
Thyroid cancer	3	3	100%	0	0%	0	0%
Other cancer	26	0	0%	26	100%	0	0%
Fractures							
Hip fracture	69	44	64%	24	35%	1	1%

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

Table 9.1
Age[1] Distribution by Race/Ethnicity for Active[2] WHI Extension Study 2010-2015 Participants

Data as of: September 17, 2012

Age at start of Extension 2010-2015 (September 30, 2010)	Total		Race/Ethnicity											
			American Indian/ Alaskan Native		Asian/Pacific Islander		Black/African American		Hispanic/ Latino		White		Unknown	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
<65	966	1.1	10	3.5	48	2.7	153	2.7	81	3.6	660	0.9	14	1.4
65-69	14855	16.8	70	24.2	398	22.5	1291	22.5	619	27.2	12300	15.9	177	17.3
70-79	44645	50.5	138	47.8	851	48.2	3087	53.9	1145	50.3	38943	50.3	481	46.9
80-89	26206	29.6	69	23.9	436	24.7	1123	19.6	418	18.4	23830	30.8	330	32.2
90+	1780	2.0	2	0.7	32	1.8	76	1.3	14	0.6	1633	2.1	23	2.2

[1] Age on September 30, 2010.
[2] Vital status is alive with current participation on September 17, 2012.

Table 9.2
Distribution of Aging Indicators Collected During the WHI Extension 2010-2015 Study Stratified by Age at the Beginning of the WHI Extension Study 2005-2010 for WHI Extension Study 2010-2015 Participants

Data as of: September 17, 2012

	Total (N = 93,558)		Age on September 30, 2010									
			<65 (N = 1,013)		65-69 (N = 15,265)		70-79 (N = 46,377)		80-89 (N = 28,696)		90+ (N = 2,207)	
	N	%	N	%	N	%	N	%	N	%	N	%
Never completed Form 155	15215	16.3	153	15.1	1945	12.7	6170	13.3	6148	21.4	799	36.2
Perceived Health Status												
Excellent	9469	12.4	194	22.8	2497	19.0	5076	12.9	1617	7.4	85	6.4
Very good	32865	43.0	384	45.1	6390	48.5	17761	45.1	7935	36.5	395	29.8
Good	27002	35.3	219	25.7	3570	27.1	13438	34.1	9209	42.3	566	42.7
Fair	6503	8.5	45	5.3	644	4.9	2854	7.2	2717	12.5	243	18.4
Poor	629	0.8	10	1.2	64	0.5	246	0.6	274	1.3	35	2.6
Quality of Life												
Worst, 0-3	1190	1.6	15	1.8	144	1.1	495	1.3	471	2.2	65	5.0
Halfway, 4-6	11869	15.6	89	10.5	1237	9.4	5464	13.9	4713	21.8	366	28.1
Best, 7-10	63059	82.8	743	87.7	11746	89.5	33249	84.8	16448	76.0	873	66.9
Functional Capacity, ADL Dependencies												
None[1]	68193	88.8	809	95.1	12634	95.8	36358	92.0	17688	80.8	704	52.6
Eating	394	0.5	5	0.6	23	0.2	152	0.4	179	0.8	35	2.6
Dressing	1293	1.7	9	1.1	79	0.6	483	1.2	610	2.8	112	8.4
Transferring	753	1.0	7	0.8	43	0.3	280	0.7	344	1.6	79	5.9
Bathing	1998	2.6	11	1.3	86	0.7	638	1.6	1044	4.8	219	16.6
Grocery Shopping	7093	9.3	31	3.7	392	3.0	2507	6.4	3597	16.5	566	43.2
Taking Medication	2124	2.8	6	0.7	94	0.7	646	1.6	1158	5.3	220	16.7
Performance Measures, Rand-36 Scale												
0-25	7477	10.1	33	3.9	529	4.1	2896	7.6	3574	17.3	445	36.6
25-50	12221	16.6	59	7.1	1100	8.5	5607	14.7	5111	24.7	344	28.3
51-75	19033	25.8	133	15.9	2491	19.3	9974	26.2	6151	29.7	284	23.3
76-100	35049	47.5	611	73.1	8781	68.1	19645	51.5	5868	28.3	144	11.8
Independence												
Supportive Services Availability	8740	12.5	37	4.8	610	5.1	3396	9.5	4226	21.1	471	39.2
Supportive Services Use	2424	28.7	2	5.7	54	9.2	568	17.4	1539	37.5	261	58.4
Need for nursing care	1944	2.6	9	1.1	146	1.1	805	2.1	880	4.2	104	8.2
Use of walking aid [2]	10577	13.9	34	4.0	570	4.3	3754	9.6	5523	25.8	696	54.3
Lives alone	30436	41.4	225	26.7	3823	29.8	14337	37.6	11292	55.0	759	62.7
Geriatric Conditions[3]	**(N = 41,495)**		**(N = 309)**		**(N = 6,606)**		**(N = 21,677)**		**(N = 12,079)**		**(N = 824)**	
Cognitive Impairment[4]	191	3.1	0	0.0	0	0.0	19	2.4	143	2.9	29	7.3
Falls[5]	2042	4.9	13	4.2	308	4.7	1025	4.7	623	5.2	73	8.9
Incontinence	30480	76.9	199	70.6	4632	74.4	15855	76.4	9175	79.1	619	79.2
Low BMI (<18.5 kg/m^2)	246	0.6	3	1.0	31	0.5	121	0.6	80	0.7	11	1.3
Dizziness	8520	21.5	70	24.6	1118	18.0	4183	20.2	2921	25.2	228	29.3
Vision Impairment	8888	22.6	57	20.1	1174	19.0	4335	21.0	3066	26.7	256	33.4
Hearing Impairment	11847	30.0	49	17.3	1132	18.2	5346	25.9	4855	42.1	465	59.5

[1] No limitations or need for help reported at any follow-up visit.
[2] Cane, crutches, walker, or wheelchair.
[3] Data not collected during WHI Extension Study 2010-2015; limited to WHI-CT participants.
[4] Limited to WHI HT participants 65 years and older at baseline.
[5] Two or more falls per year between April 1, 2002 and March 31, 2005.

Table 9.3
Distribution of Aging Indicators Collected During the WHI Extension 2010-2015 Study Stratified by Race/Ethnicity for WHI Extension Study 2010-2015 Participants

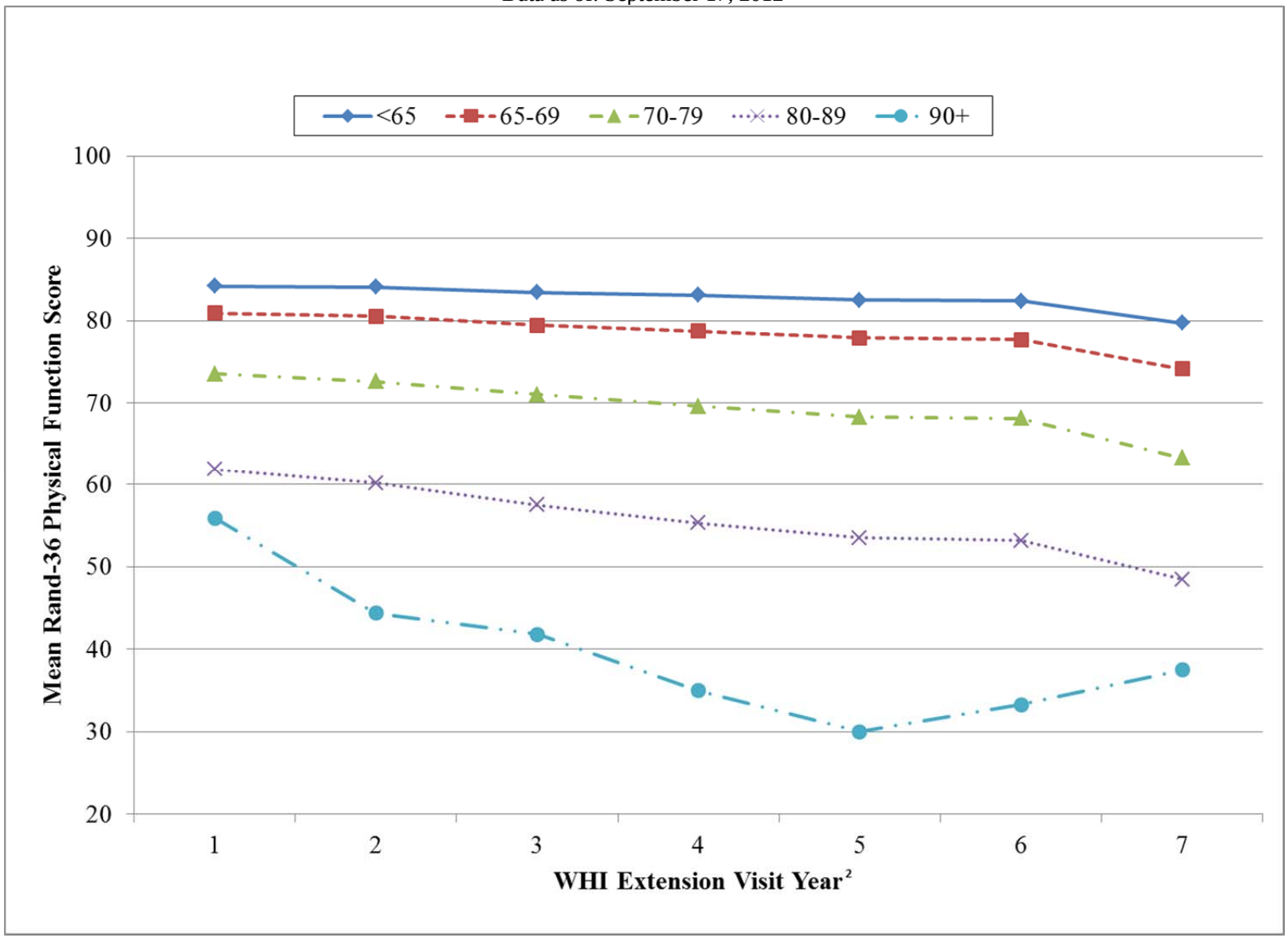
Data as of: September 17, 2012

	Race/Ethnicity											
	American Indian/ Alaskan Native (N =317)		Asian/Pacific Islander (N =1,880)		Black/African American (N =6,134)		Hispanic/ Latino (N =2,472)		White (N =81,653)		Unknown (N = 1,102)	
	N	%	N	%	N	%	N	%	N	%	N	%
Never completed Form 155	73	23.0	299	15.9	1736	28.3	592	23.9	12291	15.1	224	20.3
Perceived Health Status												
Excellent	25	10.6	136	8.8	259	6.1	207	11.3	8762	12.9	80	9.4
Very good	103	43.6	640	41.3	1409	32.9	696	37.9	29671	43.8	346	40.8
Good	74	31.4	620	40.0	2022	47.3	690	37.6	23274	34.4	322	38.0
Fair	30	12.7	144	9.3	541	12.6	221	12.0	5474	8.1	93	11.0
Poor	4	1.7	10	0.6	46	1.1	21	1.1	541	0.8	7	0.8
Quality of Life												
Worst, 0-3	7	2.9	19	1.2	48	1.1	11	0.6	1087	1.6	18	2.1
Halfway, 4-6	44	18.4	247	16.0	825	19.4	343	18.8	10263	15.2	147	17.5
Best, 7-10	188	78.7	1279	82.8	3370	79.4	1471	80.6	56076	83.2	675	80.4
Functional Capacity, ADL Dependencies												
None[1]	202	85.6	1422	91.3	3760	87.2	1643	89.1	60421	88.9	745	86.7
Eating	2	0.8	7	0.4	27	0.6	10	0.5	344	0.5	4	0.5
Dressing	5	2.1	12	0.8	75	1.7	23	1.3	1161	1.7	17	2.0
Transferring	3	1.3	8	0.5	43	1.0	20	1.1	666	1.0	13	1.5
Bathing	6	2.5	12	0.8	152	3.5	24	1.3	1778	2.6	26	3.0
Grocery Shopping	27	11.4	111	7.2	476	11.1	148	8.1	6239	9.2	92	10.8
Taking Medication	8	3.4	27	1.7	100	2.3	44	2.4	1920	2.8	25	3.0
Performance Measures, Rand-36 Scale												
0-25	31	13.7	97	6.5	482	11.9	136	7.9	6655	10.2	76	9.4
25-50	32	14.2	165	11.1	781	19.3	207	12.0	10899	16.6	137	17.0
51-75	63	27.9	390	26.2	1071	26.5	431	25.1	16877	25.8	201	24.9
76-100	100	44.2	838	56.2	1704	42.2	946	55.0	31067	47.4	394	48.8
Independence												
Supportive Services Availability	31	14.0	239	17.9	402	10.1	162	9.8	7794	12.6	112	14.5
Supportive Services Use	8	26.7	29	12.7	117	30.5	27	17.1	2212	29.3	31	28.7
Need for nursing care	3	1.3	17	1.1	81	1.9	15	0.8	1801	2.7	27	3.2
Use of walking aid[2]	37	15.9	128	8.3	829	19.6	176	9.7	9281	13.8	126	15.0
Lives alone	103	45.2	432	28.8	1970	47.6	607	34.6	27014	41.5	310	37.7
Geriatric Conditions[3]	**(N = 146)**		**(N = 845)**		**(N = 3419)**		**(N = 1,226)**		**(N = 35,361)**		**(N = 498)**	
Cognitive Impairment[4]	0	0.0	8	9.8	48	14.3	11	9.4	118	2.1	6	8.3
Falls[5]	11	7.5	26	3.1	111	3.2	48	3.9	1816	5.1	30	6.0
Incontinence	108	78.3	562	69.6	1886	59.1	748	67.0	26849	79.1	327	69.3
Low BMI (<18.5 kg/m^2)	0	0.0	14	1.7	12	0.4	5	0.4	213	0.6	2	0.4
Dizziness	36	26.5	170	21.0	779	24.5	267	24.1	7154	21.1	114	24.2
Vision Impairment	37	27.4	232	28.7	794	25.3	304	27.8	7411	22.0	110	23.7
Hearing Impairment	40	29.4	246	30.4	629	19.8	320	28.9	10463	31.0	149	31.6

[1] No limitations or need for help reported at any follow-up visit.
[2] Cane, crutches, walker, or wheelchair.
[3] Data not collected during WHI Extension Study 2010-2015; limited to WHI-CT participants.
[4] Limited to WHI HT participants 65 years and older at baseline.
[5] Two or more falls per year between April 1, 2002 and March 31, 2005.

Figure 9.1
Mean Rand-36 Physical Function Score Over Time by Age[1] at the Beginning of the WHI Extension Study 2005-2010

Data as of: September 17, 2012



[1] Age on April 1, 2005.
[2] WHI Extension Visit Years 6 and 7 data correspond to WHI Extension Study 2010-2015 visit years 1 and 2.

Table 10.1
Medication Inventory Response Rates

Data as of: September 17, 2012

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

Table 10.2
Barriers to Prescription Medication

Data as of: September 17, 2012

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

Table 10.3
Top 20 Therapeutic Classes from the WHI Extension Study 2005-2010
Medication Inventory by WHI Extension Study 2010-2015 Cohort

Data as of: September 17, 2012

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

Table 11.1
Extension Study 2010-2015 Form 33 – Medical History Update Processing

Data as of September 2012

	Form 33 -- Due 07-01-11 thru 06-30-12													Cases to Forward to CCC[7]	
	Self-Report and Screening Outcomes Qxs 2-16									Outcomes Qxs 17-46					
	Total		CCC Mailings[2] Not Collected		Ppts Due for RC Collection[3]				Incomplete Qx 2-16		Incomplete[5] Qx 17-end			Incomplete Form 33[6]		
	# Due	% Collected	#	%	#	% of Due	Not Collected #	Not Collected %	#	% of Collected	# Required[4]	#	% of Collected	# Forms	# Cases	# Not Scanned at CCC
Boston	10,177	95.4	1,158	11.4	718	7.1	26	3.6	0		650	0		0	721	0
Buffalo	10,415	98.1	1,240	11.9	1,109	10.6	66	6.0	0		906	2	0.2	2	1,140	3
Columbus	10,938	97.8	1,060	9.7	914	8.4	93	10.2	0		940	0		0	1,067	5
Gainesville	8,492	96.3	1,014	11.9	742	8.7	44	5.9	0		706	2	0.3	2	711	3
Iowa	8,723	94.6	645	7.4	180	2.1	6	3.3	4	0.0	720	6	0.8	6	702	37
Medstar	4,662	96.2	696	14.9	546	11.7	26	4.8	0		534	0		0	462	99
Pittsburgh	4,201	97.6	558	13.3	484	11.5	26	5.4	0		426	2	0.5	2	511	0
Seattle/LaJolla	4,491	94.0	438	9.8	182	4.1	14	7.7	2	0.0	338	2	0.6	2	412	0
Stanford	15,860	97.0	1,410	8.9	977	6.2	48	4.9	2	0.0	1,016	0		2	1,244	11
Tucson	6,128	95.2	661	10.8	380	6.2	16	4.2	0		406	0		0	450	0
Wakeforest	9,707	93.5	1,248	12.9	641	6.6	20	3.1	0		760	2	0.3	2	674	57
All RCs	93,794	96.1	10,128	10.8	6,873	7.3	385	5.6	8	0.0	7,402	16	0.2	18	8,094	62

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

Table 11.2
Extension Study 2010-2015 Outcomes Processing Workload

Data as of September 2012

	Outcomes Cases[1]	Closed Cases[2]				Open Cases[3]								
		Total Closed		Sent to CCC[4]		Total Open		No MRs Requested[5]		No MRs Received[6]		Some MRs Received[7]		Open > 12 Mos
	Total #	#	%	#	% of Closed	#	%	#	% of Open	#	% of Open	#	% of Open	#
Boston	985	904	91.8	721	79.8	81	8.2	11	13.6	59	72.8	11	13.6	0
Buffalo	1,442	1,340	92.9	1,140	85.1	102	7.1	30	29.4	38	37.3	34	33.3	0
Columbus	1,270	1,141	89.8	1,067	93.5	129	10.2	50	38.8	74	57.4	5	3.9	1
Gainesville	889	795	89.4	711	89.4	94	10.6	31	33.0	45	47.9	18	19.1	1
Iowa	965	824	85.4	702	85.2	141	14.6	43	30.5	60	42.6	38	27.0	3
Medstar	596	542	90.9	462	85.2	54	9.1	11	20.4	31	57.4	12	22.2	0
Pittsburgh	671	624	93.0	511	81.9	47	7.0	29	61.7	14	29.8	4	8.5	6
Seattle/LaJolla	513	490	95.5	412	84.1	23	4.5	7	30.4	8	34.8	8	34.8	0
Stanford	1,580	1,451	91.8	1,244	85.7	129	8.2	48	37.2	14	10.9	67	51.9	1
Tucson	586	533	91.0	450	84.4	53	9.0	1	1.9	29	54.7	23	43.4	1
Wakeforest	870	784	90.1	674	86.0	86	9.9	21	24.4	43	50.0	22	25.6	0
All RCs	10,367	9,428	90.9	8,094	85.9	939	9.1	282	30.0	415	44.2	242	25.8	13

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

Table 11.3
Extension Study 2010–2015 Workload for Form 33 and Outcomes

Data as of September 2012

	Form 33 Workload			Outcomes Workload			Combined Form 33 and Outcomes Workload	MRC Deaths[3]			# Open Cases with Deaths[3,4]
	Missing and Incomplete Forms[1]	Ave # Collected/Mo last 12 Mo	Est Months to Catch Up	Open Cases[2]	Avg # Cases Closed/Mo last 12 Mo	Est Months to Catch Up		Cum	Open		
	# Forms	# Forms	# Months	# Cases	# Cases	# Months	# Months	#	#	%	#
Boston	26	58	0.5	81	42	1.9	2.4	60	18	30.0	34
Buffalo	68	87	0.8	102	59	1.7	2.5	94	25	26.6	27
Columbus	93	68	1.4	129	53	2.5	3.8	79	26	32.9	54
Gainesville	46	58	0.8	94	47	2.0	2.8	83	38	45.8	27
Iowa	12	15	0.8	141	41	3.5	4.3	64	34	53.1	35
Medstar	26	43	0.6	54	26	2.1	2.7	29	9	31.0	9
Pittsburgh	28	38	0.7	47	29	1.6	2.4	29	6	20.7	8
Seattle/LaJolla	16	14	1.1	23	20	1.1	2.3	35	8	22.9	11
Stanford	50	77	0.6	129	59	2.2	2.9	98	13	13.3	21
Tucson	16	30	0.5	53	24	2.2	2.7	45	8	17.8	8
Wakeforest	22	52	0.4	86	52	1.6	2.1	65	22	33.8	17
All RCs	403	541	0.7	939	451	2.1	2.8	681	207	30.4	251

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

Table 11.4
Extension Study 2010-2015 Closure Codes for Closed Outcomes Cases

Data as of September 2012

	Closed Cases[1]	**Send to CCC** (Code 9)		**Adjudication Not Needed** (Code 10)		**Duplicate** (Code 11)		**No Doc in 12 Months** (Code 12)		**No ROI** (Code 13)		**Administrative** (Code 14)	
	#	#	%	#	%	#	%	#	%	#	%	#	%
Boston	904	721	79.8	84	9.3	88	9.7	2	0.2	9	1.0	0	
Buffalo	1,340	1,140	85.1	122	9.1	38	2.8	11	0.8	29	2.2	0	
Columbus	1,141	1,067	93.5	27	2.4	32	2.8	3	0.3	12	1.1	0	
Gainesville	795	711	89.4	41	5.2	17	2.1	9	1.1	17	2.1	0	
Iowa	824	702	85.2	72	8.7	38	4.6	2	0.2	10	1.2	0	
Medstar	542	462	85.2	45	8.3	16	3.0	12	2.2	7	1.3	0	
Pittsburgh	624	511	81.9	15	2.4	74	11.9	3	0.5	21	3.4	0	
Seattle/LaJolla	490	412	84.1	33	6.7	39	8.0	4	0.8	2	0.4	0	
Stanford	1,451	1,244	85.7	125	8.6	70	4.8	5	0.3	7	0.5	0	
Tucson	533	450	84.4	25	4.7	37	6.9	5	0.9	16	3.0	0	
Wakeforest	784	674	86.0	43	5.5	39	5.0	6	0.8	22	2.8	0	
All RCs	9,428	8,094	85.9	632	6.7	488	5.2	62	0.7	152	1.6	0	

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

Table 11.5
Extension Study 2010-2015 Participant Follow-up Status[1]

Data as of September 2012

	# Participants	Full		Partial/Custom		Proxy		Lost		No Follow-up		Absolutely No Contact		Deceased	
		#	%	#	%	#	%	#	%	#	%	#	%	#	%
Boston	10,092	9,555	94.7	188	1.9	54	0.5	4	0.0	11	0.1	29	0.3	251	2.5
Buffalo	10,391	9,139	88.0	755	7.3	108	1.0	0		31	0.3	20	0.2	338	3.3
Columbus	10,825	9,784	90.4	621	5.7	42	0.4	25	0.2	2	0.0	45	0.4	306	2.8
Gainesville	8,477	7,350	86.7	744	8.8	17	0.2	17	0.2	53	0.6	50	0.6	246	2.9
Iowa	8,744	7,914	90.5	459	5.2	42	0.5	89	1.0	15	0.2	16	0.2	209	2.4
Medstar	4,576	4,083	89.2	362	7.9	10	0.2	20	0.4	2	0.0	9	0.2	90	2.0
Pittsburgh	4,201	3,712	88.4	311	7.4	38	0.9	6	0.1	0		11	0.3	123	2.9
Seattle/LaJolla	4,551	4,022	88.4	280	6.2	40	0.9	9	0.2	12	0.3	18	0.4	170	3.7
Stanford	15,948	14,398	90.3	880	5.5	90	0.6	33	0.2	18	0.1	39	0.2	490	3.1
Tucson	6,117	5,457	89.2	354	5.8	38	0.6	53	0.9	4	0.1	29	0.5	182	3.0
Wakeforest	9,637	8,893	92.3	350	3.6	27	0.3	70	0.7	19	0.2	17	0.2	261	2.7
All RCs	93,559	84,307	90.1	5,304	5.7	506	0.5	326	0.3	167	0.2	283	0.3	2,666	2.8

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

Table 11.6
Extension Study 2012-2015 Form Collection

Data as of 10-15-12

	Form 151 - Activities of Daily Living 07-01-11 thru 9-30-11				Form 155 - Lifestyle Questionnaire 10-1-11 thru 06-30-12			
	Total Collected		Not Collected		Total Collected		Not Collected	
	# Due[1]	% Collected[2]	#	%	# Due[1]	% Collected	#	%
Boston	2,462	98.5	38	1.5	7,669	87.1	990	12.9
Buffalo	2,973	98.5	45	1.5	7,390	86.8	976	13.2
Columbus	2,927	98.2	53	1.8	7,882	89.8	805	10.2
Gainesville	2,029	96.5	71	3.5	6,395	87.5	798	12.5
Iowa	2,217	97.2	62	2.8	6,493	91.3	562	8.7
Medstar	1,286	97.5	32	2.5	3,338	84.5	517	15.5
Pittsburgh	995	99.1	9	0.9	3,195	85.9	452	14.1
Seattle/LaJolla	1,098	95.7	47	4.3	3,391	89.0	373	11.0
Stanford	4,405	98.2	78	1.8	11,401	89.9	1,156	10.1
Tucson	1,610	93.5	104	6.5	4,483	87.8	546	12.2
Wakeforest	2,657	93.9	161	6.1	6,997	86.5	946	13.5
All RCs	24,659	97.2	700	2.8	68,634	88.2	8,121	11.8

[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 11.7
Extension Study 2010-2015 CCC Data Entry Volume

10-1-11 to 9-30-12

Form	Forms					Sheets Scanned	Forms with Comments	
	Total	Key-Entered		Scanned				
	#	#	%	#	%	#	#	%
33 - Medical History Update	83,600	310	0.4	83,290	99.6	666,320	12,021	14.4
115 - Extension 2 Consent Status	12	12	100.0					
120 - Report Of Death	595	595	100.0					
150 - Hormone Use Update [1]	2	2	100.0					
151 - Activities Of Daily Living	6,112	85	1.4	6,027	98.6	6,027	76	1.3
153 - Medication And Supplement Inventory	97	97	100.0					
155 - Lifestyle Questionnaire	77,165	16	0.0	77,149	100.0	617,192	647	0.8
Totals	167,583	1,117	0.7	166,466	99.3	1,289,539	12,744	7.9

[1] Includes forms from only Extension Study 1 (2005-2010)

Table 11.8
Extension Study 2010-2015 Outcomes Cases Received from RCs

Data as of 10-15-12

Committees	Total # Cases in WHIX	Cases at RCs Not Yet Sent to CCC				Cases at CCC					
						Referred From					
		< 14 Days	14-29 Days	≥ 30 Days	Total (not sent)	Rec'd from RCs	Form 125 Review	Other Committee	Cases from RCs and Referrals	QA Cases	# Cases to Adjudicate
ES 2010-2015 (ES2)[1]											
Cancers[2]	3,083	26	6	2	34	3,038	10	1	3,049	264	3,313
CVD[3]	1,663	15	15	5	35	1,519	37	72	1,628		1,628
Heart Failure	506	7	5	1	13	470	18	5	493		493
Fatal Events	527	10	6	3	19	505		3	508		508
Stroke	441		4	2	6	408	18	9	429		429
Fracture	191	2	1		3	188			188		188
Extension Total	**6,411**	**60**	**37**	**13**	**110**	**6,128**	**83**	**90**	**6,295**	**264**	**6,559**
Form 125-Hospital	2,338	37	17	8	62	2,276			2,276		2,276
Retrospective Cases[5]											
HF (UNC)[6]	3,600					3,600			3,600		3,600
Stroke[7]	3,380					3,377			3,380		3,380

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

Table 11.9
Extension Study 2010-2015 Status of Outcomes Adjudication

Data as of 10-15-12

	# 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]	3,313	1,744	1,569	1,390	149		27		3
CVD[3]	1,628	1,081	547	214	279		3	2	49
Heart Failure	493	0	493	227	266				0
Fatal Events	508	399	109	25	10				74
Stroke	429	362	67	2	53			8	4
Fracture	188	178	10	9	0				1
Extension Total	**6,559**	**3,764**	**2,795**	**1,867**	**757**	**0**	**30**	**10**	**158**
Form 125-Hospitalization	2,276	730	1,546	1,148	45				353
Retrospective Cases[5]									
HF (UNC)[6]	3,600	0	3,600	3,600					
Stroke[7]	3,380	889	2,491	2,459	21				11

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

Table 12.1

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

					Volume of Designated Blood Components (mL)** as of 9/2012																	
Visit	Outcome As of 9/12	Total*** Ppts	No Draw*	Blood Type	0*		>0 - <.5		.5 - <1		1 - <1.5		1.5 - <2		2 - <2.5		2.5 - <3		3 - <3.5		3.5 - <4		4+	
					Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%
Base-line	Breast Cancer	4253	11	Serum	17	0%	3	0%	5	0%	49	1%	33	1%	182	4%	269	6%	675	16%	838	20%	2182	51%
				Citrate	32	1%	8	0%	4	0%	60	1%	16	0%	254	6%	62	1%	3717	87%			100	2%
				EDTA	61	1%			2	0%	17	0%	16	0%	307	7%	991	23%	2761	65%			98	2%
	Breast Cancer In Situ	862	4	Serum	5	1%	1	0%	1	0%	7	1%	1	0%	19	2%	37	4%	99	11%	200	23%	492	57%
				Citrate	7	1%	3	0%	1	0%	8	1%	3	0%	48	6%	10	1%	765	89%			17	2%
				EDTA	13	2%					6	1%	5	1%	52	6%	28	3%	741	86%			17	2%
	Breast Cancer Invasive	3450	7	Serum	12	0%	2	0%	4	0%	43	1%	32	1%	164	5%	237	7%	581	17%	648	19%	1727	50%
				Citrate	25	1%	5	0%	3	0%	53	2%	13	0%	208	6%	54	2%	3002	87%			87	3%
				EDTA	49	1%			2	0%	11	0%	11	0%	257	7%	978	28%	2057	60%			85	2%
	CHD	3601	10	Serum	20	1%	8	0%	36	1%	86	2%	122	3%	216	6%	191	5%	567	16%	501	14%	1854	51%
				Citrate	35	1%	34	1%	33	1%	236	7%	66	2%	330	9%	65	2%	2700	75%			102	3%
				EDTA	53	1%	10	0%	22	1%	73	2%	192	5%	422	12%	151	4%	2577	72%	2	0%	99	3%
	Clinical MI	2699	9	Serum	17	1%	4	0%	27	1%	65	2%	101	4%	165	6%	135	5%	425	16%	380	14%	1380	51%
				Citrate	26	1%	29	1%	27	1%	181	7%	52	2%	248	9%	46	2%	2013	75%			77	3%
				EDTA	44	2%	9	0%	17	1%	62	2%	142	5%	317	12%	99	4%	1933	72%	1	0%	75	3%
	Colorectal Cancer	1094	2	Serum	3	0%	1	0%	2	0%	21	2%	16	1%	85	8%	79	7%	332	30%	112	10%	443	40%
				Citrate	10	1%	4	0%	3	0%	18	2%	5	0%	73	7%	25	2%	938	86%			18	2%
				EDTA	19	2%			3	0%	5	0%	6	1%	91	8%	39	4%	913	83%			18	2%
	DVT/PE	939	2	Serum	2	0%	3	0%	6	1%	18	2%	23	2%	87	9%	136	14%	287	31%	165	18%	212	23%
				Citrate	12	1%	21	2%	28	3%	154	16%	66	7%	52	6%	213	23%	361	38%	1	0%	31	3%
				EDTA	11	1%	4	0%	4	0%	28	3%	22	2%	257	27%	53	6%	527	56%			33	4%
	Endometrial Cancer	578	3	Serum	5	1%	2	0%	1	0	7	1%	3	1%	14	2%	8	1%	69	12%	50	9%	419	72%
				Citrate	6	1%			2	0%	12	2%	3	1%	34	6%	5	1%	505	87%			11	2%
				EDTA	7	1%					4	1%	6	1%	43	7%	21	4%	487	84%			10	2%
	Hip Fracture	1704	3	Serum	10	1%	3	0%	3	0%	24	1%	22	1%	75	4%	89	5%	308	18%	267	16%	903	53%
				Citrate	20	1%	6	0%	7	0%	61	4%	19	1%	108	6%	33	2%	1408	83%	1	0	41	2%
				EDTA	23	1%	2	0%	2	0%	12	1%	23	1%	158	9%	87	5%	1356	80%			41	2%
	Ovarian Cancer	370	1	Serum	1	0%			3	1%	4	1%	5	1%	8	2%	12	3%	53	14%	82	22%	202	55%
				Citrate	5	1%	1	0%	1	0%	9	2%			27	7%	6	2%	312	84%			9	2%
				EDTA	2	1%					5	1%	5	1%	32	9%	14	4%	303	82%			9	2%
	Stroke	2827	8	Serum	18	1%	6	0%	15	1%	50	2%	65	2%	165	6%	275	10%	423	15%	495	18%	1315	47%
				Citrate	40	1%	25	1%	30	1%	274	10%	30	1%	627	22%	56	2%	1683	60%	1	0%	61	2%
				EDTA	43	2%	3	0%	3	0%	40	1%	44	2%	710	25%	90	3%	1834	65%			60	2%

*Participants with no draw included in 0 volume column

** Includes sample reserved for BAA (1 mL each serum, citrate and EDTA) and future WHI use (1 mL each serum, citrate and EDTA)
Represents conservative estimate of 1 ml in each vial collected, with 4 serum, 3 citrate and 3 EDTA vials collected at Baseline for CT/OS , at AV1 for CT, and at AV3 for OS.

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

Table 12.1 (continued)
CT Outcomes Cases with Remaining Blood Sample by Estimated Volume (in ml)
After Accounting for Approved Core, BAA, and Ancillary Studies

					Volume of Designated Blood Components (mL)** as of 9/2012																	
Visit	Outcome As of 9/12	Total*** Ppts	No Draw*	Blood Type	0*		>0 - <.5		.5 - <1		1 - <1.5		1.5 - <2		2 - <2.5		2.5 - <3		3 - <3.5		3.5 - <4		4+	
					Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%
AV1	Breast Cancer	4052	211	Serum	219	5%			3	0%	28	1%	8	0%	87	2%	87	2%	559	14%	411	10%	2650	65%
				Citrate	232	6%	4	0%	1	0%	46	1%	10	0%	253	6%	36	1%	3468	86%			5	0%
				EDTA	270	7%	1	0%			20	0%	12	0%	272	7%	834	21%	2643	65%			5	0%
	Breast Cancer In Situ	819	28	Serum	28	3%					6	1%			9	1%	8	1%	59	7%	48	6%	661	81%
				Citrate	34	4%	2	0%			8	1%	1	0%	51	6%	7	1%	716	87%			1	0%
				EDTA	43	5%	1	0%			4	0%	2	0%	49	6%	15	2%	705	86%			1	0%
	Breast Cancer Invasive	3292	184	Serum	192	6%			3	0%	24	1%	8	0%	78	2%	79	2%	505	15%	369	11%	2034	62%
				Citrate	199	6%	2	0%	1	0%	39	1%	9	0%	204	6%	29	1%	2806	85%			5	0%
				EDTA	229	7%					16	0%	10	0%	225	7%	832	25%	1979	60%			5	0%
	CHD	3387	247	Serum	255	8%			3	0%	20	1%	14	0%	48	1%	55	2%	329	10%	246	7%	2419	71%
				Citrate	288	9%	20	1%	17	1%	158	5%	51	2%	286	8%	42	1%	2528	75%			2	0%
				EDTA	302	9%	4	0%	13	0%	50	1%	104	3%	341	10%	47	1%	2530	75%			2	0%
	Clinical MI	2519	162	Serum	168	7%			3	0%	16	1%	13	1%	34	1%	41	2%	241	10%	190	8%	1815	72%
				Citrate	197	8%	17	1%	14	1%	126	5%	43	2%	199	8%	33	1%	1893	75%			2	0%
				EDTA	208	8%	4	0%	8	0%	44	2%	80	3%	253	10%	36	1%	1890	75%			2	0%
	Colorectal Cancer	1015	63	Serum	65	6%	1	0%			11	1%	1	0%	13	1%	12	1%	92	9%	85	8%	736	73%
				Citrate	69	7%	3	0%	2	0%	16	2%	4	0%	75	7%	14	1%	832	82%			1	0%
				EDTA	76	7%			1	0%	6	1%	4	0%	80	8%	16	2%	832	82%			1	0%
	DVT/PE	853	40	Serum	41	5%					1	0%	1	0%	13	2%	23	3%	126	15%	102	12%	546	64%
				Citrate	54	6%	13	2%	20	2%	89	10%	52	6%	54	6%	198	23%	373	44%			1	0%
				EDTA	52	6%	2	0%	2	0%	23	3%	9	1%	183	21%	39	5%	543	64%			1	0%
	Endometrial Cancer	538	27	Serum	27	5%					3	1%	1	0%	9	2%	6	1%	42	8%	22	4%	428	80%
				Citrate	33	6%					10	2%	2	0%	31	6%	2	0%	461	86%				
				EDTA	32	6%					2	0%	3	1%	39	7%	10	2%	454	84%				
	Hip Fracture	1654	84	Serum	87	5%	1	0%	1	0%	12	1%	3	0%	28	2%	24	1%	144	9%	134	8%	1220	74%
				Citrate	103	6%	4	0%	8	0%	48	3%	10	1%	99	6%	26	2%	1357	82%			1	0%
				EDTA	111	7%			1	0%	18	1%	9	1%	123	7%	32	2%	1361	82%			1	0%
	Ovarian Cancer	350	18	Serum	18	5%					4	1%			1	0%	3	1%	45	13%	57	16%	222	63%
				Citrate	19	5%	1	0%	1	0%	4	1%	1	0%	30	9%	3	1%	291	83%				
				EDTA	23	7%					1	0%	2	1%	36	10%	2	1%	286	82%				
	Stroke	2686	160	Serum	168	6%	3	0%	1	0%	16	1%	7	0%	32	1%	66	2%	283	11%	226	8%	1884	70%
				Citrate	187	7%	21	1%	25	1%	187	7%	28	1%	342	13%	49	2%	1847	69%			1	0%
				EDTA	203	8%			1	0%	39	1%	21	1%	348	13%	40	1%	2034	76%			1	0%

*Participants with no draw included in 0 volume column

** Includes sample reserved for BAA (1 mL each serum, citrate and EDTA) and future WHI use (1 mL each serum, citrate and EDTA)
Represents conservative estimate of 1 ml in each vial collected, with 4 serum, 3 citrate and 3 EDTA vials collected at Baseline for CT/OS , at AV1 for CT, and at AV3 for OS.

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

Table 12.2
OS Outcomes Cases with Remaining Blood Sample by Estimated Volume (in ml)
After Accounting for Approved Core, BAA, and Ancillary Studies

					Volume of Designated Blood Components (mL)** as of 9/2012																	
Visit	Outcome As of 9/12	Total*** Ppts	No Draw*	Blood Type	0*		>0 - <.5		.5 - <1		1 - <1.5		1.5 - <2		2 - <2.5		2.5 - <3		3 - <3.5		3.5 - <4		4+	
					Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%
Base-line	Breast Cancer	6095	3	Serum	19	0%	8	0%	9	0%	50	1%	52	1%	314	5%	407	7%	740	12%	1399	23%	3097	51%
				Citrate	68	1%	5	0%	6	0%	57	1%	76	1%	520	9%	934	15%	4309	71%			120	2%
				EDTA	123	2%	4	0%	6	0%	112	2%	136	2%	677	11%	934	15%	3983	65%	2	0%	118	2%
	Breast Cancer In Situ	1098	0	Serum	2	0%	1	0%	3	0%	9	1%	8	1%	29	3%	37	3%	92	8%	258	23%	659	60%
				Citrate	9	1%			1	0%	9	1%	7	1%	66	6%	130	12%	860	78%			16	1%
				EDTA	18	2%			1	0%	13	1%	23	2%	112	10%	76	7%	839	76%			16	1%
	Breast Cancer Invasive	5059	3	Serum	17	0%	8	0%	6	0%	42	1%	45	1%	287	6%	374	7%	656	13%	1155	23%	2469	49%
				Citrate	60	1%	5	0%	5	0%	48	1%	69	1%	458	9%	817	16%	3493	69%			104	2%
				EDTA	106	2%	4	0%	5	0%	100	2%	115	2%	571	11%	864	17%	3190	63%	2	0%	102	2%
	Colorectal Cancer	1328	1	Serum	5	0%	6	0%	6	0%	23	2%	31	2%	148	11%	84	6%	358	27%	224	17%	443	33%
				Citrate	15	1%	6	0%	5	0%	29	2%	45	3%	304	23%	347	26%	540	41%			37	3%
				EDTA	35	3%	9	1%	11	1%	102	8%	124	9%	613	46%	184	14%	216	16%			34	3%
	Endometrial Cancer	835	1	Serum	11	1%	11	1%	16	2%	54	6%	55	7%	195	23%	81	10%	199	24%	69	8%	144	17%
				Citrate	10	1%					11	1%	14	2%	89	11%	199	24%	494	59%			18	2%
				EDTA	19	2%			2	0%	21	3%	27	3%	75	9%	76	9%	597	71%			18	2%
	Ovarian Cancer	557	0	Serum	1	0%	5	1%	6	1%	27	5%	35	6%	96	17%	48	9%	162	29%	68	12%	109	20%
				Citrate	4	1%			1	0%	4	1%	11	2%	43	8%	467	84%	17	3%			10	2%
				EDTA	6	1%	2	0%	1	0%	9	2%	18	3%	61	11%	92	17%	358	64%			10	2%
	CHD	4182	3	Serum	18	0%	13	0%	24	1%	93	2%	60	1%	336	8%	121	3%	495	12%	696	17%	2326	56%
				Citrate	65	2%	30	1%	37	1%	185	4%	175	4%	762	18%	526	13%	2291	55%	2	0%	109	3%
				EDTA	101	2%	9	0%	43	1%	250	6%	676	16%	1231	29%	1683	40%	82	2%	2	0%	105	3%
	Clinical MI	3093	1	Serum	13	0%	11	0%	18	1%	75	2%	46	1%	261	8%	93	3%	384	12%	551	18%	1641	53%
				Citrate	50	2%	25	1%	36	1%	142	5%	151	5%	599	19%	389	13%	1622	52%	2	0%	77	2%
				EDTA	78	3%	6	0%	38	1%	196	6%	539	17%	942	30%	1185	38%	31	1%	1	0%	77	2%
	Stroke	3304	0	Serum	5	0%	7	0%	16	0%	44	1%	50	2%	157	5%	101	3%	506	15%	901	27%	1517	46%
				Citrate	37	1%	16	0%	18	1%	180	5%	338	10%	986	30%	149	5%	1504	46%			76	2%
				EDTA	61	2%	37	1%	66	2%	493	15%	501	15%	710	21%	485	15%	876	27%	5	0%	70	2%
	Hip Fracture	2202	2	Serum	10	0%	15	1%	47	2%	72	3%	104	5%	207	9%	177	8%	334	15%	221	10%	1015	46%
				Citrate	24	1%	2	0%	1	0%	20	1%	41	2%	212	10%	172	8%	1689	77%			41	2%
				EDTA	47	2%	3	0%	4	0%	58	3%	86	4%	287	13%	357	16%	1321	60%			39	2%

*Participants with no draw included in 0 volume column

** Includes sample reserved for BAA (1 mL each serum, citrate and EDTA) and future WHI use (1 mL each serum, citrate and EDTA)
Represents conservative estimate of 1 ml in each vial collected, with 4 serum, 3 citrate and 3 EDTA vials collected at Baseline for CT/OS , at AV1 for CT, and at AV3 for OS.

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

Table 12.2 (continued)
OS Outcomes Cases with Remaining Blood Sample by Estimated Volume (in ml)
After Accounting for Approved Core, BAA, and Ancillary Studies

					Volume of Designated Blood Components (mL)** as of 9/2012																	
Visit	Outcome As of 9/12	Total*** Ppts	No Draw*	Blood Type	0*		>0 - <.5		.5 - <1		1 - <1.5		1.5 - <2		2 - <2.5		2.5 - <3		3 - <3.5		3.5 - <4		4+	
					Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%
	Breast Cancer	4488	545	Serum	564	13%					12	0%			29	1%	2	0%	67	1%	87	2%	3732	83%
				Citrate	618	14%					22	0%			51	1%	7	0%	3814	85%			1	0%
AV3				EDTA	673	15%	1	0%	1	0%	27	1%	15	0%	226	5%	307	7%	3281	73%			2	0%
	Breast Cancer In Situ	826	87	Serum	87	11%					2	0%			3	0%			11	1%	16	2%	707	86%
				Citrate	98	12%					5	1%			7	1%	1	0%	717	87%				
				EDTA	111	13%					2	0%	1	0%	25	3%	13	2%	683	83%				
	Breast Cancer Invasive	3718	465	Serum	484	13%					11	0%			26	1%	2	0%	57	2%	71	2%	3072	83%
				Citrate	527	14%					18	0%			44	1%	6	0%	3145	85%			1	0%
				EDTA	569	15%	1	0%	1	0%	25	1%	15	0%	204	5%	296	8%	2641	71%			2	0%
	Colorectal Cancer	996	157	Serum	165	17%	1	0%	1	0%	3	0%	2	0%	6	1%	3	0%	50	5%	230	23%	538	54%
				Citrate	170	17%					2	0%			21	2%	8	1%	800	80%				
				EDTA	180	18%					9	1%	4	0%	60	6%	75	8%	674	68%				
	Endometrial Cancer	622	84	Serum	87	14%									5	1%			17	3%	16	3%	498	80%
				Citrate	92	15%					3	0%			9	1%			520	84%				
				EDTA	98	16%					2	0%	1	0%	17	3%	16	3%	493	79%				
	Ovarian Cancer	421	69	Serum	72	17%									2	0%			20	5%	59	14%	268	64%
				Citrate	75	18%					3	1%			2	0%			342	81%				
				EDTA	77	18%					2	0%	2	0%	14	3%	57	14%	271	64%				
	CHD	3429	594	Serum	614	18%					7	0%	1	0%	23	1%	14	0%	94	3%	108	3%	2575	75%
				Citrate	648	19%					9	0%			103	3%	9	0%	2670	78%			1	0%
				EDTA	682	20%	1	0%			36	1%	34	1%	522	15%	146	4%	2026	59%			1	0%
	Clinical MI	2451	353	Serum	372	15%					3	0%	1	0%	17	1%	11	0%	65	3%	80	3%	1909	78%
				Citrate	394	16%					6	0%			81	3%	8	0%	1973	80%				
				EDTA	420	17%	1	0%			30	1%	27	1%	420	17%	110	4%	1462	60%				
	Stroke	2722	439	Serum	457	17%					7	0%			24	1%	2	0%	51	2%	39	1%	2145	79%
				Citrate	485	18%					15	1%			45	2%	7	0%	2179	80%				
				EDTA	526	19%					17	1%	4	0%	117	4%	53	2%	2019	74%				
	Hip Fracture	1908	280	Serum	294	15%					1	0%			9	0%			30	2%	27	1%	1548	81%
				Citrate	311	16%					6	0%			24	1%	32	2%	1534	80%			1	0%
				EDTA	327	17%	1	0%	1	0%	8	0%	4	0%	64	3%	89	5%	1415	74%			1	0%

*Participants with no draw included in 0 volume column

** Includes sample reserved for BAA (1 mL each serum, citrate and EDTA) and future WHI use (1 mL each serum, citrate and EDTA)
Represents conservative estimate of 1 ml in each vial collected, with 4 serum, 3 citrate and 3 EDTA vials collected at Baseline for CT/OS , at AV1 for CT, and at AV3 for OS.

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

Table 12.3
CT and OS Outcomes Cases with DNA* Available
Data as of 9/2012

		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 9/12	**Ppts**	**#**	**%**	**#**	**%**	**#**	**%**	**#**	**%**
CT									
Breast Cancer	4253	66	1.6%	39	1.0%	582	14.0%	3566	83.8%
Breast Cancer Invasive	3450	48	1.4%	37	1.1%	271	7.9%	3094	89.7%
CHD	3602	72	2.0%	50	1.4%	374	10.4%	3106	86.2%
Clinical MI	2700	51	1.9%	42	1.6%	243	9.0%	2364	87.6%
Colorectal Cancer	1094	17	1.6%	16	1.5%	106	9.7%	955	87.3%
Endometrial Cancer	578	10	1.7%	6	1.0%	81	14.0%	481	83.2%
Hip Fracture	1704	41	2.4%	47	2.8%	127	7.5%	1489	87.4%
Ovarian Cancer	370	4	1.1%	3	0.8%	49	13.2%	314	84.9%
Stroke	2827	43	1.5%	84	3.0%	265	9.4%	2435	86.0%
OS									
Breast Cancer	6095	62	1.0%	40	0.7%	2057	33.7%	3936	64.6%
Breast Cancer Invasive	5059	56	1.1%	37	0.7%	1521	30.1%	3445	68.1%
CHD	4182	55	1.3%	52	1.2%	818	19.6%	3257	77.9%
Clinical MI	3093	34	1.1%	39	1.3%	556	18.0%	2464	79.7%
Colorectal Cancer	1328	20	1.5%	12	0.9%	81	6.1%	1215	91.5%
Endometrial Cancer	835	8	1.0%	3	0.4%	150	18.0%	674	80.7%
Hip Fracture	2202	24	1.1%	22	1.0%	402	18.3%	1754	79.7%
Ovarian Cancer	557	7	1.3%	6	1.1%	118	21.2%	426	76.5%
Stroke	3304	43	1.3%	59	1.8%	487	14.7%	2715	82.2%

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

Table 12.4
Number of Completed and 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			1	1			1
Breast Cancer	9	1	6	4	2		17
Colon Cancer	1		1	1			2
Colorectal Cancer	6	4	5	1		1	15
Endometrial Cancer	3		2				5
Gastric/Esophageal Cancer		1		1			1
Glioma			1	1			1
Kidney Cancer			1	1			1
Lung Cancer	1	3	1				5
Lymphoma, Non Hodgkins		1	2	1			3
Melanoma	1		2				3
Multiple Myeloma		1					1
Pancreatic Cancer	1	2	1	1		1	4
Ovarian Cancer	5		1				6
Cardiovascular							
CHD	12	2	5	2		1	19
Hypertension		1					1
Stroke	10	2	7	2		1	19
VTE	2	1	2	1			5
Fracture							
Elbow, Lower Humerus	1						1
Hip Fracture	4	2	2	1		1	8
Spine	2						2
Overall Fracture	1						1
Other							
Cognitive decline	1		1			1	2
Eye Disease	1		1				2
Fraility-disability	1	1					2
Sarcopenia		1					1
Type 2 Diabetes	1	1	4	1			6
Blacks/Hispanics			1	1			1

[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 13.1
Approved and Proposed Core Studies[1]

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

Table 13.1 (continued)
Approved and Proposed Core Studies[1]

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

Table 13.1 (continued)
Approved and Proposed Core Studies[1]

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

Table 13.1 (continued)
Approved and Proposed Core Studies[1]

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

Table 13.1 (continued)
Approved and Proposed Core Studies[1]

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

Table 13.1 (continued)
Approved and Proposed Core Studies[1]

Ref #	Title	Status	Study Population	Blood	Analytes/Data	Used in Approved Publications
W27	Nutrition and physical activity assessment study (AS218) lab work	Funded	OS *450 ppts	Y	EDTA 1.8ml: NPAAS-24hr Urine 1.8ml 4ml: 24 hr urine volume, unirary nitrogen g/day, urinary nitrogen g/L NPAAS-24hr Urine 1.8ml 4ml NPAAS-24hr Urine 1.8ml 1ml NPAAS-Spot Urine 4ml: % Fat; BMI; DSRATIO; Fat-free mass; Fluid; Isotope Approval; Nd; No; RCO2-3/5; RCO2-4/6; RQ; TEE; TEE mj/day; Total Body Water; r-H2O; %Fat; DE-SU3; DE-SU4; DE-SU5; DE-SU6; EE3/5; EE4/6; Fat-free mass; Fluid; H2CONST; Internal check DSRatio; LOT; Nd; No; O18-SU3; O18-SU4; O18-SU5; O18-SU6; O18CONST; RCO2-3/5; RCO2-4/6; TEE-CONRQ RQ Control group (38.1/44.7/17.2 %E from F/C/P); TEE-INTVRQ Intervention (29.8/52.7/17.5 %E from F/C/P); TEE-USRQ RQ assumed general US (34/47/18 %E F/C/P); Total Body Water; r-H2O Serum 1ml	1178, 1385, 1532, 1903
W28	Medicare claims data linkage	Complete	General Population	N		
W30	Dietary assessment study	Complete	DM *160 ppts for 4DFR analyses, repeat 24 hr recalls, and repeat FFQs	N		35
W31	4DFR on DM ovarian cancers	Complete	DM Ovarian Cancer:160 *For DM Other Cancer paper	N		469
W33	4DFR and DM breast cancer	Complete	DM Breast Cancer:1800 *For DM Breast Cancer paper	N		448

Table 13.1 (continued)
Approved and Proposed Core Studies[1]

Ref #	Title	Status	Study Population	Blood	Analytes/Data	Used in Approved Publications
W34	Extension of WHI stroke genome-wide association study (W-7)	Complete	General Population Stroke:2096 Controls:2096	Y	DNA 2ug: SNPs 5.4K	
W35	Full CMS data on all CT and OS participants aged 65 or over	Complete	General Population	N		889, 1217, 1371, 1372, 1373, 1394, 1409, 1608, 1623, 1640, 1658, 1659, 1660, 1730, 1747, 1765, 1766, 1767, 1839, 1840, 1916, 1917
W39	27-hydroxycholesterol in CVD biomarkers (W-6)	Complete	HRT CHD:359 Controls:820 *CHD cases from W6-HT CVD Biomarkers	Y	Serum .55ml: Chol, 27-OH	1300
W40	Validation of E-alone proteins in W19-HT proteomics	Complete	HRT Controls:100 *100 E-Alone ppts in active treatment arm	Y	Serum .4ml: AHSG; CLL16; CP; FIX; FX; ICAM-1; IGF-I; IGFBP-1; IGFBP-2; IGFBP-3; IGFBP-4; IGFBP-6; KNG1; MCAM; MMP-2; NOV; Protein Z; Proteomics; SHBG; TFF3; VTN; VitD Binding	843
W41	Medications inventory on WHI Extension participants	Complete	General Population	N		
W42	SEER code WHI and ES non-primary cancers	Complete	General Population	N		
W43	Gene sequencing of selected genes in breast cancer and stroke SNP studies (W7 and W34)	Complete	HRT E+P Breast Cancer:60 Controls:60 *60 active treatment. 60 placebo	Y	DNA 0ug: Gene seq; Use samples from W7 and W34.	
W44	Biological validation of E+P effects on the serum proteome and comparison of E+P and E-Alone effects (see W19 and W40)	Complete	HRT Controls:50 *50 E+P ppts at baseline,AV1	Y	Serum .55ml: ACE; AGTASE; ANG; Apo D; Apo F; B2M; CAPPT; CCL18; CP; CSF1; FX; ICAM-1; IGF-I; IGFBP-1; IGFBP-2; IGFBP-4; KNG1; LCN2; LGALS3BP; LYVE1; MCAM; MCSF1; MMP-2; NOV; PARCq; RNASE4; TFF3; THBS1; TNC; VTN; XLKD1	921
W45	Proteomic Colon Cancer Study	Complete	OS Colon cancer:100 Controls:100	Y	Citrate .15ml: ADAMTS13; APP; CEA; ENO1; IGFBP-1; IGFBP-2; IGFBP-6; LGALS3BP; LRG1; LTF; MAPRE1; MMP-2; NID1; PKM2; PPBP; PPIA; SPARC	

Table 13.1 (continued)
Approved and Proposed Core Studies[1]

Ref #	Title	Status	Study Population	Blood	Analytes/Data	Used in Approved Publications
W47	Breast Tumor Tissue Pilot	Complete	General Population	N		
W51	Transfer of AS62-WHISE blood samples to WHI repository	Complete	General Population	N		
W52	SHARe data clean-up	Complete	General Population	N		
W54	CVD Biomarkers for 2010-2015 (SHARe cohort only)	Complete	General Population Controls:12008 *SHARe ppts (12,008)	Y	Serum .25ml: CREA; hsCRP; Cholesterol; Glucose; HDL; Insulin; LDL; Trig; Lipid panel, creatinine	1872
W57	Proposal to Extend CVD Biomarker Study using HT Proteomics Study	Complete	General Population CHD:356 Stroke:348 Controls: 704 *B+Yr 1	Y	Citrate .15ml: B2M Citrate .15ml: IGFBP-4	1065
W58	CVD Biomarkers on non-SHARe participants	Complete	General Population	Y	Serum .25ml: CREA; hsCRP; Cholesterol; Glucose; HDL; Insulin; LDL; Trig; Lipid panel, creatinine	
W59	Collaborative telomere studies pilot study	Complete	General Population	Y	DNA .0625ug: Leukocyte Telomere	
W61	DNA Extraction of Medical Records Cohort Participants	Complete	General Population Controls:12000 *~12,000 Med Records Cohort ppts who need to be extracted.	Y		
W63	GWAS on the 80+ Year Old Women	Funded	General Population	Y		1902, 1919, 1920, 1921, 1925, 1926, 1927, 1932
W64	In-Person Visit	Funded	General Population	N		
AS286[2]	Objective physical activity and cardiovascular health in women aged 80 and older	Funded	CT *6500 E+P women, 2500 E - alone women, 1000 SHARe participants	N		
M3[2]	NCI Cancer Genetic Markers of Susceptibility (CGEMS) Initiative: Replication Phase	Complete	OS Breast Cancer:2956 Controls:2956 *Caucasians only.	Y	DNA 4ug: SNPs 30K	874, 906, 907, 908, 1104, 1109, 1814

Table 13.1 (continued)
Approved and Proposed Core Studies[1]

Ref #	Title	Status	Study Population	Blood	Analytes/Data	Used in Approved Publications
M4[2]	Whole genome scan for pancreatic cancer risk in the pancreatic cancer cohort consortium (PANSCAN)	Analysis	General Population Pancreatic Cancer:283 Controls:283	Y	DNA 4ug: GWAS	875, 930, 931, 932, 933, 934, 936, 1075, 1085, 1201, 1266, 1276, 1530, 1588, 1663, 1808, 1955
M5[2]	SHARe (SNP Health Association Resource) GWAS	Analysis	General Population Controls:12500 *Blacks, Hispanics who signed Supplemental Consent	Y	DNA 2ug: GWAS	981, 982, 983, 984, 985, 986, 987, 988, 989, 990, 991, 993, 994, 995, 996, 998, 999, 1001, 1002, 1003, 1004, 1006, 1007, 1008, 1010, 1013, 1014, 1015, 1016, 1018, 1019, 1020, 1022, 1024, 1050, 1082, 1089, 1092, 1105, 1108, 1112, 1119, 1122, 1157, 1160, 1167, 1176, 1180, 1199, 1219, 1256, 1258, 1268, 1286, 1299, 1313, 1314, 1316, 1356, 1370, 1401, 1423, 1453, 1459, 1469, 1486, 1505, 1520, 1552, 1559, 1633, 1637, 1638, 1639, 1649, 1678, 1728, 1740, 1753, 1754, 1778, 1784, 1856, 1872, 1881, 1893, 1925, 1926, 1927, 1954

Table 13.1 (continued)
Approved and Proposed Core Studies[1]

Ref #	Title	Status	Study Population	Blood	Analytes/Data	Used in Approved Publications
M6[2]	PAGE: Population Architecture of Genes and Environment (formally Epidemiologic investigation of putative causal genetic variants: The Women's Health Initiative)	Funded	General Population Colorectal Cancer:1436 Endometrial Cancer:1103 CHD:4274 Type 2 Diabetes:4000 Stroke:3455 Ovarian Cancer:703 Lung Cancer:1751 Melanoma - Skin:1102 Lymphoma, Non Hodgkins:843 Breast Cancer - Invasive:1961 Controls:80000 *~20,000 ppts (cases & controls) every year for 4 years (new set of outcomes each year); Yr 01 Outcomes: CVD, Stroke, T2D	Y	DNA 1ug: Metabochip DNA 2ug: SNPs 96 DNA 2ug: SNPs 384; year 2 DNA 2ug: SNPs 384 ekg DNA 2ug: AIMS	1072, 1073, 1170, 1171, 1172, 1192, 1193, 1194, 1221, 1235, 1236, 1237, 1238, 1239, 1240, 1241, 1242, 1243, 1244, 1245, 1246, 1247, 1248, 1249, 1250, 1345, 1346, 1347, 1348, 1349, 1350, 1351, 1352, 1353, 1380, 1423, 1439, 1440, 1441, 1491, 1589, 1590, 1606, 1610, 1642, 1645, 1648, 1674, 1759, 1788, 1807, 1832, 1862, 1871, 1879, 1879, 1885, 1922, 1923
M13[2]	HT CVD/Diabetes GWAS of treatment response in randomized clinical trials	Funded	General Population CHD:615 Type 2 Diabetes:1184 Stroke:438 VTE:373 Controls:2610	Y	DNA 2ug: Illumina 1M Omni DNA 2ug: Phase II Validation	1122, 1342, 1362, 1483, 1559, 1630, 1649, 1651, 1675, 1777, 1778, 1890, 1894, 1919, 1920, 1921
M24[2]	WHI Sequencing Project (WHISP)	Funded	General Population *Phase I: BMI/T2D, Early MI. Phase II: Stroke, Blood Pressure, Deeply Phenotyped Reference Group (DPR)	Y	DNA 5ug: DNA 5ug: Exomic Sequencing; large-scale genetic sequencing DNA 5ug:	1458, 1501, 1543, 1544, 1545, 1546, 1547, 1548, 1549, 1550, 1551, 1679, 1680, 1681, 1682, 1709, 1736, 1802, 1818, 1819, 1820, 1821, 1822, 1823, 1824, 1825, 1826, 1848, 1863, 1875, 1918, 1919, 1920, 1921, 1924, 1938, 1954, 1958

[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 13.2
Broad Agency Announcement Activities

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

Table 13.2 (continued)
Broad Agency Announcement Activities

BAA	Title	PI	Institution	Approved Publications
14	Inflammation and thrombosis gene pathways and cardiovascular disease	Dr. Alex Reiner	Fred Hutchinson Cancer Research Center	1186, 1215, 1216, 1251, 1252, 1508, 1533, 1626, 1728, 1794, 1795, 1919, 1920, 1921
15	Discovery and confirmation of cancer specific serum protein markers for ovarian cancer early detection	Dr. Martin McIntosh	Fred Hutchinson Cancer Research Center	1433
16	Identifying biomarkers for pancreatic cancer	Dr. Sunil Hingorani	Fred Hutchinson Cancer Research Center	
17	Proteomics based discovery of blood based biomarkers and risk factors for lung cancer among women smokers and never smokers	Dr. Sam Hanash	Fred Hutchinson Cancer Research Center	
18	Follow-up studies of genetically determined risk factors	Dr. Rebecca Jackson	Ohio State University	1554
19	Omega-3 fatty acid biomarkers and cognitive decline in WHIMS	Dr. William Harris	Sanford Research/University of South Dakota	1058, 1259, 1260, 1558, 1746, 1780, 1816
20	Evaluation of specific markers of rheumatoid arthritis, Inflammation, thrombogenesis and risk of cardiovascular disease and total mortality	Dr. Larry Mooreland	University of Pittsburgh	1078, 1701, 1732, 1838
21	Understanding the role of sex hormones in colorectal cancer	Dr. Marc Gunter	Albert Einstein College of Medicine	1173, 1218, 1338
22	Predictive modeling for CVD in a multiethnic cohort in women	Dr. Nancy Cook	Brigham and Women’s Hospital and Harvard Medical School	1272, 1318, 1319, 1496, 1555, 1745

Table 13.3
Summary of Ancillary Studies

Data as of September 2012

Current Status	Number of Studies	Led by WHI Investigator	
		Yes	No
Dropped	171	59	112
Seeking approval	51	14	37
Approved	52	23	29
Funded	43	22	21
Data analysis in progress	50	28	22
Complete	62	37	25
Total	**429**	**183**	**246**

Table 13.4
All Approved Ancillary Studies
(From Oct. 1, 2011)

Anc #	Title	PI	WHI PI	Status	Study Dates	Case Controls	Blood Study	Ms #(s)
387	Determinants of end-stage renal disease in aging women	Franceschini - University of North Carolina at Chapel Hill	N	Approved	07/01/13-06/30/17	General population	Y	
386	Natural environment and cardiovascular incidence and mortality: The WHI	Donovan - USDA Forest Service, PNW Research Station	N	Approved	09/01/12-09/30/14	General population	N	
385	WHI Strong & Healthy (WHISH) pilot/feasibility study (for AS360)	Stefanick - Stanford University	Y	Approved	07/15/12-09/30/12	CT	N	
384	Methylation profiling of early stage lung tumors in short and long-term survivors (Pilot to AS370)	Anderson - Fred Hutchinson Cancer Research Center	Y	Funded	06/01/12-08/31/12	General population	N	
383	Circulating vitamin D levels & risk of breast and colorectal cancer: a pooled analysis	Smith-Warner - Harvard School of Public Health	N	Approved	08/01/12-12/31/14	CaD	Y	
382	The Buffalo osteoporosis and periodontal (OsteoPerio): 15-year follow-up feasibility study	Wactawski-Wende - University of Buffalo	Y	Approved	08/01/12-12/31/12	OS	N	
380	Women's driving and mobility study	Shumaker - Wake Forest School of Medicine	Y	Approved	07/01/13-06/30/15	HT	N	
375	Cancer prognosis among breast cancer patients with and without diabetes mellitus	Luo - West Virginia University	Y	Approved	12/01/12-11/30/14	General population	N	
374	HPV antibodies and head and neck cancer risk within the NCI Cohort Consortium	Schlecht - Albert Einstein College of Medicine	N	Approved	01/01/13-12/31/16	General population	Y	
373	Understanding older smokers' unique challenges in quitting: prelude to a smoking cessation RCT in the WHI extension 2	Tindle - University of Pittsburgh	Y	Analysis	05/01/12-10/01/12	General population	N	

Table 13.4 (continued)
All Approved Ancillary Studies
(From Oct. 1, 2011)

Anc #	Title	PI	WHI PI	Status	Study Dates	Case Controls	Blood Study	Ms #(s)
371	Continuity of care for acute myocardial infarction in the WHI	Kucharska-Newton - University of North Carolina at Chapel Hill	N	Approved	03/01/12-12/31/16	OS	N	1765, 1766, 1767
370	WHI cancer survivor cohort	Anderson - Fred Hutchinson Cancer Research Center	Y	Approved	12/01/12-11/30/17	General population	N	
368	Patient specific risk scores to predict early hospital readmission after stroke	Lakshminarayan - University of Minnesota	N	Approved	09/01/12-08/30/14	OS	N	
366	Common and distinct pathways linking obesity with breast cancer and heart disease	Hanash - MD Anderson Cancer Center	Y	Approved	09/01/12-08/31/17	General population	Y	
365	Understanding the link between obesity and increased postmenopausal breast cancer risk	Pitteri - Stanford University	N	Approved	01/01/13-12/31/17	General population	Y	
364	Serum markers for the paradoxical immune responses and risk of lung cancer	Ho - Albert Einstein College of Medicine	N	Approved	01/01/13-12/31/15	General population	Y	
362	Advanced glycation end-products and risk of pancreatic cancer	Jiao - Baylor College of Medicine	Y	Approved	12/01/12-11/30/15	General population	Y	
361	Whole genome sequencing in African Americans to identify CVD genetic risk factors	Peters - Fred Hutchinson Cancer Research Center	N	Approved	09/01/12-08/31/17	General population	Y	
359	Protein supplementation for the prevention of sarcopenia in older women	Thomson - University of Arizona	Y	Approved	01/01/13-12/31/17	OS	N	
358	Immunologic metabolic, and genetic mediators of the obesity and postmenopausal breast cancer association	Prentice - Fred Hutchinson Cancer Research Center	Y	Approved	07/01/12-06/30/16	General population	Y	

Table 13.4 (continued)
All Approved Ancillary Studies
(From Oct. 1, 2011)

Anc #	Title	PI	WHI PI	Status	Study Dates	Case Controls	Blood Study	Ms #(s)
356	Prevalence of islet cell autoimmunity and determinants of diabetes related morbidity and mortality in menopausal women treated with insulin	Barinas-Mitchell - University of Pittsburgh	N	Approved	04/01/12-03/31/16	General population	Y	
355	Trial of alpha-linolenic acid and cocoa for CVD prevention among high-risk WHI participants	Manson - Brigham and Women's/Harvard University	Y	Approved	04/01/13-03/31/18	General population	N	
354	Epigenetic analysis of blood pressure variation in women	Williams - University of Tennessee	N	Approved	09/01/12-09/30/17	General population	Y	
353	Ocular and Nutritional Factors Related to Reducing Risk for Cognitive Impairment and Decline	Mares - University of Wisconsin	Y	Approved	12/01/12-11/20/17	OS	Y	
352	PILOT for Trial of vitamin D, alpha-linolenic acid, and resveratrol for CVD and cancer prevention among high-risk WHI participants	Manson - Brigham and Women's/Harvard University	Y	Complete	10/31/11-04/30/12	General population	N	
351	Epigenetics, dietary intake and ovarian cancer risk	Genkinger - Mailman School of Public Health at Columbia University	N	Approved	09/01/12-08/31/17	OS	Y	1575
346	Serum, vitamin D, and risk of melanoma in WHI-OS	Tang - Stanford University	Y	Funded	07/01/12-06/30/13	OS	Y	
330	The relationship between the FTO obesity gene, regional brain volumes, ventricular size and incident dementia in the WHIMS-MRI study	Kerwin - Northwestern University	N	Approved	07/01/11-06/30/12	HT	Y	
329	FMR1 CGG repeat polymorphism: examination of its effect on ovarian insufficiency	Sherman - Emory University School of Medicine	N	Approved	04/01/13-03/31/16	General population	Y	

Table 13.5a
Recruitment to Ancillary Studies Requiring Separate Consents by Field Centers[1]

Data as of September 2012

	9	15	34	36	39	62	65	68	84	98	100	103	105	117
	Oral Bone Loss	The Relationship Between Osteopenia and Periodontitis	Ethnic Differences in Hip Bone Geometry by DXA and QCT	HRT and Changes in Mammographic Density	The Effects of HRT on the Development and Progression of Dementia (WHIMS)	Prevention of Age-Related Maculopathy in the WHI HRT CT: WHI-SE	Benign Breast Disease	Coronary Artery Calcification Detected with Ultrafast CT as an Indication of CAD in OS	Estrogen, Vitamin E and Cognitive Change in Women	Bone Mineral Density as a Predictor for Periodontitis	Genetic, Biochemical and Behav. Determinants of Obesity	Effects of HRT on Cognitive Aging: WHI Study of Cognitive Aging (WHISCA)	Carotenoids in Age-Related Eye Disease Study	Risk Factors for Dry Eye Syndrome in Postmenopausal Women
Total	**450**	**1468**	**311**	**857**	**7528**	**4430**	**101**	**735**	**546**	**969**	**797**	**2266**	**2007**	**217**

Table 13.5a (continued)
Recruitment to Ancillary Studies Requiring Separate Consents by Field Centers[1]

Data as of September 2012

	130	153	178	197	216	218	219	233	262	272	W25	W30	W47
	Randomized Controlled Trial of Fat Reduction, Calcium/ Vit D Supplementation, HRT, and Risk of Proliferative Forms of Benign Breast Disease	Longitudinal Changes in Hip Geometry and Skeletal Muscle	Mammographic Density and Invasive Breast Cancer	Validity of self-reported diabetes mellitus in the WHI	Decision-making About Cancer Screening Among Older Women	WHI Nutrition and Physical Activity Assessment Study (NPAAS)	Diet and Eye Health in the WHI: End of Trial Study	WHIMS Extension	Memory Study of Younger Women (WHIMS-Y)	WHI Nutrition and Physical Activity Assessment Study (NPAAS)	WHI Coronary Artery Calcification Study in E-Alone	Dietary Assessment Study	Breast Tumor Tissue Pilot
Total	**3901**	**47**	**793**	**738**	**1300**	**450**	**400**	**3074**	**1373**	**93**	**1141**	**134**	**340**

[1] Table 11a 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 11b 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 11a and 11b).

Table 13.5b
Recruitment to Ancillary Studies Requiring Separate Consents by Regional Centers[1]

Data as of September 2012

	117[2]	197[2]	262[2]	272[2,3]	286	352	384[3]	W47[2]	W64[3]
	Risk Factors for Dry Eye Syndrome in Postmenopausal Women	Validity of self-reported diabetes mellitus in the Women's Health Initiative	Women's Health Initiative memory study of younger women (WHIMS-Y)	WHI Nutrition and Physical Activity Assessment Study (NPAAS) (Competitive Renewal)	Objective physical activity and cardiovascular health in women aged 80 and older	PILOT for Trial of vitamin D, alpha-linolenic acid, and resveratrol for CVD and cancer prevention among high-risk WHI participants	Methylation profiling of early stage lung tumors in short and long-term survivors (Pilot to AS370)	Breast Tumor Tissue Pilot	Long Life Study
TOTAL	**217**	**738**	**1373**	**93**	**5859**	**835**	**114**	**340**	**6294**

[1] Table 11a 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 11b 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 11a and 11b).

[2] Ancillary studies that are found in both Tables 11a and 11b are 117, 197, 262, 272, and W47.

[3] Ancillary studies 272, 384, and W64 (Long Life Study) are still recruiting.

Table 13.6
Participant Enrollment in WHI Ancillary Studies
Requiring Separate Consents

Data as of September 2012

CT+OS

	Ppts	%	
CT+OS	161808		
Not Enrolled in Ancillary Studies	133364	82.42	
Enrolled in Ancillary Studies	28444	17.58	
Number of Studies	**Ppts**	**%**	**Enrollments**
1	17577	10.86	17577
2	6638	4.10	13276
3	2215	1.37	6645
4	1145	0.71	4580
5	648	0.40	3240
6	193	0.12	1158
7	27	0.02	189
8	1	0.00	8
Total	**28444**	**17.58**	**46673**

Extension 1

	Ppts	%	
Consented to Extension 1	115407		
Not Enrolled in Ancillary Studies	91182	79.01	
Enrolled in Ancillary Studies	24225	20.99	
Number of Studies	**Ppts**	**%**	**Enrollments**
1	14069	12.19	14069
2	6041	5.23	12082
3	2109	1.83	6327
4	1138	0.99	4552
5	647	0.56	3235
6	193	0.17	1158
7	27	0.02	189
8	1	0.00	8
Total	**24225**	**20.99**	**41620**

Extension 2

	Ppts	%	
Consented to Extension 2	93558		
Not Enrolled in Ancillary Studies	73249	78.29	
Enrolled in Ancillary Studies	20309	21.71	
Number of Studies	**Ppts**	**%**	**Enrollments**
1	11587	12.38	11587
2	5181	5.54	10362
3	1670	1.78	5010
4	1016	1.09	4064
5	635	0.68	3175
6	192	0.21	1152
7	27	0.03	189
8	1	0.00	8
Total	**20309**	**21.71**	**35547**

Table 13.7
Funded BAA and Ancillary Studies PI List
(as of Sept. 2012)

Last Name	First Name	WHI Investigator	Institution	Anc PI for	WHI PI for	CCC PI for
Anderson	Garnet	Yes	Fred Hutchinson Cancer Research Center	97, 384	97, 150, 282, 297, 337, 384, M11, W47, W64,	97, 121, 129, 140, 150, 282, 297, 384, BA6, BA11, BA15, BA21, M8, M9, M11, W47
Assimes	Tim	Yes	Stanford University School of Medicine	332		
Barnhart	Janice	No	Albert Einstein College of Medicine	127		
Bassford	Tamsen	Former	University of Arizona		153, 113, 175, 199, 191	
Beasley	Jeannette	No	Fred Hutchinson Cancer Research Center	340		
Beresford	Shirley	Yes	University of Washington		272	
Berndt	Sonja	No	National Institute of Health - NCI	301		
Bird	Cloe	No	Rand Corp	220		
Bowen	Deborah	Former	Fred Hutchinson Cancer Research Center		5	39
Bray	Paul	Former	Thomas Jefferson University	137		
Brennan	Paul	No	International Agency for Research on Cancer (IARC)	294		
Brinton	Louise	No	National Institute of Health - NCI	297		
Burke	Greg	Former	Wake Forest University School of Medicine		56, 139	
Burrows	Beth	Yes	Fred Hutchinson Cancer Research Center	50		
Caan	Bette	Yes	Kaiser Foundation Research Institute - Oakland		243	
Carty	Cara	Yes	Fred Hutchinson Cancer Research Center			M16
Cauley	Jane	Yes	University of Pittsburgh	181, 161, BA9		
Chanock	Stephen	No	National Institute of Health	M3, M8		
Chen	Jiu-Chiuan	No	University of Southern California Keck School of Medicine	226, 252		
Chen	Zhao	Yes	University of Arizona	82, 153, 191, 199, M2		
Chlebowski	Rowan	Yes	UCLA Medical Center	76, 99	76, 99, 108,	
Cochrane	Barbara	Yes	Fred Hutchinson Cancer Research Center			110, 133, 134, 146, 167, 192, 196, 214, 242, 250, 262
Colditz	Graham	No	Washington University Saint Louis	207		

Table 13.7 (continued)
Funded BAA and Ancillary Studies PI List

Last Name	First Name	WHI Investigator	Institution	Anc PI for	WHI PI for	CCC PI for
Cook	Nancy	No	Brigham and Women's/Harvard University	BA22		
Coy	Christine	No	UC-Irvine	118		
Criqui	Michael	Former	University of California, San Diego	93		
Cummings	Steve	Former	UC-San Francisco	90, 167, BA7		
Curb	David	Former	Pacific Health Research and Education Institute		25, 95, 122	
DeRoos	Anneclaire	No	University of Washington	BA13		
Dorn	Joan	No	University of Buffalo	141		
Driscoll	Ira	No	National Institute of Health - NIA	250		
Dunn	Julie	Former	Tufts University - Boston	84		
Eaton	Charles	Yes	Memorial Hospital of RI		251	
Edlefsen	Kerstin	Yes	University of Washington	337		
Fouad	Mona	Yes	University of Alabama at Birmingham	78, 102		
Franceschini	Nora	No	University of North Carolina at Chapel Hill	376		
Fuchs	Charles	No	Brigham and Women's Hospital	146, 214		
Glanz	Karen	No	University of Hawaii System	122		
Going	Scott	Yes	University of Arizona	14		
Green	Pamela	No	Fred Hutchinson Cancer Research Center	5		
Grimm	Richard	Former	Berman Center for Clinical Research		50	
Gunter	Marc	No	Albert Einstein College of Medicine	BA21		
Haan	Mary	Former	UC-San Francisco	62		
Haines	Pam	No	University of North Carolina	63		
Hakim	Iman	No	University of Arizona	113		
Han	Jiali	No	Brigham and Women's Hospital	242		
Hanash	Sam	Former	MD Anderson Cancer Center - Houston	BA17, W45		
Harris	William S.	No	Sanford Health	BA19		
Hays	Jennifer	Yes	Scott and White Health Care	100, 163	100, 137, 163	
He	Ka	No	University of North Carolina	187		
Heiss	Gerardo	Yes	UNC School of Medicine		36, 63, 70, 140, 165, 178, 226, 236, 252, 264, 376	
Hendrix	Susan	Former	Wayne State University Medical School		34	

Table 13.7 (continued)
Funded BAA and Ancillary Studies PI List

Last Name	First Name	WHI Investigator	Institution	Anc PI for	WHI PI for	CCC PI for
Hingorani	Sunil	No	Fred Hutchinson Cancer Research Center	BA16		
Ho	Gloria	No	Albert Einstein College of Medicine	152, 208, 266, BA10,		
Howard	Barbara	Yes	MedStar Research Institute		217	
Hsia	Judith	Yes	George Washington University	68	68	
Hubble	Allan	Yes	University of California - Irvine		118	
Hulka	Barbara	Former	University of North Carolina	36		
Hunt	Julie	Yes	Fred Hutchinson Cancer Research Center			220, 223, 226, 252
Hunter	David	No	Harvard	M18		
Jackson	Rebecca	Yes	Ohio State University	271, BA3, BA18, M24	117, 223, 271, 301, BA3, M24, W22	
Jeffcoat	Marjorie	No	Penn Dental School	9		
Jiao	Li	Yes	Baylor College of Medicine	292		
Kaufman	Joel	No	University of Washington	150		
Kerwin	Diana	No	Northwestern University	235		
Kipnis	Victor	No	National Institute of Health	289, M12		
Klein	Liviu	No	University of California San Francisco	196		
Kleinstein	Robert	No	University of Alabama at Birmingham	31		
Kooperberg	Charles	Yes	Fred Hutchinson Cancer Research Center	M6	M6, M13, M26	90, 126, BA10, BA12, BA18, BA19, BA20, M4,
Kotchen	Jane	Yes	Medical College of Wisconsin		235	
Kripke	Daniel	No	University of California, San Diego	11		
Kuller	Lew	Yes	University of Pittsburgh	BA12	13, 121, 134, 161, 181, 189, M9	
LaCroix	Andrea	Yes	Fred Hutchinson Cancer Research Center	179, 286, W64	179, 286, 290, 340, M4,	83, 137, 153, 165, 179, 181, 191, 199, 286, 290, 340, BA3, BA7, BA9, BA13, BA14, BA22, M2
Lane	Dorothy	Yes	Stony Brook University - New York		216	
Langer	Robert	Former	University of California - San Diego		11, 24 73, 93, 47, 124,	
Lasser	Norm	Former	University of Medicine and		17	

Table 13.7 (continued)
Funded BAA and Ancillary Studies PI List

Last Name	First Name	WHI Investigator	Institution	Anc PI for	WHI PI for	CCC PI for
			Dentistry of New Jersey			
Lee	I-Minn	No	Brigham and Women's/Harvard University	BA11		
Lewis	Cora (Beth)	Yes	University of Alabama at Birmingham		9, 111	
Li	Christopher	No	Fred Hutchinson Cancer Research Center	316		
Li	Rongling	No	University of Tennessee Health Science Center	BA5		
Lichtenstein	Alice	No	Tufts University	BA8		
Lin	Henry	No	Harbor-UCLA	108		
Liu	Simin	Yes	University of California	132, 238, 254		
Lorenz	Carol	No	University of North Carolina	165		
Lund	Bernedine	Yes	Fred Hutchinson Cancer Research Center			206, 352, W54, W61
Luo	Juhua	Yes	West Virginia University			
Mackey	Rachel	Yes	University of Pittsburgh,	189		
Mann	Sue	Yes	Fred Hutchinson Cancer Research Center			224, M26
Manson	JoAnn	Yes	Brigham and Women's/Harvard University	352, W25	83, 110, 133, 132, 146, 192, 207, 214, 242, 352, BA11	
Mares	Julie	Former	University of Wisconsin	105, 219, 257, M1		
Margolis	Karen	Yes	Health Partners Minnesota	197	197, 220	
Masaki	Kamal	Former	Pacific Health Research and Education Institute	25		
Mayo	Charlotte	No	University of Alabama at Birmingham	33		
McGlynn	Katherine	No	National Institute of Health - NCI	296		
McIntosh	Martin	Yes	Fred Hutchinson Cancer Research Center	BA15		
McTiernan	Anne	Yes	Fred Hutchinson Cancer Research Center			36, 178
Melnikow	Joy	No	University of California - Davis	104		
Messina	Catherine	Yes	Stony Brook University Medical Center	216		
Michael	Yvonne	Yes	Drexel University	171		
Millen	Amy	Yes	University of Buffalo	304		
Modugno	Francesmary	No	Carnegie Mellon University	121, 134		
Moon	Tom	Former	University of Arizona		14	

Table 13.7 (continued)
Funded BAA and Ancillary Studies PI List

Last Name	First Name	WHI Investigator	Institution	Anc PI for	WHI PI for	CCC PI for
Moreland	Larry W.	No	University of Pittsburgh	BA20		
Mouton	Charles	Former	Howard University	17		
Namie	Joylin	No	University of California - San Diego	124		
Nathan	Lauren	Former	UCLA Medical Center		238, 254	
Nelson	Dorothy	No	Wayne State University School of Medicine	34		
Neuhouser	Marian	Yes	Fred Hutchinson Cancer Research Center			130, 195, 207, 236, 275, BA8
Newcomb	Polly	No	Fred Hutchinson Cancer Research Center	290		
Nicholas	J. Skye	No	University of Arizona	175		
Nichols	Kelley	No	University of Houston	117		
Nygaard	Ingrid	No	University of Utah Health Sciences	135		
Ober	Beth	No	UC-Davis	61		
Oberman	Albert	Former	University of Alabama at Birmingham		31, 33, 60, 78, 102	
Ockene	Judith	Yes	University of Massachusetts Medical Center		75, 275	
Paskett	Electra	Yes	Ohio State University	139, 223		
Patterson	Ruth	Former	UCSD Moores Cancer Center		177	65, 108
Peters	Ulrike	No	Fred Hutchinson Cancer Research Center	206, 224, M26		
Pisano	Etta	No	University of North Carolina - School of Medicine	178		
Pleuss	Joan	Former	Wake Forest University	56		
Polk	M.J.	No	University of Texas - San Antonio	86		
Prentice	Ross	Yes	Fred Hutchinson Cancer Research Center	218, 272, 343, 377, BA2, BA4	195, 206, 218, 224, 289, 294, 316, 343, 377, M3, M12, M18, W31, W33, W45, W57	84, 263,316, BA1, BA2, BA4, BA5, BA16, BA17, W22, W44, W58
Purdue	Mark	No	National Institute of Health - NCI	M9		
Rajkovic	Aleksandar	Yes	Baylor College of Medicine		M8	
Reiner	Alexander	Yes	University of Washington	BA14, M13		337
Rexrode	Kathryn	Yes	Partners Health Care	110		
Ridker	Paul	No	Partners Health Care	83		
Ritenbaugh	Cheryl	Former	University of Arizona	57, 73	57, 82, 160, 171,	
Robbins	John	Yes	University of California - Davis		61, 62, 104,	

Table 13.7 (continued)
Funded BAA and Ancillary Studies PI List

Last Name	First Name	WHI Investigator	Institution	Anc PI for	WHI PI for	CCC PI for
					BA1	
Rodriguez	Beatriz	Yes	University of Hawaii System	95		
Rohan	Tom	Yes	Albert Einstein College of Medicine	65, 130		
Rosal	Milagros	Yes	University of Massachusetts Medical School	75		
Sangi-Haghpeykar	Haleh	Yes	Baylor College of Medicine		292	
Sarto	Gloria	Yes	University of Wisconsin		105, 219, 257, M1	
Schenken	Robert	Former	University of Texas - San Antonio		86	
Schneider	Diane	No	University of California - San Diego	24		
Seldin	Michael	No	University of California - Davis	BA1		
Sesso	Howard	Yes	Brigham and Women's Hospital	133		
Sheps	David	Former	University of Florida Department of Medicine	70		
Shikany	James	Former	University of Alabama at Birmingham	60, 111		
Shumaker	Sally	Yes	Wake Forest School of Medicine	39, 103, 183, 233, 244, 262	39, 103, 183, 233, 244, 250, 262, 373	
Siega-Riz	Anna Maria	No	University of North Carolina	236		
Smoller	Sylvia	Yes	Albert Einstein College of Medicine	40, 48, 126, M16	40, 48, 126, 127, 129, 130, 152, 208, 266, BA10, M16	
Stefanick	Marcia	Yes	Stanford University		332, 346	
Sternfeld	Barbara	No	Kaiser Permanente Division of Research	243		
Stolzenberg-Solomon	Rachael	No	National Institute of Health - NCI	M4		
Strickler	Howard	No	Albert Einstein College of Medicine	129		
Sturgeon	Susan	No	University of Massachusetts	275		
Subar	Amy	No	National Institute of Health	177		
Sun	Jielin	No	Wake Forest University	263		
Tang	Jean	Yes	Stanford University	346		
Taylor	Phil	No	National Institute of Health	M11		
Tindle	Hilary	Yes	University of Pittsburgh	373		
Tinker	Lesley	Yes	Fred Hutchinson Cancer Research Center			105, 111, 132, 152, 187, 189, 208, 218, 219,

Table 13.7 (continued)
Funded BAA and Ancillary Studies PI List

Last Name	First Name	WHI Investigator	Institution	Anc PI for	WHI PI for	CCC PI for
						238, 251, 254, 257, 264, 266, 271, 292, 296, 301, 332, 315, 376, 346, M1, M12,
Trevisan	Maurizio	Yes	State University of New York - Buffalo		98, 141, 15, 74	
Ulrich	Cornelia	No	Fred Hutchinson Cancer Research Center	195		
Urban	Nicole	Yes	Fred Hutchinson Cancer Research Center	282		
Valanis	Barbara	Former	Kaiser Permanente Center for Health Research, Portland	160		
Van Horn	Linda	Yes	Northwestern University		84, 187, 196, 315	
Vitolins	Mara	Yes	Wake Forest University		263	
Vogt	Molly	No	University of Pittsburgh	13		
Wactawski-Wende	Jean	Yes	University of Buffalo	15, 98, 303, M25	296, 303, 304, M25	
Walitt	Brian	Yes	MedStar Research Institute	217		
Wallace	Robert	Yes	University of Iowa		135	
Wang	CY	Former	Fred Hutchinson Cancer Research Center			9
Wellenius	Greg	No	Brown University	251		
Whitsel	Eric	Yes	University of North Carolina	140, 264, 315		
Wodarski	Lois	No	State University of New York - Buffalo	74		
Xu	Jianfeng	No	Wake Forest University School of Medicine	BA6		
Zhang	Shumin	Yes	Brigham and Women's Hospital	192		

Table 14.1
WHI Manuscript Stages

Stage #	Definition	Number
12*	Published	730
11	In press / accepted by journal	17
10	Submitted to journal	47
9	Final manuscript approved by P&P Committee	135
8	Final manuscript submitted to P&P Committee	20
7	Draft manuscript	32
6	Analysis completed	30
5	Analysis in progress	84
4	Analysis proposed	8
3	Manuscript proposal and writing group approved	474
2	Approved/Writing group nominations open	25
Total		**1602**

*Only Stage 12 papers are included in Table 14.2

Table 14.2
Publications since October 2011

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
334	Patterns and predictors of sexual activity among women in the Hormone Therapy trials of the Women's Health Initiative	Gass, Cochrane, Barad, Barnabei, Brzyski, Lane, LaValleur, Manson, Mouton, Ockene	12	CT	Menopause. 2011 Oct 1. [Epub ahead of print]	
494	Prospective analysis of association between use of statins and melanoma risk in the Women's Health Initiative	Jagtap, Rosenberg, Martin, Pettinger, Khandekar, Lane, Ockene, Simon	12	Gen	Cancer. 2012 Mar 20. [Epub ahead of print]	
499	Prospective analysis of association between use of statins or other lipid-lowering agents and colorectal cancer risk	Simon, Rosenberg, Rodabough, Greenland, Ockene, Roy, Lane, Cauley, Khandekar	12	Gen	Ann Epidemiol. 2011 Nov 3. [Epub ahead of print]	
654	Plasma adiponectin and the risk of hypertension in White and Black postmenopausal women	Wang, Manson, Gaziano, Liu, Cochrane, Cook, Ridker, Rifai, Sesso	12	OS	Clin Chem. 2012 Aug 2. [Epub ahead of print]	AS133
714	Inflammatory markers and risk of hip fracture: The Women's Health Initiative	Barbour, Boudreau, Danielson, Youk, Wactawski-Wende, Greep, LaCroix, Jackson, Wallace, Bauer, Allison, Cauley	12	OS	J Bone Miner Res. 2012 Jan 27. [Epub ahead of print]	AS181
804	Recreational physical activity in postmenopausal women is stable over 8-years of follow-up	Nguyen, Herting, Kohen, Perry, LaCroix, Adams-Campbell	12	Gen	J Phys Act Health. 2012 Sep 18. [Epub ahead of print]	
822	A low-fat dietary pattern and risk of metabolic syndrome in postmenopausal women: The Women's Health Initiative	Neuhouser, Howard, Liu, Tinker, Van Horn, Caan, Rohan, Stefanick, Thomson	12	CT	Metabolism. 2012 May 25. [Epub ahead of print]	
829	Lipid and lipoprotein biomarkers and the risk of ischemic stroke in postmenopausal women	Berger, McGinn, Howard, Kuller, Manson, Otvos, Curb, Eaton, Kaplan, Lynch, Rosenbaum, Wassertheil-Smoller	12	OS	Stroke. 2012 Feb 2. [Epub ahead of print]	AS126
853	Determinants of racial/ethnic disparities in incidence of diabetes in postmenopausal women in the U.S.: The Women's Health Initiative 1993-2009	Ma, Hebert, Manson, Balasubramanian, Liu, LaMonte, Ockene, Qiao, Olendzki, Schneider, Bird, Rosal, Wactawski-Wende, Stefanick, Phillips, Sepavich, et al.	12	Gen	Diabetes Care. 2012 Jul 25. [E-pub ahead of print]	
872	Improvement in stroke risk prediction: role of C-reactive protein and lipoprotein-associated phospholipase A(2) in the Women's Health Initiative	Wassertheil-Smoller, McGinn, Allison, Cai, Curb, Eaton, Hendrix, Kaplan, Ko, Martin, Xue	12	OS	Int J Stroke. 2012 Oct 23. [Epub ahead of print]	AS126

Table 14.2 (continued)
Publications since October 2011

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
876	A prospective study of serum 25-hydroxyvitamin D levels, blood pressure, and incident hypertension in postmenopausal women	Margolis, Martin, Ray, Kerby, Allison, Curb, Kotchen, Liu, Wassertheil-Smoller, Manson	12	CT	Am J Epidemiol. 2012 Jan 1;175(1):22-32. Epub 2011 Nov 29	W15, W24
877	Diabetes, metformin, and breast cancer in postmenopausal women	Chlebowski, McTiernan, Wactawski-Wende, Manson, Aragaki, Rohan, Ipp, Kaklamani, Vitolins, Wallace, Gunter, Phillips, Strickler, Margolis, Euhus	12	Gen	J Clin Oncol. 2012 Jun 11. [Epub ahead of print]	
878	Prospective association of vitamin D concentrations with mortality in postmenopausal women: results from the Women's Health Initiative (WHI)	Eaton, Young, Allison, Robinson, Martin, Kuller, Johnson, Curb, Van Horn, McTiernan, Liu, Manson	12	Gen	Am J Clin Nutr. 2011 Oct 26. [Epub ahead of print]	AS181, W15, W24
885	Predictors of change in pain and physical functioning among post-menopausal women with recurrent pain conditions in the Women's Health Initiative Observational Cohort	Brennan Braden, Young, Sullivan, Walitt, LaCroix, Martin	12	OS	J Pain. 2012 Jan;13(1):64-72	
887	Racial and ethnic differences in incident hospitalized heart failure in post menopausal Women: The Women's Health Initiative	Eaton, Abdulbaki, Margolis, Manson, Limacher, Klein, Allison, Robinson, Curb, Martin, Liu, Howard	12	Gen	Circulation. 2012 July 2. [Epub ahead of print]	
897	Hip geometry in diabetic women: implications for fracture risk	Garg, Chen, Beck, Cauley, Wu, Nelson, Lewis, LaCroix, LeBoff	12	OS	Metabolism. 2012 Jun 20. [Epub ahead of print]	AS153
916	Hormone therapy, estrogen metabolism, and risk of breast cancer in the Women's Health Initiative Hormone Therapy Trial	Mackey, Fanelli, Modugno, Cauley, McTigue, Brooks, Chlebowski, Manson, Klug, Kip, Curb, Kuller	12	CT	Cancer Epidemiol Biomarkers Prev. 2012 Aug 29. [Epub ahead of print]	BAA12
922	Adipokines linking obesity with colorectal cancer risk in postmenopausal women	Ho, Gunter, Kaplan, Rajpathak, Rohan, Wassertheil-Smoller, Strickler, Xue, Wang, Cushman, Scherer, Vitolins, Chlebowski	12	OS	Cancer Res. 2012 Jun 15;72(12):3029-37. Epub 2012 Apr 17	BAA10
941	Biomarker-calibrated dietary energy and protein intake associations with diabetes risk among postmenopausal women from the Women's Health Initiative	Tinker, Sarto, Howard, Huang, Neuhouser, Mossavar-Rahmani, Beasley, Margolis, Eaton, Phillips, Prentice	12	Gen	Am J Clin Nutr. 2011 Dec;94(6):1600-6. Epub 2011 Nov 9	W8
944	Trans fat, aspirin, and ischemic stroke in postmenopausal women	Yaemsiri, Sen, Tinker, Rosamond, Wassertheil-Smoller, He	12	OS	Ann Neurol. 2012 March 1 [Epub ahead of print]	AS126, AS187

Table 14.2 (continued)
Publications since October 2011

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
946	Impact of nutritional factors on incident kidney stone formation: A report from the WHI OS	Sorensen, Kahn, Reiner, Tseng, Shikany, Wallace, Chi, Wactawski-Wende, Jackson, O'Sullivan, Sadetsky, Stoller	12	Gen	J Urol. 2012 Mar 14. [Epub ahead of print]	
957	Antidepressant use, depressive symptoms, and incident frailty in women aged 65 and older from the Women's Health Initiative Observational Study	Lakey, LaCroix, Gray, Borson, Williams, Calhoun, Goveas, Smoller, Ockene, Masaki, Coday, Rosal, Woods	12	OS	J Am Geriatr Soc. 2012 May;60(5):854-61. Epub 2012 May 9	
984	Genome-wide meta-analyses of smoking behaviors in African Americans	David, Hamidovic, Chen, Bergen, Wessel, Kasberger, Brown, Petruzella, Thacker, Kim, Nalls, Tranah, Sung, Ambrosone, Arnett, Bandera, et al.	12	Gen	Transl Psychiatry. 2012 May 22;2:e119	M5
992	Psychological and social characteristics associated with religiosity in Women's Health Initiative participants	Schnall, Kalkstein, Fitchett, Salmoirago-Blotcher, Ockene, Tindle, Thomas, Hunt, Wassertheil-Smoller	12	OS	J Relig Health. 2012 Mar;51(1):20-31. Epub 2011 Nov 9	
1015	Genome-wide association study of body height in African-Americans: the Women's Health Initiative SNP Health Association Resource (SHARe)	Carty, Johnson, Hutter, Reiner, Peters, Tang, Kooperberg	12	Gen	Hum Mol Genet. 2011 Oct 21. [Epub ahead of print]	M5
1051	Vitamin D supplementation and depression in the Women's Health Initiative Calcium and Vitamin D Trial	Bertone-Johnson, Powers, Spangler, Larson, Michael, Millen, Bueche, Salmoirago-Blotcher, Wassertheil-Smoller, Brunner, Ockene, Ockene, Liu, Manson	12	CT	Am J Epidemiol. 2012 May 9. [Epub ahead of print]	
1063	Vitamin D and calcium supplementation and one-year change in mammographic density in the Women's Health Initiative Calcium and Vitamin D Trial	Bertone-Johnson, McTiernan, Thomson, Wactawski-Wende, Aragaki, Rohan, Vitolins, Tamimi, Johnson, Lane, Rexrode, Peck, Chlebowski, Sarto, Manson	12	CT	Cancer Epidemiol Biomarkers Prev. 2012 Jan 17. [Epub ahead of print]	
1073	Associations between incident ischemic stroke events and stroke and cardiovascular disease-related GWAS SNPs in the Population Architecture Using Genomics and Epidemiology (PAGE) Study	Carty, Buzkova, Fornage, Franceschini, Cole, Heiss, Hindorff, Howard, Mann, Martin, Zhang, Matise, Prentice, Reiner, Kooperberg	12	Gen	Circ Cardiovasc Genet. 2012 Mar 8. [Epub ahead of print]	M6
1079	Toward a positive aging phenotype for older women: Observations from the Women's Health Initiative	Woods, Cochrane, LaCroix, Seguin, Zaslavsky, Liu, Beasley, Brunner, Espeland, Goveas, Lane, Manson, Mouton, Robinson, Tinker	12	Gen	J Gerontol A Biol Sci Med Sci. 2012 Nov;67(11):1191-6. Epub 2012 Apr 19	

Table 14.2 (continued)
Publications since October 2011

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
1086	Evaluating breast cancer risk projections for Hispanic women	Banegas, Gail, LaCroix, Thompson, Martinez, Wactawski-Wende, John, Hubbell, Yasmeen, Katki	12	Gen	Breast Cancer Res Treat. 2011 Dec 7. [Epub ahead of print]	
1091	Hazard ratio estimation for biomarker-calibrated dietary intake exposures	Shaw, Prentice	12	CT	Biometrics. 2012 Jun;68(2):397-407. Epub 2011 Oct 17	
1114	Tissue factor pathway inhibitor, activated protein C resistance, and risk of ischemic stroke due to postmenopausal hormone therapy	Rossouw, Johnson, Pettinger, Cushman, Sandset, Kuller, Rosendaal, Rosing, Wassertheil-Smoller, Martin, Manson, Lakshminarayan, Merino, Lynch	12	CT	Stroke. 2012 Feb 23. [Epub ahead of print]	W11, W14
1117	Breast tenderness and breast cancer risk in the estrogen plus progestin and estrogen-alone Women's Health Initiative Clinical Trials	Crandall, Aragaki, Cauley, McTiernan, Manson, Anderson, Chlebowski	12	CT	Breast Cancer Res Treat. 2012 Feb;132(1):275-85. Epub 2011 Nov 1	
1129	Calcium and vitamin D supplementation and incident rheumatoid arthritis: the Women's Health Initiative Calcium plus Vitamin D trial	Racovan, Walitt, Collins, Pettinger, Parks, Shikany, Wactawski-Wende, Manson, Moreland, Wright, Jackson, Howard	12	CT	Rheumatol Int. 2011 Dec 22. [Epub ahead of print]	
1135	The influence of health and lifestyle characteristics on the relation of serum 25-Hydroxyvitamin D with risk of colorectal and breast cancer in postmenopausal women	Neuhouser, Manson, Millen, Pettinger, Margolis, Jacobs, Shikany, Vitolins, Adams-Campbell, Liu, LeBlanc, Johnson, Wactawski-Wende	12	CT	Am J Epidemiol. 2012 Feb 22. [Epub ahead of print]	
1136	Conjugated equine oestrogen and breast cancer incidence and mortality in postmenopausal women with hysterectomy: extended follow-up of the Women's Health Initiative randomised placebo-controlled trial	Anderson, Kuller, Hubbell, Lane, Bluhm, Wactawski-Wende, Manson, Ockene, Martin, Gass, Schenken, Chlebowski, Connelly, Rohan	12	CT	Lancet Oncol. 2012 Mar 6. [Epub ahead of print]	
1138	Estrogen plus progestin and colorectal cancer incidence and mortality	Simon, Chlebowski, Wactawski-Wende, Johnson, Muscovitz, Kato, Young, Hubbell, Prentice	12	Gen	J Clin Oncol. 2012 Sep 24. [Epub ahead of print]	
1143	Sedentary behavior and physical function decline in older women: findings from the Women's Health Initiative	Seguin, LaMonte, Tinker, Liu, Woods, Michael, Bushnell, LaCroix	12	OS	J Aging Res. 2012;2012:271589. Epub 2012 May 21	

Table 14.2 (continued)
Publications since October 2011

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
1150	Cognitive function and retinal and ischemic brain changes: The Women's Health Initiative	Haan, Espeland, Klein, Casanova, Gaussoin, Jackson, Millen, Resnick, Rossouw, Shumaker, Wallace, Yaffe	12	CT	Neurology. 2012 Mar 14. [Epub ahead of print]	AS183, AS39, AS62
1151	Dietary patterns are associated with disease risk among participants in the Women's Health Initiative Observational Study	Van Horn, Tian, Neuhouser, Howard, Eaton, Snetselaar, Matthan, Lichtenstein	12	OS	J Nutr. 2012 Feb;142(2):284-91. Epub 2011 Dec 21	BAA8
1156	Depressive symptoms, antidepressant use, and future cognitive health in postmenopausal women: the Women's Health Initiative Memory Study	Goveas, Hogan, Kotchen, Smoller, Denburg, Manson, Tummala, Mysiw, Ockene, Woods, Espeland, Wassertheil-Smoller	12	WHIMS	Int Psychogeriatr. 2012 Feb 3:1-13. [Epub ahead of print]	AS39
1163	Shorter telomeres associate with a reduced risk of melanoma development	Nan, Du, De Vivo, Manson, Liu, McTiernan, Curb, Lessin, Bonner, Guo, Qureshi, Hunter, Han	12	OS	Cancer Res. 2011 Oct 25. [Epub ahead of print]	AS242
1164	Pre-diagnosis biomarkers of insulin-like growth factor-1, insulin, and interleukin-6 dysregulation and multiple myeloma risk in the Multiple Myeloma Cohort Consortium.	Birmann, Neuhouser, Rosner, Albanes, Buring, Giles, Lan, Lee, Purdue, Rothman, Severi, Yuan, Anderson, Pollak, Yuan, Landgren, et al.	12	Gen	Blood. 2012 Oct 16. [Epub ahead of print]	AS207
1170	Association of genetic variants and incident coronary heart disease in multiethnic cohorts: The PAGE Study	Franceschini, Carty, Buzkova, Reiner, Garrett, Hindorff, Cole, Boerwinkle, Lin, Bookman, Best, Bella, Eaton, Greenland, Jenny, Lin, et al.	12	Gen	Circ Cardiovasc Genet. 2011 Dec 1;4(6):661-672. Epub 2011 Oct 31	M6
1173	Quantifying mediating effects of endogenous estrogen and insulin in the relation between obesity, alcohol consumption and breast cancer	Hvidtfeldt, Gunter, Lange, Chlebowski, Lane, Farhat, Freiberg, Keiding, Lee, Prentice, Tjønneland, Vitolins, Wassertheil-Smoller, Strickler, Rod	12	OS	Cancer Epidemiol Biomarkers Prev. 2012 May 7. [Epub ahead of print]	AS129, AS167, BAA21
1182	Plasma 25-Hydroxyvitamin D and risk of pancreatic cancer	Wolpin, Ng, Bao, Kraft, Stampfer, Michaud, Ma, Buring, Sesso, Lee, Rifai, Cochrane, Wactawski-Wende, Chlebowski, Willett, Manson, et al.	12	OS	Cancer Epidemiol Biomarkers Prev. 2012 Jan;21(1):82-91. Epub 2011 Nov 15	AS214
1189	Statin use and risk of diabetes mellitus in postmenopausal women in the Women's Health Initiative	Culver, Ockene, Balasubramanian, Olendzki, Sepavich, Wactawski-Wende, Manson, Qiao, Liu, Merriam, Rahilly-Tierny, Thomas, Berger, Ockene, Curb, Ma, et al.	12	Gen	Arch Intern Med. 2012 Jan 10. [Epub ahead of print]	

Table 14.2 (continued)
Publications since October 2011

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
1211	Diabetes mellitus as a risk factor for gastrointestinal cancers among postmenopausal women	Luo, Chlebowski, Liu, McGlynn, Parekh, White, Margolis	12	Gen	Cancer Causes Control. 2012 May 24. [Epub ahead of print]	
1224	A prospective study of leukocyte telomere length and risk of type 2 diabetes in postmenopausal women	You, Chen, Song, Lu, Chen, Manson, Kang, Howard, Margolis, Curb, Phillips, Stefanick, Tinker, Liu	12	OS	Diabetes. 2012 Jul 24. [Epub ahead of print]	AS254
1242	Consistent directions of effect for established type 2 diabetes risk variants across populations: The Population Architecture using Genomics and Epidemiology (PAGE) Consortium	Haiman, Fesinmeyer, Spencer, Buzkova, Voruganti, Wan, Haessler, Franceschini, Monroe, Howard, Jackson, Florez, Kolonel, Buyske, Goodloe, Liu, et al.	12	Gen	Diabetes. 2012 Jun;61(6):1642-7. Epub 2012 Apr 3	M6
1245	Fine-mapping and initial characterization of QT interval loci in African Americans	Avery, Sethupathy, Buyske, He, Lin, Anderson, Arking, Duggan, Fox, Deelman, Fesinmeyer, Hindorff, Jeff, Klein, Patton, Shohet, et al.	12	Gen	2012 Aug 9. PLoS Genetics 8(8): e1002870	M6
1261	Smoking and alcohol consumption in relation to risk of thyroid cancer in postmenopausal women	Kabat, Kim, Wactawski-Wende, Rohan	12	Gen	Cancer Epidemiol. 2012 Apr 4. [Epub ahead of print]	
1262	Anthropometric factors and physical activity and risk of thyroid cancer in postmenopausal women	Kabat, Kim, Thomson, Luo, Wactawski-Wende, Rohan	12	Gen	Cancer Causes Control. 2012 Jan 3. [Epub ahead of print]	
1272	Comparison of the Framingham and Reynolds Risk Scores for global cardiovascular risk prediction in the multiethnic Women's Health Initiative	Cook, Paynter, Eaton, Manson, Martin, Robinson, Rossouw, Wassertheil-Smoller, Ridker	12	OS	2012 Apr 10;125(14):1748-56, S1-11. Epub 2012 Mar 7	BAA22
1277	Vitamin D with calcium reduces mortality: patient level pooled analysis of 70,528 patients from eight major vitamin D trials	Rejnmark, Avenell, Masud, Anderson, Meyer, Sanders, Salovaara, Cooper, Smith, Jacobs, Torgerson, Jackson, Manson, Brixen, Mosekilde, Robbins, et al.	12	CT	J Clin Endocrinol Metab. 2012 May 17. [Epub ahead of print]	
1279	Intake of antioxidant nutrients and risk of Non-Hodgkin's lymphoma in the Women's Health Initiative	Kabat, Kim, Wactawski-Wende, Shikany, Vitolins, Rohan	12	Gen	Nutr Cancer. 2012 Jan 2. [Epub ahead of print]	
1287	Alcohol consumption and body weight change in postmenopausal women: results from the Women's Health Initiative	Thomson, Wertheim, Hingle, Wang, Neuhouser, Gong, Garcia, Stefanick, Manson	12	Gen	Int J Obes (Lond). 2012 Jun 12. [Epub ahead of print]	

Table 14.2 (continued)
Publications since October 2011

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
1292	The association of red blood cell n-3 and n-6 fatty acids to dietary fatty acid intake, bone mineral density and hip fracture risk in The Women's Health Initiative	Orchard, Ing, Lu, Belury, Johnson, Wactawski-Wende, Jackson	12	Gen	Miner Res. 2012 Sep 27. [Epub ahead of print]	AS271
1296	The association between NSAID use and colorectal cancer mortality: Results from the Women's Health Initiative	Coghill, Phipps, Bavry, Wactawski-Wende, Lane, LaCroix, Newcomb	12	Gen	Cancer Epidemiol Biomarkers Prev. 2012 Aug 29. [Epub ahead of print]	
1300	Relationships of coronary heart disease with 27-hydroxycholesterol, low density lipoprotein cholesterol, and menopausal hormone therapy	Rossouw, Prentice, Manson, Aragaki, Hsia, Martin, Kuller, Johnson, Eaton, Jackson, Trevisan, Allison, Hoogeveen	12	CT	Circulation. 2012 Aug 29. [Epub ahead of print]	W39
1311	Association between annual visit-to-visit blood pressure variability and stroke in postmenopausal women: Data from the Women's Health Initiative	Shimbo, Newman, Aragaki, LaMonte, Bavry, Allison, Manson, Wassertheil-Smoller	12	Gen	Hypertension. 2012 Jul 2. [Epub ahead of print]	
1314	Estimating kinship in admixed populations.	Thornton, Tang, Hoffmann, Ochs-Balcom, Caan, Risch	12	CT	Am J Hum Genet. 2012 Jul 13;91(1):122-38. Epub 2012 Jun 28	M5
1315	Relationship between diabetes risk and admixture in postmenopausal African American and Hispanic American women	Qi, Nassir, Kosoy, Garcia, Curb, Tinker, Howard, Robbins, Seldin	12	Gen	Diabetologia. 2012 Feb 10. [Epub ahead of print]	BAA1
1316	Replication of loci influencing ages at menarche and menopause in Hispanic women: the Women's Health Initiative SHARe study	Chen, Rhodes, Brzyski, Carlson, Chen, Heiss, North, Woods, Rajkovic, Kooperberg, Franceschini	12	Gen	Hum Mol Genet. 2011 Nov 30. [Epub ahead of print]	M5
1317	Mortality risk associated with bundle branch blocks and related repolarization abnormalities (from the Women's Health Initiative [WHI])	Zhang, Rautaharju, Soliman, Manson, Cain, Martin, Bavry, Mehta, Vitolins, Prineas	12	CT	Am J Cardiol. 2012 Aug 1. [Epub ahead of print]	
1322	Diabetes and lung cancer among postmenopausal women	Luo, Chlebowski, Wactawski-Wende, Schlecht, Tinker, Margolis	12	Gen	Diabetes Care. 2012 May 22. [Epub ahead of print]	
1344	Smoking cessation, weight gain, and risk of type 2 diabetes mellitus among post-menopausal women	Luo, Rossouw, Tong, Giovino, Lee, Chen, Ockene, Qi, Margolis	12	Gen	Arch Intern Med. 2012;172(5):438-440	
1349	HNF1B and endometrial cancer risk: Results from the PAGE study	Setiawan, Haessler, Schumacher, Cote, Deelman, Fesinmeyer, Henderson, Jackson, Vöckler, Wilkens, Yasmeen, Haiman, Peters, Le Marchand, Kooperberg	12	Gen	PLoS ONE. 2012 Jan 27;7(1):e30390	M6

Table 14.2 (continued)
Publications since October 2011

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
1353	Boosting for detection of gene-environment interactions	Pashova, LeBlanc, Kooperberg	12	Gen	Stat Med. 2012 Jul 5. [Epub ahead of print]	M6
1356	A meta-analysis and genome-wide association study of platelet count and mean platelet volume in African Americans	Qayyum, Snively, Ziv, Nalls, Liu, Tang, Yanek, Lange, Evans, Ganesh, Austin, Lettre, Becker, Zonderman, Singleton, Harris, et al.	12	Gen	PLoS Genetics. 2012 Mar;8(3):e1002491. Epub 2012 Mar 8	M5
1358	Intraindividual variation in plasma 25-hydroxyvitamin D measures 5 years apart among postmenopausal women	Meng, Hovey, Wactawski-Wende, Andrews, LaMonte, Horst, Genco, Millen	12	OS	Cancer Epidemiol Biomarkers Prev. 2012 Apr 20. [Epub ahead of print]	AS15
1365	Menstrual and reproductive factors, exogenous hormone use, and risk of thyroid carcinoma in postmenopausal women.	Kabat, Kim, Wactawski-Wende, Lane, Wassertheil-Smoller, Rohan	12	Gen	Cancer Causes Control. 2012 Oct 23. [Epub ahead of print]	
1374	Markers of b-cell activation in relation to risk of non-Hodgkin lymphoma	De Roos, Mirick, Edlefsen, LaCroix, Kopecky, Madeleine, Magpantay, Martinez-Maza	12	OS	Cancer Res. 2012 Jul 30. [Epub ahead of print]	BAA13
1380	Genetic risk factors for body mass index and obesity in an ethnically diverse population: results from the Population Architecture using Genomics and Epidemiology (PAGE) Study	Fesinmeyer, North, Ritchie, Lim, Franceschini, Wilkens, Gross, Buzkova, Glenn, Quibrera, Fernández-Rhodes, Li, Fowke, Li, Carlson, Prentice, et al.	12	Gen	Obesity (Silver Spring). 2012 Jun 22. [Epub ahead of print]	M6
1381	Using regression calibration equations that combine self-reported intake and biomarker measures to obtain unbiased estimates and more powerful tests of dietary associations	Freedman, Midthune, Carroll, Tasevska, Schatzkin, Mares, Tinker, Potischman, Kipnis	12	OS	Am J Epidemiol. 2011 Nov 1. [Epub ahead of print]	AS105
1387	Social networks, social support and burden in relationships, and mortality after breast cancer diagnosis	Kroenke, Michael, Tindle, Gage, Chlebowski, Garcia, Messina, Manson, Caan	12	CT	Breast Cancer Res Treat. 2012 Feb 14. [Epub ahead of print]	
1400	A longitudinal study of serum insulin and glucose levels in relation to colorectal cancer risk among postmenopausal women	Kabat, Kim, Strickler, Shikany, Lane, Luo, Ning, Gunter, Rohan	12	CT	Br J Cancer. 2011 Nov 29. doi: 10.1038/bjc.2011.512. [Epub ahead of print]	
1402	Repeated measurements of serum carotenoid, retinol and tocopherol levels in relation to colorectal cancer risk in the Women's Health Initiative	Kabat, Kim, Sarto, Shikany, Rohan	12	Gen	Eur J Clin Nutr. 2011 Dec 14. [Epub ahead of print]	

Table 14.2 (continued)
Publications since October 2011

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
1423	Genotype imputation of metabochipSNPs using a study-specific reference panel of ~4,000 haplotypes in African Americans from the Women's Health Initiative	Liu, Buyske, Aragaki, Peters, Boerwinkle, Carlson, Carty, Crawford, Haessler, Hindorff, Le Marchand, Manolio, Matise, Wang, Kooperberg, North, et al.	12	Gen	Genet Epidemiol. 2012 Feb;36(2):107-17	M5, M6
1447	Breast tenderness after initiation of conjugated equine estrogens and mammographic density change	Crandall, Aragaki, Cauley, McTiernan, Manson, Anderson, Wactawski-Wende, Chlebowski	12	CT	Breast Cancer Res Treat. 2012 Feb;131(3):969-79. Epub 2011 Oct 7	AS36
1450	Migraine history, nonsteroidal anti-inflammatory drug use, and risk of postmenopausal endometrial cancer	Phipps, Anderson, Cochrane, Li, Wactawski-Wende, Ho, O'Sullivan, Newcomb	12	Gen	Horm Cancer. 2012 Jul 24. [Epub ahead of print]	
1452	Sex hormone-binding globulin and risk of clinical diabetes in American Black, Hispanic, and Asian/Pacific Islander postmenopausal women	Chen, Brennan, Goto, Song, Aziz, You, Wellons, Manson, White, Butch, Liu	12	OS	Clin Chem. 2012 Aug 20. [Epub ahead of print]	AS238
1453	Smoking and genetic risk variation across populations of European, Asian, and African American ancestry - a meta-analysis of chromosome 15q25	Chen, Saccone, Culverhouse, Bracci, Chen, Dueker, Han, Huang, Jin, Kohno, Ma, Przybeck, Sanders, Smith, Sung	12	Gen	Genet Epidemiol. 2012 May;36(4):340-51	M5
1457	Effects of a dietary intervention and weight change on vasomotor symptoms in the Women's Health Initiative	Kroenke, Caan, Stefanick, Anderson, Brzyski, Johnson, LeBlanc, Lee, LaCroix, Park, Sims, Vitolins, Wallace	12	CT	Menopause. 2012 Jul 9. [Epub ahead of print]	
1466	Developing a dimensional model for successful cognitive and emotional aging	Vahia, Thompson, Depp, Allison, Jeste	12	CT	Int Psychogeriatr. 2011 Nov 4:1-9. [Epub ahead of print]	
1468	A longitudinal study of the metabolic syndrome and risk of colorectal cancer in postmenopausal women	Kabat, Kim, Peters, Stefanick, Hou, Wactawski-Wende, Messina, Shikany, Rohan	12	Gen	Eur J Cancer Prev. 2012 Jul;21(4):326-332. Epub 2011 Oct 31	
1470	Recreational physical activity, body mass index and survival in women with colorectal cancer	Kuiper, Phipps, Neuhouser, Chlebowski, Thomson, Irwin, Lane, Wactawski-Wende, Hou, Jackson, Kampman, Newcomb	12	Gen	Cancer Causes Control. 2012 Sep 18. [Epub ahead of print]	
1473	Changes in vitamin D supplement use and baseline plasma 25-hydroxyvitamin D concentration predict 5-y change in concentration in postmenopausal women	Kluczynski, Wactawski-Wende, Platek, DeNysschen, Hovey, Millen	12	OS	J. Nutr. September 1, 2012 vol. 142 no. 9 1705-1712	AS304

Table 14.2 (continued)
Publications since October 2011

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
1476	Social influences on smoking in middle-aged and older women	Holahan, Holahan, Powers, North, Hayes, Ockene	12	OS	Psychol Addict Behav. 2011 Oct 17. [Epub ahead of print]	
1486	A novel variational Bayes multiple locus Z-statistic for genome-wide association studies with Bayesian model averaging	Logsdon, Carty, Reiner, Dai, Kooperberg	12	Gen	Bioinformatics. 2012 May 4. [Epub ahead of print]	M5
1496	Clinical utility of lipoprotein-associated phospholipase A2 for cardiovascular disease prediction in a multiethnic cohort of women	Cook, Paynter, Manson, Martin, Robinson, Wassertheil-Smoller, Ridker	12	OS	Clin Chem. 2012 Aug 2. [Epub ahead of print]	BAA22
1507	The aromatase gene (CYP19A1) variants and circulating hepatocyte growth factor in postmenopausal women	Lin, Gunter, Manson, Rexrode, Cook, Kraft, Cochrane, Chlebowski, Ho, Zhang	12		PLoS One. 2012;7(7):e42079. Epub 2012 Jul 25	AS152, AS192, BAA10
1508	The interleukin-6 receptor as a target for prevention of coronary heart disease: a mendelian randomisation analysis	Swerdlow, Keating, Wilson, Robinson, Bielinski, Tang, Hoogeveen, Pankow, Gross, Jacobs, Green, Lange, Tracy, Durda, Smith	12	CT	Lancet. 2012 Mar 13. [Epub ahead of print]	BAA14
1518	Influence of type 2 diabetes on brain volumes and changes in brain volumes: Results from the Women's Health Initiative Magnetic Resonance Imaging Studies	Espeland, Bryan, Goveas, Robinson, Siddiqui, Liu, Hogan, Casanova, Coker, Yaffe, Masaki, Rossom, Resnick	12	Gen	Diabetes Care. 2012 Aug 29. [Epub ahead of print]	AS183
1558	Correcting the effects of -20°C storage and aliquot size on erythrocyte fatty acid content in the Women's Health Initiative	Pottala, Espeland, Polreis, Robinson, Harris	12	CT	Lipids. 2012 Sep;47(9):835-46. Epub 2012 Jul 11	AS39, BAA19
1576	Simultaneously testing for marginal genetic association and gene-environment interaction	Dai, Logsdon, Huang, Hsu, Reiner, Prentice, Kooperberg	12	N/A	Am J Epidemiol. 2012 Jul 6. [Epub ahead of print]	
1582	Characterization of gene-environment interactions for colorectal cancer susceptibility loci	Hutter, Chang-Claude, Slattery, Pflugeisen, Lin, Duggan, Nan, Lemire, Rangrej, Figueiredo, Jiao, Harrison, Liu, Chen, Stelling, Warnick, et al.	12	Gen	Cancer Res. 2012 Feb 24. [Epub ahead of print]	AS224
1641	Five year changes in periodontal disease measures among postmenopausal women. The Buffalo Osteo-Perio Study.	LaMonte, Hovey, Genco, Millen, Trevisan, Wactawski-Wende	12	OS	J Periodontol. 2012 Jul 19. [Epub ahead of print]	AS98
1653	Exploring the interaction between SNP genotype and postmenopausal hormone therapy effects on stroke risk	Huang, Ballinger, Stokowski, Beilarz, Robinson, Liu, Robinson, Henderson, Rossouw, Prentice	12	Gen	Genome Med. 2012 Jul 13;4(7):57. [Epub ahead of print]	W7

Table 14.2 (continued)
Publications since October 2011

MS ID	Title	Authors	Stage	Data Focus	Reference	Study #
1676	Caution in reinterpreting the Women's Health Initiative (WHI) Calcium and Vitamin D Trial breast cancer results	Chlebowski, Pettinger, Kooperberg	12	N/A	Am J Clin Nutr. 2012 Jan;95(1):258-9	
1678	Genome-wide association and population genetic analysis of C-reactive protein in African American and Hispanic American women	Reiner, Beleza, Franceschini, Auer, Robinson, Kooperberg, Peters, Tang	12	Gen	Am J Hum Genet. 2012 Aug 28. [Epub ahead of print]	M5
1682	Evolution and functional impact of rare coding variation from deep sequencing of human exomes	Tennessen, Bigham, O'Connor, Fu, Kenny, Gravel, McGee, Do, Liu, Jun, Kang, Jordan, Leal, Gabriel, Rieder, Abecasis, et al.	12		Science. 2012 Jul 6;337(6090):64-9. Epub 2012 May 17	M24
1705	Smoking status, physical health-related quality of life, and mortality in middle-aged and older women	Holahan, Holahan, North, Hayes, Powers, Ockene	12	OS	Nicotine Tob Res. 2012 Sep 10. [Epub ahead of print]	
1745	Concordant release of glycolysis proteins into the plasma preceding a diagnosis of ER+ breast cancer	Amon, Pitteri, Li, McIntosh, Ladd, Disis, Porter, Wong, Zhang, Lampe, Prentice, Hanash	12	OS	Cancer Res. 2012 Feb 24. [Epub ahead of print]	BAA22
1760	Changing concepts: Menopausal hormone therapy and breast cancer	Chlebowski, Anderson	12	N/A	J Natl Cancer Inst. 2012 Mar 16. [Epub ahead of print]	
1782	Discovery and preliminary confirmation of novel early detection biomarkers for triple-negative breast cancer using preclinical plasma samples from the Women's Health Initiative observational study	Li, Mirus, Zhang, Ramirez, Ladd, Prentice, McIntosh, Hanash, Zhang	12	OS	Breast Cancer Res Treat. 2012 Aug 19. [Epub ahead of print]	AS316, BAA5
1934	Menopausal hormone therapy and coronary heart disease: Reconciling divergent findings from observational studies and clinical trials	Rossouw	12	N/A	Stat Biosci. 2012 Aug 31. [Epub ahead of print]	

Appendix A

Women's Health Initiative

Memory Suite of Studies

2012 Annual Progress Report

Report Date: October 29, 2012

Meeting Date: November 29, 2012

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

Table of Contents

Section 1.

Introduction

Introduction

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

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

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

Materials are drawn from study databases and records in October 2012 to provide an up-to-date accounting. Live study databases were accessed at time points spanning several weeks so that minor discrepancies may exist across exhibits.

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

WHIMS Coordinating Center
October 29, 2012

Section 2.

Overview of Suite of Studies

The Women's Health Initiative Memory Study (WHIMS)

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

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

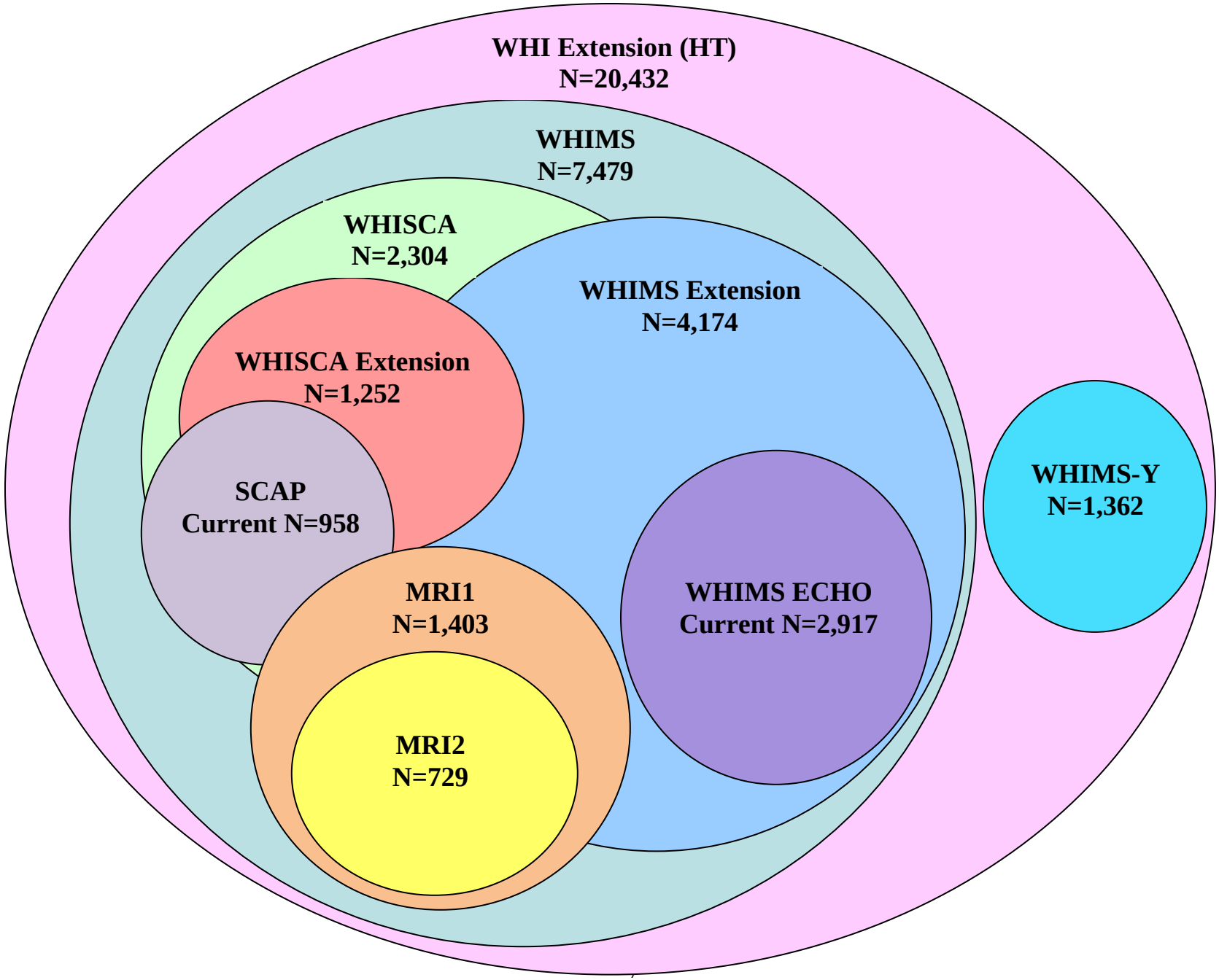
The Women's Health Initiative Memory Study of Younger Women (WHIMS-Y)

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

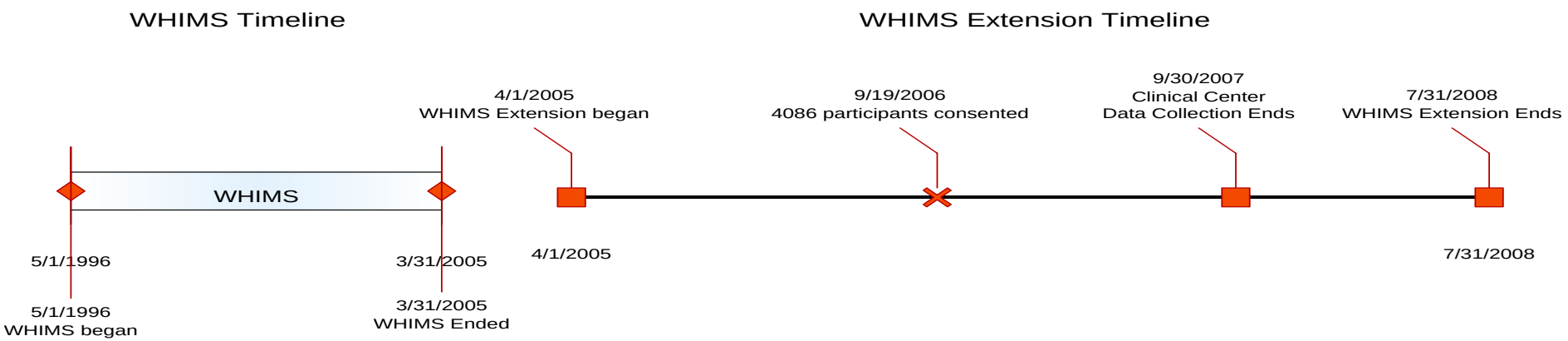
The Women's Health Initiative Study of Cognitive Aging (WHISCA) Extension

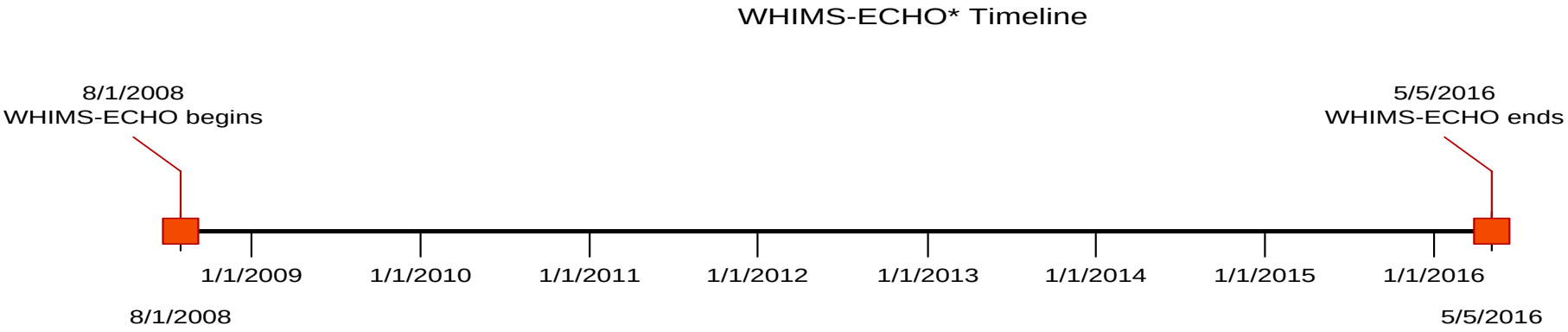
The Women's Health Initiative Memory Study of Cerebral Magnetic Resonance Imaging (WHIMS-MRI-1+2)

2.1 Relationships Among Study Cohorts



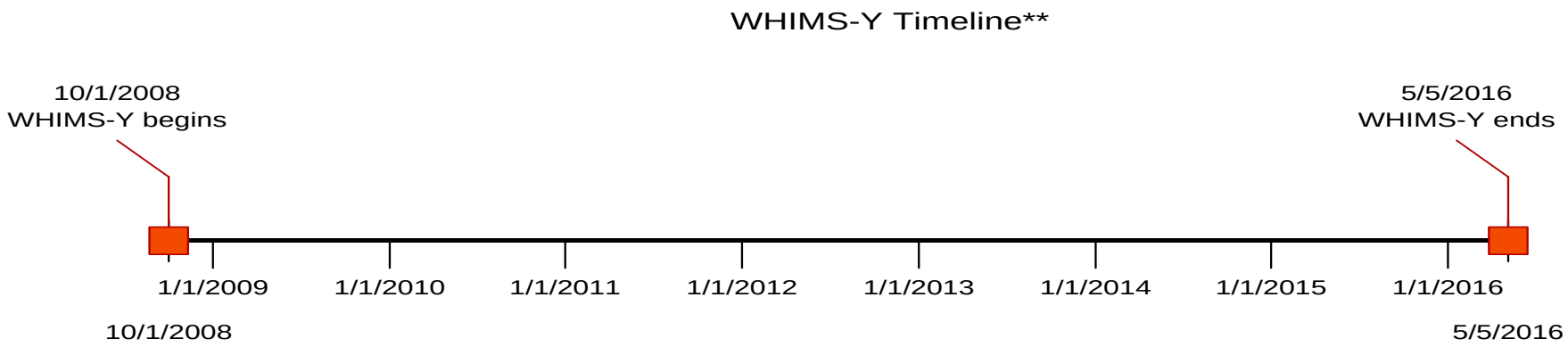
2.2 Timelines for the WHIMS, WHIMS Extension, WHIMS-ECHO, WHIMS-MRI, WHIMS-MRI2, WHISCA, WHISCA Extension, and WHIMS-Y Studies



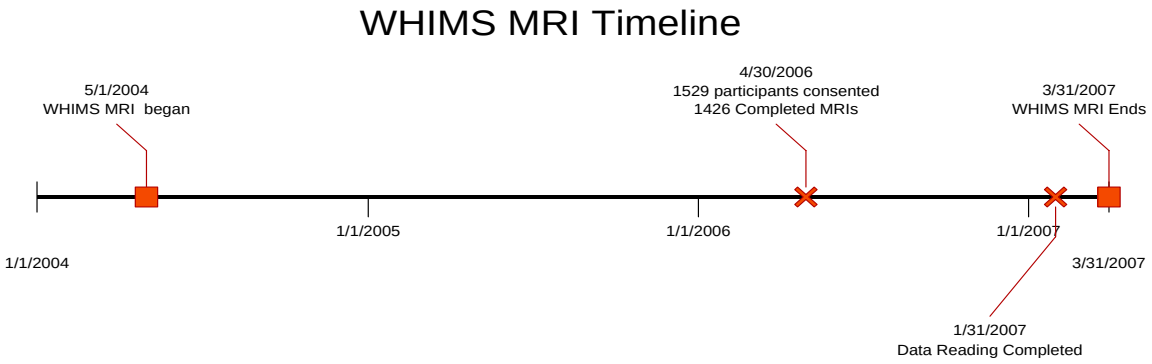


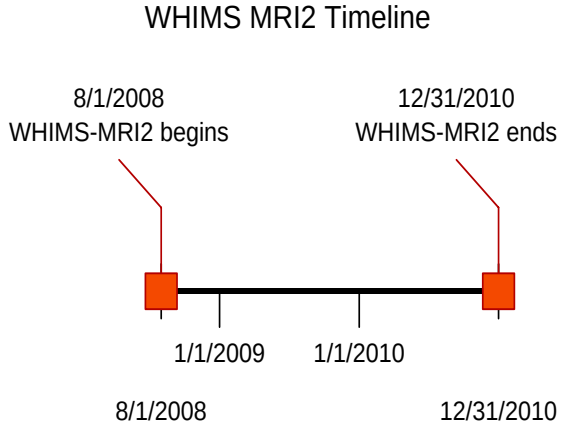
**Funding for WHIMS-ECHO: 8/1/2008-5/5/2011 – NHLBI
5/5/2011-5/6/2016 – NIA

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

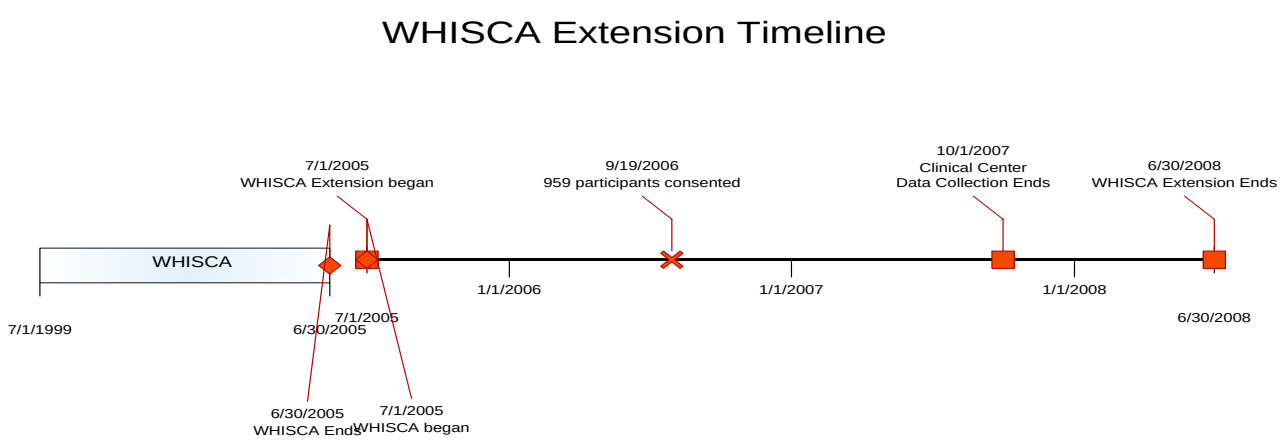


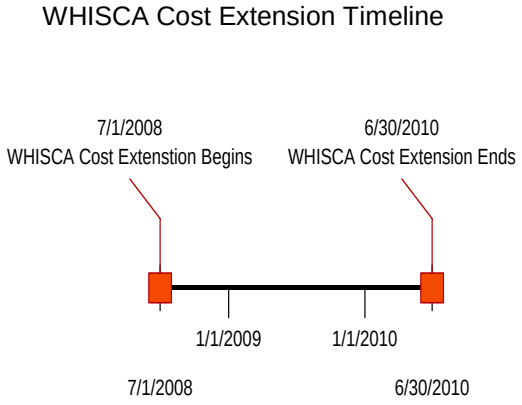
**Funding for WHIMS-Y: 10/1/2008-5/5/2011 – NHLBI
5/6/2011-5/6/2016 – NIA





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





2.3 Studies Objectives

2.3.1 Women's Health Initiative Memory Study (WHIMS)

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

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

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

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

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

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

WHIMS-MRI-1 was a cross-sectional sub-study of 1,403 women who were enrolled in the WHIMS E+P and E-Alone studies. Thirteen of the 14 participating MRI sites were also

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

Section 3.

WHIMS ECHO

3.1 WHIMS ECHO Protocol Summary

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

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

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

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

3.2 WHIMS ECHO Progress Report

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

CoC contact, and 907 declined to release contact information. Of those, 2,917 participants enrolled in the WHIMS ECHO (Table 3.1).

3.3 Enrollment: Overall and by Clinical Site

Table 3-1 WHIMS-ECHO Recruitment Process

	Targeted for enrollment	Agreed to initial contact by WHIMS CoC		Deceased before contacted		Never Reached		Declined to participate		Agreed to participate	
Field Center	Number	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
All Field Centers	***4175***	***3204***	***76.7***	***71***	***1.7***	***62***	***2.0***	***154***	***4.9***	***2917***	***93.1***
11=Davenport	24	20	83.3	0	0.0	1	5.0	1	5.0	18	90.0
12=Birmingham	96	68	70.8	0	0.0	3	4.4	1	1.5	64	94.1
13=Greensboro	21	18	85.7	0	0.0	0	0.0	2	11.1	16	88.9
14=Boston	101	92	91.1	0	0.0	1	1.1	0	0.0	91	98.9
15=Buffalo	117	91	77.8	3	2.6	0	0.0	7	8.0	81	92.0
16=Chicago	5	3	60.0	0	0.0	0	0.0	0	0.0	3	100.0
19=Atlanta	70	58	82.9	3	4.3	1	1.8	5	9.1	49	89.1
20=Chicago-Evanston	13	6	46.2	0	0.0	0	0.0	0	0.0	6	100.0
21=Iowa City	21	18	85.7	1	4.8	0	0.0	1	5.9	16	94.1
23=Pawtucket	109	89	81.7	5	4.6	4	4.8	6	7.1	74	88.1
24=Memphis	45	34	75.6	1	2.2	0	0.0	0	0.0	33	97.1
25=Minneapolis	126	96	76.2	2	1.6	0	0.0	3	3.2	91	96.8
26=Newark	74	57	77.0	1	1.4	1	1.8	3	5.4	52	92.9
27=Phoenix	49	39	79.6	2	4.1	2	5.4	1	2.7	34	91.9
28=Pittsburgh	108	93	86.1	4	3.7	2	2.2	2	2.2	85	95.5
29=Tucson	57	44	77.2	2	3.5	0	0.0	3	7.1	39	92.9
30=Davis	120	83	69.2	1	0.8	2	2.4	5	6.0	75	91.5
42=Stanford	193	146	75.6	3	1.6	1	0.7	6	4.2	136	95.1
43=Milwaukee	148	98	66.2	0	0.0	2	2.0	1	1.0	95	96.9
44=George Wash.	116	94	81.0	2	1.7	1	1.1	3	3.3	88	95.7
45=Honolulu	58	40	69.0	1	1.7	2	5.1	6	15.4	31	79.5
46=Gainesville	101	68	67.3	2	2.0	4	6.1	2	3.0	60	90.9
47=Houston	59	53	89.8	0	0.0	1	1.9	4	7.5	48	90.6
48=Worcester	197	144	73.1	6	3.0	1	0.7	7	5.1	130	94.2
49=New York	165	114	69.1	2	1.2	5	4.5	9	8.0	98	87.5
50=Columbus	139	111	79.9	1	0.7	1	0.9	2	1.8	107	97.3
51=Medlantic	114	89	78.1	1	0.9	3	3.4	6	6.8	79	89.8
53=Oakland	116	92	79.3	4	3.4	2	2.3	2	2.3	84	95.5
54=Jacksonville	62	46	74.2	1	1.6	2	4.4	2	4.4	41	91.1
55=Torrance	24	20	83.3	0	0.0	0	0.0	2	10.0	18	90.0

56=Madison	98	87	88.8	1	1.0	0	0.0	3	3.5	83	96.5
57=Stony Brook	153	118	77.1	1	0.7	0	0.0	5	4.3	112	95.7
58=Chapel Hill	147	126	85.7	2	1.4	1	0.8	14	11.3	109	87.9
59/60=Chicago-Rush	71	49	69.0	1	1.4	0	0.0	0	0.0	48	98.0
61=Cincinnati	118	94	79.7	4	3.4	5	5.6	7	7.8	78	86.7
62=Detroit	63	57	90.5	2	3.2	2	3.6	2	3.6	51	92.7
63=Irvine	87	61	70.1	1	1.1	0	0.0	1	1.7	59	98.3
65=Nevada	112	96	85.7	2	1.8	3	3.2	4	4.3	87	92.6
66=Portland	130	83	63.8	1	0.8	1	1.2	2	2.4	79	96.3
67=San Antonio	38	30	78.9	1	2.6	2	6.9	1	3.4	26	89.7
68=Los Angeles	102	62	60.8	0	0.0	2	3.2	1	1.6	59	95.2
69=Fall River	96	76	79.2	3	3.1	2	2.7	2	2.7	69	94.5
70=Pauline	28	15	53.6	0	0.0	1	6.7	1	6.7	13	86.7
71=Bowman Gray	13	10	76.9	0	0.0	0	0.0	0	0.0	10	100.0
72=New Brunswick	126	101	80.2	2	1.6	1	1.0	8	8.1	90	90.9
73=Des Moines	145	115	79.3	2	1.4	0	0.0	11	9.7	102	89.5

3.4 Overall Status of Last Call Attempts by Year

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

	Year 1		Year 2		Year 3		Year 4		Year 5	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Agreed to participate	2663		238		16		0		0	
---- Cumulative number	2663	100.0	2901	100.0	2917	100.0	2917	100.0	2917	100.0
Lost to follow-up										
---- Deceased	0		62		81		68		5	
---- Withdrew	0		7		91		139		57	
---- Attempts to locate exhausted	0		0		0		0		0	
Due for telephone contact	2663	100.0	2832	97.6	2676	91.7	2469	84.6	2407	82.5

	Year 1		Year 2		Year 3		Year 4		Year 5	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Completed test battery	2615	98.2	2469	87.2	2252	84.2	1641	66.8	27	1.1
Failed after 8 attempts	2	0.1	105	3.7	163	6.1	87	3.5	1	0.0
Declined	2	0.1	88	3.1	165	6.2	113	4.6	4	0.2
Phone disconnected	0	0.0	66	2.3	42	1.6	62	2.5	4	0.2
Unable to locate	0	0.0	10	0.4	8	0.3	3	0.1	0	0.0
Recontact	2	0.1	29	1.0	0	0.0	0	0.0	0	0.0
Hearing impaired	26	1.0	40	1.4	21	0.8	13	0.5	1	0.0
Discontinued	15	0.6	22	0.8	11	0.4	7	0.3	0	0.0
No answer	1	0.0	0	0.0	2	0.1	8	0.3	6	0.3
Left message	0	0.0	1	0.0	2	0.1	14	0.6	6	0.3
Scheduled	0	0.0	1	0.0	4	0.1	57	2.3	19	0.8
Busy	0	0.0	1	0.0	1	0.0	2	0.1	1	0.0
No message	0	0.0	0	0.0	3	0.1	40	1.6	6	0.3
Other	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Not attempted	0	0.0	0	0.0	2	0.1	408	16.6	2298	96.8

3.5 Characteristics of Enrollees

Table 3-3 WHIMS-ECHO Characteristics of Enrollees (N=2917)

Characteristic	N (%)
WHI Treatment Assignment	
E-Alone Placebo	542 (19)
E-Alone	529 (18)
E+P	892 (31)
E+P Placebo	954 (33)
Age at WHI Enrollment	
64-69	1528 (52)
70-74	1027 (35)
75+	362 (12)
Age as of October 1, 2012	
< 80	47 (2)
80-84	1389 (48)
85-89	1093 (37)
90+	388 (13)
Baseline WHIMS 3MS	
Less than 90	99 (3)
90-94	433 (15)
95-100	2327 (81)
Race/Ethnicity	
American Indian/Alaskan native	6 (0)
Asian/Pacific Islander	42 (1)
Black/African American	188 (6)
Hispanic/Latino	46 (2)
White	2591 (89)
Other	44 (2)

3.6 WHIMS ECHO Adjudication

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

available, cases still proceed through the adjudication process. Should adjudicators be unable to classify a case, they are permitted to designate the case as 'unable to classify'.

Pre-classification is used to control the number of cases sent to adjudication. It is based on an algorithm designed to maximize sensitivity and specificity by using responses on items from two sections of the DQ: (a) observed cognitive impairment and (b) impairment of daily functions by cognitive impairment. If (a) and (b) are present, the case is pre-classified as PD; whereas if (a) is present but not (b), then the case is pre-classified as possible MCI; and, if neither (a) nor (b) is present then the case is pre-classified as possible ND. Note when DQ data are not available, the case automatically goes forward to adjudication with all other data (listed below) provided to the adjudicators; PD or MCI cases derived from these women are tracked separately in the analyses.

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

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

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

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

From WHIMS ECHO currently, 1,654 women were eligible for the DQ based on their TICSm scores which were below the study cut-point. Of these, 1,553 progressed to administration of the DQ.

Table 3-4 Dementia Questionnaire Progressions in WHIMS-ECHO

	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	TOTAL
TICS Administrations	2624	2468	2257	1585	4	8938
DQ Progressions	446 (17.0%)	472 (19.1%)	424 (18.8%)	310 (19.6%)	2 (50.0%)	1654 (18.5%)
Withdrawals	28 (6.3%)	28 (5.9%)	9 (2.1%)	0 (0%)	0 (0%)	65 (3.9%)
Missing Proxy information	9 (2.0%)	12 (2.5%)	9 (2.1%)	6 (1.9%)	0 (0%)	36 (2.2%)
Total Eligible DQ Progressions	409 (91.7%)	432 (91.5%)	406 (95.8%)	304 (98.1%)	2 (100%)	1553 (93.9%)

Table 3-5 Dementia Questionnaire Administration in WHIMS-ECHO

Outcome	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	TOTAL
DQ's completed^^	241 (58.9%)	203 (47.0%)	250 (61.6%)	162 (53.3%)	0 (0.0%)	856 (55.1%)
DQ's in process	0 (0.0%)	0 (0.0%)	6 (1.5%)	40 (13.2%)	1 (50.0%)	47 (3.0%)
Phone Disconnected/Unable to locate/Hearing Impaired	23 (5.6%)	26 (6.0%)	26 (6.4%)	10 (3.3%)	0 (0.0%)	85 (5.5%)
Proxy Refused DQ	42 (10.3%)	41 (9.5%)	26 (6.4%)	9 (3.0%)	1 (50.0%)	119 (7.7%)
PD	19 (4.6%)	45 (10.4%)	32 (7.9%)	49 (16.1%)	0 (0.0%)	145 (9.3%)
4th attempt	71 (17.4%)	63 (14.6%)	62 (15.3%)	34 (11.2%)	0 (0.0%)	230 (14.8%)
Permanently Missing	13 (3.2%)	54 (12.5%)	4 (1.0%)	0 (0.0%)	0 (0.0%)	71 (4.6%)
TOTAL	409	432	406	304	2	1553

There are 29 (1.9%) eligible adjudication cases in process. 591 (39.0%) adjudication complete and 895 (59.1%) were not selected to further adjudication based on algorithm.

Table 3-6 Cases Eligible to be Reviewed by Adjudication Committee					
	N (%)				
^	Year 1	Year 2	Year 3	Year 4	Total
Adjudication in process	0 (0.0%)	0 (0.0%)	3 (0.8%)	26 (12.6%)	29 (1.9%)
Adjudication complete	157 (35.0%)	131 (27.8%)	201 (51.9%)	102 (49.3%)	591 (39.0%)
- - - - ND	30 (19.1%)	35 (26.7%)	48 (23.9%)	32 (31.4%)	145 (24.5%)
- - - - MCI	73 (46.5%)	48 (36.6%)	80 (39.8%)	38 (37.3%)	239 (40.4%)
- - - - PD	54 (34.4%)	44 (33.6%)	73 (36.3%)	32 (31.4%)	203 (34.3%)
- - - - UTC-CI	0 (0.0%)	3 (2.3%)	0 (0.0%)	0 (0.0%)	3 (0.5%)
- - - - UTC-FI	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
Not Adjudicated (ND)	85 (19.0%)	70 (14.8%)	38 (9.8%)	24 (11.6%)	217 (14.3%)
Not Adjudicated (UTC-CI)	84 (18.8%)	143 (30.3%)	81 (20.9%)	26 (12.6%)	334 (22.0%)
Not Adjudicated (UTC-No CI+No DQ)	122 (27.2%)	128 (27.1%)	64 (16.5%)	29 (14.0%)	344 (22.7%)
TOTAL	448	472	387	207	1515

Section 4.

Supplemental Case Ascertainment Protocol (SCAP)

4.1. SCAP Protocol Summary

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

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

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

4.2 SCAP DQ Call Tracking Report

Overall, the WHIMS field centers have 958 participants who have either the status of proxy or deceased, who are SCAP-eligible. Of the 958 SCAP-eligible, 653 proxies have been contacted by the WHIMS CoC.

Table 4-1 shows the current progress as outlined.

Call Outcome	N	%
Attempts at DQ completion ended		
-----Call Completed	356	54.52
-----Declined	38	5.82
-----Phone Disconnected	35	5.36
-----Unable to locate	7	1.07
-----Hearing Impaired	0	0.00
-----Discontinued	0	0.00
-----Deceased	0	0.00
-----No Proxy provided	6	0.92
-----No Answer - 4th and final attempt	125	19.14
DQ completion possible		
-----Other		
-----Left a Message	70	10.72
-----Scheduled	0	0.00
-----Re-Contact		
-----Busy	0	0.00
-----No Message	2	0.31
-----No Answer - 1st attempt	4	0.61
-----No Answer - 2nd attempt	5	0.77
-----No Answer - 3rd attempt	5	0.77

4.3 SCAP Adjudication

With SCAP adjudication,

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

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

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

These activities have yielded 264 cases of SCAP protocols for adjudication. Of those, 79 (29.9%) have been adjudicated and 27 (10.2%) are under review. There are 158 (59.8%) protocols that were not adjudicated (ND or MCI).

Additionally, 487 cases where attempts to complete the DQ have ceased due to proxy declined, phone disconnected, 4^{th} attempt, or unable to locate were classified as Probable No Dementia (PND) without full adjudication by a single adjudicator.

The overall classification of SCAP protocols (Adjudicated + Not Adjudicated) includes 724 cases. Of those, 172 (23.76%) were classified as ND, 487 (67.27%) as PND, 15 (2.07%) were MCI and 50 (6.91%) were PD.

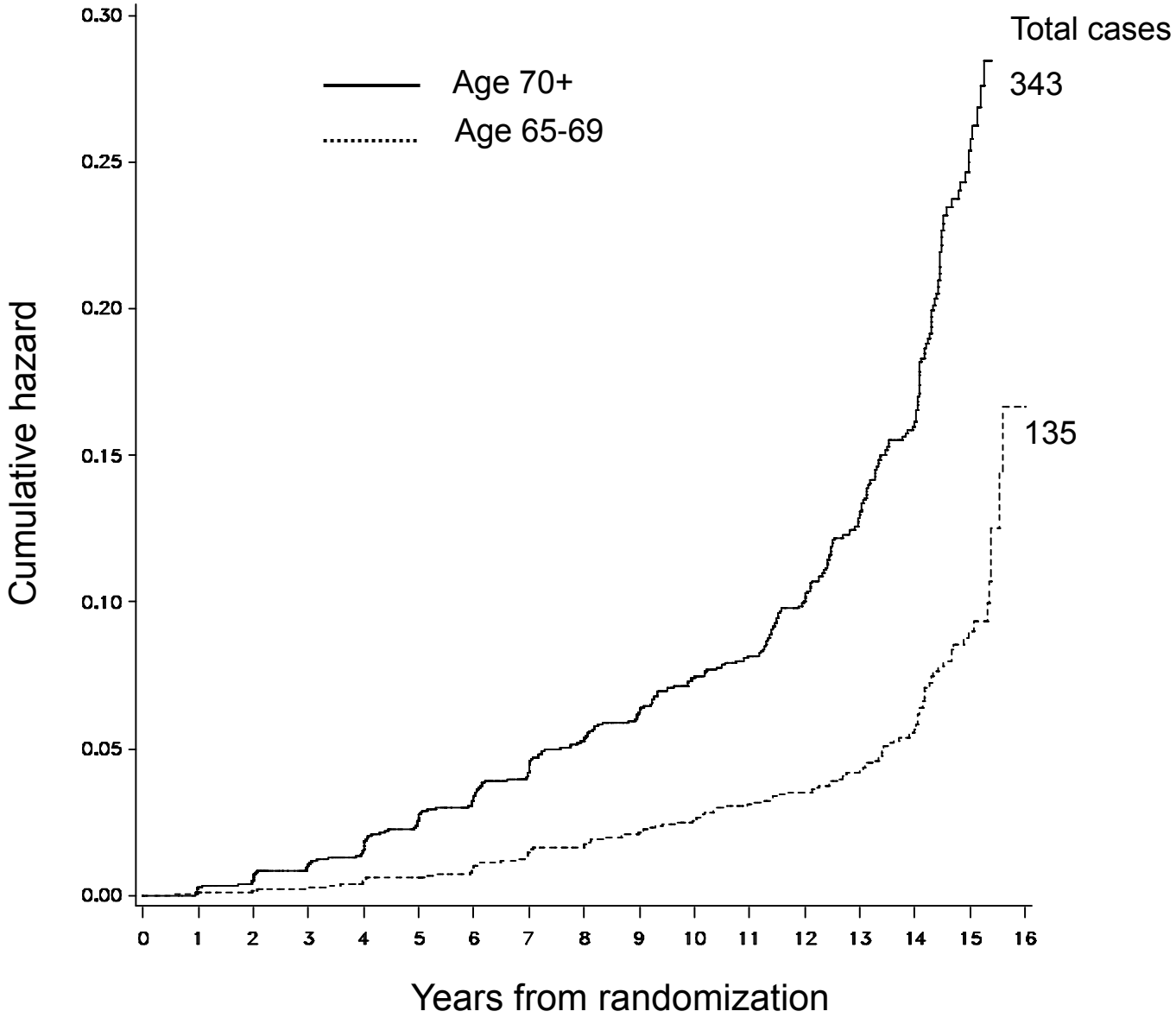
Table 4-2 SCAP Protocols		
	Subtotal	
	N	%
SCAP Phase 2 Protocols	751	
- - - - Adjudicated Protocols	79	10.52
- - - - Protocols Under Review by Adjudicators	27	3.6
- - - - Protocols Not Adjudicated (ND or MCI)	158	21.04
- - - - Protocols Classified Without Full Adjudication (PND)	487	64.85

Table 4-3 Overall Classification of SCAP Protocols		
	Subtotal	
	N	%
Overall Classification of Protocols	724	
----ND	172	23.76
----PND	487	67.27
----MCI	15	2.07
----PD	50	6.91

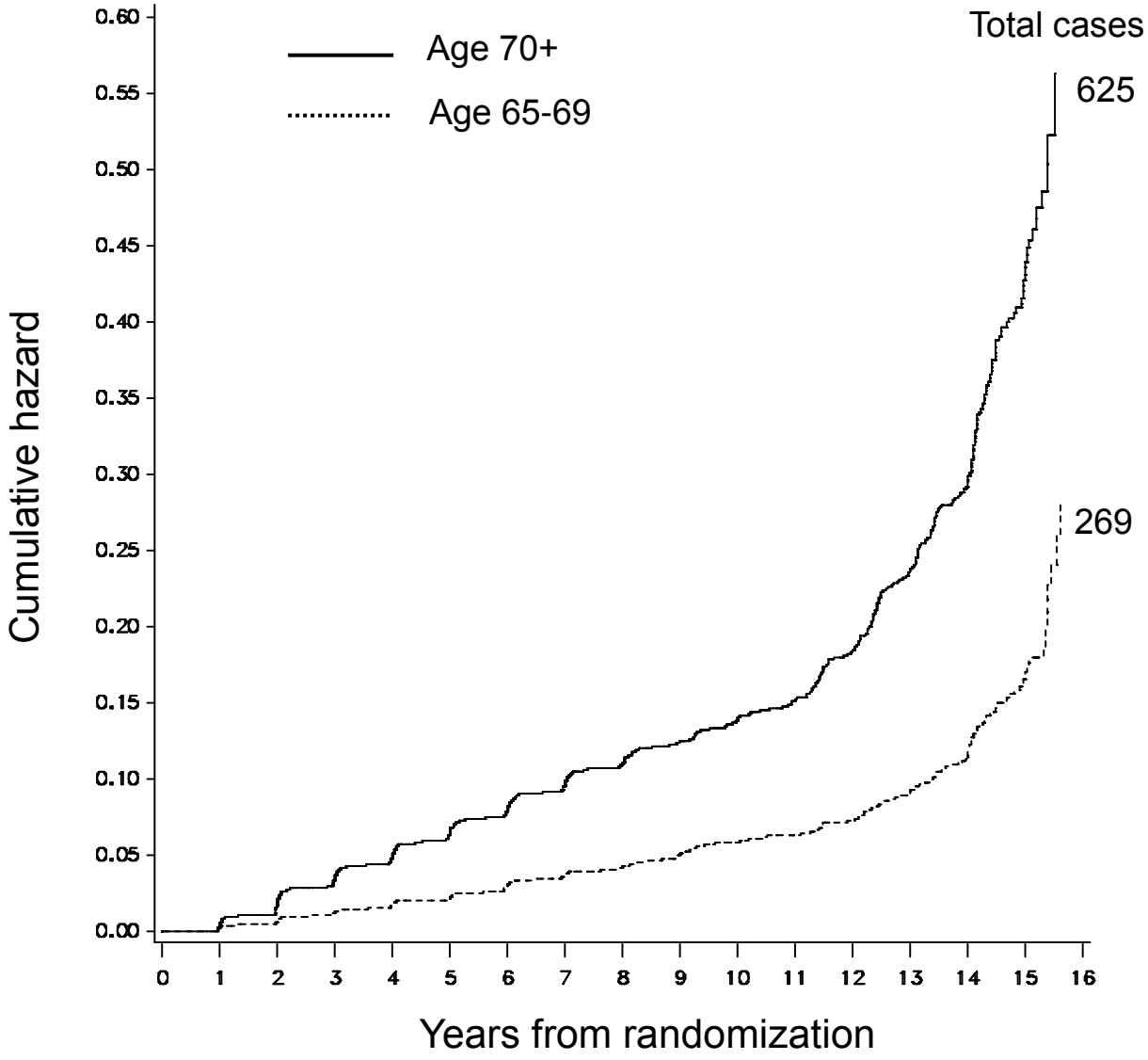
Section 5.

WHIMS Cohort

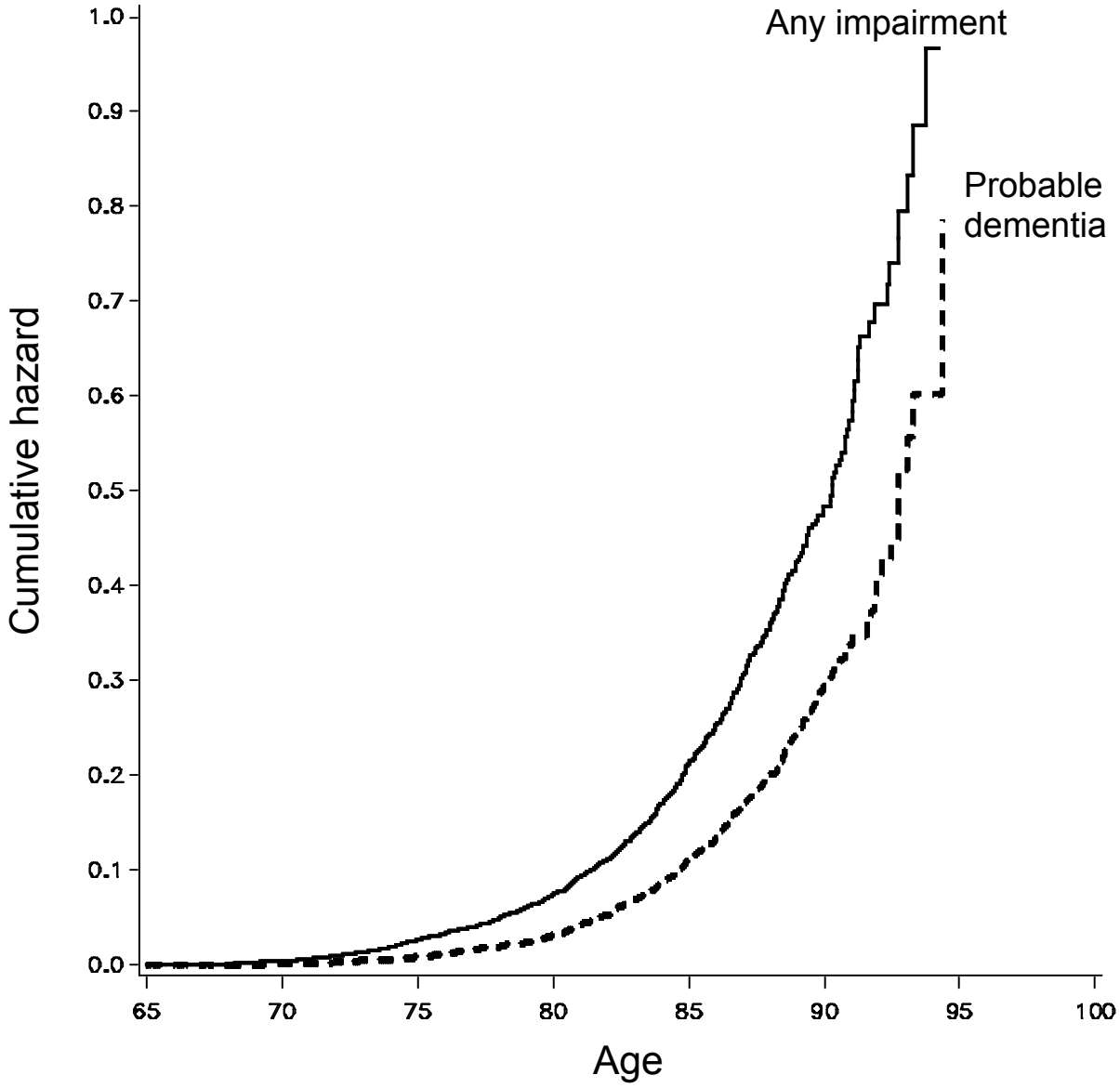
5.1 Incidence of Probable Dementia by Age at Enrollment



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.

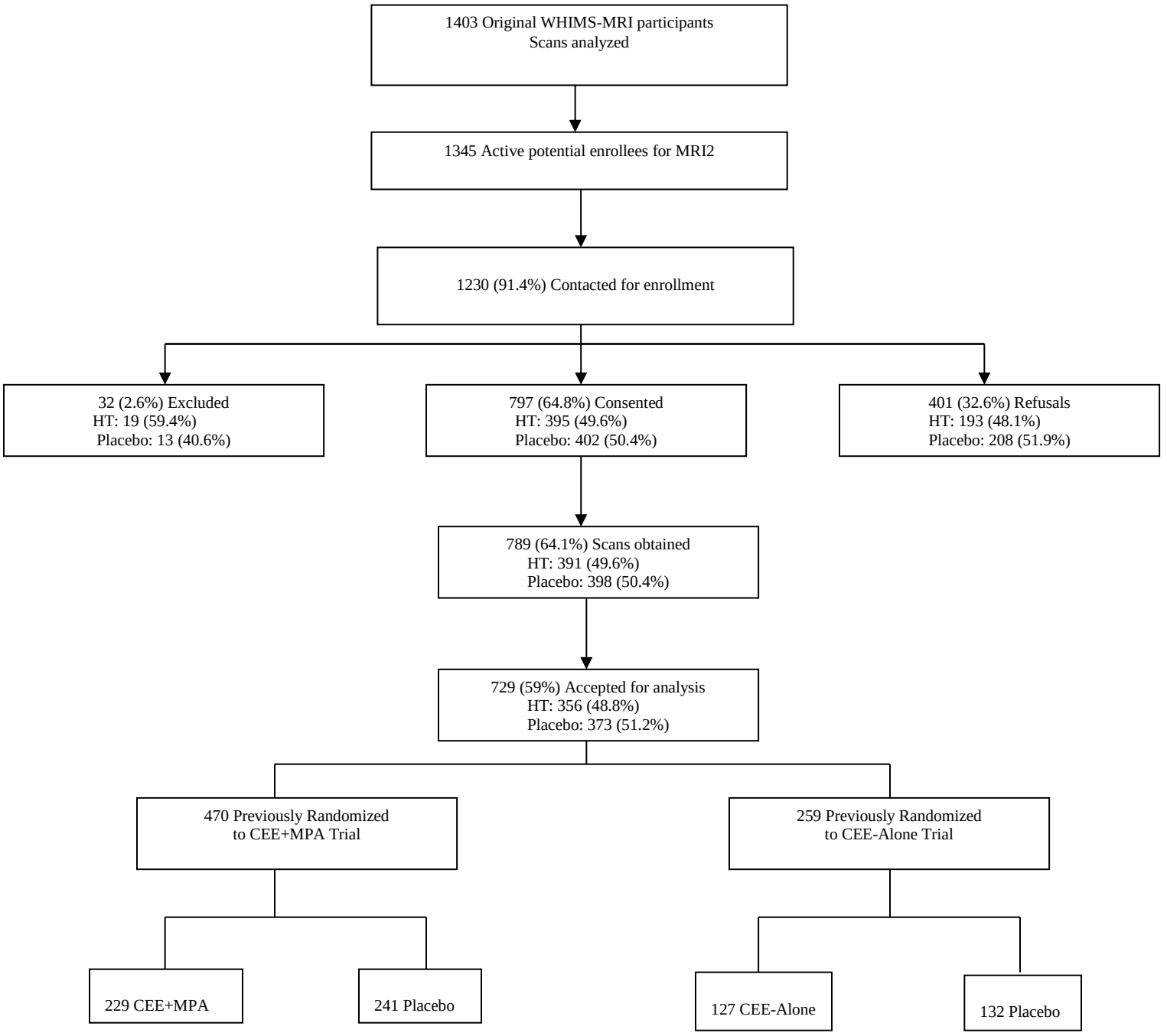
6.2 WHIMS-MRI2 Progress Report

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).

Figure 6.1: WHIMS-MRI2 Consort Diagram



6.2.2 WHIMS-MRIQCC Activities

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

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

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

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

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

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

6.2.3 WHIMS MRI2 Publications

Journal Articles Published

Espeland MA, Bryan RN, Goveas JS, Robinson J, Siddiqui MS, Liu S, Hogan PE, Casanova R, Coker LH, Yaffe K, Masaki K, Rossom R, Resnick SM for the WHIMS-MRI2 Study Group. Influence of type 2 diabetes mellitus on brain volumes and changes in brain volumes: Results from the Women's Health Initiative Magnetic Resonance Imaging Studies. Diabetes Care, EPubmed ahead of print August 29, 2012

Abstracts Published

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

WHI P&P Approved Manuscript Topics

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

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

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

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

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

Presentations

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

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

Section 7.

WHIMS-Y

7.1 WHIMS-Y Protocol Summary

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

7.2 WHIMS-Y Progress Report and Overall Enrollment

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

Table 7-1 WHIMS-Y Recruitment Process

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

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

7.3 WHIMS-Y Call Completion Rates

Table 7-2 WHIMS-Y Overall Status of Last Call Attempts by Year								
	Year 1		Year 2		Year 3		Year 4	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Agreed to participate	1362		0		0		0	
---- Cumulative number	1362	100.0	1362	100.0	1362	100.0	1362	100.0
Lost to follow-up								
---- Deceased	1		5		9		2	
---- Withdrew	2		5		32		13	
---- Attempts to locate exhausted	0		0		0		0	
Due for telephone contact	1359	100.0	1349	99.0	1308	96.0	1293	94.9
Completed test battery	1265	93.2	1175	87.1	898	68.7	49	3.8
Failed after 8 attempts	65	4.8	113	8.4	143	10.9	5	0.4
Declined	4	0.3	44	3.3	37	2.8	2	0.2
Phone disconnected	18	1.3	11	0.8	7	0.5	1	0.1
Unable to locate	4	0.3	3	0.2	0	0.0	0	0.0
Recontact	0	0.0	0	0.0	0	0.0	0	0.0
Hearing impaired	1	0.1	1	0.1	0	0.0	0	0.0
Discontinued	0	0.0	1	0.1	0	0.0	0	0.0
No answer	0	0.0	0	0.0	3	0.2	1	0.1
Left message	0	0.0	1	0.1	4	0.3	5	0.4
Scheduled	2	0.1	0	0.0	16	1.2	17	1.3
Busy	0	0.0	0	0.0	0	0.0	0	0.0
No message	0	0.0	0	0.0	7	0.5	3	0.2
Other	0	0.0	0	0.0	0	0.0	0	0.0
Not attempted	0	0.0	0	0.0	193	14.8	1203	93.5

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

Table 7-3 Characteristics of Enrollees	
Characteristic	N (%)
WHI Treatment Assignment	
E-Alone	271 (20)
E-Alone Placebo	255 (19)
E+P	446 (33)
E+P Placebo	390 (29)
Age at WHI Enrollment	
50-54	1362 (100)
Age as of October 1, 2012	
65-69	817 (60)
70-74	545 (40)
Race/Ethnicity	
American Indian/Alaskan native	5 (0)
Asian/Pacific Islander	16 (1)
Black/African American	169 (12)
Hispanic/Latino	60 (4)
White	1093 (80)
Other	16 (1)

7.5 WHIMS-Y Adjudication

The WHIMS-Y adjudication process is identical to the one utilized in WHIMS-ECHO. Currently, 175 WHIMS-Y women were eligible for the DQ based on their TICSm scores which were below the study cut-points. Of these, 166 progressed to administration of the DQ.

Table 7-4 Dementia Questionnaire Progressions in WHIMS-Y				
	Visit 1	Visit 2	Visit 3	TOTAL
Administrations	1264	1174	855	3293
DQ Progressions	61 (4.8%)	78 (6.6%)	36 (4.2%)	175 (5.3%)
Missing Proxy information	4 (6.6%)	4 (5.1%)	1 (2.8%)	9 (5.1%)
Total Eligible DQ Progressions	57 (93.4%)	74 (94.9%)	35 (97.2%)	166 (94.9%)

Table 7-5 Dementia Questionnaire Administration in WHIMS-Y				
Outcome	Visit 1	Visit 2	Visit 3	TOTAL
DQ's ready and completed for adjudication	31 (54.4%)	38 (51.4%)	18 (51.4%)	87 (52.4%)
DQ's in process	0 (0.0%)	4 (5.4%)	7 (20.0%)	11 (6.6%)
Phone Disconnected/Unable to locate/Hearing Impaired	3 (5.3%)	4 (5.4%)	0 (0.0%)	7 (4.2%)
Proxy Refused DQ	8 (14.0%)	8 (10.8%)	3 (8.6%)	19 (11.4%)
4th attempt	15 (26.3%)	20 (27.0%)	7 (20.0%)	42 (25.3%)
TOTAL	57	74	35	166

There are 13 (14.9%) eligible adjudication cases in process. 23 (26.4%) adjudication complete and 51 (58.6%) were not selected to further adjudication based on algorithm.

Table 7-6 Cases Eligible to be Reviewed by Adjudication Committee				
	N (%)			
	Visit 1	Visit 2	Visit 3	TOTAL
Adjudication in process	1 (3.2%)	4 (10.5%)	8 (44.4%)	13 (14.9%)
Adjudication complete	12 (38.7%)	10 (26.3%)	1 (5.6%)	23 (26.4%)
- - - - ND	6 (50.0%)	6 (60.0%)	0 (0.0%)	12 (52.2%)
- - - - MCI	6 (50.0%)	3 (30.0%)	1 (100%)	10 (43.5%)
- - - - PD	0 (0.0%)	1 (10.0%)	0 (0.0%)	1 (4.3%)
Not Adjudicated (ND)	18 (58.1%)	24 (63.2%)	9 (50.0%)	51 (58.6%)
TOTAL	31	38	18	87

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

September 2012

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

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

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

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

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

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

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

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

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

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

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

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

Ms1121: Calcium Plus Vitamin D Supplementation & Cognitive Impairment in the WHI
Chair: Rebecca Rossom
Biostatistical Collaborator: Mark Espeland

Ms 1259: Omega-3 Fatty Acid Biomarkers and Domains of Cognitive Function, Affect and Mood
Chair: Jennifer Robinson
Biostatistical Collaborator: Eric Amman

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

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

Ms 1384: Risk of Alzheimer's Disease Amongst Cancer Patients
Chair: Robert White
Biostatistical Collaborator: Not Assigned

Ms 1414: Rates of Change in Brain Volumes & Ischemic Lesion Volumes Following Exposure to CEE Therapies: Results From the WHIMS-MRI
Chair: Laura Coker
Biostatistical Collaborator: Patricia Hogan

Ms 1415: Vascular Factor-Depression Interactions & Future Cognitive Function: WHIMS & WHISCA
Chair: Joe Goveas
Biostatistical Collaborator: Patricia Hogan

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

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

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

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

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

Ms 1613: Long Term Effects on Cognitive Function of Postmenopausal Hormone Therapy Prescribed to Women Aged 50-54 Years: Results from the Women's Health Initiative Memory Study of Younger Women (WHIMSY)
Chair: Mark Espeland
Biostatistical Collaborator: Mark Espeland

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

Ms 1786: A Prospective Association Between Calcium Intake and White Matter Lesions in Older Women: The Women's Health Initiative MRI Study
Chair: Martha Payne
Biostatistical Collaborator: Ramon Casanova

Ms 1787: A Longitudinal Association Between Higher Calcium Intake and White Matter Lesion Subtypes in Older Women: The Women's Health Initiative MRI Study
Chair: Martha Payne
Biostatistical Collaborator: Ramon Casanova

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

Ms 1887: Rationale, Design, and Baseline Characteristics of the Women's Health Initiative Memory Study of Younger Women (WHIMSY)
Chair: Leslie Vaughan
Biostatistical Collaborator: Mark Espeland/Beverly Snively

Section 9.

Publications Activities

9.1 WHIMS SUITE OF STUDIES BIBLIOGRAPHY

Espeland MA, Bryan N, Goveas JS, Robinson J, Siddiqui MS, Li S, Hogan PE, Casanova R, Coker LH, Yaffee K, Masaki K, Rossum R, Resnick SM. Influence of Type 2 Diabetes on Brain Volumes and Changes in Brain Volumes: Results from the WHIMS-MRI. Diabetes Care. 2012 Aug 29. [Epub ahead of print] PMID:22933440.

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WHI Cognition Program Publications

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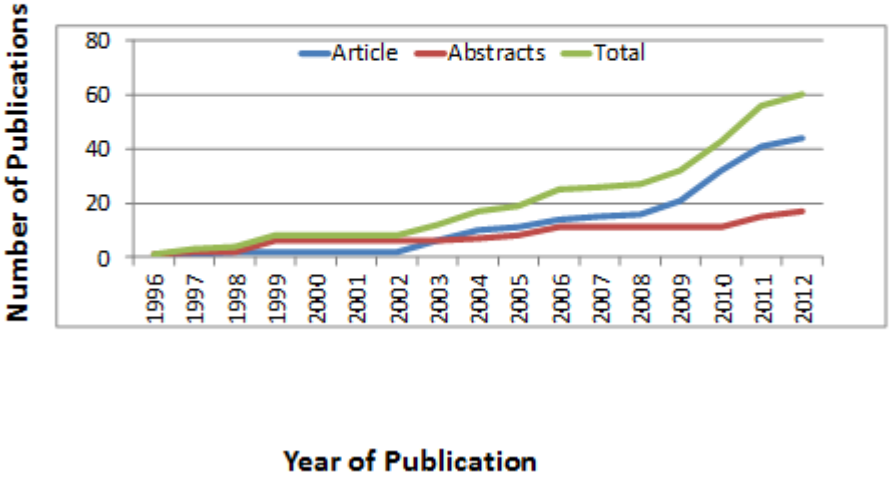

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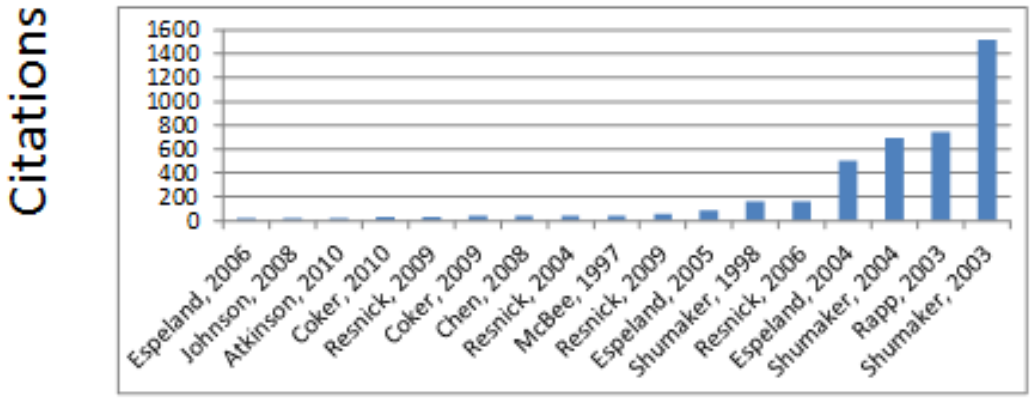

Section 10.

Ancillary Studies

Table 10-1 Funded Ancillary Studies from the WHIMS

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

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

*Number of Field Centers includes number of satellite sites.

Table 10-2 Proposed Ancillary Studies from the WHIMS

Investigators, Institutions	Proposal Title	Data Source	Relevant SIG
Laura H Coker, Peggye Dilworth-Anderson, Stephen Rapp, Sally Shumaker (Wake Forest University Health Sciences [WFUHS]; UNC-Greensboro)	Characteristics of caregivers and outcomes of care recipients	Caregiver Questionnaire (new); WHI participant (care recipient) data from the OS, HT WHIMS and WHISCA trial databases.	Psychosocial & behavioral Health (PBH)
Elizabeth Dugan (UMass-Boston); Sally Shumaker (WFUHS)	Women's mobility and driving	New questionnaire (10-15 minutes) to capture driving status, accidents, safety, behavior and needs; cognition status from WHIMS/WHISCA; US Census.	CAFS, 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.	CAFS
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	CAFS
Daniel Kim-Shapiro, W Jack Rejeski (Wake Forest University), Sally Shumaker (WFUHS)	Plasma nitrite and functional health	Plasma nitrite concentrations; 400-m walk speed and MAT-SF test scores.	CAFS
Stephen Rapp (WFUHS)	Depression, morbidity and mortality	Interview to obtain current and past depressive symptoms, diagnoses of major and minor depression and treatments; WHIMS (ECHO) data on cognition, risk factors, potential confounders.	CAFS, 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	CAFS, 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	CAFS, 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: Cognition, Aging, and Functional Status (CAFS); 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:

- "Presence of retinopathy was associated with poorer 3MSE scores (mean difference = 1.01, SE: 0.43) (p = 0.019) over a 10-year follow-up period and greater ischemic volumes in the total brain (47% larger, p = 0.04) and the parietal lobe (68% larger, p = 0.01) but not with measures of regional brain atrophy. The correspondence we found between retinopathy and cognitive impairment, along with larger ischemic lesion volumes, strengthens existing evidence that retinopathy as a marker of small vessel disease is a risk factor for cerebrovascular disease that may influence cognitive performance and related brain changes. Retinopathy may be useful as a clinical tool if it can be shown to be an early marker related to neurologic outcomes." Haan M, Espeland MA, Klein BE, et al. Cognitive function and retinal and ischemic brain changes: the Women's Health Initiative. Neurology 2012;78:942-949.

- "Augmenting the clinic-based cases with those identified from proxy interviews reduced undercounting and materially altered observed relationships that years since menopause, smoking status, diabetes, and prior use of hormone therapy had with incidence of probable dementia. Although proxy interviews were successful in reducing biases in estimated incidence rates and risk factor relationships, it is unlikely that they will fully eliminate many biases. Proxy-based assessments are necessary in longer term studies to reduce undercounting of dementia cases and to characterize risk factor relationships." Gaussoin S, Espeland MA, Absher J, Howard BV, Jones BM, Rapp. Ascertaining dementia-related outcomes for deceased or proxy-dependent participants: an overview of the Women's Health Initiative Memory Study supplemental case ascertainment protocol/ Int J Geriatr Psychiatry 2012;27:205-214.

- "RBC samples should always be stored at -80 °C. The FA compositions of the degraded RBC samples from WHIMS were rehabilitated by application of regression calibration equations and multiple imputations, and these imputed datasets should be used in all future WHIMS studies. Pottala JV, Espeland MA, Polreis J, Robinson J, Harris WS. Bryan RN, Goveas JS, et al. Correcting the effects of -20 °C storage and aliquot size on erythrocyte fatty acid content in the Women's Health Initiative. Lipids 2012;47:835-846.

- "Antidepressant use and different levels of depression severity were associated with subsequent cognitive impairment in a large cohort of postmenopausal women. Future research should examine the role of antidepressants in the depression-dementia relationship and determine if antidepressants can prevent incident MCI and dementia in individuals with late-life depression subtypes with different levels of severity. Goveas JS, Hogan PE, Kotchen JM, et al. Depressive symptoms, antidepressant use, and future cognitive health in postmenopausal women: the Women's Health Initiative Memory Study. Int Psychogeriatr 2012;24:1252-1264.

- "Diabetes was associated with lower scores in global cognitive function and its subdomains. These relative deficits were only partially accounted for by brain volumes and risk factors for cognitive deficits. Diabetes is associated with smaller brain volumes in gray but not white matter and increasing ischemic lesion volumes throughout the brain. These markers are associated with but do not fully account for diabetes-related deficits in cognitive function." Espeland MA, Bryan RN, Goveas JS, et al. Influence of type 2 diabetes on brain volumes and changes in brain volumes: results from the Women's Health Initiative Magnetic Resonance Imaging Studies. Diab Care (EPub: In press, 2012).

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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