
# Women's Health Initiative
# 2007 Annual Progress Report

**Data as of: August 15, 2007**

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# 1. Overview

## 1.1 Preliminary Remarks

This report documents the experience of the WHI Extension Study (ES) activities through August 15, 2007, summarizing consenting activities, follow-up response rates, study outcomes and performance. In addition, this report includes summaries of efforts using core resources for biomarker and intermediate endpoint studies, ancillary studies with particular focus on those using the biospecimen repository, and a summary of publications.

The implementation of the WHI Extension Study required a recruitment process to obtain consent from WHI participants and some modification of the follow-up and outcomes adjudication process primarily aimed at streamlining. These activities are documented below. Data presentations on vital status and outcome rates for each study component are provided without further explanation as these follow the same conventions as have been previously described. A few introductory remarks are presented below as orientation to the presentations on core and ancillary study activities.

The NHLBI contracted with 39 of the original WHI Clinical Centers (now referred to as Field Centers) to conduct follow-up through 2010. The Principal Investigators and the sponsoring institutions are presented in Table 1.1. Several changes have occurred during this past year. Drs. Henry Black (Chicago-Rush Presbyterian), Denise Bonds (Wake Forest University), Jennifer Hays (Houston—Baylor), and Judith Hsia (George Washington University) have left WHI to pursue other activities. WHI welcomes new Principal Investigators Drs. William Elliot, Mara Vitolins, Aleksander Rajkovic, and Richard Katz (interim) in these sites. We also note with sadness the death of Dr. Howard Judd, the longtime UCLA Principal Investigator.

The UCSD center (La Jolla) was not funded to conduct follow-up during the ES. The Clinical Coordinating Center now follows LaJolla participants who consented to the ES.

## 1.2 Consent to Extension Study Follow-up

Approval of WHI-ES follow-up was received from NHLBI on October 12, 2004. Clinical trial participants were consented primarily in conjunction with their close-out visits, scheduled to occur between October 1, 2004 and March 31, 2005. Observational Study participants were consented by various means as determined by individual centers (mail, phone/mail, group meetings). The opportunity to join the WHI-ES will not be closed to any WHI participant but active efforts to recruit participants have ended.

WHI-ES consent rates are provided by study component and arm in Table 1.2, by demographic characteristics in Table 1.3 and by center in Table 1.4. Overall, 82% of CT participants and 73% of OS participants have agreed to further follow-up.

## 1.3 Extension Study Follow-up

The ES study follow-up plan entails an annual mailed contact to obtain self-reported outcomes (Form 33–*Medical History Update*), hormone therapy use (Form 150–*Hormone Use Update*) among HT trial participants, and quality of life (Form 151–*Activities of Daily Life*). A one-time collection of historical diagnoses of Parkinson's disease and diabetes (Form 134–*Addendum to Medical History Update*) was also collected during the first ES follow-up year. A repeated attempt to capture Form 134 data was implemented by including Form 134 in the routine year 2 mailings to year 1 non-respondents.

The annual contact is primarily administered through up to three mailings from the CCC over a five month period. Form 33–*Medical History Update* is viewed as the primary indicator of response. Estimated response rates for the second follow-up year are high (85% respond to the first mailing, 93.6% respond overall) and comparable to first year results, as shown in Table 1.5. Response rates for other data collection instruments are similar, except for the attempt to collect Form 134 from non-responders in year 2. Response rates are somewhat lower in the clinical trial components than in the observational study, but similar in the three trials.

Field centers are responsible for data collection from women that cannot be followed by mail and from non-responders to the three CCC mailings. During the past year the procedures for this follow-up were changed to make the effort more timely. For follow-up year 2, 89.9% of those requiring FC follow-up responded with a Form 33, an improvement of 10% over the previous year (Table 1.6), giving an estimated overall response rate of 98.7%. The response rates for Form 151 are somewhat lower than for other instruments at this stage because FC follow-up for this form is optional. Differences between study components are small with the exception that follow-up of HT participants appears to be somewhat more difficult.

## 1.4 Outcomes

Outcomes adjudication for the WHI-ES is centralized. Field centers collect documents from self-reported or proxy-reported cases and forward them to the CCC. The CCC forwards purported cases of designated WHI outcomes to an adjudicator specific to the disease category. Outcomes identified from other hospitalizations are reviewed by CCC outcomes staff and then either forwarded to an appropriate adjudicator, or closed administratively. Adjudicators are divided into committees responsible for cardiovascular events (which include VTE but not stroke), stroke, hip fractures, fatal events, and cancer. The cancer committee consists of trained cancer coders at the CCC. All other committees consist of physician adjudicators, many of whom were local physician adjudicators during WHI. There is a large overlap between the fatal events committee and the cardiovascular committee. Every case is reviewed by a single adjudicator. QA procedures, which involve double adjudication of at least 10% of the cases by another adjudicator from the same committee, have been implemented.

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

- Angina and CHF are no longer adjudicated
- Outpatient stroke is adjudicated (not adjudicated during WHI)
- Hip fracture continues to be adjudicated but no others (during WHI other fractures were adjudicated for Clinical Trial participants)
- Hospitalizations of a single night are no longer investigated, unless they occur in conjunction with a self-report of a designated WHI-ES outcome

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

A tabulation of all designated outcomes currently available based on the current adjudication procedures are presented by age and race/ethnicity for HT, DM, CaD, OS and for CT participants combined in Sections 2 through 6 respectively.

## 1.5 Central Adjudication

Agreement rates between self-report and confirmed outcomes occurring during the WHI extension are provided in Tables 7.1 and 7.2. Table 7.1 presents the final status of self-reported events that are designated for adjudication in WHI. A self-report for a particular outcome is considered closed if all adjudications associated with the outcome are closed. For closed cases, a self-report is considered "confirmed" if any of the associated adjudication cases confirms the exact self-reported outcome. If not, the result is classified by whether a related outcome is found in the documentation. For this purpose, all cardiovascular outcomes are considered related, all cancers are considered related, and all fractures are considered related. If no related outcome is confirmed, we determine whether any outcome has been confirmed. For the denied cases, we separate those that are denied for administrative reasons (e.g., no release of information [ROI] obtained) from those where the records indicate that no outcomes occurred. These agreement rates vary considerably across diseases.

In the rare situation where a self-report of a specific event is associated with several adjudication cases, perhaps because of several associated hospitalizations, the original event would not be considered closed in this table, even if the original event has been confirmed until all associated cases are adjudicated. This is a reason for discrepancies between numbers in these tables and other tables in this report.

Table 7.2 examines agreement in the reverse direction, tabulating the fraction of confirmed outcomes investigated as a result of a self-report for that exact outcome, a related outcome, an unrelated outcome, or a hospitalization.

## 1.6 Data Quality and Study Performance Reports

Reports summarizing field center activities (Tables 8.1 to 8.5) are produced monthly and posted on the staff website for investigators and field center staff use. The Performance Monitoring Committee also uses these reports to monitor study activities.

Participants return questionnaires to the CCC by mail for scanning. Forms that cannot be scanned are key-entered. CCC staff also review all the returned forms for comments the participant may have written on the form and indicate which forms need to be reviewed by field center staff (Table 8.6).

The current status indicates that outcomes processing by FCs is excellent, with timeliness of documenting and forwarding cases better than it ever was during WHI. All adjudications are up-to-date with the flow of cases with the exception of stroke and other hospitalizations. For stroke, additional adjudicators were engaged in the process during the last year and have recently completed their training so we expect substantial progress in the next year. Adjudication of other hospitalizations is a lower priority; a plan for streamlining their processing to focus on capture of designated outcomes rather than all 2-night hospitalizations is under consideration.

## 1.7 Specimen Repository

The current inventory of the WHI specimen repository is described in Tables 9.1–*CT Outcomes Cases with Blood* and 9.2–*OS Outcomes Cases with Blood.* These tabulations show the estimated volume of each type of specimen (serum, EDTA plasma, citrate plasma) available according to the primary outcomes of interest in the clinical trial and observational study components separately. Specimen availability is not shown for women who have not experienced one of these outcomes because of the large supply of potential controls. Urine samples, collected at the three bone mineral densitometry clinics, are also not shown but these resources have not yet been used for any purpose.

The WHI specimen resources have been divided into three accounts, (1) that which is available to WHI investigators now to support core or ancillary study activities, (2) that which is reserved for Broad Agency Announcement awardees (see below); and (3) that which is reserved for use by WHI investigators at the end of the Extension Follow-up period. Tabulations for each of these accounts is available upon request.

## 1.8 Core, Ancillary Study, and Broad Agency Announcement Activities

WHI investigators are involved in numerous activities funded by the program designed to further explicate the results of the clinical trials, to expand the scope of our understanding of intervention effects, and to identify and evaluate biomarkers of disease through use of the WHI repository. These core studies are summarized briefly in Table 10.1.

WHI investigators and their colleagues continue to propose ancillary studies to use WHI resources. Together these efforts are aimed to maximize the use of these resources to provide insight into the causes and mechanisms of disease. To date, 253 ancillary studies have been proposed, 129 approved and 102 funded, including 41 from non-WHI investigators. Table 11.1 lists all proposed ancillary studies along with their WHI approval and funding status.

In January 2006, the NHLBI released a Broad Agency Announcement (BAA) to the larger scientific community, requesting proposals designed to use WHI specimens. The 12 awardees, listed in Table 11.2, were announced in January 2007 and all are now active.

Table 11.3 provides additional information on BAA and ancillary studies that are approved to use WHI biospecimens by disease focus.

Participant enrollments to ancillary studies requiring a separate consent are tabulated by field center and shown in Table 11.4. Nearly 33,500 participant enrollments have occurred in WHI. Table 11.5 provides the distribution of enrollments per participant. Approximately 17% of ES participants are enrolled in one or more ancillary study, and of these, the majority participate in only one.

Researchers involved in ancillary or BAA studies as either PIs or sponsoring WHI PIs are listed in Table 11.6.

## 1.9 Publications

WHI investigators remain engaged in the publication process. To date, 698 manuscript proposals have been received and 590 approved for development by the Publications and Presentations committee. Of these, 235 have been published or are in press, including 61 since the last report (Table 12.1). Non-WHI investigators were lead authors on 58 of the published articles. Citations of all published papers are available at www.whiscience.org.

**Table 1.1**
**WHI Centers and Principal Investigators**

| Principal Investigator | Institution | Location |
|---|---|---|
| Annlouise Assaf, PhD | Memorial Hospital of Rhode Island | Pawtucket, RI |
| Shirley Beresford, PhD | Fred Hutchinson Cancer Research Center | Seattle, WA |
| Robert Brunner, PhD | University of Nevada | Reno, NV |
| Robert Brzyski, MD | University of Texas | San Antonio, TX |
| Bette Caan, PhD | Kaiser Foundation Research Institute | Oakland, CA |
| Rowan Chlebowski, MD PhD | University of California, Los Angeles | Torrance, CA |
| David Curb, MD | University of Hawaii | Honolulu, HI |
| William Elliott, MD | Rush Presbyterian/St. Luke's Medical Ctr. | Chicago, IL |
| Margery Gass, MD | University of Cincinnati | Cincinnati, OH |
| Gerardo Heiss, MD MPH | University of North Carolina, Chapel Hill | Chapel Hill, NC |
| Susan Hendrix, DO | Wayne State University | Detroit, MI |
| Barbara Howard, PhD | MedStar Research Institute | Washington, D.C. |
| Allan Hubbell, MD | University of California, Irvine | Irvine, CA |
| Rebecca Jackson, MD | Ohio State University | Columbus, OH |
| Karen Johnson, MD, MPH | University of Tennessee | Memphis, TN |
| Richard Katz, MD (Interim) | George Washington University | Washington, DC |
| Jane Kotchen MD MPH | Medical College of Wisconsin | Milwaukee, WI |
| Lewis Kuller, MD DrPH | University of Pittsburgh | Pittsburgh, PA |
| Dorothy Lane, MD MPH | Research Foundation SUNY, Stony Brook | Stony Brook, NY |
| Norman Lasser, MD PhD | University of Medicine and Dentistry | Newark, NJ |
| Cora Lewis, MD MSPH | University of Alabama at Birmingham | Birmingham, AL |
| Marian Limacher, MD | University of Florida | Gainesville/ Jacksonville, FL |
| JoAnn Manson, MD DrPH | Brigham and Women's Hospital | Boston, MA |
| Karen Margolis, MD | University of Minnesota | Minneapolis, MN |
| Lauren Nathan, MD | University of California, Los Angeles | Los Angeles, CA |
| Mary-Jo O'Sullivan, MD | University of Miami | Miami, FL |
| Judith Ockene, PhD | University of Massachusetts | Worcester, MA |
| Larry Phillips, MD | Emory University | Atlanta, GA |
| Aleksandar Rajkovic, MD, PhD | Baylor College of Medicine | Houston, TX |
| John Robbins, MD | University of California, Davis | Sacramento, CA |
| Gloria Sarto, MD | University of Wisconsin | Madison, WI |
| Marcia Stefanick, PhD | Stanford University | San Jose, CA |
| Cyndi Thomson, PhD RD | University of Arizona | Tucson and Phoenix, AZ |
| Linda Van Horn, PhD RD | Northwestern University | Chicago and Evanston, IL |
| Mara Vitolins, PhD | Wake Forest University | Winston-Salem/Greensboro, NC |
| Sylvia Wassertheil-Smoller, PhD | Albert Einstein College of Medicine | Bronx, NY |
| Jean Wactawski-Wende, PhD | State University of New York, Buffalo | Buffalo, NY |
| Robert Wallace, MD | University of Iowa | Iowa City/Bettendorf, IA |
| Evelyn Whitlock, MD | Kaiser Foundation Research Institute | Portland, OR |
| Ross Prentice, PhD | Clinical Coordinating Center, Fred Hutchinson Cancer Research Center | Seattle, WA |
| Sally Shumaker, PhD | WHI Memory Study Coordinating Center, Wake Forest University | Winston-Salem, NC |

**Table 1.2**
**Consent Status by Study Component and Arm**

Data as of: August 15, 2007

| WHI Enrollment | Enrolled in WHI | Eligible for extension[1] | Consented N | Consented % |
|---|---|---|---|---|
| Hormone Therapy | 27347 | 25193 | 20432 | 81.1 |
| With Uterus | 16608 | 15407 | 12787 | 83.0 |
| E+P | 8506 | 7877 | 6545 | 83.1 |
| Placebo | 8102 | 7530 | 6242 | 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 | 37857 | 83.1 |
| Intervention | 19541 | 18207 | 14768 | 81.1 |
| Comparison | 29294 | 27353 | 23089 | 84.4 |
| Calcium and Vitamin D | 36282 | 34447 | 29861 | 86.7 |
| Active | 18176 | 17280 | 15024 | 86.9 |
| Placebo | 18106 | 17167 | 14837 | 86.4 |
| Clinical Trial Total | 68132 | 63331 | 52174 | 82.4 |
| Observational Study | 93676 | 86744 | 63229 | 72.9 |
| Total | 161808 | 150075 | 115403 | 76.9 |

[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: August 15, 2007

| WHI Enrollment | Enrolled in WHI | Eligible for extension[1] | Consented N | Consented % |
|---|---|---|---|---|
| **Clinical Trial** | 68132 | 63331 | 52174 | 82.4 |
| Age | | | | |
| 50-54 | 9188 | 8754 | 7237 | 82.7 |
| 55-59 | 14661 | 13940 | 11723 | 84.1 |
| 60-69 | 31389 | 29290 | 24527 | 83.7 |
| 70-79 | 12894 | 11347 | 8687 | 76.6 |
| Race/Ethnicity | | | | |
| American Indian | 292 | 260 | 185 | 71.2 |
| Asian/Pacific Islander | 1519 | 1414 | 1105 | 78.1 |
| Black | 6983 | 6423 | 4769 | 74.2 |
| Hispanic | 2875 | 2686 | 1791 | 66.7 |
| White | 55525 | 51681 | 43678 | 84.5 |
| Unknown | 938 | 867 | 646 | 74.5 |
| **Observational Study** | 93676 | 86744 | 63229 | 72.9 |
| Age | | | | |
| 50-54 | 12381 | 11969 | 8995 | 75.2 |
| 55-59 | 17329 | 16565 | 12732 | 76.9 |
| 60-69 | 41200 | 38502 | 28581 | 74.2 |
| 70-79 | 22766 | 19708 | 12921 | 65.6 |
| Race/Ethnicity | | | | |
| American Indian | 421 | 372 | 217 | 58.3 |
| Asian/Pacific Islander | 2671 | 2444 | 1291 | 52.8 |
| Black | 7635 | 6868 | 3585 | 52.2 |
| Hispanic | 3609 | 3333 | 1598 | 47.9 |
| White | 78016 | 72504 | 55765 | 76.9 |
| Unknown | 1324 | 1223 | 773 | 63.2 |

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

**Table 1.4**
**Extension Consent Summary by Field Center**

Data as of August 15, 2007

| | DM | | | HT | | | CaD | | | CT | | | OS | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Eligible | Consent | % | Eligible | Consent | % | Eligible | Consent | % | Eligible | Consent | % | Eligible | Consent | % |
| Atlanta | 1329 | 1068 | 80.4 | 534 | 441 | 82.6 | 834 | 722 | 86.6 | 1611 | 1298 | 80.6 | 2311 | 1831 | 79.2 |
| Bettendorf | 470 | 400 | 85.1 | 708 | 624 | 88.1 | 658 | 596 | 90.6 | 1051 | 922 | 87.7 | 1404 | 1110 | 79.1 |
| Birmingham | 1237 | 955 | 77.2 | 705 | 579 | 82.1 | 887 | 762 | 85.9 | 1695 | 1334 | 78.7 | 2303 | 1343 | 58.3 |
| Bowman | 1024 | 808 | 78.9 | 567 | 425 | 75.0 | 652 | 539 | 82.7 | 1408 | 1091 | 77.5 | 2083 | 1569 | 75.3 |
| Brigham | 1643 | 1429 | 87.0 | 770 | 664 | 86.2 | 1024 | 939 | 91.7 | 2206 | 1906 | 86.4 | 2841 | 2310 | 81.3 |
| Buffalo | 1057 | 1001 | 94.7 | 631 | 577 | 91.4 | 921 | 883 | 95.9 | 1490 | 1395 | 93.6 | 2042 | 1733 | 84.9 |
| Chapel Hill | 1061 | 943 | 88.9 | 586 | 488 | 83.3 | 719 | 650 | 90.4 | 1447 | 1264 | 87.4 | 1972 | 1584 | 80.3 |
| Chi-Rush | 872 | 627 | 71.9 | 494 | 353 | 71.5 | 785 | 604 | 76.9 | 1225 | 880 | 71.8 | 1881 | 1028 | 54.7 |
| Chicago | 1121 | 952 | 84.9 | 518 | 443 | 85.5 | 759 | 687 | 90.5 | 1493 | 1266 | 84.8 | 1754 | 1369 | 78.1 |
| Cincinnati | 967 | 881 | 91.1 | 495 | 444 | 89.7 | 859 | 803 | 93.5 | 1298 | 1176 | 90.6 | 2076 | 1616 | 77.8 |
| Columbus | 1072 | 898 | 83.8 | 558 | 454 | 81.4 | 845 | 732 | 86.6 | 1456 | 1199 | 82.3 | 2098 | 1705 | 81.3 |
| Des Moines | 478 | 400 | 83.7 | 865 | 624 | 72.1 | 807 | 638 | 79.1 | 1237 | 938 | 75.8 | 1513 | 1091 | 72.1 |
| Detroit | 914 | 706 | 77.2 | 470 | 359 | 76.4 | 806 | 649 | 80.5 | 1220 | 936 | 76.7 | 1911 | 1416 | 74.1 |
| Gainesville | 1289 | 1182 | 91.7 | 875 | 800 | 91.4 | 852 | 798 | 93.7 | 1935 | 1771 | 91.5 | 2565 | 2176 | 84.8 |
| GWU-DC | 1069 | 929 | 86.9 | 525 | 453 | 86.3 | 814 | 746 | 91.6 | 1443 | 1245 | 86.3 | 2132 | 1681 | 78.8 |
| Honolulu | 1006 | 804 | 79.9 | 372 | 283 | 76.1 | 628 | 523 | 83.3 | 1280 | 1003 | 78.4 | 1897 | 984 | 51.9 |
| Houston | 845 | 636 | 75.3 | 427 | 269 | 63.0 | 573 | 437 | 76.3 | 1160 | 829 | 71.5 | 1906 | 1403 | 73.6 |
| Irvine | 1104 | 943 | 85.4 | 550 | 452 | 82.2 | 881 | 779 | 88.4 | 1509 | 1274 | 84.4 | 2062 | 1665 | 80.7 |
| L.A. | 1156 | 912 | 78.9 | 554 | 410 | 74.0 | 971 | 803 | 82.7 | 1559 | 1213 | 77.8 | 2056 | 1615 | 78.6 |
| La Jolla | 1525 | 976 | 64.0 | 682 | 329 | 48.2 | 1080 | 721 | 66.8 | 1986 | 1194 | 60.1 | 3188 | 1884 | 59.1 |
| Madison | 1032 | 929 | 90.0 | 622 | 563 | 90.5 | 867 | 801 | 92.4 | 1484 | 1343 | 90.5 | 1855 | 1420 | 76.5 |
| Medlantic | 1027 | 880 | 85.7 | 544 | 448 | 82.4 | 782 | 694 | 88.7 | 1367 | 1157 | 84.6 | 2036 | 1456 | 71.5 |
| Memphis | 1164 | 866 | 74.4 | 663 | 483 | 72.9 | 839 | 661 | 78.8 | 1558 | 1148 | 73.7 | 2250 | 1250 | 55.6 |
| Miami | 1009 | 729 | 72.2 | 544 | 387 | 71.1 | 500 | 378 | 75.6 | 1377 | 987 | 71.7 | 1254 | 695 | 55.4 |
| Milwaukee | 1084 | 973 | 89.8 | 683 | 589 | 86.2 | 953 | 876 | 91.9 | 1531 | 1352 | 88.3 | 2113 | 1586 | 75.1 |
| Minneapolis | 1262 | 1097 | 86.9 | 793 | 654 | 82.5 | 1045 | 949 | 90.8 | 1877 | 1606 | 85.6 | 2576 | 1949 | 75.7 |
| Nevada | 980 | 849 | 86.6 | 572 | 480 | 83.9 | 923 | 816 | 88.4 | 1362 | 1163 | 85.4 | 1957 | 1550 | 79.2 |
| Newark | 1269 | 1011 | 79.7 | 490 | 393 | 80.2 | 836 | 713 | 85.3 | 1600 | 1277 | 79.8 | 2369 | 1686 | 71.2 |
| New Brunswick | 375 | 328 | 87.5 | 368 | 330 | 89.7 | 436 | 402 | 92.2 | 657 | 580 | 88.3 | 779 | 651 | 83.6 |
| NY-City | 1223 | 1003 | 82.0 | 698 | 560 | 80.2 | 827 | 718 | 86.8 | 1767 | 1435 | 81.2 | 2710 | 1526 | 56.3 |
| Oakland | 1022 | 903 | 88.4 | 583 | 512 | 87.8 | 628 | 577 | 91.9 | 1468 | 1296 | 88.3 | 1895 | 1480 | 78.1 |
| Pawtucket | 1892 | 1676 | 88.6 | 898 | 780 | 86.9 | 1328 | 1217 | 91.6 | 2488 | 2187 | 87.9 | 3395 | 2685 | 79.1 |
| Pittsburgh | 1096 | 1005 | 91.7 | 595 | 540 | 90.8 | 804 | 754 | 93.8 | 1528 | 1395 | 91.3 | 1733 | 1381 | 79.7 |
| Portland | 1111 | 950 | 85.5 | 592 | 524 | 88.5 | 827 | 750 | 90.7 | 1523 | 1323 | 86.9 | 2082 | 1565 | 75.2 |
| San Antonio | 873 | 621 | 71.1 | 658 | 448 | 68.1 | 793 | 584 | 73.6 | 1261 | 875 | 69.4 | 1709 | 962 | 56.3 |
| Seattle | 1097 | 904 | 82.4 | 686 | 542 | 79.0 | 804 | 682 | 84.8 | 1681 | 1358 | 80.8 | 1515 | 1070 | 70.6 |

**Table 1.4 (continued)**
**Extension Consent Summary by Field Center**

Data as of August 15, 2007

| | DM | | | HT | | | CaD | | | CT | | | OS | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Eligible | Consent | % | Eligible | Consent | % | Eligible | Consent | % | Eligible | Consent | % | Eligible | Consent | % |
| Stanford | 1226 | 1071 | 87.4 | 633 | 558 | 88.2 | 948 | 866 | 91.4 | 1639 | 1445 | 88.2 | 2465 | 2045 | 83.0 |
| Stonybrook | 936 | 801 | 85.6 | 473 | 400 | 84.6 | 572 | 509 | 89.0 | 1266 | 1083 | 85.5 | 1915 | 1467 | 76.6 |
| Torrance | 745 | 554 | 74.4 | 288 | 206 | 71.5 | 507 | 405 | 79.9 | 916 | 673 | 73.5 | 1385 | 877 | 63.3 |
| Tucson | 1387 | 1077 | 77.6 | 714 | 508 | 71.1 | 1007 | 816 | 81.0 | 1929 | 1461 | 75.7 | 2544 | 1650 | 64.9 |
| UC Davis | 1358 | 1135 | 83.6 | 642 | 542 | 84.4 | 1033 | 904 | 87.5 | 1790 | 1488 | 83.1 | 2107 | 1393 | 66.1 |
| Worcester | 1153 | 1045 | 90.6 | 568 | 514 | 90.5 | 833 | 778 | 93.4 | 1553 | 1408 | 90.7 | 2105 | 1772 | 84.2 |
| Total | 45560 | 37857 | 83.1 | 25193 | 20432 | 81.1 | 34447 | 29861 | 86.7 | 63331 | 52174 | 82.4 | 86744 | 63229 | 72.9 |

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

Data as of August 15, 2007

| | 1st Mailing Period | | | | 2nd Mailing Period | | | | | 3rd Mailing Period | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Study | Form | Sent Mail 1 | Response | | Past 2nd mailing period | Sent Mail 2 | | Response | | Cumulative response | Past 3rd mailing period | Sent Mail 3 | | Response | | Cumulative Response |
| Total | 33 | 113982 | 96608 | 84.8% | 113982 | 17827 | 15.6% | 8717 | 48.9% | 92.4% | 113982 | 7884 | 6.9% | 2903 | 36.8% | 95.0% |
| | 134 | 113992 | 95149 | 83.4% | 113992 | 19197 | 16.8% | 9588 | 50.0% | 91.9% | 113992 | 8316 | 7.3% | 3042 | 36.6% | 94.6% |
| | 150 | 20240 | 15903 | 78.6% | 20240 | 4496 | 22.2% | 1904 | 42.4% | 88.0% | 20240 | 2247 | 11.1% | 737 | 32.8% | 91.6% |
| | 151 | 81907 | 67510 | 82.4% | 81907 | 14827 | 18.1% | 7200 | 48.6% | 91.2% | 81907 | 6560 | 8.0% | 2374 | 36.2% | 94.1% |
| HT | 33 | 20235 | 15887 | 78.5% | 20235 | 4503 | 22.3% | 1903 | 42.3% | 87.9% | 20235 | 2243 | 11.1% | 734 | 32.7% | 91.5% |
| | 134 | 20237 | 15707 | 77.6% | 20237 | 4680 | 23.1% | 1999 | 42.7% | 87.5% | 20237 | 2311 | 11.4% | 736 | 31.9% | 91.1% |
| | 150 | 20240 | 15903 | 78.6% | 20240 | 4496 | 22.2% | 1904 | 42.4% | 88.0% | 20240 | 2247 | 11.1% | 737 | 32.8% | 91.6% |
| | 151 | 20241 | 15875 | 78.4% | 20241 | 4520 | 22.3% | 1917 | 42.4% | 87.9% | 20241 | 2258 | 11.2% | 747 | 33.1% | 91.6% |
| DM | 33 | 37611 | 30715 | 81.7% | 37611 | 7216 | 19.2% | 3430 | 47.5% | 90.8% | 37611 | 3257 | 8.7% | 1153 | 35.4% | 93.9% |
| | 134 | 37614 | 30339 | 80.7% | 37614 | 7589 | 20.2% | 3648 | 48.1% | 90.4% | 37614 | 3407 | 9.1% | 1189 | 34.9% | 93.5% |
| | 150 | 6060 | 4655 | 76.8% | 6060 | 1473 | 24.3% | 615 | 41.8% | 87.0% | 6060 | 763 | 12.6% | 235 | 30.8% | 90.8% |
| | 151 | 37618 | 30564 | 81.3% | 37618 | 7390 | 19.6% | 3573 | 48.4% | 90.8% | 37618 | 3293 | 8.8% | 1178 | 35.8% | 93.9% |
| CaD | 33 | 29670 | 24166 | 81.5% | 29670 | 5746 | 19.4% | 2673 | 46.5% | 90.5% | 29670 | 2633 | 8.9% | 943 | 35.8% | 93.6% |
| | 134 | 29673 | 23898 | 80.5% | 29673 | 6008 | 20.3% | 2819 | 46.9% | 90.0% | 29673 | 2735 | 9.2% | 964 | 35.3% | 93.3% |
| | 150 | 12815 | 10148 | 79.2% | 12815 | 2771 | 21.6% | 1187 | 42.8% | 88.5% | 12815 | 1365 | 10.7% | 469 | 34.4% | 92.1% |
| | 151 | 29678 | 24078 | 81.1% | 29678 | 5846 | 19.7% | 2756 | 47.1% | 90.4% | 29678 | 2657 | 9.0% | 963 | 36.2% | 93.7% |
| OS | 33 | 62196 | 54662 | 87.9% | 62196 | 7579 | 12.2% | 3991 | 52.7% | 94.3% | 62196 | 3148 | 5.1% | 1251 | 39.7% | 96.3% |
| | 134 | 62201 | 53708 | 86.4% | 62201 | 8448 | 13.6% | 4581 | 54.2% | 93.7% | 62201 | 3376 | 5.4% | 1347 | 39.9% | 95.9% |
| | 151 | 30108 | 25724 | 85.4% | 30108 | 4392 | 14.6% | 2329 | 53.0% | 93.2% | 30108 | 1772 | 5.9% | 683 | 38.5% | 95.4% |

**Table 1.5 (continued for year 2)**
**Response Rates to CCC Annual Mailings, Extension Year 2**

Data as of August 15, 2007

| | 1st Mailing Period | | | | 2nd Mailing Period | | | | | | 3rd Mailing Period | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Study | Form | Sent Mail 1 | Response | | Past 2nd mailing period | Sent Mail 2 | | Response | | Cumulative Response | Past 3rd mailing period | Sent Mail 3 | | Response | | Cumulative Response |
| Total | 33 | 100007 | 85018 | 85.0% | 95595 | 15395 | 16.1% | 6625 | 43.0% | 92.1% | 95595 | 4950 | 5.2% | 1461 | 29.5% | 93.6% |
| | 134 | 1273 | 524 | 41.2% | 1232 | 665 | 54.0% | 112 | 16.8% | 50.9% | 1232 | 346 | 28.1% | 44 | 12.7% | 54.5% |
| | 150 | 14859 | 11788 | 79.3% | 13201 | 2856 | 21.6% | 1085 | 38.0% | 87.7% | 13201 | 953 | 7.2% | 244 | 25.6% | 89.5% |
| | 151 | 100053 | 84891 | 84.9% | 95641 | 15566 | 16.3% | 6745 | 43.3% | 92.0% | 95641 | 4991 | 5.2% | 1488 | 29.8% | 93.6% |
| HT | 33 | 14856 | 11779 | 79.3% | 13198 | 2861 | 21.7% | 1092 | 38.2% | 87.7% | 13198 | 950 | 7.2% | 244 | 25.7% | 89.5% |
| | 134 | 247 | 51 | 20.7% | 222 | 162 | 73.0% | 27 | 16.7% | 33.8% | 222 | 87 | 39.2% | 5 | 5.8% | 36.0% |
| | 150 | 14859 | 11788 | 79.3% | 13201 | 2856 | 21.6% | 1085 | 38.0% | 87.7% | 13201 | 953 | 7.2% | 244 | 25.6% | 89.5% |
| | 151 | 14861 | 11780 | 79.3% | 13203 | 2876 | 21.8% | 1094 | 38.0% | 87.7% | 13203 | 961 | 7.3% | 249 | 25.9% | 89.6% |
| DM | 33 | 27482 | 22862 | 83.2% | 24264 | 4464 | 18.4% | 1865 | 41.8% | 90.8% | 24264 | 1322 | 5.5% | 363 | 27.5% | 92.3% |
| | 134 | 297 | 71 | 23.9% | 276 | 191 | 69.2% | 12 | 6.3% | 27.5% | 276 | 107 | 38.8% | 12 | 11.2% | 31.9% |
| | 150 | 4428 | 3468 | 78.3% | 3964 | 922 | 23.3% | 345 | 37.4% | 86.8% | 3964 | 317 | 8.0% | 86 | 27.1% | 89.0% |
| | 151 | 27491 | 22842 | 83.1% | 24273 | 4492 | 18.5% | 1890 | 42.1% | 90.8% | 24273 | 1326 | 5.5% | 363 | 27.4% | 92.3% |
| CaD | 33 | 21732 | 18016 | 82.9% | 19119 | 3562 | 18.6% | 1443 | 40.5% | 90.4% | 19119 | 1066 | 5.6% | 283 | 26.6% | 91.9% |
| | 134 | 269 | 62 | 23.1% | 247 | 170 | 68.8% | 14 | 8.2% | 29.3% | 247 | 96 | 38.9% | 8 | 8.3% | 32.4% |
| | 150 | 9432 | 7571 | 80.3% | 8378 | 1752 | 20.9% | 675 | 38.5% | 88.4% | 8378 | 573 | 6.8% | 150 | 26.2% | 90.2% |
| | 151 | 21733 | 17989 | 82.8% | 19120 | 3592 | 18.8% | 1458 | 40.6% | 90.4% | 19120 | 1074 | 5.6% | 287 | 26.7% | 91.9% |
| OS | 33 | 62095 | 53838 | 86.7% | 62095 | 8997 | 14.5% | 4018 | 44.7% | 93.2% | 62095 | 2995 | 4.8% | 940 | 31.4% | 94.7% |
| | 134 | 804 | 415 | 51.6% | 804 | 365 | 45.4% | 79 | 21.6% | 61.4% | 804 | 179 | 22.3% | 27 | 15.1% | 64.8% |
| | 151 | 62128 | 53731 | 86.5% | 62128 | 9125 | 14.7% | 4108 | 45.0% | 93.1% | 62128 | 3025 | 4.9% | 961 | 31.8% | 94.6% |

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

Data as of August 15, 2007

| Study | Form | Eligible for FC Follow-up | Respondents | | Total Estimated Response Rate |
|---|---|---|---|---|---|
| **Total** | 33 | 6254 | 4983 | 79.7% | 98.3% |
| | 134 | 6924 | 4970 | 71.8% | 97.9% |
| | 150 | 1667 | 1150 | 69.0% | 96.8% |
| | 151 | 5708 | 1667 | 29.2% | 94.8% |
| **HT** | 33 | 1592 | 1326 | 83.3% | 97.6% |
| | 134 | 1730 | 1302 | 75.3% | 97.0% |
| | 150 | 1667 | 1150 | 69.0% | 96.8% |
| | 151 | 1684 | 602 | 35.8% | 94.0% |
| **DM** | 33 | 2240 | 1876 | 83.8% | 98.4% |
| | 134 | 2437 | 1839 | 75.5% | 98.0% |
| | 150 | 556 | 390 | 70.1% | 96.7% |
| | 151 | 2354 | 736 | 31.3% | 95.4% |
| **CaD** | 33 | 1771 | 1477 | 83.4% | 98.2% |
| | 134 | 1932 | 1457 | 75.4% | 97.8% |
| | 150 | 974 | 672 | 69.0% | 96.9% |
| | 151 | 1866 | 621 | 33.3% | 95.4% |
| **OS** | 33 | 2959 | 2231 | 75.4% | 98.4% |
| | 134 | 3330 | 2271 | 68.2% | 98.0% |
| | 151 | 2228 | 525 | 23.6% | 94.2% |

**Table 1.6 (continued for year 2)**
**Response Rates to Field Center Follow-up and Cumulative Response--Extension Study Follow-up Year 2**

Data as of August 15, 2007

| Study | Form | Eligible for FC Follow-up | Respondents | | Total Estimated Response Rate |
|---|---|---|---|---|---|
| **Total** | 33 | 1439 | 1294 | 89.9% | 98.7% |
| | 134 | 451 | 117 | 25.9% | 61.1% |
| | 150 | 176 | 122 | 69.3% | 95.8% |
| | 151 | 1569 | 831 | 53.0% | 97.2% |
| **HT** | 33 | 171 | 137 | 80.1% | 96.6% |
| | 134 | 51 | 16 | 31.4% | 50.6% |
| | 150 | 176 | 122 | 69.3% | 95.8% |
| | 151 | 178 | 93 | 52.3% | 94.3% |
| **DM** | 33 | 220 | 188 | 85.5% | 97.9% |
| | 134 | 67 | 15 | 22.4% | 44.0% |
| | 150 | 67 | 49 | 73.1% | 95.5% |
| | 151 | 241 | 120 | 49.8% | 95.8% |
| **CaD** | 33 | 181 | 156 | 86.2% | 97.9% |
| | 134 | 48 | 12 | 25.0% | 50.0% |
| | 150 | 112 | 82 | 73.2% | 96.2% |
| | 151 | 194 | 104 | 53.6% | 95.8% |
| **OS** | 33 | 1113 | 1022 | 91.8% | 98.9% |
| | 134 | 352 | 92 | 26.1% | 63.8% |
| | 151 | 1219 | 658 | 54.0% | 97.5% |

**Table 2.1**
**Hormone Therapy Component Age – and Race/Ethnicity**

Data as of August 15, 2007

| HT Participants | Total Randomized | % of Overall Goal | Distribution | Design Assumption |
|---|---|---|---|---|
| **Age** | | | | |
| **Overall** | **27,347** | | | |
| 50-54 | 3,420 | 125% | 13% | 10% |
| 55-59 | 5,413 | 99% | 20% | 20% |
| 60-69 | 12,360 | 100% | 45% | 45% |
| 70-79 | 6,154 | 90% | 23% | 25% |
| **Without Uterus** | **10,739** | | | |
| 50-54 | 1,396 | 113% | 13% | 10% |
| 55-59 | 1,917 | 78% | 18% | 20% |
| 60-69 | 4,851 | 88% | 45% | 45% |
| 70-79 | 2,575 | 84% | 24% | 25% |
| **With Uterus** | **16,608** | | | |
| 50-54 | 2,024 | 135% | 12% | 10% |
| 55-59 | 3,496 | 116% | 21% | 20% |
| 60-69 | 7,509 | 111% | 45% | 45% |
| 70-79 | 3,579 | 95% | 22% | 25% |
| **Race/Ethnicity** | | | | |
| **Overall** | **27,347** | | | |
| American Indian | 130 | | <1% | |
| Asian | 527 | | 2% | |
| Black | 2,738 | | 10% | |
| Hispanic | 1,537 | | 6% | |
| White | 22,030 | | 81% | |
| Unknown | 385 | | 1% | |
| | 130 | | <1% | |
| **Without Uterus** | **10,739** | | | |
| American Indian | 75 | | 1% | |
| Asian | 164 | | 2% | |
| Black | 1,616 | | 15% | |
| Hispanic | 651 | | 6% | |
| White | 8,084 | | 75% | |
| Unknown | 149 | | 1% | |
| **With Uterus** | **16,608** | | | |
| American Indian | 55 | | <1% | |
| Asian | 363 | | 2% | |
| Black | 1,122 | | 7% | |
| Hispanic | 886 | | 5% | |
| White | 13,946 | | 84% | |
| Unknown | 236 | | 1% | |

**Table 2.2**
**Lost-to-Follow-up and Vital Status: HT Participants by Hysterectomy Status**

Data as of: August 15, 2007

**Extension Participants Only**

| | Without Uterus (N=7,645) | | With Uterus (N=12,787) | | HT Participants (N=20,432) | |
|---|---|---|---|---|---|---|
| | N | % | N | % | N | % |
| **Vital Status/Participation** | | | | | | |
| Deceased | 186 | 2.4 | 290 | 2.3 | 476 | 2.3 |
| Alive: Current Participation[1] | 7144 | 93.4 | 11988 | 93.8 | 19132 | 93.6 |
| Alive: Recent Participation[2] | 182 | 2.4 | 302 | 2.4 | 484 | 2.4 |
| Alive: Past/Unknown Participation[3] | 5 | 0.1 | 13 | 0.1 | 18 | 0.1 |
| Stopped Follow-Up[4] | 61 | 0.8 | 103 | 0.8 | 164 | 0.8 |
| Lost to Follow-Up[5] | 67 | 0.9 | 91 | 0.7 | 158 | 0.8 |

Data as of: September 12, 2005

**Events through Study Closeout**

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

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

**Table 2.3**
**Verified Outcomes (Annualized Percentages) by Age for Hormone Therapy**

Data as of: August 15, 2007

| Outcomes | Total | | Age 50-54 | | 55-59 | | 60-69 | | 70-79 | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Number randomized** | 27347 | | 3420 | | 5413 | | 12360 | | 6154 | |
| **Mean follow-up (months)** | 113.0 | | 119.2 | | 116.4 | | 112.7 | | 107.2 | |
| **Cardiovascular** | | | | | | | | | | |
| CHD[1] | 1233 | (0.48%) | 61 | (0.18%) | 134 | (0.26%) | 571 | (0.49%) | 467 | (0.85%) |
| CHD death[2] | 366 | (0.14%) | 13 | (0.04%) | 29 | (0.06%) | 151 | (0.13%) | 173 | (0.31%) |
| Total MI[3] | 976 | (0.38%) | 50 | (0.15%) | 112 | (0.21%) | 456 | (0.39%) | 358 | (0.65%) |
| Clinical MI | 942 | (0.37%) | 49 | (0.14%) | 110 | (0.21%) | 439 | (0.38%) | 344 | (0.63%) |
| CABG/PTCA | 1481 | (0.58%) | 70 | (0.21%) | 189 | (0.36%) | 743 | (0.64%) | 479 | (0.87%) |
| Carotid artery disease | 252 | (0.10%) | 5 | (0.01%) | 27 | (0.05%) | 135 | (0.12%) | 85 | (0.15%) |
| Stroke | 837 | (0.33%) | 32 | (0.09%) | 77 | (0.15%) | 375 | (0.32%) | 353 | (0.64%) |
| Non-disabling stroke[4] | 463 | (0.18%) | 26 | (0.08%) | 52 | (0.10%) | 199 | (0.17%) | 186 | (0.34%) |
| Fatal/disabling stroke[4] | 311 | (0.12%) | 3 | (0.01%) | 19 | (0.04%) | 143 | (0.12%) | 146 | (0.27%) |
| Unknown status from stroke[4] | 63 | (0.02%) | 3 | (0.01%) | 6 | (0.01%) | 33 | (0.03%) | 21 | (0.04%) |
| PVD | 248 | (0.10%) | 12 | (0.04%) | 25 | (0.05%) | 132 | (0.11%) | 79 | (0.14%) |
| DVT | 467 | (0.18%) | 26 | (0.08%) | 67 | (0.13%) | 215 | (0.19%) | 159 | (0.29%) |
| Pulmonary embolism | 333 | (0.13%) | 22 | (0.06%) | 47 | (0.09%) | 156 | (0.13%) | 108 | (0.20%) |
| Coronary disease[5] | 2989 | (1.16%) | 160 | (0.47%) | 353 | (0.67%) | 1406 | (1.21%) | 1070 | (1.95%) |
| DVT/PE | 647 | (0.25%) | 35 | (0.10%) | 88 | (0.17%) | 312 | (0.27%) | 212 | (0.39%) |
| **Total cardiovascular disease** | 4415 | (1.71%) | 229 | (0.67%) | 522 | (0.99%) | 2081 | (1.79%) | 1583 | (2.88%) |
| **Cancer** | | | | | | | | | | |
| Breast cancer | 1099 | (0.43%) | 111 | (0.33%) | 203 | (0.39%) | 517 | (0.45%) | 268 | (0.49%) |
| Invasive breast cancer | 890 | (0.35%) | 85 | (0.25%) | 163 | (0.31%) | 411 | (0.35%) | 231 | (0.42%) |
| Non-invasive breast cancer | 219 | (0.09%) | 27 | (0.08%) | 41 | (0.08%) | 112 | (0.10%) | 39 | (0.07%) |
| Ovarian cancer | 88 | (0.03%) | 4 | (0.01%) | 17 | (0.03%) | 47 | (0.04%) | 20 | (0.04%) |
| Endometrial cancer[6] | 115 | (0.04%) | 9 | (0.03%) | 26 | (0.05%) | 58 | (0.05%) | 22 | (0.04%) |
| Colorectal cancer | 368 | (0.14%) | 21 | (0.06%) | 43 | (0.08%) | 181 | (0.16%) | 123 | (0.22%) |
| Other cancer[7] | 1475 | (0.57%) | 111 | (0.33%) | 220 | (0.42%) | 696 | (0.60%) | 448 | (0.81%) |
| **Total cancer** | 3014 | (1.17%) | 246 | (0.72%) | 497 | (0.95%) | 1430 | (1.23%) | 841 | (1.53%) |
| **Fractures** | | | | | | | | | | |
| Hip fracture | 490 | (0.19%) | 7 | (0.02%) | 33 | (0.06%) | 165 | (0.14%) | 285 | (0.52%) |
| **Deaths** | | | | | | | | | | |
| Cardiovascular deaths | 647 | (0.25%) | 23 | (0.07%) | 48 | (0.09%) | 256 | (0.22%) | 320 | (0.58%) |
| Cancer deaths | 859 | (0.33%) | 42 | (0.12%) | 101 | (0.19%) | 407 | (0.35%) | 309 | (0.56%) |
| Other known cause | 429 | (0.17%) | 17 | (0.05%) | 52 | (0.10%) | 173 | (0.15%) | 187 | (0.34%) |
| Unknown cause | 70 | (0.03%) | 5 | (0.01%) | 7 | (0.01%) | 33 | (0.03%) | 25 | (0.05%) |
| Not yet adjudicated | 194 | (0.08%) | 11 | (0.03%) | 26 | (0.05%) | 71 | (0.06%) | 86 | (0.16%) |
| **Total death** | 2199 | (0.85%) | 98 | (0.29%) | 234 | (0.45%) | 940 | (0.81%) | 927 | (1.69%) |

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Study.
[2] "CHD death" includes definite and possible CHD death.
[3] "Total MI' includes clinical MI and evolving Q-wave MI; Q-wave MI is not collected in the WHI Extension Study.
[4] Non-disabling stroke includes Glasgow scales 1 and 2; fatal/disabling includes Glasgow scales 3-5 and death within 1 month of stroke; and unknown status includes Glasgow scale 6 and status not yet known.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA; Q-wave MI, angina, and congestive heart failure are not collected in the WHI Extension Study.
[6] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[7] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.

**Table 2.3 (continued)**
**Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Hormone Therapy**
Data as of: August 15, 2007

| Outcomes | Race/Ethnicity: American Indian/ Alaskan Native | | Asian/Pacific Islander | | Black/African American | | Hispanic/ Latino | | White | | Unknown | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Number randomized** | 130 | | 527 | | 2738 | | 1537 | | 22030 | | 385 | |
| **Mean follow-up (months)** | 106.8 | | 107.0 | | 110.7 | | 106.0 | | 114.0 | | 107.8 | |
| **Cardiovascular** | | | | | | | | | | | | |
| CHD[1] | 5 | (0.43%) | 16 | (0.34%) | 126 | (0.50%) | 36 | (0.27%) | 1028 | (0.49%) | 22 | (0.64%) |
| CHD death[2] | 2 | (0.17%) | 6 | (0.13%) | 60 | (0.24%) | 6 | (0.04%) | 289 | (0.14%) | 3 | (0.09%) |
| Total MI[3] | 4 | (0.35%) | 14 | (0.30%) | 81 | (0.32%) | 31 | (0.23%) | 826 | (0.39%) | 20 | (0.58%) |
| Clinical MI | 4 | (0.35%) | 13 | (0.28%) | 80 | (0.32%) | 29 | (0.21%) | 797 | (0.38%) | 19 | (0.55%) |
| CABG/PTCA | 7 | (0.61%) | 16 | (0.34%) | 120 | (0.48%) | 54 | (0.40%) | 1262 | (0.60%) | 22 | (0.64%) |
| Carotid artery disease | 1 | (0.09%) | 1 | (0.02%) | 10 | (0.04%) | 2 | (0.01%) | 235 | (0.11%) | 3 | (0.09%) |
| Stroke | 6 | (0.52%) | 14 | (0.30%) | 109 | (0.43%) | 25 | (0.18%) | 669 | (0.32%) | 14 | (0.40%) |
| Non-disabling stroke[4] | 3 | (0.26%) | 8 | (0.17%) | 56 | (0.22%) | 15 | (0.11%) | 374 | (0.18%) | 7 | (0.20%) |
| Fatal/disabling stroke[4] | 3 | (0.26%) | 6 | (0.13%) | 43 | (0.17%) | 6 | (0.04%) | 249 | (0.12%) | 4 | (0.12%) |
| Unknown status from stroke[4] | 0 | (0.00%) | 0 | (0.00%) | 10 | (0.04%) | 4 | (0.03%) | 46 | (0.02%) | 3 | (0.09%) |
| PVD | 2 | (0.17%) | 3 | (0.06%) | 27 | (0.11%) | 2 | (0.01%) | 214 | (0.10%) | 0 | (0.00%) |
| DVT | 3 | (0.26%) | 2 | (0.04%) | 49 | (0.19%) | 7 | (0.05%) | 403 | (0.19%) | 3 | (0.09%) |
| Pulmonary embolism | 3 | (0.26%) | 1 | (0.02%) | 41 | (0.16%) | 4 | (0.03%) | 282 | (0.13%) | 2 | (0.06%) |
| Coronary disease[5] | 12 | (1.04%) | 36 | (0.77%) | 325 | (1.29%) | 108 | (0.80%) | 2464 | (1.18%) | 44 | (1.27%) |
| DVT/PE | 6 | (0.52%) | 2 | (0.04%) | 73 | (0.29%) | 9 | (0.07%) | 553 | (0.26%) | 4 | (0.12%) |
| **Total cardiovascular disease** | 22 | (1.90%) | 51 | (1.09%) | 482 | (1.91%) | 140 | (1.03%) | 3667 | (1.75%) | 53 | (1.53%) |
| **Cancer** | | | | | | | | | | | | |
| Breast cancer | 3 | (0.26%) | 24 | (0.51%) | 97 | (0.38%) | 36 | (0.27%) | 927 | (0.44%) | 12 | (0.35%) |
| Invasive breast cancer | 3 | (0.26%) | 18 | (0.38%) | 79 | (0.31%) | 27 | (0.20%) | 755 | (0.36%) | 8 | (0.23%) |
| Non-invasive breast cancer | 0 | (0.00%) | 7 | (0.15%) | 18 | (0.07%) | 9 | (0.07%) | 181 | (0.09%) | 4 | (0.12%) |
| Ovarian cancer | 0 | (0.00%) | 1 | (0.02%) | 6 | (0.02%) | 0 | (0.00%) | 79 | (0.04%) | 2 | (0.06%) |
| Endometrial cancer[6] | 1 | (0.09%) | 1 | (0.02%) | 7 | (0.03%) | 5 | (0.04%) | 100 | (0.05%) | 1 | (0.03%) |
| Colorectal cancer | 1 | (0.09%) | 9 | (0.19%) | 28 | (0.11%) | 14 | (0.10%) | 307 | (0.15%) | 9 | (0.26%) |
| Other cancer[7] | 7 | (0.61%) | 29 | (0.62%) | 107 | (0.42%) | 47 | (0.35%) | 1267 | (0.61%) | 18 | (0.52%) |
| **Total cancer** | 12 | (1.04%) | 64 | (1.36%) | 236 | (0.93%) | 96 | (0.71%) | 2567 | (1.23%) | 39 | (1.13%) |
| **Fractures** | | | | | | | | | | | | |
| Hip fracture | 3 | (0.26%) | 4 | (0.09%) | 10 | (0.04%) | 7 | (0.05%) | 462 | (0.22%) | 4 | (0.12%) |
| **Deaths** | | | | | | | | | | | | |
| Cardiovascular deaths | 4 | (0.35%) | 11 | (0.23%) | 99 | (0.39%) | 11 | (0.08%) | 516 | (0.25%) | 6 | (0.17%) |
| Cancer deaths | 5 | (0.43%) | 18 | (0.38%) | 72 | (0.29%) | 31 | (0.23%) | 722 | (0.34%) | 11 | (0.32%) |
| Other known cause | 4 | (0.35%) | 3 | (0.06%) | 36 | (0.14%) | 7 | (0.05%) | 372 | (0.18%) | 7 | (0.20%) |
| Unknown cause | 0 | (0.00%) | 2 | (0.04%) | 14 | (0.06%) | 3 | (0.02%) | 50 | (0.02%) | 1 | (0.03%) |
| Not yet adjudicated | 1 | (0.09%) | 1 | (0.02%) | 13 | (0.05%) | 9 | (0.07%) | 167 | (0.08%) | 3 | (0.09%) |
| **Total Death** | 14 | (1.21%) | 35 | (0.74%) | 234 | (0.93%) | 61 | (0.45%) | 1827 | (0.87%) | 28 | (0.81%) |

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Study.
[2] "CHD death" includes definite and possible CHD death.
[3] "Total MI" includes clinical MI and evolving Q-wave MI; Q-wave MI is not collected in the WHI Extension Study.
[4] Non-disabling stroke includes Glasgow scales 1 and 2; fatal/disabling includes Glasgow scales 3-5 and death within 1 month of stroke; and unknown status includes Glasgow scale 6 and status not yet known.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA; Q-wave MI, angina, and congestive heart failure are not collected in the WHI Extension Study.
[6] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[7] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.

**Table 2.4**
**Verified Outcomes (Annualized Percentages) for HT Participants Without and With Uterus**

Data as of: August 15, 2007

| Outcomes | Without Uterus | | With Uterus | |
|---|---|---|---|---|
| **Number randomized** | 10739 | | 16608 | |
| **Mean follow-up (months)** | 111.7 | | 113.9 | |
| **Cardiovascular** | | | | |
| CHD[1] | 570 | (0.57%) | 663 | (0.42%) |
| CHD death[2] | 190 | (0.19%) | 176 | (0.11%) |
| Total MI[3] | 440 | (0.44%) | 536 | (0.34%) |
| Clinical MI | 425 | (0.43%) | 517 | (0.33%) |
| CABG/PTCA | 691 | (0.69%) | 790 | (0.50%) |
| Carotid artery disease | 128 | (0.13%) | 124 | (0.08%) |
| Stroke | 374 | (0.37%) | 463 | (0.29%) |
| Non-disabling stroke[4] | 196 | (0.20%) | 267 | (0.17%) |
| Fatal/disabling stroke[4] | 144 | (0.14%) | 167 | (0.11%) |
| Unknown status from stroke[4] | 34 | (0.03%) | 29 | (0.02%) |
| PVD | 116 | (0.12%) | 132 | (0.08%) |
| DVT | 187 | (0.19%) | 280 | (0.18%) |
| Pulmonary embolism | 124 | (0.12%) | 209 | (0.13%) |
| Coronary disease[5] | 1438 | (1.44%) | 1551 | (0.98%) |
| DVT/PE | 260 | (0.26%) | 387 | (0.25%) |
| **Total cardiovascular disease** | 2044 | (2.05%) | 2371 | (1.50%) |
| **Cancer** | | | | |
| Breast cancer | 373 | (0.37%) | 726 | (0.46%) |
| Invasive breast cancer | 307 | (0.31%) | 583 | (0.37%) |
| Non-invasive breast cancer | 68 | (0.07%) | 151 | (0.10%) |
| Ovarian cancer | 22 | (0.02%) | 66 | (0.04%) |
| Endometrial cancer[6] | 0 | N/A | 115 | (0.07%) |
| Colorectal cancer | 149 | (0.15%) | 219 | (0.14%) |
| Other cancer[7] | 579 | (0.58%) | 896 | (0.57%) |
| **Total cancer** | 1087 | (1.09%) | 1927 | (1.22%) |
| **Fractures** | | | | |
| Hip fracture | 181 | (0.18%) | 309 | (0.20%) |
| **Deaths** | | | | |
| Cardiovascular deaths | 313 | (0.31%) | 334 | (0.21%) |
| Cancer deaths | 357 | (0.36%) | 502 | (0.32%) |
| Other known cause | 169 | (0.17%) | 260 | (0.17%) |
| Unknown cause | 30 | (0.03%) | 40 | (0.03%) |
| Not yet adjudicated | 83 | (0.08%) | 111 | (0.07%) |
| **Total death** | 952 | (0.95%) | 1247 | (0.79%) |

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Study.
[2] "CHD death" includes definite and possible CHD death.
[3] "Total MI" includes clinical MI and evolving Q-wave MI; Q-wave MI is not collected in the WHI Extension Study.
[4] Non-disabling stroke includes Glasgow scales 1 and 2; fatal/disabling includes Glasgow scales 3-5 and death within 1 month of stroke; and unknown status includes Glasgow scale 6 and status not yet known.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA; Q-wave MI, angina, and congestive heart failure are not collected in the WHI Extension Study.
[6] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[7] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.

**Table 2.5**
**Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for HT Participants Who Did Not Report a Prevalent Condition at Baseline**
Data as of: August 15, 2007

| Outcome | Total | | Age 50-54 | | 55-59 | | 60-69 | | 70-79 | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Number randomized** | 27347 | | 3420 | | 5413 | | 12360 | | 6154 | |
| **Mean follow-up (months)** | 113.0 | | 119.2 | | 116.4 | | 112.7 | | 107.2 | |
| **Hospitalizations** | | | | | | | | | | |
| Ever | 15443 | (6.00%) | 1400 | (4.12%) | 2470 | (4.70%) | 7236 | (6.23%) | 4337 | (7.89%) |
| Two or more | 9292 | (3.61%) | 675 | (1.99%) | 1343 | (2.56%) | 4355 | (3.75%) | 2919 | (5.31%) |
| **Other** | | | | | | | | | | |
| Diabetes (treated) | 2793 | (1.14%) | 400 | (1.23%) | 545 | (1.10%) | 1296 | (1.18%) | 552 | (1.06%) |
| Gallbladder disease[1, 2] | 2117 | (1.07%) | 282 | (1.04%) | 443 | (1.07%) | 988 | (1.12%) | 404 | (0.98%) |
| Hysterectomy | 828 | (0.53%) | 74 | (0.37%) | 171 | (0.50%) | 405 | (0.57%) | 178 | (0.55%) |
| Glaucoma[2] | 3203 | (1.41%) | 287 | (0.93%) | 548 | (1.16%) | 1519 | (1.49%) | 849 | (1.80%) |
| Osteoporosis[2] | 6115 | (2.72%) | 477 | (1.55%) | 962 | (2.05%) | 2955 | (2.92%) | 1721 | (3.75%) |
| Osteoarthritis[3] | 5728 | (3.57%) | 737 | (2.85%) | 1169 | (3.18%) | 2631 | (3.78%) | 1191 | (4.26%) |
| Rheumatoid arthritis[2] | 1698 | (0.75%) | 211 | (0.70%) | 341 | (0.73%) | 764 | (0.75%) | 382 | (0.80%) |
| Intestinal polyps | 4771 | (1.99%) | 526 | (1.60%) | 922 | (1.84%) | 2365 | (2.19%) | 958 | (1.97%) |
| Lupus | 305 | (0.12%) | 35 | (0.10%) | 65 | (0.12%) | 138 | (0.12%) | 67 | (0.12%) |
| Kidney stones[2, 3] | 769 | (0.38%) | 94 | (0.36%) | 143 | (0.35%) | 346 | (0.38%) | 186 | (0.42%) |
| Cataracts[2, 3] | 8650 | (4.85%) | 505 | (1.94%) | 1345 | (3.33%) | 4578 | (5.61%) | 2222 | (7.40%) |
| Pills for hypertension | 8485 | (4.63%) | 973 | (3.54%) | 1675 | (4.12%) | 3897 | (4.83%) | 1940 | (5.59%) |

| 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)** | 106.8 | | 107.0 | | 110.7 | | 106.0 | | 114.0 | | 107.8 | |
| **Hospitalizations** | | | | | | | | | | | | |
| Ever | 75 | (6.48%) | 221 | (4.70%) | 1553 | (6.15%) | 663 | (4.88%) | 12727 | (6.08%) | 204 | (5.90%) |
| Two or more | 52 | (4.50%) | 116 | (2.47%) | 935 | (3.70%) | 332 | (2.45%) | 7741 | (3.70%) | 116 | (3.35%) |
| **Other** | | | | | | | | | | | | |
| Diabetes (treated) | 14 | (1.39%) | 59 | (1.37%) | 429 | (1.94%) | 243 | (1.94%) | 2007 | (1.00%) | 41 | (1.28%) |
| Gallbladder disease[1, 2] | 13 | (1.58%) | 32 | (0.81%) | 187 | (0.89%) | 129 | (1.35%) | 1730 | (1.08%) | 26 | (0.99%) |
| Hysterectomy | 2 | (0.42%) | 7 | (0.21%) | 53 | (0.51%) | 39 | (0.50%) | 718 | (0.54%) | 9 | (0.42%) |
| Glaucoma[2] | 16 | (1.59%) | 60 | (1.44%) | 410 | (1.90%) | 190 | (1.55%) | 2480 | (1.34%) | 47 | (1.58%) |
| Osteoporosis[2] | 32 | (3.13%) | 141 | (3.39%) | 349 | (1.55%) | 338 | (2.85%) | 5162 | (2.83%) | 93 | (3.08%) |
| Osteoarthritis[3] | 38 | (4.85%) | 119 | (3.58%) | 571 | (3.71%) | 401 | (4.25%) | 4508 | (3.49%) | 91 | (4.05%) |
| Rheumatoid arthritis[2] | 15 | (1.58%) | 30 | (0.73%) | 272 | (1.27%) | 220 | (1.82%) | 1126 | (0.61%) | 35 | (1.16%) |
| Intestinal polyps | 23 | (2.15%) | 72 | (1.69%) | 498 | (2.12%) | 223 | (1.72%) | 3901 | (2.01%) | 54 | (1.70%) |
| Lupus | 2 | (0.17%) | 4 | (0.09%) | 34 | (0.14%) | 24 | (0.18%) | 240 | (0.12%) | 1 | (0.03%) |
| Kidney stones[2, 3] | 9 | (1.04%) | 25 | (0.67%) | 82 | (0.41%) | 62 | (0.58%) | 583 | (0.36%) | 8 | (0.29%) |
| Cataracts[2, 3] | 44 | (5.26%) | 143 | (4.35%) | 790 | (4.45%) | 450 | (4.34%) | 7110 | (4.95%) | 113 | (4.69%) |
| Pills for hypertension | 49 | (5.96%) | 150 | (4.56%) | 753 | (5.98%) | 513 | (5.03%) | 6920 | (4.49%) | 100 | (4.41%) |

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

**Table 2.6**
**Selected Medication Use after Stopping of the HT Intervention**

Data as of: August 15, 2007

| | Without Uterus | | | | With Uterus | | | |
|---|---|---|---|---|---|---|---|---|
| | E-alone | | Placebo | | E+P | | Placebo | |
| | N | % | N | % | N | % | N | % |
| **Use after stopping but before closeout**[1] | | | | | | | | |
| Number due for medication collection | | | | | 7463 | | 7063 | |
| % missing medication information | | | | | 20.3% | | 21.0% | |
| Estrogen | N/A | | N/A | | 385 | 6.5 | 301 | 5.4 |
| Osteoporosis[2] | N/A | | N/A | | 739 | 12.4 | 949 | 17.0 |
| SERM | N/A | | N/A | | 124 | 2.1 | 118 | 2.1 |
| **Use during extension**[3] | | | | | | | | |
| Number in extension | 3778 | | 3867 | | 6545 | | 6242 | |
| **Extension Year 1** | | | | | | | | |
| Any prescription hormone | 219 | 6.6 | 122 | 3.6 | 241 | 4.2 | 177 | 3.2 |
| E-alone use | 154 | 4.6 | 92 | 2.7 | 152 | 2.6 | 122 | 2.2 |
| E+P use | 18 | 0.5 | 16 | 0.5 | 110 | 1.9 | 43 | 0.8 |
| Non-prescription (natural) hormone | 92 | 2.8 | 84 | 2.5 | 172 | 3.0 | 155 | 2.8 |
| Osteoporosis[4] | 572 | 17.5 | 690 | 20.9 | 1276 | 22.5 | 1458 | 26.9 |
| SERM | 72 | 2.2 | 95 | 2.9 | 224 | 3.9 | 167 | 3.0 |
| **Extension Year 2** | | | | | | | | |
| Any prescription hormone | 164 | 5.6 | 99 | 3.3 | 200 | 3.8 | 121 | 2.4 |
| E-alone use | 122 | 4.1 | 92 | 3.0 | 137 | 2.6 | 109 | 2.1 |
| E+P use | 19 | 0.6 | 16 | 0.5 | 79 | 1.5 | 36 | 0.7 |
| Non-prescription (natural) hormone | 54 | 1.8 | 65 | 2.2 | 104 | 2.0 | 111 | 2.2 |
| Osteoporosis[4] | 513 | 17.4 | 621 | 20.6 | 1173 | 22.5 | 1328 | 26.8 |
| SERM | 73 | 2.4 | 89 | 2.9 | 180 | 3.4 | 155 | 3.1 |

[1] Collected at annual visits 1, 3, 6, and 9. Insufficient data available on the E-alone participants.
[2] Bisphosphonate or calcitonin.
[3] Use at any time during the extension year.
[4] Bisphosphonate, calcitonin, or PTH.

**Table 3.1**
**Dietary Modification Component Age – and Race/Ethnicity – Specific Recruitment**

Data as of August 15, 2007

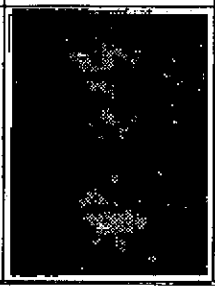
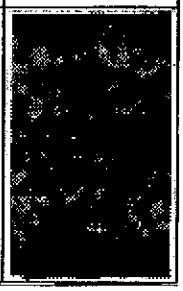
| | Total Randomized | % of Overall Goal | Distribution | Design Assumption |
|---|---|---|---|---|
| **Age** | **48,835** | | | |
| 50-54 | 6,961 | 149% | 14% | 10% |
| 55-59 | 11,037 | 118% | 23% | 20% |
| 60-69 | 22,715 | 108% | 47% | 45% |
| 70-79 | 8,122 | 70% | 17% | 25% |
| **Race/Ethnicity** | **48,835** |  | |  |
| American Indian | 202 | | <1% | |
| Asian | 1,105 | | 2% | |
| Black | 5,262 | | 11% | |
| Hispanic | 1,845 | | 4% | |
| White | 39,762 | | 81% | |
| Unknown | 659 | | 1% | |

**Table 3.2**
**Lost-to-Follow-up and Vital Status: DM Participants**

Data as of: August 15, 2007

**Extension Participants Only**

| | DM Participants (N=37,857) | |
|---|---|---|
| | N | % |
| **Vital Status/Participation** | | |
| Deceased | 641 | 1.7 |
| Alive: Current Participation[1] | 36122 | 95.4 |
| Alive: Recent Participation[2] | 710 | 1.9 |
| Alive: Past/Unknown Participation[3] | 18 | <0.1 |
| Stopped Follow-Up[4] | 176 | 0.5 |
| Lost to Follow-Up[5] | 190 | 0.5 |

Data as of: September 12, 2005

**Events through Study Closeout**

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

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

**Table 3.3**
**Nutrient Intake Monitoring**

Data as of August 15, 2007

| | Intervention | | | Control | | | Difference | | |
|---|---|---|---|---|---|---|---|---|---|
| | N | Mean | SD | N | Mean | SD | Mean[1] | SE | p-value[2] |
| **% Energy from Fat** | | | | | | | | | |
| 24 Hr Recall, post-baseline | 226 | 23.0 | 9.2 | 262 | 32.1 | 7.6 | 9.2 | 0.8 | <.01 |
| 24 Hr Recall, Year 3 Cohort | 787 | 24.8 | 8.5 | 1183 | 33.0 | 7.6 | 8.3 | 0.4 | <.01 |
| 24 Hr Recall, Year 6 Cohort | 766 | 26.6 | 9.1 | 1167 | 33.9 | 7.8 | 7.3 | 0.4 | <.01 |
| 24 Hr Recall, Year 9 Cohort | 154 | 28.5 | 8.6 | 264 | 35.2 | 8.4 | 6.7 | 0.9 | <.01 |
| 24 Hr Recall, Ext. Year 1 Cohort | 146 | 30.6 | 9.4 | 176 | 35.1 | 9.7 | 4.6 | 1.1 | <.01 |
| **Total Energy (kcal)** | | | | | | | | | |
| 24 Hr Recall, post-baseline | 226 | 1519.8 | 418.2 | 262 | 1652.8 | 516.5 | 133.0 | 43.0 | <.01 |
| 24 Hr Recall, Year 3 Cohort | 787 | 1431.8 | 391.6 | 1183 | 1589.9 | 489.3 | 158.1 | 20.8 | <.01 |
| 24 Hr Recall, Year 6 Cohort | 766 | 1388.8 | 391.0 | 1167 | 1544.2 | 482.1 | 155.4 | 20.8 | <.01 |
| 24 Hr Recall, Year 9 Cohort | 154 | 1406.7 | 384.6 | 264 | 1516.8 | 452.9 | 110.2 | 43.5 | 0.02 |
| 24 Hr Recall, Ext. Year 1 Cohort | 146 | 1450.6 | 458.8 | 176 | 1588.1 | 538.1 | 137.5 | 56.4 | 0.01 |
| **Total Fat (g)** | | | | | | | | | |
| 24 Hr Recall, post-baseline | 226 | 39.6 | 21.9 | 262 | 60.5 | 26.9 | 20.9 | 2.2 | <.01 |
| 24 Hr Recall, Year 3 Cohort | 787 | 39.8 | 18.7 | 1183 | 59.9 | 25.6 | 20.0 | 1.1 | <.01 |
| 24 Hr Recall, Year 6 Cohort | 766 | 41.5 | 20.0 | 1167 | 59.7 | 26.1 | 18.1 | 1.1 | <.01 |
| 24 Hr Recall, Year 9 Cohort | 154 | 45.1 | 18.6 | 264 | 60.9 | 26.3 | 15.9 | 2.4 | <.01 |
| 24 Hr Recall, Ext. Year 1 Cohort | 146 | 49.7 | 23.7 | 176 | 64.0 | 33.9 | 14.3 | 3.3 | <.01 |
| **Saturated Fat (g)** | | | | | | | | | |
| 24 Hr Recall, post-baseline | 226 | 12.9 | 7.9 | 262 | 20.1 | 9.6 | 7.2 | 0.8 | <.01 |
| 24 Hr Recall, Year 3 Cohort | 787 | 12.4 | 6.8 | 1183 | 19.7 | 9.3 | 7.3 | 0.4 | <.01 |
| 24 Hr Recall, Year 6 Cohort | 766 | 13.1 | 7.1 | 1167 | 19.5 | 9.7 | 6.4 | 0.4 | <.01 |
| 24 Hr Recall, Year 9 Cohort | 154 | 14.5 | 6.8 | 264 | 20.6 | 10.2 | 6.1 | 0.9 | <.01 |
| 24 Hr Recall, Ext. Year 1 Cohort | 146 | 15.6 | 8.8 | 176 | 22.1 | 16.5 | 6.5 | 1.5 | <.01 |
| **Polyunsaturated Fat (g)** | | | | | | | | | |
| 24 Hr Recall, post-baseline | 226 | 8.3 | 5.0 | 262 | 12.6 | 7.3 | 4.3 | 0.6 | <.01 |
| 24 Hr Recall, Year 3 Cohort | 787 | 8.7 | 4.6 | 1183 | 12.2 | 6.9 | 3.6 | 0.3 | <.01 |
| 24 Hr Recall, Year 6 Cohort | 766 | 8.8 | 4.6 | 1167 | 12.3 | 6.2 | 3.5 | 0.3 | <.01 |
| 24 Hr Recall, Year 9 Cohort | 154 | 9.6 | 4.4 | 264 | 12.2 | 5.7 | 2.7 | 0.5 | <.01 |
| 24 Hr Recall, Ext. Year 1 Cohort | 146 | 11.1 | 7.0 | 176 | 13.6 | 8.6 | 2.4 | 0.9 | <.01 |

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.

**Table 3.4**
**Verified Outcomes (Annualized Percentages) by Age for Dietary Modification**

Data as of: August 15, 2007

| Outcome | Total | | Age 50-54 | | 55-59 | | 60-69 | | 70-79 | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Number randomized** | 48835 | | 6961 | | 11037 | | 22715 | | 8122 | |
| **Mean follow-up (months)** | 116.4 | | 123.8 | | 120.1 | | 114.8 | | 109.5 | |
| **Cancer** | | | | | | | | | | |
| Breast cancer | 2474 | (0.52%) | 307 | (0.43%) | 565 | (0.51%) | 1168 | (0.54%) | 434 | (0.59%) |
| Invasive breast cancer | 2001 | (0.42%) | 228 | (0.32%) | 459 | (0.42%) | 957 | (0.44%) | 357 | (0.48%) |
| Non-invasive breast cancer | 499 | (0.11%) | 82 | (0.11%) | 112 | (0.10%) | 223 | (0.10%) | 82 | (0.11%) |
| Ovarian cancer | 214 | (0.05%) | 24 | (0.03%) | 41 | (0.04%) | 106 | (0.05%) | 43 | (0.06%) |
| Endometrial cancer[1] | 352 | (0.07%) | 44 | (0.06%) | 85 | (0.08%) | 166 | (0.08%) | 57 | (0.08%) |
| Colorectal cancer | 585 | (0.12%) | 37 | (0.05%) | 97 | (0.09%) | 296 | (0.14%) | 155 | (0.21%) |
| Other cancer[2] | 2400 | (0.51%) | 209 | (0.29%) | 419 | (0.38%) | 1214 | (0.56%) | 558 | (0.75%) |
| **Total cancer** | 5739 | (1.21%) | 594 | (0.83%) | 1150 | (1.04%) | 2800 | (1.29%) | 1195 | (1.61%) |
| **Cardiovascular** | | | | | | | | | | |
| CHD[3] | 1673 | (0.35%) | 90 | (0.13%) | 204 | (0.18%) | 809 | (0.37%) | 570 | (0.77%) |
| CHD death[4] | 456 | (0.10%) | 21 | (0.03%) | 34 | (0.03%) | 217 | (0.10%) | 184 | (0.25%) |
| Total MI[5] | 1361 | (0.29%) | 72 | (0.10%) | 178 | (0.16%) | 655 | (0.30%) | 456 | (0.62%) |
| Clinical MI | 1307 | (0.28%) | 66 | (0.09%) | 171 | (0.15%) | 629 | (0.29%) | 441 | (0.60%) |
| CABG/PTCA | 2187 | (0.46%) | 106 | (0.15%) | 300 | (0.27%) | 1177 | (0.54%) | 604 | (0.82%) |
| Carotid artery disease | 344 | (0.07%) | 12 | (0.02%) | 42 | (0.04%) | 186 | (0.09%) | 104 | (0.14%) |
| Stroke | 1153 | (0.24%) | 49 | (0.07%) | 119 | (0.11%) | 542 | (0.25%) | 443 | (0.60%) |
| PVD | 300 | (0.06%) | 15 | (0.02%) | 40 | (0.04%) | 150 | (0.07%) | 95 | (0.13%) |
| Coronary disease[6] | 4378 | (0.92%) | 245 | (0.34%) | 584 | (0.53%) | 2215 | (1.02%) | 1334 | (1.80%) |
| **Total cardiovascular disease** | 5683 | (1.20%) | 302 | (0.42%) | 743 | (0.67%) | 2851 | (1.31%) | 1787 | (2.41%) |
| **Fractures** | | | | | | | | | | |
| Hip fracture | 635 | (0.13%) | 15 | (0.02%) | 45 | (0.04%) | 266 | (0.12%) | 309 | (0.42%) |
| **Deaths** | | | | | | | | | | |
| Cardiovascular deaths | 858 | (0.18%) | 36 | (0.05%) | 62 | (0.06%) | 371 | (0.17%) | 389 | (0.53%) |
| Cancer deaths | 1349 | (0.28%) | 83 | (0.12%) | 195 | (0.18%) | 671 | (0.31%) | 400 | (0.54%) |
| Other known cause | 596 | (0.13%) | 32 | (0.04%) | 64 | (0.06%) | 250 | (0.12%) | 250 | (0.34%) |
| Unknown cause | 82 | (0.02%) | 2 | (<0.01%) | 8 | (0.01%) | 43 | (0.02%) | 29 | (0.04%) |
| Not yet adjudicated | 275 | (0.06%) | 10 | (0.01%) | 27 | (0.02%) | 137 | (0.06%) | 101 | (0.14%) |
| **Total death** | 3160 | (0.67%) | 163 | (0.23%) | 356 | (0.32%) | 1472 | (0.68%) | 1169 | (1.58%) |

[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 is not collected in the WHI Extension Study.

[6] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA; Q-wave MI, angina, and congestive heart failure are not collected in the WHI Extension Study.

**Table 3.4 (continued)**
**Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Dietary Modification**

Data as of: August 15, 2007

| 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)** | 112.0 | | 112.5 | | 112.4 | | 107.3 | | 117.6 | | 110.3 | |
| **Cancer** | | | | | | | | | | | | |
| Breast cancer | 5 | (0.27%) | 57 | (0.55%) | 204 | (0.41%) | 61 | (0.37%) | 2118 | (0.54%) | 29 | (0.48%) |
| Invasive breast cancer | 4 | (0.21%) | 44 | (0.42%) | 155 | (0.31%) | 49 | (0.30%) | 1726 | (0.44%) | 23 | (0.38%) |
| Non-invasive breast cancer | 1 | (0.05%) | 13 | (0.13%) | 51 | (0.10%) | 13 | (0.08%) | 415 | (0.11%) | 6 | (0.10%) |
| Ovarian cancer | 1 | (0.05%) | 6 | (0.06%) | 11 | (0.02%) | 8 | (0.05%) | 185 | (0.05%) | 3 | (0.05%) |
| Endometrial cancer[1] | 0 | (0.00%) | 3 | (0.03%) | 21 | (0.04%) | 9 | (0.05%) | 313 | (0.08%) | 6 | (0.10%) |
| Colorectal cancer | 3 | (0.16%) | 10 | (0.10%) | 66 | (0.13%) | 18 | (0.11%) | 481 | (0.12%) | 7 | (0.12%) |
| Other cancer[2] | 7 | (0.37%) | 37 | (0.36%) | 180 | (0.37%) | 50 | (0.30%) | 2096 | (0.54%) | 30 | (0.50%) |
| **Total cancer** | 14 | (0.74%) | 108 | (1.04%) | 459 | (0.93%) | 137 | (0.83%) | 4953 | (1.27%) | 68 | (1.12%) |
| **Cardiovascular** | | | | | | | | | | | | |
| CHD[3] | 4 | (0.21%) | 18 | (0.17%) | 176 | (0.36%) | 29 | (0.18%) | 1425 | (0.37%) | 21 | (0.35%) |
| CHD death[4] | 0 | (0.00%) | 4 | (0.04%) | 68 | (0.14%) | 9 | (0.05%) | 365 | (0.09%) | 10 | (0.17%) |
| Total MI[5] | 4 | (0.21%) | 17 | (0.16%) | 127 | (0.26%) | 23 | (0.14%) | 1173 | (0.30%) | 17 | (0.28%) |
| Clinical MI | 4 | (0.21%) | 17 | (0.16%) | 122 | (0.25%) | 22 | (0.13%) | 1126 | (0.29%) | 16 | (0.26%) |
| CABG/PTCA | 7 | (0.37%) | 19 | (0.18%) | 202 | (0.41%) | 48 | (0.29%) | 1889 | (0.48%) | 22 | (0.36%) |
| Carotid artery disease | 2 | (0.11%) | 1 | (0.01%) | 22 | (0.04%) | 3 | (0.02%) | 311 | (0.08%) | 5 | (0.08%) |
| Stroke | 5 | (0.27%) | 20 | (0.19%) | 160 | (0.32%) | 28 | (0.17%) | 924 | (0.24%) | 16 | (0.26%) |
| PVD | 3 | (0.16%) | 3 | (0.03%) | 55 | (0.11%) | 3 | (0.02%) | 232 | (0.06%) | 4 | (0.07%) |
| Coronary disease[6] | 16 | (0.85%) | 48 | (0.46%) | 540 | (1.10%) | 110 | (0.67%) | 3610 | (0.93%) | 54 | (0.89%) |
| **Total cardiovascular disease** | 24 | (1.27%) | 71 | (0.69%) | 695 | (1.41%) | 140 | (0.85%) | 4681 | (1.20%) | 72 | (1.19%) |
| **Fractures** | | | | | | | | | | | | |
| Hip fracture | 2 | (0.11%) | 4 | (0.04%) | 16 | (0.03%) | 12 | (0.07%) | 593 | (0.15%) | 8 | (0.13%) |
| **Deaths** | | | | | | | | | | | | |
| Cardiovascular deaths | 2 | (0.11%) | 12 | (0.12%) | 123 | (0.25%) | 15 | (0.09%) | 695 | (0.18%) | 11 | (0.18%) |
| Cancer deaths | 7 | (0.37%) | 21 | (0.20%) | 111 | (0.23%) | 35 | (0.21%) | 1155 | (0.30%) | 20 | (0.33%) |
| Other known cause | 9 | (0.48%) | 8 | (0.08%) | 66 | (0.13%) | 13 | (0.08%) | 492 | (0.13%) | 8 | (0.13%) |
| Unknown cause | 0 | (0.00%) | 1 | (0.01%) | 15 | (0.03%) | 1 | (0.01%) | 61 | (0.02%) | 4 | (0.07%) |
| Not yet adjudicated | 1 | (0.05%) | 0 | (0.00%) | 37 | (0.08%) | 3 | (0.02%) | 230 | (0.06%) | 4 | (0.07%) |
| **Total death** | 19 | (1.01%) | 42 | (0.41%) | 352 | (0.71%) | 67 | (0.41%) | 2633 | (0.68%) | 47 | (0.78%) |

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

**Table 3.5**
**Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for DM Participants Who Did Not Report a Prevalent Condition at Baseline**

Data as of: August 15, 2007

| Outcome | Total | | Age 50-54 | | 55-59 | | 60-69 | | 70-79 | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Number randomized** | 48835 | | 6961 | | 11037 | | 22715 | | 8122 | |
| **Mean follow-up (months)** | 116.4 | | 123.8 | | 120.1 | | 114.8 | | 109.5 | |
| **Hospitalizations** | | | | | | | | | | |
| Ever | 27161 | (5.73%) | 2898 | (4.04%) | 5236 | (4.74%) | 13252 | (6.10%) | 5775 | (7.79%) |
| Two or more | 15811 | (3.34%) | 1355 | (1.89%) | 2747 | (2.49%) | 7884 | (3.63%) | 3825 | (5.16%) |
| **Other** | | | | | | | | | | |
| DVT[1] | 638 | (0.14%) | 39 | (0.06%) | 95 | (0.09%) | 307 | (0.15%) | 197 | (0.28%) |
| Pulmonary embolism | 452 | (0.10%) | 33 | (0.05%) | 73 | (0.07%) | 229 | (0.11%) | 117 | (0.16%) |
| Diabetes (treated) | 4598 | (1.01%) | 663 | (0.95%) | 1046 | (0.98%) | 2145 | (1.03%) | 744 | (1.06%) |
| Gallbladder disease[2, 3] | 3830 | (1.06%) | 573 | (0.98%) | 902 | (1.05%) | 1802 | (1.11%) | 553 | (1.00%) |
| Hysterectomy | 1784 | (0.66%) | 263 | (0.64%) | 430 | (0.64%) | 850 | (0.70%) | 241 | (0.60%) |
| Glaucoma[3] | 5318 | (1.28%) | 567 | (0.87%) | 1098 | (1.11%) | 2589 | (1.36%) | 1064 | (1.68%) |
| Osteoporosis[3] | 10221 | (2.50%) | 1129 | (1.75%) | 1969 | (2.02%) | 5021 | (2.71%) | 2102 | (3.44%) |
| Osteoarthritis[4] | 11091 | (3.78%) | 1700 | (3.16%) | 2648 | (3.50%) | 5081 | (4.01%) | 1662 | (4.49%) |
| Rheumatoid arthritis[3] | 2849 | (0.68%) | 399 | (0.62%) | 631 | (0.65%) | 1319 | (0.69%) | 500 | (0.77%) |
| Intestinal polyps | 9249 | (2.10%) | 1246 | (1.79%) | 2113 | (2.01%) | 4547 | (2.27%) | 1343 | (2.04%) |
| Lupus | 503 | (0.11%) | 82 | (0.11%) | 116 | (0.11%) | 237 | (0.11%) | 68 | (0.09%) |
| Kidney stones[3, 4] | 1319 | (0.36%) | 175 | (0.33%) | 281 | (0.34%) | 654 | (0.39%) | 209 | (0.36%) |
| Cataracts[3, 4] | 15485 | (4.68%) | 1157 | (2.14%) | 2859 | (3.43%) | 8462 | (5.55%) | 3007 | (7.36%) |
| Pills for hypertension | 14387 | (4.34%) | 1932 | (3.34%) | 3263 | (3.91%) | 6827 | (4.67%) | 2365 | (5.36%) |

| 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)** | 112.0 | | 112.5 | | 112.4 | | 107.3 | | 117.6 | | 110.3 | |
| **Hospitalizations** | | | | | | | | | | | | |
| Ever | 105 | (5.57%) | 443 | (4.28%) | 2843 | (5.77%) | 817 | (4.95%) | 22615 | (5.80%) | 338 | (5.58%) |
| Two or more | 68 | (3.61%) | 206 | (1.99%) | 1704 | (3.46%) | 428 | (2.59%) | 13213 | (3.39%) | 192 | (3.17%) |
| **Other** | | | | | | | | | | | | |
| DVT[1] | 2 | (0.11%) | 0 | (0.00%) | 61 | (0.13%) | 10 | (0.06%) | 555 | (0.15%) | 10 | (0.17%) |
| Pulmonary embolism | 2 | (0.11%) | 1 | (0.01%) | 47 | (0.10%) | 5 | (0.03%) | 391 | (0.10%) | 6 | (0.10%) |
| Diabetes (treated) | 21 | (1.20%) | 125 | (1.28%) | 796 | (1.82%) | 240 | (1.55%) | 3344 | (0.89%) | 72 | (1.25%) |
| Gallbladder disease[2, 3] | 14 | (1.12%) | 60 | (0.70%) | 304 | (0.75%) | 152 | (1.32%) | 3250 | (1.10%) | 50 | (1.05%) |
| Hysterectomy | 5 | (0.57%) | 32 | (0.49%) | 113 | (0.51%) | 54 | (0.61%) | 1568 | (0.69%) | 12 | (0.35%) |
| Glaucoma[3] | 30 | (1.80%) | 108 | (1.19%) | 763 | (1.80%) | 201 | (1.36%) | 4152 | (1.21%) | 64 | (1.22%) |
| Osteoporosis[3] | 43 | (2.59%) | 272 | (3.04%) | 679 | (1.55%) | 409 | (2.87%) | 8678 | (2.59%) | 140 | (2.72%) |
| Osteoarthritis[4] | 47 | (4.34%) | 257 | (3.42%) | 1137 | (3.84%) | 457 | (4.07%) | 9026 | (3.76%) | 167 | (4.45%) |
| Rheumatoid arthritis[3] | 23 | (1.47%) | 49 | (0.54%) | 506 | (1.19%) | 222 | (1.53%) | 1998 | (0.58%) | 51 | (0.97%) |
| Intestinal polyps | 47 | (2.68%) | 197 | (2.08%) | 1020 | (2.22%) | 292 | (1.86%) | 7563 | (2.09%) | 130 | (2.33%) |
| Lupus | 4 | (0.22%) | 8 | (0.08%) | 72 | (0.15%) | 20 | (0.12%) | 392 | (0.10%) | 7 | (0.12%) |
| Kidney stones[3, 4] | 9 | (0.64%) | 27 | (0.34%) | 137 | (0.36%) | 58 | (0.45%) | 1071 | (0.36%) | 17 | (0.36%) |
| Cataracts[3, 4] | 61 | (4.74%) | 306 | (4.17%) | 1510 | (4.29%) | 537 | (4.34%) | 12867 | (4.76%) | 204 | (4.78%) |
| Pills for hypertension | 50 | (4.10%) | 290 | (4.16%) | 1451 | (5.87%) | 584 | (4.77%) | 11835 | (4.19%) | 177 | (4.34%) |

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

**Table 4.1**
**Calcium and Vitamin D Component Age – and Race/Ethnicity – Specific Recruitment**

Data as of August 15, 2007

| | Total Randomized | % of Overall Goal | Distribution | Design Assumption |
|---|---|---|---|---|
| **Age** | **36,282** | | | |
| 50-54 | 5,153 | 118% | 14% | 10% |
| 55-59 | 8,269 | 95% | 23% | 20% |
| 60-69 | 16,519 | 84% | 46% | 45% |
| 70-79 | 6,341 | 58% | 17% | 25% |
| **Race/Ethnicity** | **36,282** | | | |
| American Indian | 149 | | <1% | |
| Asian | 721 | | 2% | |
| Black | 3,315 | | 9% | |
| Hispanic | 1,502 | | 4% | |
| White | 30,155 | | 83% | |
| Unknown | 440 | | 1% | |

**Table 4.2**
**Lost-to-Follow-up and Vital Status: CaD Participants**

Data as of August 15, 2007

**Extension Participants Only**

| | CaD Participants (N=29,861) N | % |
|---|---|---|
| **Vital Status/Participation** | | |
| Deceased | 558 | 1.9 |
| Alive: Current Participation[1] | 28402 | 95.1 |
| Alive: Recent Participation[2] | 563 | 1.9 |
| Alive: Past/Unknown Participation[3] | 16 | 0.1 |
| Stopped Follow-Up[4] | 152 | 0.5 |
| Lost to Follow-Up[5] | 170 | 0.6 |

Data as of: September 12, 2005

**Events through Study Closeout**

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

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

**Table 4.3**
**Verified Outcomes (Annualized Percentages) by Age for Calcium and Vitamin D**

Data as of August 15, 2007

| Outcome | Total | | Age 50-54 | | 55-59 | | 60-69 | | 70-79 | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Number of participants** | 36282 | | 5153 | | 8269 | | 16519 | | 6341 | |
| **Mean follow-up (months)** | 105.0 | | 111.3 | | 108.4 | | 103.7 | | 99.0 | |
| **Fractures** | | | | | | | | | | |
| Hip fracture | 487 | (0.15%) | 10 | (0.02%) | 49 | (0.07%) | 177 | (0.12%) | 251 | (0.48%) |
| **Cancer** | | | | | | | | | | |
| Colorectal cancer | 396 | (0.12%) | 27 | (0.06%) | 57 | (0.08%) | 198 | (0.14%) | 114 | (0.22%) |
| Breast cancer | 1601 | (0.50%) | 197 | (0.41%) | 378 | (0.51%) | 745 | (0.52%) | 281 | (0.54%) |
| Invasive breast cancer | 1284 | (0.40%) | 149 | (0.31%) | 303 | (0.41%) | 604 | (0.42%) | 228 | (0.44%) |
| Non-invasive breast cancer | 334 | (0.11%) | 49 | (0.10%) | 78 | (0.10%) | 149 | (0.10%) | 58 | (0.11%) |
| Ovarian cancer | 142 | (0.04%) | 17 | (0.04%) | 36 | (0.05%) | 63 | (0.04%) | 26 | (0.05%) |
| Endometrial cancer[1] | 215 | (0.07%) | 30 | (0.06%) | 52 | (0.07%) | 95 | (0.07%) | 38 | (0.07%) |
| Other cancer[2] | 1669 | (0.53%) | 145 | (0.30%) | 289 | (0.39%) | 831 | (0.58%) | 404 | (0.77%) |
| **Total cancer** | 3861 | (1.22%) | 404 | (0.85%) | 786 | (1.05%) | 1844 | (1.29%) | 827 | (1.58%) |
| **Cardiovascular** | | | | | | | | | | |
| CHD[3] | 1202 | (0.38%) | 61 | (0.13%) | 145 | (0.19%) | 576 | (0.40%) | 420 | (0.80%) |
| CHD death[4] | 324 | (0.10%) | 13 | (0.03%) | 27 | (0.04%) | 137 | (0.10%) | 147 | (0.28%) |
| Total MI[5] | 977 | (0.31%) | 51 | (0.11%) | 122 | (0.16%) | 482 | (0.34%) | 322 | (0.62%) |
| Clinical MI | 926 | (0.29%) | 47 | (0.10%) | 117 | (0.16%) | 458 | (0.32%) | 304 | (0.58%) |
| CABG/PTCA | 1582 | (0.50%) | 80 | (0.17%) | 208 | (0.28%) | 842 | (0.59%) | 452 | (0.86%) |
| Carotid artery disease | 268 | (0.08%) | 11 | (0.02%) | 31 | (0.04%) | 151 | (0.11%) | 75 | (0.14%) |
| Stroke | 835 | (0.26%) | 37 | (0.08%) | 88 | (0.12%) | 367 | (0.26%) | 343 | (0.66%) |
| PVD | 231 | (0.07%) | 8 | (0.02%) | 30 | (0.04%) | 116 | (0.08%) | 77 | (0.15%) |
| Coronary disease[6] | 3126 | (0.98%) | 174 | (0.36%) | 417 | (0.56%) | 1558 | (1.09%) | 977 | (1.87%) |
| **Total cardiovascular disease** | 4101 | (1.29%) | 219 | (0.46%) | 536 | (0.72%) | 2020 | (1.41%) | 1326 | (2.53%) |
| **Deaths** | | | | | | | | | | |
| Cardiovascular deaths | 599 | (0.19%) | 24 | (0.05%) | 47 | (0.06%) | 246 | (0.17%) | 282 | (0.54%) |
| Cancer deaths | 921 | (0.29%) | 66 | (0.14%) | 133 | (0.18%) | 452 | (0.32%) | 270 | (0.52%) |
| Other known cause | 399 | (0.13%) | 19 | (0.04%) | 52 | (0.07%) | 169 | (0.12%) | 159 | (0.30%) |
| Unknown cause | 63 | (0.02%) | 3 | (0.01%) | 10 | (0.01%) | 31 | (0.02%) | 19 | (0.04%) |
| Not yet adjudicated | 226 | (0.07%) | 13 | (0.03%) | 27 | (0.04%) | 108 | (0.08%) | 78 | (0.15%) |
| **Total death** | 2208 | (0.70%) | 125 | (0.26%) | 269 | (0.36%) | 1006 | (0.70%) | 808 | (1.54%) |

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

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

Data as of August 15, 2007

| Outcome | Race/Ethnicity | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | American Indian/Alaskan Native | | Asian/Pacific Islander | | Black/African American | | Hispanic/ Latino | | White | | Unknown | |
| **Number of participants** | 149 | | 721 | | 3315 | | 1502 | | 30155 | | 440 | |
| **Mean follow-up (months)** | 102.1 | | 100.1 | | 101.7 | | 99.0 | | 105.9 | | 99.3 | |
| **Fractures** | | | | | | | | | | | | |
| Hip fracture | 3 | (0.24%) | 6 | (0.10%) | 7 | (0.02%) | 4 | (0.03%) | 466 | (0.18%) | 1 | (0.03%) |
| **Cancer** | | | | | | | | | | | | |
| Colorectal cancer | 2 | (0.16%) | 6 | (0.10%) | 37 | (0.13%) | 10 | (0.08%) | 335 | (0.13%) | 6 | (0.16%) |
| Breast cancer | 4 | (0.32%) | 31 | (0.52%) | 120 | (0.43%) | 43 | (0.35%) | 1387 | (0.52%) | 16 | (0.44%) |
| Invasive breast cancer | 3 | (0.24%) | 22 | (0.37%) | 92 | (0.33%) | 34 | (0.27%) | 1119 | (0.42%) | 14 | (0.38%) |
| Non-invasive breast cancer | 1 | (0.08%) | 10 | (0.17%) | 29 | (0.10%) | 10 | (0.08%) | 282 | (0.11%) | 2 | (0.05%) |
| Ovarian cancer | 0 | (0.00%) | 5 | (0.08%) | 7 | (0.02%) | 6 | (0.05%) | 122 | (0.05%) | 2 | (0.05%) |
| Endometrial cancer[1] | 1 | (0.08%) | 3 | (0.05%) | 9 | (0.03%) | 5 | (0.04%) | 194 | (0.07%) | 3 | (0.08%) |
| Other cancer[2] | 5 | (0.39%) | 28 | (0.47%) | 107 | (0.38%) | 37 | (0.30%) | 1477 | (0.55%) | 15 | (0.41%) |
| **Total cancer** | 11 | (0.87%) | 70 | (1.16%) | 270 | (0.96%) | 94 | (0.76%) | 3375 | (1.27%) | 41 | (1.13%) |
| **Cardiovascular** | | | | | | | | | | | | |
| CHD[3] | 5 | (0.39%) | 10 | (0.17%) | 108 | (0.38%) | 26 | (0.21%) | 1036 | (0.39%) | 17 | (0.47%) |
| CHD death[4] | 1 | (0.08%) | 2 | (0.03%) | 45 | (0.16%) | 7 | (0.06%) | 262 | (0.10%) | 7 | (0.19%) |
| Total MI[5] | 5 | (0.39%) | 9 | (0.15%) | 74 | (0.26%) | 22 | (0.18%) | 853 | (0.32%) | 14 | (0.38%) |
| Clinical MI | 5 | (0.39%) | 9 | (0.15%) | 71 | (0.25%) | 21 | (0.17%) | 807 | (0.30%) | 13 | (0.36%) |
| CABG/PTCA | 5 | (0.39%) | 15 | (0.25%) | 128 | (0.46%) | 47 | (0.38%) | 1367 | (0.51%) | 20 | (0.55%) |
| Carotid artery disease | 1 | (0.08%) | 1 | (0.02%) | 12 | (0.04%) | 3 | (0.02%) | 247 | (0.09%) | 4 | (0.11%) |
| Stroke | 6 | (0.47%) | 18 | (0.30%) | 91 | (0.32%) | 22 | (0.18%) | 685 | (0.26%) | 13 | (0.36%) |
| PVD | 2 | (0.16%) | 3 | (0.05%) | 30 | (0.11%) | 1 | (0.01%) | 194 | (0.07%) | 1 | (0.03%) |
| Coronary disease[6] | 10 | (0.79%) | 31 | (0.52%) | 326 | (1.16%) | 94 | (0.76%) | 2627 | (0.99%) | 38 | (1.04%) |
| **Total cardiovascular disease** | 16 | (1.26%) | 49 | (0.81%) | 423 | (1.51%) | 118 | (0.95%) | 3445 | (1.29%) | 50 | (1.37%) |
| **Deaths** | | | | | | | | | | | | |
| Cardiovascular deaths | 1 | (0.08%) | 10 | (0.17%) | 78 | (0.28%) | 14 | (0.11%) | 487 | (0.18%) | 9 | (0.25%) |
| Cancer deaths | 2 | (0.16%) | 20 | (0.33%) | 64 | (0.23%) | 24 | (0.19%) | 798 | (0.30%) | 13 | (0.36%) |
| Other known cause | 7 | (0.55%) | 5 | (0.08%) | 33 | (0.12%) | 7 | (0.06%) | 341 | (0.13%) | 6 | (0.16%) |
| Unknown cause | 0 | (0.00%) | 1 | (0.02%) | 12 | (0.04%) | 1 | (0.01%) | 47 | (0.02%) | 2 | (0.05%) |
| Not yet adjudicated | 1 | (0.08%) | 0 | (0.00%) | 19 | (0.07%) | 9 | (0.07%) | 194 | (0.07%) | 3 | (0.08%) |
| **Total death** | 11 | (0.87%) | 36 | (0.60%) | 206 | (0.73%) | 55 | (0.44%) | 1867 | (0.70%) | 33 | (0.91%) |

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

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

Data as of August 15, 2007

| Outcome | Total | Age 50-54 | 55-59 | 60-69 | 70-79 |
|---|---|---|---|---|---|
| **Number randomized** | 36282 | 5153 | 8269 | 16519 | 6341 |
| **Mean follow-up (months)** | 105.0 | 111.3 | 108.4 | 103.7 | 99.0 |
| **Hospitalizations** | | | | | |
| Ever | 19090 (6.01%) | 1990 (4.16%) | 3649 (4.89%) | 9169 (6.42%) | 4282 (8.18%) |
| Two or more | 10666 (3.36%) | 866 (1.81%) | 1878 (2.51%) | 5223 (3.66%) | 2699 (5.16%) |
| **Other** | | | | | |
| DVT[1] | 455 (0.15%) | 28 (0.06%) | 79 (0.11%) | 203 (0.15%) | 145 (0.29%) |
| Pulmonary embolism | 310 (0.10%) | 26 (0.05%) | 58 (0.08%) | 156 (0.11%) | 70 (0.13%) |
| Diabetes (treated) | 3403 (1.12%) | 514 (1.10%) | 753 (1.05%) | 1575 (1.15%) | 561 (1.13%) |
| Gallbladder disease[2, 3] | 2485 (1.02%) | 367 (0.95%) | 602 (1.03%) | 1157 (1.07%) | 359 (0.91%) |
| Hysterectomy | 1151 (0.62%) | 158 (0.57%) | 293 (0.64%) | 533 (0.64%) | 167 (0.57%) |
| Glaucoma[3] | 3730 (1.33%) | 401 (0.93%) | 770 (1.16%) | 1773 (1.42%) | 786 (1.75%) |
| Osteoporosis[3] | 7136 (2.58%) | 736 (1.71%) | 1362 (2.06%) | 3451 (2.80%) | 1587 (3.63%) |
| Osteoarthritis[4] | 7815 (3.93%) | 1198 (3.34%) | 1849 (3.59%) | 3548 (4.19%) | 1220 (4.56%) |
| Rheumatoid arthritis[3] | 1879 (0.67%) | 267 (0.63%) | 435 (0.66%) | 834 (0.67%) | 343 (0.75%) |
| Intestinal polyps | 6436 (2.17%) | 878 (1.90%) | 1450 (2.04%) | 3095 (2.34%) | 1013 (2.17%) |
| Lupus | 352 (0.11%) | 57 (0.12%) | 82 (0.11%) | 149 (0.10%) | 64 (0.12%) |
| Kidney stones[3, 4] | 819 (0.33%) | 111 (0.30%) | 180 (0.31%) | 383 (0.34%) | 145 (0.34%) |
| Cataracts[3, 4] | 11122 (5.02%) | 818 (2.27%) | 2096 (3.71%) | 5937 (5.92%) | 2271 (7.85%) |
| Pills for hypertension | 10914 (4.80%) | 1460 (3.74%) | 2486 (4.32%) | 5048 (5.14%) | 1920 (5.95%) |

| 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)** | 102.1 | 100.1 | 101.7 | 99.0 | 105.9 | 99.3 |
| **Hospitalizations** | | | | | | |
| Ever | 74 (5.84%) | 280 (4.66%) | 1723 (6.14%) | 620 (5.00%) | 16175 (6.08%) | 218 (5.99%) |
| Two or more | 51 (4.02%) | 130 (2.16%) | 995 (3.54%) | 300 (2.42%) | 9065 (3.41%) | 125 (3.43%) |
| **Other** | | | | | | |
| DVT[1] | 5 (0.41%) | 1 (0.02%) | 43 (0.16%) | 9 (0.07%) | 392 (0.15%) | 5 (0.14%) |
| Pulmonary embolism | 3 (0.24%) | 0 (0.00%) | 31 (0.11%) | 4 (0.03%) | 268 (0.10%) | 4 (0.11%) |
| Diabetes (treated) | 14 (1.19%) | 84 (1.48%) | 495 (1.97%) | 216 (1.85%) | 2542 (0.99%) | 52 (1.53%) |
| Gallbladder disease[2, 3] | 10 (1.11%) | 39 (0.78%) | 169 (0.72%) | 121 (1.37%) | 2118 (1.04%) | 28 (1.00%) |
| Hysterectomy | 2 (0.38%) | 18 (0.46%) | 58 (0.48%) | 39 (0.57%) | 1025 (0.64%) | 9 (0.44%) |
| Glaucoma[3] | 20 (1.79%) | 59 (1.12%) | 472 (1.95%) | 177 (1.59%) | 2969 (1.27%) | 33 (1.04%) |
| Osteoporosis[3] | 30 (2.68%) | 156 (2.95%) | 409 (1.64%) | 299 (2.77%) | 6160 (2.67%) | 82 (2.63%) |
| Osteoarthritis[4] | 43 (5.33%) | 158 (3.59%) | 691 (4.05%) | 376 (4.43%) | 6438 (3.89%) | 109 (4.54%) |
| Rheumatoid arthritis | 17 (1.64%) | 29 (0.55%) | 304 (1.27%) | 152 (1.38%) | 1349 (0.58%) | 28 (0.89%) |
| Intestinal polyps | 35 (3.00%) | 103 (1.86%) | 624 (2.38%) | 210 (1.77%) | 5388 (2.17%) | 76 (2.27%) |
| Lupus | 4 (0.32%) | 3 (0.05%) | 41 (0.15%) | 16 (0.13%) | 286 (0.11%) | 2 (0.06%) |
| Kidney stones[3, 4] | 7 (0.70%) | 18 (0.37%) | 73 (0.33%) | 46 (0.46%) | 667 (0.32%) | 8 (0.27%) |
| Cataracts[3, 4] | 51 (5.56%) | 178 (4.20%) | 909 (4.55%) | 440 (4.73%) | 9409 (5.09%) | 135 (5.16%) |
| Pills for hypertension | 38 (4.73%) | 188 (4.52%) | 969 (6.64%) | 494 (5.18%) | 9112 (4.65%) | 113 (4.89%) |

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

**Table 5.1**
**Observational Study Age and Race/Ethnicity Specific Recruitment**

Data as of August 15, 2007

| | Total Enrolled | Distribution |
|---|---|---|
| **Age** | **93,676** | |
| 50-54 | 12,381 | 13% |
| 55-59 | 17,329 | 18% |
| 60-69 | 41,200 | 44% |
| 70-79 | 22,766 | 24% |
| **Race/Ethnicity** | **93,676** | |
| American Indian | 421 | <1% |
| Asian | 2,671 | 3% |
| Black | 7,635 | 8% |
| Hispanic | 3,609 | 4% |
| White | 78,016 | 83% |
| Unknown | 1,324 | 1% |

**Table 5.2**
**Lost-to-Follow-up and Vital Status: OS Participants**

Data as of August 15, 2007

**Extension Participants Only**

| | OS Participants (N=63,229) | |
|---|---|---|
| | N | % |
| **Vital Status/Participation** | | |
| Deceased | 1184 | 1.9 |
| Alive: Current Participation[1] | 61066 | 96.6 |
| Alive: Recent Participation[2] | 603 | 1.0 |
| Alive: Past/Unknown Participation[3] | 49 | 0.1 |
| Stopped Follow-Up[4] | 218 | 0.3 |
| Lost to Follow-Up[5] | 109 | 0.2 |

Data as of: September 12, 200

**Events through Study Closeout**

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

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

**Table 5.3**
**Verified Outcomes (Annualized Percentages) by Age for OS Participants**

Data as of August 15, 2007

| Outcome | Total | Age 50-54 | 55-59 | 60-69 | 70-79 |
|---|---|---|---|---|---|
| **Number enrolled** | 93676 | 12381 | 17329 | 41200 | 22766 |
| **Mean follow-up (months)** | 109.4 | 115.6 | 114.2 | 109.1 | 102.8 |
| **Cardiovascular** | | | | | |
| CHD[1] | 2968 (0.35%) | 98 (0.08%) | 232 (0.14%) | 1222 (0.33%) | 1416 (0.73%) |
| CHD death[2] | 988 (0.12%) | 25 (0.02%) | 48 (0.03%) | 328 (0.09%) | 587 (0.30%) |
| Clinical MI | 2276 (0.27%) | 79 (0.07%) | 196 (0.12%) | 991 (0.26%) | 1010 (0.52%) |
| Angina | 2837 (0.33%) | 124 (0.10%) | 318 (0.19%) | 1320 (0.35%) | 1075 (0.55%) |
| CABG/PTCA | 3760 (0.44%) | 144 (0.12%) | 396 (0.24%) | 1843 (0.49%) | 1377 (0.71%) |
| Carotid artery disease | 678 (0.08%) | 32 (0.03%) | 58 (0.04%) | 295 (0.08%) | 293 (0.15%) |
| Congestive heart failure | 2305 (0.27%) | 81 (0.07%) | 174 (0.11%) | 886 (0.24%) | 1164 (0.60%) |
| Stroke | 2131 (0.25%) | 55 (0.05%) | 169 (0.10%) | 835 (0.22%) | 1072 (0.55%) |
| PVD | 630 (0.07%) | 19 (0.02%) | 59 (0.04%) | 269 (0.07%) | 283 (0.15%) |
| Coronary disease[3] | 7567 (0.89%) | 303 (0.25%) | 732 (0.44%) | 3325 (0.89%) | 3207 (1.65%) |
| **Total cardiovascular disease** | 10240 (1.20%) | 389 (0.33%) | 969 (0.59%) | 4409 (1.18%) | 4473 (2.29%) |
| **Cancer** | | | | | |
| Breast cancer | 4735 (0.55%) | 530 (0.44%) | 822 (0.50%) | 2207 (0.59%) | 1176 (0.60%) |
| Invasive breast cancer | 3933 (0.46%) | 428 (0.36%) | 665 (0.40%) | 1832 (0.49%) | 1008 (0.52%) |
| Non-invasive breast cancer | 834 (0.10%) | 108 (0.09%) | 160 (0.10%) | 391 (0.10%) | 175 (0.09%) |
| Ovarian cancer | 407 (0.05%) | 42 (0.04%) | 70 (0.04%) | 184 (0.05%) | 111 (0.06%) |
| Endometrial cancer[4] | 642 (0.07%) | 55 (0.05%) | 102 (0.06%) | 297 (0.08%) | 188 (0.10%) |
| Colorectal cancer | 1026 (0.12%) | 56 (0.05%) | 107 (0.06%) | 461 (0.12%) | 402 (0.21%) |
| Other cancer[5] | 4747 (0.56%) | 333 (0.28%) | 623 (0.38%) | 2223 (0.59%) | 1568 (0.80%) |
| **Total cancer** | 10955 (1.28%) | 975 (0.82%) | 1643 (1.00%) | 5084 (1.36%) | 3253 (1.67%) |
| **Fractures** | | | | | |
| Hip fracture | 1428 (0.17%) | 32 (0.03%) | 93 (0.06%) | 477 (0.13%) | 826 (0.42%) |
| **Deaths** | | | | | |
| Cardiovascular deaths | 2082 (0.24%) | 50 (0.04%) | 117 (0.07%) | 689 (0.18%) | 1226 (0.63%) |
| Cancer deaths | 3004 (0.35%) | 175 (0.15%) | 345 (0.21%) | 1316 (0.35%) | 1168 (0.60%) |
| Other known cause | 1623 (0.19%) | 76 (0.06%) | 134 (0.08%) | 590 (0.16%) | 823 (0.42%) |
| Unknown cause | 285 (0.03%) | 15 (0.01%) | 26 (0.02%) | 107 (0.03%) | 137 (0.07%) |
| Not yet adjudicated | 663 (0.08%) | 22 (0.02%) | 44 (0.03%) | 255 (0.07%) | 342 (0.18%) |
| **Total death** | 7657 (0.90%) | 338 (0.28%) | 666 (0.40%) | 2957 (0.79%) | 3696 (1.90%) |

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

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

Data as of August 15, 2007

| Outcomes | Ethnicity: American Indian/Alaskan Native | Asian/Pacific Islander | Black/African American | Hispanic/ Latino | White | Unknown |
|---|---|---|---|---|---|---|
| **Number enrolled** | 421 | 2671 | 7635 | 3609 | 78016 | 1324 |
| **Mean follow-up (months)** | 99.6 | 101.6 | 99.2 | 95.4 | 111.4 | 104.5 |
| **Cardiovascular** | | | | | | |
| CHD[1] | 19 (0.54%) | 49 (0.22%) | 258 (0.41%) | 52 (0.18%) | 2546 (0.35%) | 44 (0.38%) |
| CHD death[2] | 10 (0.29%) | 17 (0.08%) | 121 (0.19%) | 14 (0.05%) | 809 (0.11%) | 17 (0.15%) |
| Clinical MI | 11 (0.31%) | 37 (0.16%) | 164 (0.26%) | 43 (0.15%) | 1989 (0.27%) | 32 (0.28%) |
| Angina | 18 (0.52%) | 40 (0.18%) | 250 (0.40%) | 80 (0.28%) | 2415 (0.33%) | 34 (0.30%) |
| CABG/PTCA | 20 (0.57%) | 52 (0.23%) | 229 (0.36%) | 92 (0.32%) | 3317 (0.46%) | 50 (0.43%) |
| Carotid artery disease | 4 (0.11%) | 6 (0.03%) | 29 (0.05%) | 12 (0.04%) | 615 (0.08%) | 12 (0.10%) |
| Congestive heart failure | 16 (0.46%) | 22 (0.10%) | 235 (0.37%) | 42 (0.15%) | 1956 (0.27%) | 34 (0.30%) |
| Stroke | 13 (0.37%) | 51 (0.23%) | 205 (0.32%) | 46 (0.16%) | 1783 (0.25%) | 33 (0.29%) |
| PVD | 3 (0.09%) | 4 (0.02%) | 64 (0.10%) | 7 (0.02%) | 539 (0.07%) | 13 (0.11%) |
| Coronary disease[3] | 47 (1.35%) | 108 (0.48%) | 659 (1.04%) | 177 (0.62%) | 6478 (0.89%) | 98 (0.85%) |
| **Total cardiovascular disease** | 58 (1.66%) | 167 (0.74%) | 907 (1.44%) | 232 (0.81%) | 8730 (1.21%) | 146 (1.27%) |
| **Cancer** | | | | | | |
| Breast cancer | 14 (0.40%) | 106 (0.47%) | 305 (0.48%) | 109 (0.38%) | 4152 (0.57%) | 49 (0.43%) |
| Invasive breast cancer | 13 (0.37%) | 89 (0.39%) | 246 (0.39%) | 91 (0.32%) | 3453 (0.48%) | 41 (0.36%) |
| Non-invasive breast cancer | 1 (0.03%) | 18 (0.08%) | 62 (0.10%) | 19 (0.07%) | 725 (0.10%) | 9 (0.08%) |
| Ovarian cancer | 1 (0.03%) | 5 (0.02%) | 18 (0.03%) | 14 (0.05%) | 367 (0.05%) | 2 (0.02%) |
| Endometrial cancer[4] | 1 (0.03%) | 10 (0.04%) | 21 (0.03%) | 10 (0.03%) | 589 (0.08%) | 11 (0.09%) |
| Colorectal cancer | 3 (0.09%) | 19 (0.08%) | 103 (0.16%) | 23 (0.08%) | 867 (0.12%) | 11 (0.10%) |
| Other cancer[5] | 16 (0.46%) | 88 (0.39%) | 299 (0.47%) | 89 (0.31%) | 4190 (0.58%) | 65 (0.56%) |
| **Total cancer** | 35 (1.00%) | 216 (0.95%) | 707 (1.12%) | 239 (0.83%) | 9629 (1.33%) | 129 (1.12%) |
| **Fractures** | | | | | | |
| Hip fracture | 5 (0.14%) | 15 (0.07%) | 34 (0.05%) | 14 (0.05%) | 1341 (0.19%) | 19 (0.16%) |
| **Deaths** | | | | | | |
| Cardiovascular deaths | 16 (0.46%) | 43 (0.19%) | 233 (0.37%) | 41 (0.14%) | 1716 (0.24%) | 33 (0.29%) |
| Cancer deaths | 13 (0.37%) | 58 (0.26%) | 238 (0.38%) | 70 (0.24%) | 2591 (0.36%) | 34 (0.30%) |
| Other known cause | 23 (0.66%) | 33 (0.15%) | 139 (0.22%) | 62 (0.22%) | 1349 (0.19%) | 17 (0.15%) |
| Unknown cause | 1 (0.03%) | 5 (0.02%) | 52 (0.08%) | 12 (0.04%) | 211 (0.03%) | 4 (0.03%) |
| Not yet adjudicated | 5 (0.14%) | 6 (0.03%) | 57 (0.09%) | 17 (0.06%) | 565 (0.08%) | 13 (0.11%) |
| **Total death** | 58 (1.66%) | 145 (0.64%) | 719 (1.14%) | 202 (0.70%) | 6432 (0.89%) | 101 (0.88%) |

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

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

Data as of August 15, 2007

| Outcome | Total | Age 50-54 | 55-59 | 60-69 | 70-79 |
|---|---|---|---|---|---|
| **Number randomized** | 93676 | 12381 | 17329 | 41200 | 22766 |
| **Mean follow-up (months)** | 109.4 | 115.6 | 114.2 | 109.1 | 102.8 |
| **Hospitalizations** | | | | | |
| Ever | 49146 (5.76%) | 4573 (3.83%) | 7359 (4.46%) | 22324 (5.96%) | 14890 (7.64%) |
| Two or more | 27348 (3.20%) | 2055 (1.72%) | 3515 (2.13%) | 12415 (3.31%) | 9363 (4.80%) |
| **Other** | | | | | |
| DVT[1] | 930 (0.11%) | 61 (0.05%) | 114 (0.07%) | 423 (0.12%) | 332 (0.18%) |
| Pulmonary embolism | 639 (0.08%) | 57 (0.05%) | 86 (0.05%) | 290 (0.08%) | 206 (0.11%) |
| Diabetes (treated) | 6399 (0.78%) | 819 (0.70%) | 1197 (0.75%) | 2930 (0.81%) | 1453 (0.78%) |
| Gallbladder disease[2,3] | 5690 (0.95%) | 835 (0.96%) | 1153 (0.99%) | 2549 (0.99%) | 1153 (0.85%) |
| Hysterectomy | 3907 (0.46%) | 537 (0.45%) | 746 (0.45%) | 1808 (0.48%) | 816 (0.42%) |
| Glaucoma[3] | 8516 (1.26%) | 852 (0.89%) | 1379 (1.05%) | 3910 (1.33%) | 2375 (1.57%) |
| Osteoporosis[3] | 20767 (3.21%) | 2110 (2.23%) | 3384 (2.64%) | 9540 (3.39%) | 5733 (4.01%) |
| Osteoarthritis[4] | 18594 (3.74%) | 2512 (2.92%) | 3579 (3.31%) | 8296 (3.96%) | 4207 (4.49%) |
| Rheumatoid arthritis[3] | 4607 (0.69%) | 638 (0.68%) | 885 (0.69%) | 1898 (0.65%) | 1186 (0.77%) |
| Intestinal polyps | 15656 (2.03%) | 1937 (1.71%) | 3131 (2.03%) | 7284 (2.16%) | 3304 (1.96%) |
| Lupus | 1001 (0.12%) | 143 (0.12%) | 200 (0.12%) | 440 (0.12%) | 218 (0.11%) |
| Kidney stones[3,4] | 2327 (0.39%) | 292 (0.36%) | 436 (0.39%) | 996 (0.38%) | 603 (0.43%) |
| Cataracts[3,4] | 27206 (5.34%) | 1735 (2.13%) | 4109 (3.72%) | 14089 (6.18%) | 7273 (8.08%) |
| Pills for hypertension | 24931 (4.07%) | 2962 (2.99%) | 4474 (3.47%) | 11139 (4.26%) | 6356 (5.17%) |

| Outcomes | Race/Ethnicity: American Indian/ Alaskan Native | Asian/Pacific Islander | Black/African American | Hispanic/ Latino | White | Unknown |
|---|---|---|---|---|---|---|
| **Number randomized** | 421 | 2671 | 7635 | 3609 | 78016 | 1324 |
| **Mean follow-up (months)** | 99.6 | 101.6 | 99.2 | 95.4 | 111.4 | 104.5 |
| **Hospitalizations** | | | | | | |
| Ever | 234 (6.70%) | 904 (4.00%) | 3747 (5.94%) | 1388 (4.84%) | 42227 (5.83%) | 646 (5.61%) |
| Two or more | 139 (3.98%) | 380 (1.68%) | 2031 (3.22%) | 641 (2.23%) | 23801 (3.29%) | 356 (3.09%) |
| **Other** | | | | | | |
| DVT[1] | 4 (0.12%) | 5 (0.02%) | 82 (0.13%) | 14 (0.05%) | 814 (0.12%) | 11 (0.10%) |
| Pulmonary embolism | 2 (0.06%) | 4 (0.02%) | 44 (0.07%) | 9 (0.03%) | 575 (0.08%) | 5 (0.04%) |
| Diabetes (treated) | 54 (1.80%) | 210 (0.98%) | 905 (1.62%) | 381 (1.43%) | 4740 (0.67%) | 109 (0.99%) |
| Gallbladder disease[2,3] | 31 (1.32%) | 81 (0.46%) | 377 (0.78%) | 232 (1.20%) | 4892 (0.98%) | 77 (0.95%) |
| Hysterectomy | 18 (0.52%) | 74 (0.33%) | 238 (0.38%) | 174 (0.61%) | 3340 (0.46%) | 63 (0.55%) |
| Glaucoma[3] | 45 (1.64%) | 253 (1.35%) | 997 (1.99%) | 312 (1.33%) | 6787 (1.19%) | 122 (1.32%) |
| Osteoporosis[3] | 92 (3.36%) | 630 (3.52%) | 1078 (2.08%) | 739 (3.23%) | 17902 (3.30%) | 326 (3.67%) |
| Osteoarthritis[4] | 71 (3.66%) | 575 (3.61%) | 1431 (3.91%) | 806 (4.28%) | 15437 (3.70%) | 274 (3.90%) |
| Rheumatoid arthritis[3] | 38 (1.38%) | 98 (0.52%) | 664 (1.34%) | 385 (1.67%) | 3333 (0.59%) | 89 (0.98%) |
| Intestinal polyps | 53 (1.66%) | 377 (1.86%) | 1212 (2.10%) | 470 (1.75%) | 13349 (2.04%) | 195 (1.88%) |
| Lupus | 8 (0.23%) | 18 (0.08%) | 104 (0.17%) | 50 (0.18%) | 806 (0.11%) | 15 (0.13%) |
| Kidney stones[3,4] | 18 (0.72%) | 41 (0.24%) | 266 (0.56%) | 125 (0.59%) | 1832 (0.37%) | 45 (0.54%) |
| Cataracts[3,4] | 105 (4.88%) | 685 (4.91%) | 1951 (4.81%) | 905 (4.59%) | 23165 (5.43%) | 395 (5.67%) |
| Pills for hypertension | 109 (4.86%) | 640 (4.01%) | 1809 (5.83%) | 973 (4.52%) | 21028 (3.94%) | 372 (4.59%) |

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

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

Data as of August 15, 2007

| Outcome | Number of Events | |
|---|---|---|
| | Before AV-3 | After AV-3 |
| **Cardiovascular** | | |
| CHD[2] | 761 | 2207 |
| CHD death[3] | 178 | 810 |
| Clinical MI | 640 | 1636 |
| Angina | 1270 | 1567 |
| CABG/PTCA | 1166 | 2594 |
| Carotid artery disease | 225 | 453 |
| Congestive heart failure | 719 | 1586 |
| Stroke | 596 | 1535 |
| PVD | 198 | 432 |
| Coronary disease[4] | 2586 | 4981 |
| **Total cardiovascular disease** | 3471 | 6769 |
| **Cancer** | | |
| Breast cancer | 1606 | 3129 |
| Invasive breast cancer | 1337 | 2596 |
| Non-invasive breast cancer | 275 | 559 |
| Ovarian cancer | 136 | 271 |
| Endometrial cancer | 214 | 428 |
| Colorectal cancer | 332 | 694 |
| Other cancer[5] | 1435 | 3312 |
| **Total cancer** | 3646 | 7309 |
| **Fractures** | | |
| Hip fracture | 294 | 1134 |
| **Deaths** | | |
| Cardiovascular deaths | 372 | 1710 |
| Cancer deaths | 618 | 2386 |
| Deaths: other known cause | 225 | 1398 |
| Deaths: unknown cause | 59 | 226 |
| Deaths: not yet adjudicated | 0 | 663 |
| **Total death** | 1274 | 6383 |

[1] AV-3 date is the blood draw date for participants with an AV-3 blood draw and the OS enrollment date plus 3 years for participants without an AV-3 blood draw. All participants have been enrolled for at least 3 years.
[2] "CHD" includes clinical MI and CHD death.
[3] "CHD death" includes definite and possible CHD death.
[4] "Coronary disease" includes clinical MI, CHD death, angina, congestive heart failure, and CABG/PTCA; angina and congestive heart failure are not collected in the WHI Extension Study.
[5] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.

**Table 5.6**
**Counts of Participants with Self-Reported Outcomes Before and After AV-3[1]**
**for OS Participants Who Did Not Report a Prevalent Condition at Baseline**

Data as of August 15, 2007

| Outcome | Number of Events | |
|---|---|---|
| | Before AV-3 | After AV-3 |
| Ever hospitalized | 19160 | 29986 |
| DVT[2] | 227 | 703 |
| Pulmonary embolism | 130 | 509 |
| Diabetes (treated) | 1740 | 4659 |
| Gallbladder disease[3, 4] | 2137 | 3553 |
| Hysterectomy | 1359 | 2548 |
| Glaucoma[4] | 2755 | 5761 |
| Osteoporosis[4] | 8703 | 12064 |
| Osteoarthritis[5] | 6339 | 12255 |
| Rheumatoid arthritis[4] | 1723 | 2884 |
| Intestinal polyps | 4397 | 11259 |
| Lupus | 348 | 653 |
| Kidney stones[4, 5] | 646 | 1681 |
| Cataracts[4, 5] | 9145 | 18061 |
| Pills for hypertension | 8141 | 16790 |

[1] AV-3 date is the blood draw date for participants with an AV-3 blood draw and the OS enrollment date plus 3 years for participants without an AV-3 blood draw. All participants have been enrolled for at least 3 years.
[2] Inpatient DVT only.
[3] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[4] Not collected on Form 33 after March 31, 2005.
[5] These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

**Table 6.1**
**Verified Outcomes (Annualized Percentages) by Age for CT Participants**

Data as of: August 15, 2007

| Outcome | Total | Age 50-54 | 55-59 | 60-69 | 70-79 |
|---|---|---|---|---|---|
| **Number randomized** | 68132 | 9188 | 14661 | 31389 | 12894 |
| **Mean follow-up (months)** | 115.2 | 122.4 | 119.0 | 114.0 | 108.5 |
| **Cardiovascular** | | | | | |
| CHD[1] | 2571 (0.39%) | 136 (0.15%) | 295 (0.20%) | 1196 (0.40%) | 944 (0.81%) |
| CHD death[2] | 732 (0.11%) | 31 (0.03%) | 54 (0.04%) | 319 (0.11%) | 328 (0.28%) |
| Total MI[3] | 2062 (0.32%) | 110 (0.12%) | 252 (0.17%) | 962 (0.32%) | 738 (0.63%) |
| Clinical MI | 1983 (0.30%) | 104 (0.11%) | 244 (0.17%) | 924 (0.31%) | 711 (0.61%) |
| Angina[4] | 2414 (0.37%) | 129 (0.14%) | 331 (0.23%) | 1215 (0.41%) | 739 (0.63%) |
| CABG/PTCA | 3253 (0.50%) | 159 (0.17%) | 425 (0.29%) | 1685 (0.57%) | 984 (0.84%) |
| Carotid artery disease | 537 (0.08%) | 15 (0.02%) | 65 (0.04%) | 284 (0.10%) | 173 (0.15%) |
| Congestive heart failure[4] | 1750 (0.27%) | 81 (0.09%) | 172 (0.12%) | 746 (0.25%) | 751 (0.64%) |
| Stroke | 1742 (0.27%) | 65 (0.07%) | 169 (0.12%) | 796 (0.27%) | 712 (0.61%) |
| PVD | 481 (0.07%) | 25 (0.03%) | 61 (0.04%) | 242 (0.08%) | 153 (0.13%) |
| Coronary disease[5] | 6532 (1.00%) | 360 (0.38%) | 829 (0.57%) | 3162 (1.06%) | 2181 (1.87%) |
| **Total cardiovascular disease** | 8517 (1.30%) | 437 (0.47%) | 1054 (0.72%) | 4110 (1.38%) | 2916 (2.50%) |
| **Cancer** | | | | | |
| Breast cancer | 3220 (0.49%) | 375 (0.40%) | 693 (0.48%) | 1520 (0.51%) | 632 (0.54%) |
| Invasive breast cancer | 2608 (0.40%) | 284 (0.30%) | 564 (0.39%) | 1233 (0.41%) | 527 (0.45%) |
| Non-invasive breast cancer | 647 (0.10%) | 95 (0.10%) | 136 (0.09%) | 304 (0.10%) | 112 (0.10%) |
| Ovary cancer | 276 (0.04%) | 25 (0.03%) | 56 (0.04%) | 139 (0.05%) | 56 (0.05%) |
| Endometrial cancer[6] | 429 (0.07%) | 47 (0.05%) | 101 (0.07%) | 208 (0.07%) | 73 (0.06%) |
| Colorectal cancer | 832 (0.13%) | 48 (0.05%) | 124 (0.09%) | 418 (0.14%) | 242 (0.21%) |
| Other cancer[7] | 3441 (0.53%) | 271 (0.29%) | 572 (0.39%) | 1697 (0.57%) | 901 (0.77%) |
| **Total cancer** | 7823 (1.20%) | 734 (0.78%) | 1485 (1.02%) | 3784 (1.27%) | 1820 (1.56%) |
| **Fractures** | | | | | |
| Hip fracture | 1008 (0.15%) | 21 (0.02%) | 72 (0.05%) | 380 (0.13%) | 535 (0.46%) |
| **Deaths** | | | | | |
| Cardiovascular deaths | 1336 (0.20%) | 51 (0.05%) | 96 (0.07%) | 542 (0.18%) | 647 (0.55%) |
| Cancer deaths | 1954 (0.30%) | 112 (0.12%) | 264 (0.18%) | 955 (0.32%) | 623 (0.53%) |
| Other known cause | 919 (0.14%) | 45 (0.05%) | 97 (0.07%) | 379 (0.13%) | 398 (0.34%) |
| Unknown cause | 139 (0.02%) | 7 (0.01%) | 13 (0.01%) | 68 (0.02%) | 51 (0.04%) |
| Not yet adjudicated | 430 (0.07%) | 17 (0.02%) | 48 (0.03%) | 195 (0.07%) | 170 (0.15%) |
| **Total death** | 4778 (0.73%) | 232 (0.25%) | 518 (0.36%) | 2139 (0.72%) | 1889 (1.62%) |

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

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

Data as of: August 15, 2007

| Outcome | Race/Ethnicity: American Indian/Alaskan Native | Asian/Pacific Islander | Black/African American | Hispanic/ Latino | White | Unknown |
|---|---|---|---|---|---|---|
| **Number randomized** | 292 | 1519 | 6983 | 2875 | 55525 | 938 |
| **Mean follow-up (months)** | 109.7 | 110.8 | 111.6 | 106.6 | 116.3 | 109.4 |
| **Cardiovascular** | | | | | | |
| CHD[1] | 8 (0.30%) | 33 (0.24%) | 255 (0.39%) | 55 (0.22%) | 2184 (0.41%) | 36 (0.42%) |
| CHD death[2] | 2 (0.07%) | 9 (0.06%) | 110 (0.17%) | 13 (0.05%) | 586 (0.11%) | 12 (0.14%) |
| Total MI[3] | 7 (0.26%) | 30 (0.21%) | 176 (0.27%) | 46 (0.18%) | 1773 (0.33%) | 30 (0.35%) |
| Clinical MI | 7 (0.26%) | 29 (0.21%) | 171 (0.26%) | 44 (0.17%) | 1704 (0.32%) | 28 (0.33%) |
| Angina[4] | 12 (0.45%) | 30 (0.21%) | 298 (0.46%) | 80 (0.31%) | 1964 (0.36%) | 30 (0.35%) |
| CABG/PTCA | 13 (0.49%) | 32 (0.23%) | 286 (0.44%) | 86 (0.34%) | 2798 (0.52%) | 38 (0.44%) |
| Carotid artery disease | 3 (0.11%) | 2 (0.01%) | 31 (0.05%) | 4 (0.02%) | 489 (0.09%) | 8 (0.09%) |
| Congestive heart failure[5] | 5 (0.19%) | 17 (0.12%) | 244 (0.38%) | 49 (0.19%) | 1411 (0.26%) | 24 (0.28%) |
| Stroke | 8 (0.30%) | 32 (0.23%) | 225 (0.35%) | 47 (0.18%) | 1405 (0.26%) | 25 (0.29%) |
| PVD | 5 (0.19%) | 5 (0.04%) | 71 (0.11%) | 5 (0.02%) | 391 (0.07%) | 4 (0.05%) |
| Coronary disease[5] | 25 (0.94%) | 79 (0.56%) | 746 (1.15%) | 184 (0.72%) | 5413 (1.01%) | 85 (0.99%) |
| **Total cardiovascular disease** | 36 (1.35%) | 113 (0.81%) | 972 (1.50%) | 233 (0.91%) | 7056 (1.31%) | 107 (1.25%) |
| **Cancer** | | | | | | |
| Breast cancer | 7 (0.26%) | 75 (0.53%) | 267 (0.41%) | 81 (0.32%) | 2755 (0.51%) | 35 (0.41%) |
| Invasive breast cancer | 6 (0.22%) | 57 (0.41%) | 209 (0.32%) | 66 (0.26%) | 2243 (0.42%) | 27 (0.32%) |
| Non-invasive breast cancer | 1 (0.04%) | 19 (0.14%) | 60 (0.09%) | 16 (0.06%) | 543 (0.10%) | 8 (0.09%) |
| Ovary cancer | 1 (0.04%) | 7 (0.05%) | 15 (0.02%) | 8 (0.03%) | 240 (0.04%) | 5 (0.06%) |
| Endometrial cancer[6] | 1 (0.04%) | 4 (0.03%) | 27 (0.04%) | 12 (0.05%) | 378 (0.07%) | 7 (0.08%) |
| Colorectal cancer | 4 (0.15%) | 16 (0.11%) | 83 (0.13%) | 25 (0.10%) | 690 (0.13%) | 14 (0.16%) |
| Other cancer[7] | 12 (0.45%) | 59 (0.42%) | 245 (0.38%) | 86 (0.34%) | 3000 (0.56%) | 39 (0.46%) |
| **Total cancer** | 23 (0.86%) | 156 (1.11%) | 611 (0.94%) | 199 (0.78%) | 6742 (1.25%) | 92 (1.08%) |
| **Fractures** | | | | | | |
| Hip fracture | 5 (0.19%) | 8 (0.06%) | 25 (0.04%) | 16 (0.06%) | 945 (0.18%) | 9 (0.11%) |
| **Deaths** | | | | | | |
| Cardiovascular deaths | 6 (0.22%) | 21 (0.15%) | 188 (0.29%) | 23 (0.09%) | 1083 (0.20%) | 15 (0.18%) |
| Cancer deaths | 10 (0.37%) | 35 (0.25%) | 158 (0.24%) | 57 (0.22%) | 1669 (0.31%) | 25 (0.29%) |
| Other known cause | 10 (0.37%) | 10 (0.07%) | 87 (0.13%) | 19 (0.07%) | 780 (0.14%) | 13 (0.15%) |
| Unknown cause | 0 (0.00%) | 3 (0.02%) | 26 (0.04%) | 4 (0.02%) | 101 (0.02%) | 5 (0.06%) |
| Not yet adjudicated | 2 (0.07%) | 1 (0.01%) | 46 (0.07%) | 11 (0.04%) | 363 (0.07%) | 7 (0.08%) |
| **Total death** | 28 (1.05%) | 70 (0.50%) | 505 (0.78%) | 114 (0.45%) | 3996 (0.74%) | 65 (0.76%) |

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

**Table 6.2**
**Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for CT Participants Who Did Not Report a Prevalent Condition at Baseline**

Data as of: August 15, 2007

| Outcome | Total | Age 50-54 | 55-59 | 60-69 | 70-79 |
|---|---|---|---|---|---|
| **Number randomized** | 68132 | 9188 | 14661 | 31389 | 12894 |
| **Mean follow-up (months)** | 115.2 | 122.4 | 119.0 | 114.0 | 108.5 |
| **Hospitalizations** | | | | | |
| Ever | 38030 (5.82%) | 3800 (4.05%) | 6867 (4.72%) | 18251 (6.12%) | 9112 (7.81%) |
| Two or more | 22334 (3.42%) | 1800 (1.92%) | 3632 (2.50%) | 10844 (3.64%) | 6058 (5.20%) |
| **Other** | | | | | |
| DVT[1] | 955 (0.15%) | 59 (0.06%) | 135 (0.10%) | 446 (0.15%) | 315 (0.28%) |
| Pulmonary embolism | 635 (0.10%) | 47 (0.05%) | 95 (0.07%) | 309 (0.10%) | 184 (0.16%) |
| Diabetes (treated) | 6402 (1.02%) | 897 (0.99%) | 1360 (0.97%) | 2998 (1.06%) | 1147 (1.04%) |
| Gallbladder disease[2, 3] | 5248 (1.05%) | 746 (0.98%) | 1195 (1.05%) | 2463 (1.10%) | 844 (0.97%) |
| Hysterectomy | 2389 (0.63%) | 304 (0.56%) | 554 (0.61%) | 1154 (0.67%) | 377 (0.58%) |
| Glaucoma[3] | 7570 (1.32%) | 745 (0.88%) | 1457 (1.12%) | 3664 (1.40%) | 1704 (1.71%) |
| Osteoporosis[3] | 14702 (2.60%) | 1453 (1.72%) | 2636 (2.05%) | 7143 (2.79%) | 3470 (3.60%) |
| Osteoarthritis[4] | 15041 (3.72%) | 2167 (3.08%) | 3410 (3.40%) | 6893 (3.94%) | 2571 (4.38%) |
| Rheumatoid arthritis[3] | 4012 (0.70%) | 538 (0.64%) | 866 (0.67%) | 1823 (0.70%) | 785 (0.77%) |
| Intestinal polyps | 12529 (2.06%) | 1585 (1.74%) | 2712 (1.96%) | 6165 (2.24%) | 2067 (2.01%) |
| Lupus | 732 (0.11%) | 111 (0.12%) | 166 (0.11%) | 335 (0.11%) | 120 (0.10%) |
| Kidney stones[3, 4] | 1877 (0.37%) | 241 (0.34%) | 379 (0.34%) | 898 (0.39%) | 359 (0.39%) |
| Cataracts[3, 4] | 21575 (4.75%) | 1468 (2.07%) | 3732 (3.38%) | 11651 (5.57%) | 4724 (7.38%) |
| Pills for hypertension | 20333 (4.41%) | 2569 (3.39%) | 4359 (3.93%) | 9530 (4.69%) | 3875 (5.43%) |

| 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)** | 109.7 | 110.8 | 111.6 | 106.6 | 116.3 | 109.4 |
| **Hospitalizations** | | | | | | |
| Ever | 160 (5.99%) | 620 (4.42%) | 3836 (5.91%) | 1256 (4.92%) | 31678 (5.89%) | 480 (5.62%) |
| Two or more | 106 (3.97%) | 299 (2.13%) | 2285 (3.52%) | 647 (2.53%) | 18724 (3.48%) | 273 (3.19%) |
| **Other** | | | | | | |
| DVT[1] | 5 (0.19%) | 2 (0.01%) | 96 (0.15%) | 16 (0.06%) | 825 (0.16%) | 11 (0.13%) |
| Pulmonary embolism | 4 (0.15%) | 3 (0.02%) | 62 (0.10%) | 7 (0.03%) | 552 (0.10%) | 7 (0.08%) |
| Diabetes (treated) | 29 (1.20%) | 171 (1.30%) | 1058 (1.84%) | 402 (1.68%) | 4645 (0.89%) | 97 (1.21%) |
| Gallbladder disease[2, 3] | 22 (1.20%) | 86 (0.74%) | 420 (0.78%) | 243 (1.34%) | 4403 (1.07%) | 74 (1.11%) |
| Hysterectomy | 6 (0.51%) | 39 (0.43%) | 150 (0.53%) | 81 (0.57%) | 2094 (0.65%) | 19 (0.38%) |
| Glaucoma[3] | 40 (1.71%) | 153 (1.24%) | 1008 (1.81%) | 338 (1.47%) | 5932 (1.25%) | 99 (1.34%) |
| Osteoporosis[3] | 66 (2.80%) | 389 (3.20%) | 911 (1.58%) | 639 (2.89%) | 12488 (2.69%) | 209 (2.85%) |
| Osteoarthritis[4] | 73 (4.56%) | 358 (3.53%) | 1481 (3.79%) | 728 (4.16%) | 12167 (3.68%) | 234 (4.33%) |
| Rheumatoid arthritis[3] | 32 (1.43%) | 74 (0.60%) | 683 (1.23%) | 358 (1.58%) | 2788 (0.59%) | 77 (1.03%) |
| Intestinal polyps | 60 (2.44%) | 254 (1.98%) | 1321 (2.18%) | 432 (1.77%) | 10294 (2.06%) | 168 (2.14%) |
| Lupus | 6 (0.23%) | 12 (0.09%) | 96 (0.15%) | 40 (0.16%) | 570 (0.11%) | 8 (0.09%) |
| Kidney stones[3, 4] | 15 (0.75%) | 47 (0.43%) | 190 (0.37%) | 100 (0.50%) | 1501 (0.36%) | 24 (0.36%) |
| Cataracts[3, 4] | 92 (4.95%) | 428 (4.33%) | 2003 (4.35%) | 828 (4.30%) | 17931 (4.83%) | 293 (4.85%) |
| Pills for hypertension | 83 (4.75%) | 413 (4.32%) | 1916 (5.89%) | 913 (4.79%) | 16762 (4.27%) | 246 (4.33%) |

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

**Table 6.3**
**First Reported Verified Outcomes Before and After AV-1[1] for CT Participants**

Data as of August 15, 2007

| Outcome | Number of Events | |
|---|---|---|
| | Before AV-1 | After AV-1 |
| **Cardiovascular** | | |
| CHD[2] | 215 | 2356 |
| CHD death[3] | 44 | 688 |
| Clinical MI | 181 | 1802 |
| Angina | 300 | 2114 |
| CABG/PTCA | 252 | 3001 |
| Carotid artery disease | 63 | 474 |
| Congestive heart failure | 114 | 1636 |
| Stroke | 144 | 1598 |
| PVD | 33 | 448 |
| Coronary disease[4] | 611 | 5921 |
| **Total cardiovascular disease** | 840 | 7677 |
| **Cancer** | | |
| Breast cancer | 201 | 3019 |
| Invasive breast cancer | 158 | 2450 |
| Non-invasive breast cancer | 43 | 604 |
| Ovarian cancer | 20 | 256 |
| Endometrial cancer | 40 | 389 |
| Colorectal cancer | 79 | 753 |
| Other cancer[5] | 280 | 3161 |
| **Total cancer** | 613 | 7210 |
| **Fractures** | | |
| Hip fracture | 50 | 958 |
| **Deaths** | | |
| Cardiovascular deaths | 73 | 1263 |
| Cancer deaths | 53 | 1901 |
| Deaths: other known cause | 17 | 902 |
| Deaths: unknown cause | 5 | 134 |
| Deaths: not yet adjudicated | 0 | 430 |
| **Total death** | 148 | 4630 |

[1] AV-1 date is the blood draw for participants with an AV-1 blood draw and the CT randomization date plus 1 year for participants without an AV-1 blood draw. All participants have been enrolled for at least 1 year.
[2] "CHD" includes clinical MI and CHD death.
[3] "CHD death" includes definite and possible CHD death.
[4] "Coronary disease" includes clinical MI, CHD death, angina, congestive heart failure, and CABG/PTCA; angina and congestive heart failure are not collected in the WHI Extension Study.
[5] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.

**Table 6.4**
**Counts of Participants with Self-Reported Outcomes Before and After AV-1[1]**
**for CT Participants Who Did Not Report a Prevalent Condition at Baseline**

Data as of August 15, 2007

| Outcome | Number of Events | |
|---|---|---|
| | Before AV-1 | After AV-1 |
| Ever hospitalized | 5492 | 32538 |
| DVT[2] | 90 | 865 |
| Pulmonary embolism | 48 | 587 |
| Diabetes (treated) | 573 | 5829 |
| Gallbladder disease[3,4] | 606 | 4642 |
| Hysterectomy | 158 | 1607 |
| Glaucoma[4] | 767 | 6803 |
| Osteoporosis[4] | 1502 | 13200 |
| Osteoarthritis[5] | 1248 | 13793 |
| Rheumatoid arthritis[4] | 587 | 3425 |
| Intestinal polyps | 956 | 11573 |
| Lupus | 75 | 657 |
| Kidney stones[4,5] | 128 | 1749 |
| Cataracts [4,5] | 1660 | 19915 |
| Pills for hypertension | 2190 | 18143 |

[1] AV-1 date is the blood draw date for participants with an AV-1 blood draw and the CT randomization date plus 1 year for participants without an AV-1 blood draw. All participants have been enrolled for at least 1 year.

[2] Inpatient DVT only.

[3] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.

[4] Not collected on Form 33 after March 31,2005.

[5] These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

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

Data as of: August 15, 2007

| | CT | | OS | |
|---|---|---|---|---|
| **Number of participants** | 68132 | | 93676 | |
| **Mean follow-up time (months)** | 115.2 | | 109.4 | |
| **Ppts with other cancer** | 3441 | (0.53%) | 4747 | (0.56%) |
| Accessory sinus | 1 | (<0.01%) | 1 | (<0.01%) |
| Adrenal gland | 1 | (<0.01%) | 7 | (<0.01%) |
| Anus | 13 | (<0.01%) | 28 | (<0.01%) |
| Appendix | 9 | (<0.01%) | 11 | (<0.01%) |
| Biliary tract, parts of (other/unspecified) | 47 | (0.01%) | 51 | (0.01%) |
| Bladder | 205 | (0.03%) | 251 | (0.03%) |
| Bones/joints/articular cartilage (limbs) | 4 | (<0.01%) | 8 | (<0.01%) |
| Bones/joints/articular cartilage (other) | 5 | (<0.01%) | 2 | (<0.01%) |
| Brain | 88 | (0.01%) | 99 | (0.01%) |
| Cervix | 51 | (0.01%) | 46 | (0.01%) |
| Central Nervous System (excludes brain) | 0 | (0.00%) | 3 | (<0.01%) |
| Connective/subcutaneous/soft tissues | 35 | (0.01%) | 44 | (0.01%) |
| Endocrine glands, related structures | 6 | (<0.01%) | 7 | (<0.01%) |
| Esophagus | 39 | (0.01%) | 41 | (<0.01%) |
| Eye and adnexa | 19 | (<0.01%) | 15 | (<0.01%) |
| Genital organs | 45 | (0.01%) | 43 | (0.01%) |
| Kidney | 166 | (0.03%) | 217 | (0.03%) |
| Larynx | 16 | (<0.01%) | 13 | (<0.01%) |
| Leukemia | 167 | (0.03%) | 230 | (0.03%) |
| Liver | 40 | (0.01%) | 47 | (0.01%) |
| Lung | 674 | (0.10%) | 907 | (0.11%) |
| Lymph nodes | 12 | (<0.01%) | 9 | (<0.01%) |
| Lymphoma, Hodgkins | 21 | (<0.01%) | 20 | (<0.01%) |
| Lymphoma, Non-Hodgkins | 316 | (0.05%) | 460 | (0.05%) |
| Melanoma of the skin | 464 | (0.07%) | 603 | (0.07%) |
| Multiple myeloma | 120 | (0.02%) | 112 | (0.01%) |
| Oral (mouth) | 24 | (<0.01%) | 16 | (<0.01%) |
| Palate | 6 | (<0.01%) | 11 | (<0.01%) |
| Pancreas | 180 | (0.03%) | 215 | (0.03%) |
| Parotid gland (Stensen's duct) | 10 | (<0.01%) | 23 | (<0.01%) |
| Peripheral nerves and autonomic nervous system | 1 | (<0.01%) | 5 | (<0.01%) |
| Pyriform sinus | 0 | (0.00%) | 4 | (<0.01%) |
| Respiratory system, intrathoracic, other | 9 | (<0.01%) | 16 | (<0.01%) |
| Salivary glands, major (other/unspecified) | 3 | (<0.01%) | 11 | (<0.01%) |
| Stomach | 50 | (0.01%) | 69 | (0.01%) |
| Thyroid | 105 | (0.02%) | 143 | (0.02%) |
| Tongue, part of (other/unspecified) | 21 | (<0.01%) | 24 | (<0.01%) |
| Urinary organs (other/unspecified) | 17 | (<0.01%) | 33 | (<0.01%) |
| Uterus, not otherwise specified | 43 | (0.01%) | 86 | (0.01%) |
| Other/unknown site of cancer | 239 | (0.04%) | 334 | (0.04%) |
| Other/unknown cancers reported on death form | 262 | (0.04%) | 580 | (0.07%) |

**Table 6.6**
**Locally Verified Other Fractures (Annualized Percentages): CT and OS Participants**

Data as of August 15, 2007

| | CT | | OS | |
|---|---|---|---|---|
| **Number of participants** | 68132 | | 93676 | |
| **Mean follow-up time (months)** | 115.2 | | 109.4 | |
| **Self-Reports** | | | | |
| Elbow | 669 | (0.10%) | 843 | (0.10%) |
| Foot | 2328 | (0.36%) | 2933 | (0.34%) |
| Hand | 556 | (0.09%) | 607 | (0.07%) |
| Hip | 1108 | (0.17%) | 1580 | (0.19%) |
| Knee | 827 | (0.13%) | 1083 | (0.13%) |
| Lower arm | 3282 | (0.50%) | 4107 | (0.48%) |
| Lower leg | 2588 | (0.40%) | 3208 | (0.38%) |
| Pelvis | 569 | (0.09%) | 935 | (0.11%) |
| Tailbone | 200 | (0.03%) | 281 | (0.03%) |
| Upper arm | 1515 | (0.23%) | 1870 | (0.22%) |
| Upper leg | 389 | (0.06%) | 571 | (0.07%) |
| Spine | 1654 | (0.25%) | 2461 | (0.29%) |
| Other | 2740 | (0.42%) | 2974 | (0.35%) |
| Total fracture | 14243 | (2.18%) | 18353 | (2.15%) |

Data as of: August 18, 2006

**Events through Intervention Closeout**

| | CT | | OS | |
|---|---|---|---|---|
| **Number of participants** | 68132 | | 6365 | |
| **Mean follow-up time (months)** | 96.1 | | 97.6 | |
| **Locally verified** | | | | |
| **Ppts with other fractures**[1] | 8335 | (1.53%) | 773 | (1.49%) |
| Ankle | 1352 | (0.25%) | 128 | (0.25%) |
| Carpal bone(s) in wrist | 192 | (0.04%) | 13 | (0.03%) |
| Clavicle or collar bone | 147 | (0.03%) | 14 | (0.03%) |
| Elbow, not otherwise specified | 31 | (0.01%) | 1 | (<0.01%) |
| Humerus, shaft/unspecified | 86 | (0.02%) | 7 | (0.01%) |
| Humerus, upper end | 842 | (0.15%) | 69 | (0.13%) |
| Lower end of humerus | 104 | (0.02%) | 10 | (0.02%) |
| Metacarpal bone(s) | 272 | (0.05%) | 27 | (0.05%) |
| Patella | 358 | (0.07%) | 29 | (0.06%) |
| Pelvis | 361 | (0.07%) | 51 | (0.10%) |
| Radius or ulna | 2227 | (0.41%) | 208 | (0.40%) |
| Sacrum and coccyx | 107 | (0.02%) | 12 | (0.02%) |
| Scapula | 37 | (0.01%) | 6 | (0.01%) |
| lShaft of femur | 113 | (0.02%) | 9 | (0.02%) |
| Tarsal/metatarsal bones | 1291 | (0.24%) | 128 | (0.25%) |
| Tibia and fibula | 640 | (0.12%) | 32 | (0.06%) |
| Tibial plateau | 176 | (0.03%) | 10 | (0.02%) |
| Upper radius/ulna | 381 | (0.07%) | 34 | (0.07%) |
| Vertebral | 828 | (0.15%) | 121 | (0.23%) |
| Unknown other fracture | 1 | (<0.01%) | 0 | (0.00%) |

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

**Table 6.7**
**Cause of Death (Annualized Percentages): CT and OS Participants**

Data as of: August 15, 2007

| | CT | | OS | |
|---|---|---|---|---|
| **Number Randomized** | 68132 | | 93676 | |
| **Mean Follow-up Time (months)** | 115.2 | | 109.4 | |
| Total death | 4778 | (0.73%) | 7657 | (0.90%) |
| Adjudicated death | 4348 | (0.66%) | 6994 | (0.82%) |
| Centrally adjudicated death | 4308 | (0.66%) | 985 | (0.12%) |
| Locally adjudicated death (final) | 2 | (<0.01%) | 5889 | (0.69%) |
| Temporary adjudicated death | 0 | (0.00%) | 0 | (0.00%) |
| Identified by NDI search | 38 | (0.01%) | 120 | (0.01%) |
| **Cardiovascular** | | | | |
| Atherosclerotic cardiac | 732 | (0.11%) | 988 | (0.12%) |
| CHD deaths locally adjudicated before 10/99 | 0 | (0.00%) | 82 | (0.01%) |
| Definite CHD deaths | 342 | (0.05%) | 412 | (0.05%) |
| Possible CHD deaths | 390 | (0.06%) | 494 | (0.06%) |
| Cerebrovascular | 328 | (0.05%) | 523 | (0.06%) |
| Pulmonary embolism | 43 | (0.01%) | 53 | (0.01%) |
| Other cardiovascular | 211 | (0.03%) | 425 | (0.05%) |
| Unknown cardiovascular | 22 | (<0.01%) | 93 | (0.01%) |
| **Total cardiovascular deaths** | 1336 | (0.20%) | 2082 | (0.24%) |
| **Cancer** | | | | |
| Breast cancer | 129 | (0.02%) | 438 | (0.05%) |
| Ovarian cancer | 136 | (0.02%) | 219 | (0.03%) |
| Endometrial cancer | 31 | (<0.01%) | 53 | (0.01%) |
| Colorectal cancer | 182 | (0.03%) | 258 | (0.03%) |
| Other cancer | 1371 | (0.21%) | 1882 | (0.22%) |
| Unknown cancer site | 105 | (0.02%) | 154 | (0.02%) |
| **Total cancer deaths** | 1954 | (0.30%) | 3004 | (0.35%) |
| **Accident/injury** | | | | |
| Homicide | 7 | (<0.01%) | 10 | (<0.01%) |
| Accident | 130 | (0.02%) | 147 | (0.02%) |
| Suicide | 15 | (<0.01%) | 28 | (<0.01%) |
| Other injury | 7 | (<0.01%) | 23 | (<0.01%) |
| **Total accidental deaths** | 159 | (0.02%) | 208 | (0.02%) |
| **Other** | | | | |
| Other known cause | 760 | (0.12%) | 1415 | (0.17%) |
| Unknown cause | 569 | (0.09%) | 948 | (0.11%) |
| **Total deaths – other causes** | 1329 | (0.20%) | 2363 | (0.28%) |

**Table 7.1**
**Agreement of the Central Adjudications with Self-Reports**

Data as of: August 15, 2007

| | Participants with a self-report[1] | Closed | | Confirmed | | Denied – related outcome found[2] | | Denied – unrelated outcome found | | Denied – no outcome found | | Administrative denials | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | N | %[3] | N | (%)[3] | N | (%)[3] | N | (%)[3] | N | (%)[3] | N | (%)[3] |
| **Cardiovascular** | | | | | | | | | | | | | |
| Clinical MI | 650 | 607 | 93% | 439 | (72%) | 45 | (7%) | 4 | (1%) | 118 | (19%) | 1 | (0%) |
| CABG | 371 | 351 | 95% | 308 | (88%) | 13 | (4%) | 0 | (0%) | 30 | (9%) | 0 | (0%) |
| PTCA | 1074 | 1020 | 95% | 836 | (82%) | 59 | (6%) | 11 | (1%) | 114 | (11%) | 0 | (0%) |
| Carotid artery disease | 210 | 198 | 94% | 156 | (79%) | 18 | (9%) | 0 | (0%) | 19 | (10%) | 5 | (3%) |
| Stroke/TIA[4] | 988 | 293 | 30% | 168 | (57%) | 0 | (0%) | 0 | (0%) | 117 | (40%) | 8 | (3%) |
| PVD | 214 | 194 | 91% | 126 | (65%) | 3 | (2%) | 9 | (5%) | 56 | (29%) | 0 | (0%) |
| DVT[5] | 75 | 69 | 92% | 47 | (68%) | 7 | (10%) | 5 | (7%) | 10 | (14%) | 0 | (0%) |
| Pulmonary embolism | 36 | 36 | 100% | 31 | (86%) | 0 | (0%) | 1 | (3%) | 4 | (11%) | 0 | (0%) |
| **Cancers** | | | | | | | | | | | | | |
| Breast cancer | 1098 | 1045 | 95% | 1021 | (98%) | 3 | (0%) | 0 | (0%) | 21 | (2%) | 0 | (0%) |
| Ovarian cancer | 112 | 102 | 91% | 61 | (60%) | 36 | (35%) | 0 | (0%) | 5 | (5%) | 0 | (0%) |
| Endometrial cancer | 124 | 118 | 95% | 108 | (92%) | 5 | (4%) | 1 | (1%) | 4 | (3%) | 0 | (0%) |
| Cervical cancer | 21 | 18 | 86% | 2 | (11%) | 16 | (89%) | 0 | (0%) | 0 | (0%) | 0 | (0%) |
| Colorectal cancer | 283 | 263 | 93% | 222 | (84%) | 20 | (8%) | 0 | (0%) | 20 | (8%) | 1 | (0%) |
| Melanoma | 224 | 176 | 79% | 153 | (87%) | 11 | (6%) | 0 | (0%) | 9 | (5%) | 3 | (2%) |
| Lung cancer | 328 | 236 | 72% | 197 | (83%) | 17 | (7%) | 0 | (0%) | 22 | (9%) | 0 | (0%) |
| Liver cancer | 59 | 47 | 80% | 11 | (23%) | 19 | (40%) | 0 | (0%) | 16 | (34%) | 1 | (2%) |
| Bone cancer | 35 | 24 | 69% | 0 | (0%) | 13 | (54%) | 1 | (4%) | 10 | (42%) | 0 | (0%) |
| Lymphoma/Hodgkin's | 149 | 123 | 83% | 110 | (89%) | 4 | (3%) | 0 | (0%) | 9 | (7%) | 0 | (0%) |
| Leukemia | 95 | 65 | 68% | 58 | (89%) | 2 | (3%) | 0 | (0%) | 5 | (8%) | 0 | (0%) |
| Meningioma | 7 | 6 | 86% | 0 | (0%) | 1 | (17%) | 0 | (0%) | 5 | (83%) | 0 | (0%) |
| Other cancer[6] | 686 | 532 | 78% | N/A | N/A | 453 | (85%) | 0 | (0%) | 69 | (13%) | 10 | (2%) |
| **Fractures** | | | | | | | | | | | | | |
| Hip fracture | 597 | 549 | 92% | 456 | (83%) | 0 | (0%) | 0 | (0%) | 91 | (17%) | 2 | (0%) |
| Upper leg fracture[7] | 135 | 108 | 80% | N/A | N/A | 44 | (41%) | 0 | (0%) | 63 | (58%) | 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 parenthese are relative to "closed".
[4] Stroke and TIA have a combined self-report. Only stroke is monitored.
[5] HRT participants only.
[6] Any cancer other than those listed above, excluding non-melanoma skin cancer.
[7] Upper leg fractures are only investigated for possible occurrence of hip fracture.

**Table 7.2**
**Source of Outcomes Identified by Central Adjudications**

Data as of: August 15, 2007

| | 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 | 654 | 440 | 67% | 181 | 28% | 33 | 5% |
| CABG | 328 | 308 | 94% | 15 | 5% | 5 | 2% |
| PTCA | 888 | 838 | 94% | 48 | 5% | 2 | <1% |
| Carotid artery disease | 181 | 156 | 86% | 3 | 2% | 22 | 12% |
| Stroke | 193 | 168 | 87% | 0 | 0% | 25 | 13% |
| PVD | 176 | 127 | 72% | 34 | 19% | 15 | 9% |
| DVT | 58 | 47 | 81% | 2 | 3% | 9 | 16% |
| Pulmonary embolism | 41 | 31 | 76% | 3 | 7% | 7 | 17% |
| **Cancers** | | | | | | | |
| Breast cancer | 1027 | 1022 | 100% | 3 | <1% | 2 | <1% |
| Ovarian cancer | 73 | 61 | 84% | 3 | 4% | 9 | 12% |
| Endometrial cancer | 143 | 108 | 76% | 31 | 22% | 4 | 3% |
| Cervical cancer | 2 | 2 | 100% | 0 | 0% | 0 | 0% |
| Colorectal cancer | 224 | 213 | 95% | 4 | 2% | 7 | 3% |
| Melanoma | 156 | 153 | 98% | 3 | 2% | 0 | 0% |
| Lung cancer | 213 | 197 | 92% | 10 | 5% | 6 | 3% |
| Liver cancer | 13 | 11 | 85% | 2 | 15% | 0 | 0% |
| Lymphoma/Hodgkin's | 134 | 7 | 5% | 121 | 90% | 6 | 4% |
| Leukemia | 70 | 59 | 84% | 8 | 11% | 3 | 4% |
| Other cancer | 499 | N/A | N/A | 483 | 97% | 16 | 3% |
| **Fractures** | | | | | | | |
| Hip fracture | 512 | 456 | 89% | 40 | 8% | 16 | 3% |

[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 8.1**
**Form 33/33D - Medical History Update/(Detail) Workload**

Data as of 8-15-07

| | Form 33 – Medical History Update 5-1-06 thru 4-30-07 | | | | | | Ppts on FC Mail003-Due for FC Collection Data as of 8-2-07 | | Form 33D – Medical History Update (Detail) Cummulative | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Total | | CCC Mailings Not Collected | | Outstanding Info Errors (Cum) | | | | Due | Missing | | Incomplete | | Ave Collected per Month last 12 mo | Form 33D Workload (miss + incomp) | |
| | Due # | % Collected | # | % | # | % | # | % of Due | # | # | % | # | % | # | # cases | % months |
| Atlanta | 2,890 | 92.1 | 304 | 10.5 | 17 | 0.6 | 160 | 5.5 | 803 | 8 | 1.0 | 1 | 0.1 | 34 | 9 | 0.3 |
| Birmingham | 2,422 | 96.9 | 302 | 12.5 | 1 | 0.0 | 4 | 0.2 | 770 | 4 | 0.5 | | | 33 | 4 | 0.1 |
| Bowman | 2,400 | 93.7 | 211 | 8.8 | 11 | 0.5 | 83 | 3.5 | 696 | 5 | 0.7 | | | 27 | 5 | 0.2 |
| Brigham | 3,870 | 98.6 | 189 | 4.9 | 5 | 0.1 | 12 | 0.3 | 1,137 | 11 | 1.0 | | | 45 | 11 | 0.2 |
| Buffalo | 2,840 | 98.8 | 174 | 6.1 | 1 | 0.0 | 2 | 0.1 | 869 | 2 | 0.2 | | | 34 | 2 | 0.1 |
| Chapel Hill | 2,596 | 97.7 | 219 | 8.4 | 3 | 0.1 | 5 | 0.2 | 729 | | | | | 30 | | |
| Chicago-Rush | 1,720 | 94.6 | 193 | 11.2 | 2 | 0.1 | 50 | 2.9 | 515 | 13 | 2.5 | 2 | 0.4 | 22 | 15 | 0.7 |
| Chicago | 2,365 | 97.1 | 142 | 6.0 | 6 | 0.3 | 22 | 0.9 | 775 | 21 | 2.7 | | | 28 | 21 | 0.7 |
| Cincinnati | 2,536 | 96.8 | 160 | 6.3 | 1 | 0.0 | 31 | 1.2 | 789 | 7 | 0.9 | | | 35 | 7 | 0.2 |
| Columbus | 2,602 | 97.6 | 140 | 5.4 | 5 | 0.2 | 31 | 1.2 | 832 | 8 | 1.0 | | | 32 | 8 | 0.3 |
| Detroit | 2,175 | 93.8 | 185 | 8.5 | 10 | 0.5 | 86 | 4.0 | 632 | 30 | 4.7 | | | 22 | 30 | 1.4 |
| Gainesville | 3,565 | 97.1 | 370 | 10.4 | 9 | 0.3 | 85 | 2.4 | 1,231 | 20 | 1.6 | 2 | 0.2 | 48 | 22 | 0.5 |
| U-DC | 2,679 | 96.8 | 183 | 6.8 | 8 | 0.3 | 28 | 1.0 | 678 | 11 | 1.6 | | | 27 | 11 | |
| Honolulu | 1,807 | 98.0 | 155 | 8.6 | | | | | 368 | 1 | 0.3 | | | 14 | 1 | |
| Houston | 2,025 | 98.3 | 121 | 6.0 | | | 11 | 0.5 | 609 | 12 | 2.0 | | | 25 | 12 | |
| IC-Bettendorf | 1,838 | 99.3 | 73 | 4.0 | 2 | 0.1 | | | 615 | 6 | 1.0 | | | 25 | 6 | |
| IC-Des Moines | 1,858 | 99.0 | 58 | 3.1 | 14 | 0.8 | 8 | 0.4 | 544 | 17 | 3.1 | | | 22 | 17 | |
| Irvine | 2,686 | 96.0 | 152 | 5.7 | 14 | 0.5 | 59 | 2.2 | 637 | 34 | 5.3 | | | 24 | 34 | |
| LA | 2,561 | 96.5 | 139 | 5.4 | 3 | 0.1 | 43 | 1.7 | 718 | 24 | 3.3 | | | 30 | 24 | |
| La Jolla | 2,868 | 94.0 | 173 | 6.0 | 25 | 0.9 | 102 | 3.6 | 762 | 34 | 4.5 | | | 30 | 34 | |
| Madison | 2,491 | 97.4 | 119 | 4.8 | 12 | 0.5 | 25 | 1.0 | 705 | 25 | 3.5 | | | 25 | 25 | |
| Medlantic | 2,360 | 95.7 | 352 | 14.9 | 1 | 0.0 | 49 | 2.1 | 684 | 2 | 0.3 | 1 | 0.1 | 28 | 3 | 0.1 |
| Memphis | 2,136 | 97.6 | 174 | 8.1 | 4 | 0.2 | 8 | 0.4 | 579 | 6 | 1.0 | | | 24 | 6 | 0.3 |
| Miami | 1,521 | 92.4 | 220 | 14.5 | 21 | 1.5 | 51 | 3.4 | 400 | 5 | 1.3 | | | 18 | 5 | 0.3 |
| Milwaukee | 2,675 | 97.5 | 88 | 3.3 | 2 | 0.1 | 52 | 1.9 | 833 | 23 | 2.8 | | | 31 | 23 | 0.7 |

**Table 8.1 (continued)**
**Form 33/33D - Medical History Update/(Detail) Workload**

Data as of 8-15-07

| | Form 33 – Medical History Update 5-1-06 thru 4-30-07 | | | | | | Ppts on FC Mail003-Due for FC Collection Data as of 8-2-07 | | Form 33D – Medical History Update (Detail) Cummulative | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Total | | CCC Mailings Not Collected | | Outstanding Info Errors (Cum) | | | | Due | Missing | | Incomplete | | Ave Collected per Month last 12 mo | Form 33D Workload (miss + incomp) | |
| | Due # | % Collected | # | % | # | % | # | % of Due | # | # | % | # | % | # | # cases | % months |
| Minneapolis | 3,237 | 98.1 | 135 | 4.2 | 32 | 1.0 | 39 | 1.2 | 918 | 5 | 0.5 | | | 39 | 5 | 0.1 |
| Nevada | 2,438 | 96.6 | 186 | 7.6 | | | 37 | 1.5 | 791 | 3 | 0.4 | | | 34 | 3 | 0.1 |
| Newark | 2,706 | 93.5 | 221 | 8.2 | | | 105 | 3.9 | 789 | 18 | 2.3 | | | 31 | 18 | 0.6 |
| New Brunswick | 1,123 | 94.7 | 156 | 13.9 | 9 | 0.8 | 29 | 2.6 | 301 | 9 | 3.0 | | | 14 | 9 | 0.7 |
| NYC | 2,624 | 97.3 | 215 | 8.2 | 4 | 0.2 | 20 | 0.8 | 792 | 2 | 0.3 | | | 32 | 2 | 0.1 |
| Oakland | 2,529 | 98.3 | 144 | 5.7 | 11 | 0.4 | 16 | 0.6 | 574 | 8 | 1.4 | | | 20 | 8 | 0.4 |
| Pawtucket | 4,427 | 96.9 | 329 | 7.4 | 6 | 0.1 | 32 | 0.7 | 1,425 | 6 | 0.4 | | | 59 | 6 | 0.1 |
| Pittsburgh | 2,435 | 96.8 | 173 | 7.1 | 3 | 0.1 | 26 | 1.1 | 925 | 7 | 0.8 | | | 34 | 7 | 0.2 |
| Portland | 2,623 | 94.6 | 187 | 7.1 | 15 | 0.6 | 86 | 3.3 | 687 | 21 | 3.1 | | | 26 | 21 | 0.8 |
| San Antonio | 1,641 | 94.3 | 161 | 9.8 | | | 55 | 3.4 | 246 | 17 | 6.9 | | | 11 | 17 | 1.5 |
| Seattle | 2,164 | 95.8 | 121 | 5.6 | 5 | 0.2 | 59 | 2.7 | 599 | 5 | 0.8 | | | 22 | 5 | 0.2 |
| Stanford | 3,205 | 98.3 | 178 | 5.6 | 5 | 0.2 | 23 | 0.7 | 860 | 4 | 0.5 | | | 33 | 4 | 0.1 |
| Stony Brook | 2,301 | 98.0 | 170 | 7.4 | 13 | 0.6 | 5 | 0.2 | 898 | 11 | 1.2 | 1 | 0.1 | 34 | 12 | 0.4 |
| Torrance | 1,379 | 96.4 | 83 | 6.0 | 4 | 0.3 | 22 | 1.6 | 347 | 7 | 2.0 | | | 13 | 7 | 0.5 |
| Tucson | 2,815 | 94.6 | 263 | 9.3 | 2 | 0.1 | 61 | 2.2 | 851 | 15 | 1.8 | 1 | 0.1 | 34 | 16 | 0.5 |
| UC Davis | 2,541 | 96.6 | 169 | 6.7 | 11 | 0.4 | 38 | 1.5 | 764 | 10 | 1.3 | 3 | 0.4 | 34 | 13 | 0.4 |
| Worcester | 2,889 | 99.1 | 154 | 5.3 | 1 | 0.0 | 11 | 0.4 | 925 | 3 | 0.3 | | | 41 | 3 | 0.1 |
| All FCs | 104,563 | 96.6 | 7,641 | 7.3 | 298 | 0.3 | 1,671 | 1.6 | 30,602 | 480 | 1.6 | 11 | 0.0 | 1,225 | 491 | 0.4 |

1 - Excludes absolutely no contact and deceased participants

**Table 8.2**
**Outcomes Processing Workload**

Data as of 8-15-07

| | Open Cases | | | | | | Closed Cases | Outcomes Workload | | | Deaths | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Open Cases | No Docs Request | No Docs Receive | No Docs Process | ≥ 1 Doc Process | Open > 12 Mos | Avg # per Month for last 12 Months | Est # Months to Process Open Cases | Est Workload for Open cases and Form 33D | | Cum[1] (Ext) | Unresolved[1] (Ext) | | # Open cases with Deaths |
| | # | # | # | # | # | # | | | # cases | # months | # | # | % | |
| Atlanta | 68 | | 59 | 9 | | 6 | 35 | 2.0 | 77 | 2.2 | 52 | 11 | 21.2 | 7 |
| Birmingham | 34 | 3 | 25 | 6 | | 1 | 34 | 1.0 | 38 | 1.1 | 45 | 6 | 13.3 | 8 |
| Bowman | 100 | 44 | 56 | | | | 23 | 4.3 | 105 | 4.5 | 46 | 11 | 23.9 | 18 |
| Brigham | 76 | 24 | 52 | | | 2 | 43 | 1.8 | 87 | 2.0 | 51 | 15 | 29.4 | 26 |
| Buffalo | 117 | 24 | 59 | 34 | | 1 | 38 | 3.1 | 119 | 3.2 | 78 | 31 | 39.7 | 53 |
| Chapel Hill | 16 | | 6 | 10 | | | 27 | 0.6 | 16 | 0.6 | 47 | 0 | | |
| Chicago-Rush | 89 | 31 | 51 | 7 | | 11 | 26 | 3.4 | 104 | 4.1 | 36 | 19 | 52.8 | 22 |
| Chicago | 107 | 16 | 67 | 24 | | 2 | 32 | 3.4 | 128 | 4.1 | 57 | 21 | 36.8 | 26 |
| Cincinnati | 36 | 7 | 27 | 2 | | | 44 | 0.8 | 43 | 1.0 | 47 | 1 | 2.1 | |
| Columbus | 79 | | 79 | | | | 31 | 2.5 | 87 | 2.8 | 76 | 25 | 32.9 | 32 |
| Detroit | 93 | 29 | 45 | 19 | | | 20 | 4.7 | 123 | 6.1 | 25 | 12 | 48.0 | 10 |
| Gainesville | 95 | 52 | 35 | 7 | 1 | 2 | 57 | 1.7 | 117 | 2.1 | 75 | 12 | 16.0 | 21 |
| GWU-DC | 94 | 25 | 65 | 4 | | 1 | 25 | 3.7 | 105 | 4.1 | 47 | 9 | 19.1 | 12 |
| Honolulu | 20 | 3 | 15 | 2 | | 1 | 12 | 1.7 | 21 | 1.8 | 24 | 7 | 29.2 | 2 |
| Houston | 59 | 23 | 26 | 10 | | 1 | 28 | 2.1 | 71 | 2.6 | 31 | 9 | 29.0 | 16 |
| IC-Bettendorf | 67 | 21 | 25 | 21 | | | 25 | 2.7 | 73 | 3.0 | 31 | 9 | 29.0 | 21 |
| IC-Des Moines | 54 | 5 | 28 | 21 | | 1 | 22 | 2.5 | 71 | 3.3 | 26 | 11 | 42.3 | 20 |
| Irvine | 70 | 18 | 48 | 4 | | 2 | 20 | 3.5 | 104 | 4.9 | 36 | 32 | 88.9 | 20 |
| LA | 112 | | 95 | 17 | | 9 | 22 | 5.1 | 136 | 5.9 | 44 | 33 | 75.0 | 36 |
| La Jolla | 79 | 20 | 40 | 19 | | | 37 | 2.1 | 113 | 3.3 | 34 | 23 | 67.6 | 25 |
| Madison | 34 | 1 | 18 | 15 | | | 31 | 1.1 | 59 | 2.1 | 67 | 31 | 46.3 | 13 |
| Medlantic | 50 | 2 | 24 | 23 | 1 | 1 | 27 | 1.9 | 53 | 2.0 | 45 | 19 | 42.2 | 16 |
| Memphis | 16 | | 16 | | | | 26 | 0.6 | 22 | 0.9 | 54 | 3 | 5.6 | 6 |
| Miami | 30 | 9 | 20 | 1 | | | 15 | 2.0 | 35 | 2.3 | 22 | 7 | 31.8 | 8 |
| Milwaukee | 43 | 33 | 10 | | | | 26 | 1.7 | 66 | 2.4 | 52 | 15 | 28.8 | 16 |

**Table 8.2 (continued)**
**Outcomes Processing Workload**

Data as of 8-15-07

| | Open Cases | | | | | | Closed Cases | Outcomes Workload | | | Deaths | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Open Cases | No Docs Request | No Docs Receive | No Docs Process | ≥ 1 Doc Process | Open > 12 Mos | Avg # per Month for last 12 Months | Est # Months to Process Open Cases | Est Workload for Open cases and Form 33D | | Cum[1] (Ext) | Unresolved[1] (Ext) | | # Open cases with Deaths |
| | # | # | # | # | # | # | | | # cases | # months | # | # | % | |
| Minneapolis | 93 | 11 | 72 | 10 | | 1 | 28 | 3.3 | 98 | 3.4 | 32 | 14 | 43.8 | 15 |
| Nevada | 127 | 13 | 112 | 2 | | 2 | 42 | 3.0 | 130 | 3.1 | 69 | 18 | 26.1 | 38 |
| Newark | 127 | 17 | 110 | | | 12 | 33 | 3.9 | 145 | 4.4 | 33 | 23 | 69.7 | 35 |
| New Brunswick | 52 | 20 | 25 | 7 | | 8 | 19 | 2.7 | 61 | 3.4 | 35 | 21 | 60.0 | 25 |
| NYC | 74 | 16 | 51 | 7 | | | 29 | 2.6 | 76 | 2.6 | 52 | 16 | 30.8 | 22 |
| Oakland | 35 | 6 | 28 | 1 | | | 23 | 1.5 | 43 | 1.9 | 48 | 7 | 14.6 | 9 |
| Pawtucket | 123 | 2 | 120 | 1 | | 2 | 65 | 1.9 | 129 | 2.0 | 108 | 55 | 50.9 | 55 |
| Pittsburgh | 59 | 6 | 49 | 4 | | 1 | 45 | 1.3 | 66 | 1.5 | 71 | 17 | 23.9 | 27 |
| Portland | 60 | 24 | 28 | 8 | | 2 | 30 | 2.0 | 81 | 2.8 | 56 | 21 | 37.5 | 12 |
| San Antonio | 25 | 1 | 20 | 4 | | | 10 | 2.5 | 42 | 4.0 | 30 | 17 | 56.7 | 1 |
| Seattle | 35 | 16 | 13 | 6 | | 1 | 23 | 1.5 | 40 | 1.7 | 29 | 6 | 20.7 | 9 |
| Stanford | 40 | 11 | 19 | 10 | | | 30 | 1.3 | 44 | 1.5 | 64 | 10 | 15.6 | 12 |
| Stony Brook | 96 | 8 | 88 | | | 1 | 40 | 2.4 | 108 | 2.8 | 54 | 7 | 13.0 | 16 |
| Torrance | 57 | 5 | 51 | 1 | | 6 | 15 | 3.9 | 64 | 4.5 | 20 | 18 | 90.0 | 14 |
| Tucson | 106 | 39 | 47 | 19 | 1 | 2 | 35 | 3.0 | 122 | 3.5 | 69 | 25 | 36.2 | 37 |
| UC Davis | 156 | 76 | 2 | 78 | | 3 | 35 | 4.5 | 169 | 4.9 | 79 | 39 | 49.4 | 53 |
| Worcester | 56 | 14 | 36 | 6 | | | 40 | 1.4 | 59 | 1.5 | 64 | 6 | 9.4 | 7 |
| All FCs | 2,959 | 675 | 1,862 | 419 | 3 | 76 | 1,265 | 2.3 | 3,450 | 2.7 | 2,061 | 692 | 33.6 | 821 |

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

**Table 8.3**
**Closure Codes for Closed Outcomes Cases**

Data as of 8-15-07

| | Form 33 - Medical History Update | Forwarded to CCC C-9 | | Not Adjudicated C-10 | | Duplicate C-11 | | No Doc in 12 Months C-12 | | No ROI C13 | | Admin C-14 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | # | # | % | # | % | # | % | # | % | # | % | No | % |
| Atlanta | 733 | 626 | 85.4 | 49 | 6.7 | 31 | 4.2 | 21 | 2.9 | 6 | 0.8 | | |
| Birmingham | 743 | 673 | 90.6 | 62 | 8.3 | 7 | 0.9 | | | | | 1 | 0.1 |
| Bowman | 560 | 489 | 87.3 | 39 | 7.0 | 22 | 3.9 | 1 | 0.2 | 9 | 1.6 | | |
| Brigham | 904 | 723 | 80.0 | 96 | 10.6 | 80 | 8.8 | 1 | 0.1 | 3 | 0.3 | 1 | 0.1 |
| Buffalo | 812 | 714 | 87.9 | 64 | 7.9 | 30 | 3.7 | 1 | 0.1 | 3 | 0.4 | | |
| Chapel Hill | 642 | 622 | 96.9 | 9 | 1.4 | 8 | 1.2 | | | 3 | 0.5 | | |
| Chicago-Rush | 468 | 296 | 63.2 | 110 | 23.5 | 46 | 9.8 | 13 | 2.8 | 2 | 0.4 | 1 | 0.2 |
| Chicago | 712 | 599 | 84.1 | 47 | 6.6 | 48 | 6.7 | 3 | 0.4 | 11 | 1.5 | 4 | 0.6 |
| Cincinnati | 839 | 744 | 88.7 | 42 | 5.0 | 53 | 6.3 | | | | | | |
| Columbus | 783 | 694 | 88.6 | 76 | 9.7 | 12 | 1.5 | 1 | 0.1 | | | | |
| Detroit | 465 | 395 | 84.9 | 51 | 11.0 | 12 | 2.6 | 2 | 0.4 | 5 | 1.1 | | |
| Gainesville | 1,187 | 1,033 | 87.0 | 123 | 10.4 | 29 | 2.4 | 2 | 0.2 | | | | |
| GWU-DC | 529 | 427 | 80.7 | 65 | 12.3 | 31 | 5.9 | 6 | 1.1 | | | | |
| Honolulu | 293 | 268 | 91.5 | 16 | 5.5 | 8 | 2.7 | 1 | 0.3 | | | | |
| Houston | 487 | 385 | 79.1 | 56 | 11.5 | 22 | 4.5 | 10 | 2.1 | 14 | 2.9 | | |
| IC-Bettendorf | 552 | 479 | 86.8 | 38 | 6.9 | 34 | 6.2 | 1 | 0.2 | | | | |
| IC-Des Moines | 452 | 379 | 83.8 | 51 | 11.3 | 14 | 3.1 | 4 | 0.9 | | | 4 | 0.9 |
| Irvine | 402 | 315 | 78.4 | 58 | 14.4 | 18 | 4.5 | 6 | 1.5 | 4 | 1.0 | 1 | 0.2 |
| LA | 476 | 356 | 74.8 | 88 | 18.5 | 11 | 2.3 | 17 | 3.6 | 4 | 0.8 | | |
| La Jolla | 673 | 486 | 72.2 | 103 | 15.3 | 72 | 10.7 | 6 | 0.9 | 6 | 0.9 | | |
| Madison | 679 | 572 | 84.2 | 52 | 7.7 | 41 | 6.0 | 8 | 1.2 | 6 | 0.9 | | |
| Medlantic | 526 | 443 | 84.2 | 55 | 10.5 | 26 | 4.9 | 2 | 0.4 | | | | |
| Memphis | 537 | 481 | 89.6 | 44 | 8.2 | 5 | 0.9 | | | 5 | 0.9 | 2 | 0.4 |
| Miami | 328 | 262 | 79.9 | 45 | 13.7 | 21 | 6.4 | | | | | | |
| Milwaukee | 615 | 576 | 93.7 | 33 | 5.4 | 6 | 1.0 | | | | | | |

**Table 8.3 (continued)**
**Closure Codes for Closed Outcomes Cases**

Data as of 8-15-07

| | Form 33 - Medical History Update | Forwarded to CCC C-9 | | Not Adjudicated C-10 | | Duplicate C-11 | | No Doc in 12 Months C-12 | | No ROI C13 | | Admin C-14 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | # | # | % | # | % | # | % | # | % | # | % | No | % |
| Minneapolis | 607 | 530 | 87.3 | 52 | 8.6 | 21 | 3.5 | | | 4 | 0.7 | | |
| Nevada | 804 | 593 | 73.8 | 143 | 17.8 | 64 | 8.0 | 4 | 0.5 | | | | |
| Newark | 677 | 518 | 76.5 | 133 | 19.6 | 13 | 1.9 | 3 | 0.4 | 10 | 1.5 | | |
| New Brunswick | 324 | 280 | 86.4 | 10 | 3.1 | 10 | 3.1 | 20 | 6.2 | 3 | 0.9 | 1 | 0.3 |
| NYC | 633 | 576 | 91.0 | 40 | 6.3 | 11 | 1.7 | 3 | 0.5 | 3 | 0.5 | | |
| Oakland | 525 | 449 | 85.5 | 47 | 9.0 | 24 | 4.6 | 1 | 0.2 | 4 | 0.8 | | |
| Pawtucket | 1,263 | 1,122 | 88.8 | 114 | 9.0 | 19 | 1.5 | | | 8 | 0.6 | | |
| Pittsburgh | 1,030 | 929 | 90.2 | 47 | 4.6 | 50 | 4.9 | 3 | 0.3 | 1 | 0.1 | | |
| Portland | 610 | 473 | 77.5 | 61 | 10.0 | 52 | 8.5 | 12 | 2.0 | 6 | 1.0 | 5 | 0.8 |
| San Antonio | 189 | 156 | 82.5 | 16 | 8.5 | 6 | 3.2 | 2 | 1.1 | | | 9 | 4.8 |
| Seattle | 552 | 447 | 81.0 | 65 | 11.8 | 33 | 6.0 | 5 | 0.9 | 2 | 0.4 | | |
| Stanford | 752 | 624 | 83.0 | 80 | 10.6 | 45 | 6.0 | | | 3 | 0.4 | | |
| Stony Brook | 911 | 697 | 76.5 | 115 | 12.6 | 93 | 10.2 | | | 2 | 0.2 | 4 | 0.4 |
| Torrance | 294 | 233 | 79.3 | 47 | 16.0 | 12 | 4.1 | 1 | 0.3 | 1 | 0.3 | | |
| Tucson | 817 | 646 | 79.1 | 72 | 8.8 | 54 | 6.6 | 20 | 2.4 | 24 | 2.9 | 1 | 0.1 |
| UC Davis | 615 | 493 | 80.2 | 75 | 12.2 | 42 | 6.8 | | | 5 | 0.8 | | |
| Worcester | 857 | 727 | 84.8 | 111 | 13.0 | 19 | 2.2 | | | | 0 | | |
| All FCs | 26,857 | 22,530 | 83.9 | 2,700 | 10.1 | 1,255 | 4.7 | 180 | 0.7 | 157 | 0.6 | 34 | 0.1 |

**Table 8.4**
**Participant Follow-up Status[1]**

Data as of 8-15-07

| | # Participants | Full | | Partial/Custom | | Proxy | | Lost | | No Follow-up | | Absolutely No Contact | | Deceased | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | # | % | # | % | # | % | # | % | # | % | # | % | # | % |
| Atlanta | 3,129 | 2,709 | 86.6 | 350 | 11.2 | 9 | 0.3 | 7 | 0.2 | 1 | 0.0 | | | 53 | 1.7 |
| Birmingham | 2,677 | 2,535 | 94.7 | 73 | 2.7 | 1 | 0.0 | 3 | 0.1 | 4 | 0.1 | 13 | 0.5 | 48 | 1.8 |
| Bowman | 2,660 | 2,455 | 92.3 | 87 | 3.3 | | | 32 | 1.2 | 32 | 1.2 | 2 | 0.1 | 52 | 2.0 |
| Brigham | 4,216 | 3,977 | 94.3 | 162 | 3.8 | 14 | 0.3 | | | 4 | 0.1 | 5 | 0.1 | 54 | 1.3 |
| Buffalo | 3,128 | 2,876 | 91.9 | 120 | 3.8 | 29 | 0.9 | | | 11 | 0.4 | 6 | 0.2 | 86 | 2.7 |
| Chapel Hill | 2,848 | 2,732 | 95.9 | 28 | 1.0 | 24 | 0.8 | | | 7 | 0.2 | 5 | 0.2 | 52 | 1.8 |
| Chicago-Rush | 1,908 | 1,691 | 88.6 | 146 | 7.7 | | | 26 | 1.4 | | | 9 | 0.5 | 36 | 1.9 |
| Chicago | 2,635 | 2,226 | 84.5 | 319 | 12.1 | 13 | 0.5 | 8 | 0.3 | 5 | 0.2 | 5 | 0.2 | 59 | 2.2 |
| Cincinnati | 2,790 | 2,628 | 94.2 | 100 | 3.6 | 7 | 0.3 | 6 | 0.2 | | | 1 | 0.0 | 48 | 1.7 |
| Columbus | 2,904 | 2,685 | 92.5 | 130 | 4.5 | 2 | 0.1 | 4 | 0.1 | 1 | 0.0 | 3 | 0.1 | 79 | 2.7 |
| Detroit | 2,352 | 2,076 | 88.3 | 228 | 9.7 | 3 | 0.1 | 13 | 0.6 | | | 6 | 0.3 | 26 | 1.1 |
| Gainesville | 3,947 | 3,366 | 85.3 | 477 | 12.1 | 14 | 0.4 | 2 | 0.1 | 1 | 0.0 | 10 | 0.3 | 77 | 2.0 |
| GWU-DC | 2,926 | 2,730 | 93.3 | 106 | 3.6 | 11 | 0.4 | 11 | 0.4 | 5 | 0.2 | 13 | 0.4 | 50 | 1.7 |
| Honolulu | 1,987 | 1,885 | 94.9 | 70 | 3.5 | 1 | 0.1 | | | 1 | 0.1 | 6 | 0.3 | 24 | 1.2 |
| Houston | 2,232 | 2,063 | 92.4 | 126 | 5.6 | | | 2 | 0.1 | | | 9 | 0.4 | 32 | 1.4 |
| Iowa City-Bettendorf | 2,032 | 1,848 | 90.9 | 138 | 6.8 | 5 | 0.2 | | | | | 7 | 0.3 | 34 | 1.7 |
| Iowa City - Des Moines | 2,029 | 1,830 | 90.2 | 150 | 7.4 | 6 | 0.3 | 1 | 0.0 | 1 | 0.0 | 14 | 0.7 | 27 | 1.3 |
| Irvine | 2,939 | 2,634 | 89.6 | 210 | 7.1 | | | 36 | 1.2 | 2 | 0.1 | 19 | 0.6 | 38 | 1.3 |
| LA | 2,828 | 2,583 | 91.3 | 154 | 5.4 | | | 19 | 0.7 | 9 | 0.3 | 18 | 0.6 | 45 | 1.6 |
| La Jolla | 3,078 | 2,820 | 91.6 | 217 | 7.1 | 2 | 0.1 | 2 | 0.1 | | | 3 | 0.1 | 34 | 1.1 |
| Madison | 2,763 | 2,534 | 91.7 | 128 | 4.6 | 18 | 0.7 | 2 | 0.1 | 6 | 0.2 | 6 | 0.2 | 69 | 2.5 |
| Medlantic | 2,613 | 2,206 | 84.4 | 333 | 12.7 | 8 | 0.3 | 12 | 0.5 | 7 | 0.3 | 2 | 0.1 | 45 | 1.7 |
| Memphis | 2,398 | 2,166 | 90.3 | 142 | 5.9 | 6 | 0.3 | | | | | 28 | 1.2 | 56 | 2.3 |
| Miami | 1,682 | 1,424 | 84.7 | 201 | 12.0 | | | 26 | 1.5 | 9 | 0.5 | | | 22 | 1.3 |
| Milwaukee | 2,938 | 2,756 | 93.8 | 110 | 3.7 | 3 | 0.1 | 2 | 0.1 | 1 | 0.0 | 13 | 0.4 | 53 | 1.8 |

**Table 8.4 (continued)**
**Participant Follow-up Status[1]**

Data as of 8-15-07

| | # Participants | Full | | Partial/Custom | | Proxy | | Lost | | No Follow-up | | Absolutely No Contact | | Deceased | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | # | % | # | % | # | % | # | % | # | % | # | % | # | % |
| Minneapolis | 3,555 | 3,336 | 93.8 | 165 | 4.6 | 7 | 0.2 | 3 | 0.1 | 6 | 0.2 | 1 | 0.0 | 37 | 1.0 |
| Nevada | 2,713 | 2,539 | 93.6 | 88 | 3.2 | 1 | 0.0 | 5 | 0.2 | | | 1 | 0.0 | 79 | 2.9 |
| Newark | 2,963 | 2,759 | 93.1 | 123 | 4.2 | 2 | 0.1 | 37 | 1.2 | 3 | 0.1 | 5 | 0.2 | 34 | 1.1 |
| New Brunswick | 1,231 | 942 | 76.5 | 234 | 19.0 | 9 | 0.7 | 4 | 0.3 | 4 | 0.3 | 2 | 0.2 | 36 | 2.9 |
| NYC | 2,961 | 2,779 | 93.9 | 106 | 3.6 | | | 10 | 0.3 | | | 12 | 0.4 | 54 | 1.8 |
| Oakland | 2,776 | 2,680 | 96.5 | 24 | 0.9 | 15 | 0.5 | | | 3 | 0.1 | 1 | 0.0 | 53 | 1.9 |
| Pawtucket | 4,872 | 4,323 | 88.7 | 385 | 7.9 | 23 | 0.5 | 1 | 0.0 | 17 | 0.3 | 6 | 0.1 | 117 | 2.4 |
| Pittsburgh | 2,776 | 2,538 | 91.4 | 141 | 5.1 | 3 | 0.1 | 6 | 0.2 | 8 | 0.3 | 7 | 0.3 | 73 | 2.6 |
| Portland | 2,888 | 2,702 | 93.6 | 85 | 2.9 | 1 | 0.0 | 33 | 1.1 | 3 | 0.1 | 7 | 0.2 | 57 | 2.0 |
| San Antonio | 1,837 | 1,736 | 94.5 | 10 | 0.5 | 5 | 0.3 | 31 | 1.7 | 11 | 0.6 | 10 | 0.5 | 34 | 1.9 |
| Seattle | 2,428 | 2,142 | 88.2 | 214 | 8.8 | 8 | 0.3 | 19 | 0.8 | 3 | 0.1 | 10 | 0.4 | 32 | 1.3 |
| Stanford | 3,490 | 3,204 | 91.8 | 197 | 5.6 | 9 | 0.3 | 1 | 0.0 | 2 | 0.1 | 6 | 0.2 | 71 | 2.0 |
| Stony Brook | 2,550 | 2,371 | 93.0 | 117 | 4.6 | | | | | | | 5 | 0.2 | 57 | 2.2 |
| Torrance | 1,550 | 1,323 | 85.4 | 168 | 10.8 | 1 | 0.1 | 16 | 1.0 | 1 | 0.1 | 21 | 1.4 | 20 | 1.3 |
| Tucson | 3,111 | 2,646 | 85.1 | 335 | 10.8 | 13 | 0.4 | 13 | 0.4 | 27 | 0.9 | 6 | 0.2 | 71 | 2.3 |
| UC Davis | 2,881 | 2,543 | 88.3 | 226 | 7.8 | 5 | 0.2 | 12 | 0.4 | 2 | 0.1 | 12 | 0.4 | 81 | 2.8 |
| Worcester | 3,180 | 3,061 | 96.3 | 12 | 0.4 | 35 | 1.1 | | | | | 2 | 0.1 | 70 | 2.2 |
| All FCs | 115,401 | 105,059 | 91.0 | 6,935 | 6.0 | 313 | 0.3 | 405 | 0.4 | 197 | 0.2 | 317 | 0.3 | 2,175 | 1.9 |

1 - Follow-up Status from *Form 9-WHI ES Participation Status , Ver. 8*; Lost calculated by WHIX (see April 4, 2007, upgrade notes); Deceased from *Form 120-Initial Notification of Death* (all versions)

**Table 8.5**
**Form Collection: Forms 134, 150, and 151**

Data as of 8-15-07

| Collections for 5-1-06 thru 4-30-07 | Form 134-Addendum to Medical History Update | | | | | | Form 150- Hormone Use Update (HT) | | | | Form 151 - Activities of Daily Living | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Total | | CCC Mailings Not Collected | | Outstanding Info Errors (Cum) | | Total | | CCC Mailings Not Collected | | Total | | CCC Mailings Not Collected | |
| | # Due[1] | % Collected | # | % | # | % | # Due[1] | % Collected | # | % | # Due[1] | % Collected | # | % |
| Atlanta | 85 | 98.8 | 7 | 8.2 | 22 | 26.2 | 365 | 84.1 | 60 | 16.4 | 2,887 | 87.9 | 349 | 12.1 |
| Birmingham | 104 | 99.0 | 11 | 10.6 | 1 | 1.0 | 465 | 85.4 | 78 | 16.8 | 2,409 | 88.0 | 288 | 12.0 |
| Bowman | 121 | 95.0 | 14 | 11.6 | | | 352 | 86.1 | 51 | 14.5 | 2,402 | 90.3 | 234 | 9.7 |
| Brigham | 127 | 99.2 | 9 | 7.1 | | | 539 | 91.8 | 48 | 8.9 | 3,866 | 94.1 | 229 | 5.9 |
| Buffalo | 130 | 100.0 | 7 | 5.4 | 7 | 5.4 | 479 | 93.3 | 48 | 10.0 | 2,838 | 94.1 | 168 | 5.9 |
| Chapel Hill | 98 | 100.0 | 7 | 7.1 | | | 399 | 87.0 | 60 | 15.0 | 2,593 | 90.6 | 243 | 9.4 |
| Chicago-Rush | 61 | 100.0 | 9 | 14.8 | 1 | 1.6 | 283 | 81.6 | 58 | 20.5 | 1,716 | 88.1 | 204 | 11.9 |
| Chicago | 102 | 99.0 | 3 | 2.9 | | | 352 | 88.6 | 46 | 13.1 | 2,363 | 93.6 | 152 | 6.4 |
| Cincinnati | 83 | 100.0 | | | | | 361 | 90.0 | 41 | 11.4 | 2,536 | 93.5 | 166 | 6.5 |
| Columbus | 88 | 98.9 | 4 | 4.5 | 2 | 2.3 | 382 | 92.7 | 32 | 8.4 | 2,599 | 94.2 | 150 | 5.8 |
| Detroit | 98 | 96.9 | 9 | 9.2 | | | 305 | 84.9 | 48 | 15.7 | 2,174 | 90.6 | 204 | 9.4 |
| Gainesville | 150 | 99.3 | 13 | 8.7 | 3 | 2.0 | 648 | 88.0 | 91 | 14.0 | 3,557 | 91.4 | 305 | 8.6 |
| GWU-DC | 105 | 100.0 | 5 | 4.8 | 4 | 3.8 | 372 | 88.2 | 45 | 12.1 | 2,674 | 92.1 | 212 | 7.9 |
| Honolulu | 70 | 100.0 | 3 | 4.3 | | | 240 | 88.3 | 33 | 13.8 | 1,798 | 91.0 | 161 | 9.0 |
| Houston | 64 | 100.0 | 3 | 4.7 | | | 210 | 90.5 | 25 | 11.9 | 2,025 | 94.1 | 120 | 5.9 |
| IC-Bettendorf | 75 | 100.0 | 3 | 4.0 | | | 498 | 93.6 | 41 | 8.2 | 1,837 | 96.0 | 74 | 4.0 |
| IC-Des Moines | 77 | 100.0 | 3 | 3.9 | | | 527 | 94.9 | 31 | 5.9 | 1,858 | 96.2 | 71 | 3.8 |
| Irvine | 87 | 94.3 | 7 | 8.0 | | | 356 | 89.9 | 41 | 11.5 | 2,683 | 94.3 | 153 | 5.7 |
| LA | 90 | 97.8 | 5 | 5.6 | | | 310 | 92.6 | 35 | 11.3 | 2,553 | 95.1 | 126 | 4.9 |
| La Jolla | 94 | 100.0 | | | 1 | 1.1 | 279 | 90.3 | 27 | 9.7 | 2,865 | 91.2 | 252 | 8.8 |
| Madison | 90 | 100.0 | 3 | 3.3 | | | 460 | 92.4 | 37 | 8.0 | 2,488 | 94.9 | 126 | 5.1 |
| Medlantic | 117 | 98.3 | 20 | 17.1 | 1 | 0.9 | 365 | 86.0 | 87 | 23.8 | 2,358 | 90.6 | 221 | 9.4 |
| Memphis | 73 | 100.0 | 7 | 9.6 | | | 384 | 87.8 | 52 | 13.5 | 2,135 | 91.3 | 185 | 8.7 |
| Miami | 76 | 97.4 | 11 | 14.5 | 2 | 2.7 | 328 | 71.0 | 96 | 29.3 | 1,514 | 85.1 | 226 | 14.9 |
| Milwaukee | 106 | 98.1 | 6 | 5.7 | 1 | 1.0 | 495 | 93.7 | 31 | 6.3 | 2,677 | 95.3 | 125 | 4.7 |

**Table 8.5 (continued)**
**Form Collection: Forms 134, 150, and 151**

Data as of 8-15-07

| Collections for 5-1-06 thru 4-30-07 | Form 134-Addendum to Medical History Update | | | | | | Form 150- Hormone Use Update (HT) | | | | Form 151 - Activities of Daily Living | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Total | | CCC Mailings Not Collected | | Outstanding Info Errors (Cum) | | Total | | CCC Mailings Not Collected | | Total | | CCC Mailings Not Collected | |
| | # Due[1] | % Collected | # | % | # | % | # Due[1] | % Collected | # | % | # Due[1] | % Collected | # | % |
| Minneapolis | 117 | 99.1 | 5 | 4.3 | | | 546 | 92.5 | 47 | 8.6 | 3,234 | 94.8 | 168 | 5.2 |
| Nevada | 74 | 100.0 | 6 | 8.1 | | | 377 | 87.5 | 49 | 13.0 | 2,433 | 93.0 | 171 | 7.0 |
| Newark | 111 | 97.3 | 12 | 10.8 | | | 319 | 88.1 | 40 | 12.5 | 2,705 | 91.0 | 244 | 9.0 |
| New Brunswick | 52 | 98.1 | 8 | 15.4 | 1 | 2.0 | 273 | 81.3 | 65 | 23.8 | 1,113 | 88.9 | 123 | 11.1 |
| NYC | 119 | 99.2 | 12 | 10.1 | | | 443 | 86.0 | 77 | 17.4 | 2,614 | 90.5 | 249 | 9.5 |
| Oakland | 96 | 100.0 | 8 | 8.3 | | | 420 | 91.9 | 41 | 9.8 | 2,517 | 94.8 | 132 | 5.2 |
| Pawtucket | 167 | 98.2 | 8 | 4.8 | | | 626 | 90.4 | 68 | 10.9 | 4,421 | 91.6 | 373 | 8.4 |
| Pittsburgh | 97 | 100.0 | 5 | 5.2 | | | 387 | 88.9 | 45 | 11.6 | 2,434 | 91.7 | 203 | 8.3 |
| Portland | 99 | 94.9 | 9 | 9.1 | 15 | 16.0 | 414 | 87.0 | 56 | 13.5 | 2,605 | 92.2 | 202 | 7.8 |
| San Antonio | 71 | 100.0 | 5 | 7.0 | | | 348 | 79.9 | 74 | 21.3 | 1,641 | 90.6 | 154 | 9.4 |
| Seattle | 106 | 100.0 | 3 | 2.8 | 1 | 0.9 | 452 | 88.9 | 50 | 11.1 | 2,164 | 92.8 | 156 | 7.2 |
| Stanford | 139 | 100.0 | 8 | 5.8 | | | 447 | 92.2 | 57 | 12.8 | 3,198 | 94.5 | 177 | 5.5 |
| Stony Brook | 87 | 100.0 | 6 | 6.9 | | | 329 | 88.8 | 42 | 12.8 | 2,283 | 93.1 | 158 | 6.9 |
| Torrance | 70 | 94.3 | 7 | 10.0 | 7 | 10.6 | 150 | 84.0 | 25 | 16.7 | 1,376 | 93.3 | 92 | 6.7 |
| Tucson | 131 | 97.7 | 13 | 9.9 | 1 | 0.8 | 411 | 86.9 | 75 | 18.2 | 2,807 | 90.7 | 261 | 9.3 |
| UC Davis | 113 | 99.1 | 3 | 2.7 | 8 | 7.1 | 426 | 92.3 | 40 | 9.4 | 2,533 | 93.3 | 169 | 6.7 |
| Worcester | 97 | 100.0 | 5 | 5.2 | | | 404 | 92.1 | 36 | 8.9 | 2,888 | 93.9 | 177 | 6.1 |
| All FCs | 4,117 | 98.8 | 292 | 7.1 | 78 | 1.9 | 16,526 | 88.8 | 2,129 | 12.9 | 104,371 | 92.4 | 7,953 | 7.6 |

1 - Excludes absolutely no contact and deceased participants

**Table 8.6**
**CCC Data Entry Volume**

8-19-06 to 8-15-07

| Form | Forms | | | | | Sheets Scanned | Forms with Comments | |
|---|---|---|---|---|---|---|---|---|
| | Total | Key-Entered | | Scanned | | | | |
| | # | # | % | # | % | # | # | % |
| 33 – Medical History Update | 102,696 | 251 | 0.2 | 102,445 | 99.8 | 204,890 | 20,409 | 19.9 |
| 120 – Initial Notice of Death | 269 | 269 | 100.0 | | | | | |
| 134 – Addendum to Medical History Update | 1,772 | 8 | 0.5 | 1,764 | 99.5 | 1,765 | 2 | 0.1 |
| 150 – Hormone Use Update | 16,908 | 28 | 0.2 | 16,880 | 99.8 | 67,552 | 77 | 0.5 |
| 151 – Activities of Daily Living | 102,813 | 167 | 0.2 | 102,646 | 99.8 | 102,637 | 523 | 0.5 |
| **Totals** | 224,458 | 723 | 0.3 | 223,735 | 99.7 | 376,844 | 21,011 | 9.4 |

**Table 8.7**
**Status of Adjudication**

Data as of 8-15-07

| Committees | Total # Cases in WHIX (from Form 33D) | Cases at FCs Not Yet Forwarded to CCC | | | | | Cases at CCC | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Completed | | | Other | Total | Referred from | | | | Total |
| | | < 14 Days | 14-29 Days | ≥ 30 Days | | | FCs | Form 125 Review | Other Committee | QA[1] | |
| **Extension** | | | | | | | | | | | |
| Cancer | 3,486 | 77 | 10 | 19 | | 106 | 3,294 | 61 | 25 | 745 | 4,125 |
| CVD (plus PE, DVT) | 3,734 | 69 | 16 | 17 | | 102 | 3,018 | 569 | 40 | 5 | 3,632 |
| Fatal Events | 1,868 | 55 | 21 | 29 | | 105 | 1,742 | 13 | 5 | 3 | 1,763 |
| Stroke | 1,694 | 36 | 3 | 11 | | 50 | 1,431 | 173 | 38 | 2 | 1,644 |
| Fracture | 797 | 13 | 5 | 11 | | 29 | 711 | 15 | 8 | 34 | 768 |
| **Extension Total** | 11,579 | 250 | 55 | 87 | | 392 | 10,196 | 831 | 116 | 789 | 11,932 |
| **Form 125-Hospitalization** | 13,991 | 276 | 81 | 86 | 1 | 444 | 13,546 | | | 1 | 13,547 |
| **WHI** | | | | | | | | | | | |
| Cancer | 11,286 | | | | | | 11,284 | | 1 | 1 | 11,286 |
| CVD (plus PE, DVT) | 10,194 | | | | 2 | 2 | 10,189 | | 3 | 1 | 10,193 |
| Fatal Events | 5,616 | | | | 4 | 4 | 5,611 | | 1 | | 5,612 |
| Stroke | 2,847 | | | | | | 2,842 | 1 | 4 | | 2,847 |
| Fracture | 2,559 | | | | | | 2,559 | | | | 2,559 |
| **WHI Total** | 32,502 | | | | 6 | 6 | 32,485 | 1 | 9 | 2 | 32,497 |
| **Extension + WHI Total[2]** | 44,081 | 250 | 55 | 87 | 6 | 398 | 42,681 | 832 | 125 | 791 | 44,429 |

1 - QA Cancer includes 412 DM other cancers added in 8-06 and 333 pancreatic cancers for W21-Panscan added in 9-06
2 - Excludes *Form 125 - Hospitalization*

**Table 8.8**
**CCC Adjudication Workload**

Data as of 8-15-07

| Committees | # Cases at CCC | | | CCC Action Required | | |
|---|---|---|---|---|---|---|
| | Total | Closed | Remaining | Forward to Adjudicator[1] | Wait for Return from Adjudicator | Data Enter and Close |
| **Extension** | | | | | | |
| Cancer | 4,125 | 3,770 | 355 | 265 | 51 | **39** |
| CVD (plus PE, DVT) | 3,632 | 3,544 | 88 | 28 | 10 | **50** |
| Fatal Events | 1,763 | 1,700 | 63 | 15 | 16 | **32** |
| Stroke | 1,644 | 677 | 967 | 874 | 48 | **45** |
| Fracture | 768 | 744 | 24 | 15 | | **9** |
| **Extension Total** | 11,932 | 10,435 | 1,497 | 1,197 | 125 | **175** |
| **Form 125-Hospital** | 13,547 | 8,601 | 4,946 | 4,671 | 256 | **19** |
| | | | | **Subtotal of Data Enter and Close** | | **194** |
| | | | | **Less Problem Cases[2]** | | **115** |
| | | | | **Total Ready to Data Enter and Close** | | **79** |
| **WHI[3]** | | | | | | |
| Cancer | 11,286 | 11,286 | | | | |
| CVD (plus PE, DVT) | 10,193 | 10,193 | | | | |
| Fatal Events | 5,612 | 5,612 | | | | |
| Stroke | 2,847 | 2,847 | | | | |
| Fracture | 2,559 | 2,559 | | | | |
| **WHI Total** | 32,497 | 32,497 | | | | |
| **Extension + WHI[3] Total** | 44,429 | 42,932 | | | | |

1 - 265 cancers to be adjudicated: 10 primary cancers, 245 other cancers, and 10 unassembled cancer cases
2 - 115 problem cases include pending queries: 106; returned queries waiting adj review: 3; forms failed QA waiting adj review: 6
3 - WHI totals to adjudicate adjusted to remove not required cases

**Table 9.1**
**CT Outcomes Cases with Blood Sample by Estimated Volume (in ml)**
**After Accounting for Approved Core and Ancillary Studies**

| | | | | | Volume of Designated Blood Components (ml) | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 0* | | >0 - <.5 | | .5 - <1 | | 1 - <1.5 | | 1.5 - <2 | | 2 - <2.5 | | 2.5 - <3 | | 3 - <3.5 | | 3.5 - <4 | | 4+ | |
| Visit | Outcome | Total Ppts | No Draw | Blood Type | Ppt | % | Ppt | % | Ppt | % | Ppt | % | Ppt | % | Ppt | % | Ppt | % | Ppt | % | Ppt | % | Ppt | % |
| Base | Breast Cancer | 3220 | 10 | Serum | 19 | 0% | 1 | 0% | 15 | 0% | 23 | 1% | 135 | 4% | 69 | 2% | 432 | 13% | 395 | 12% | 41 | 1% | 2090 | 65% |
| | | | | Citrate | 22 | 1% | 4 | 0% | 1 | 0% | 41 | 1% | 13 | 0% | 209 | 6% | 8 | 0% | 2922 | 91% | | | | |
| | | | | EDTA | 45 | 1% | | | 1 | 0% | 12 | 0% | 12 | 0% | 233 | 7% | | | 2917 | 91% | | | | |
| | Breast Cancer, Invasive | 2608 | 8 | Serum | 14 | 1% | 1 | 0% | 15 | 1% | 20 | 1% | 117 | 4% | 63 | 2% | 296 | 11% | 359 | 14% | 40 | 2% | 1683 | 65% |
| | | | | Citrate | 16 | 1% | 2 | 0% | 1 | 0% | 37 | 1% | 11 | 0% | 172 | 7% | 6 | 0% | 2363 | 91% | | | | |
| | | | | EDTA | 37 | 1% | | | 1 | 0% | 9 | 0% | 8 | 0% | 192 | 7% | | | 2361 | 91% | | | | |
| | Breast Cancer, Non Invasive | 647 | 2 | Serum | 5 | 1% | | | | | 3 | 0% | 18 | 3% | 7 | 1% | 142 | 22% | 40 | 6% | 1 | 0% | 431 | 67% |
| | | | | Citrate | 6 | 1% | 2 | 0% | | | 5 | 1% | 2 | 0% | 40 | 6% | 2 | 0% | 590 | 91% | | | | |
| | | | | EDTA | 9 | 1% | | | | | 3 | 0% | 4 | 1% | 44 | 7% | | | 587 | 91% | | | | |
| | CHD | 2571 | 11 | Serum | 19 | 1% | 4 | 0% | 16 | 1% | 65 | 3% | 56 | 2% | 301 | 12% | 78 | 3% | 308 | 12% | 165 | 6% | 1559 | 61% |
| | | | | Citrate | 28 | 1% | 19 | 1% | 16 | 1% | 192 | 7% | 63 | 2% | 293 | 11% | 4 | 0% | 1956 | 76% | | | | |
| | | | | EDTA | 42 | 2% | 8 | 0% | 22 | 1% | 61 | 2% | 186 | 7% | 287 | 11% | | | 1965 | 76% | | | | |
| | Clinical MI | 1983 | 10 | Serum | 16 | 1% | 2 | 0% | 13 | 1% | 47 | 2% | 47 | 2% | 237 | 12% | 58 | 3% | 233 | 12% | 130 | 7% | 1200 | 61% |
| | | | | Citrate | 21 | 1% | 15 | 1% | 14 | 1% | 151 | 8% | 51 | 3% | 228 | 11% | 4 | 0% | 1499 | 76% | | | | |
| | | | | EDTA | 33 | 2% | 8 | 0% | 15 | 1% | 50 | 3% | 143 | 7% | 222 | 11% | | | 1512 | 76% | | | | |
| | Colorectal Cancer | 832 | 2 | Serum | 3 | 0% | | | 1 | 0% | 10 | 1% | 9 | 1% | 16 | 2% | 28 | 3% | 99 | 12% | 20 | 2% | 646 | 78% |
| | | | | Citrate | 9 | 1% | 4 | 0% | 1 | 0% | 19 | 2% | 3 | 0% | 63 | 8% | 1 | 0% | 732 | 88% | | | | |
| | | | | EDTA | 18 | 2% | | | 2 | 0% | 7 | 1% | 3 | 0% | 73 | 9% | | | 729 | 88% | | | | |
| | DVT/PE | 695 | 3 | Serum | 3 | 0% | 3 | 0% | 3 | 0% | 14 | 2% | 29 | 4% | 71 | 10% | 80 | 12% | 228 | 33% | 78 | 11% | 186 | 27% |
| | | | | Citrate | 10 | 1% | 23 | 3% | 7 | 1% | 166 | 24% | 42 | 6% | 53 | 8% | 1 | 0% | 393 | 57% | | | | |
| | | | | EDTA | 10 | 1% | 3 | 0% | 3 | 0% | 31 | 4% | 10 | 1% | 244 | 35% | | | 394 | 57% | | | | |
| | Endometrial Cancer | 430 | 2 | Serum | 4 | 1% | | | 1 | 0% | 3 | 1% | 2 | 0% | 10 | 2% | 8 | 2% | 30 | 7% | 2 | 0% | 370 | 86% |
| | | | | Citrate | 5 | 1% | | | | | 11 | 3% | 4 | 1% | 20 | 5% | | | 390 | 91% | | | | |
| | | | | EDTA | 6 | 1% | | | | | 3 | 1% | 6 | 1% | 29 | 7% | | | 386 | 90% | | | | |
| | Hip Fracture | 1008 | 3 | Serum | 8 | 1% | 2 | 0% | 12 | 1% | 11 | 1% | 56 | 6% | 30 | 3% | 180 | 18% | 141 | 14% | 15 | 1% | 553 | 55% |
| | | | | Citrate | 7 | 1% | 5 | 0% | 1 | 0% | 37 | 4% | 15 | 1% | 67 | 7% | 3 | 0% | 873 | 87% | | | | |
| | | | | EDTA | 8 | 1% | 1 | 0% | 1 | 0% | 8 | 1% | 12 | 1% | 93 | 9% | | | 885 | 88% | | | | |
| | Ovarian Cancer | 276 | 0 | Serum | | | | | 2 | 1% | 5 | 2% | 1 | 0% | 5 | 2% | 6 | 2% | 29 | 11% | 4 | 1% | 224 | 81% |
| | | | | Citrate | 3 | 1% | | | 1 | 0% | 7 | 3% | 2 | 1% | 18 | 7% | | | 245 | 89% | | | | |
| | | | | EDTA | 1 | 0% | | | | | 4 | 1% | 4 | 1% | 23 | 8% | | | 244 | 88% | | | | |
| | Stroke | 1742 | 8 | Serum | 15 | 1% | 8 | 0% | 12 | 1% | 42 | 2% | 60 | 3% | 244 | 14% | 74 | 4% | 251 | 14% | 21 | 1% | 1015 | 58% |
| | | | | Citrate | 24 | 1% | 20 | 1% | 11 | 1% | 241 | 14% | 59 | 3% | 269 | 15% | 44 | 3% | 1074 | 62% | | | | |
| | | | | EDTA | 29 | 2% | 1 | 0% | 2 | 0% | 39 | 2% | 21 | 1% | 357 | 2% | | | 1293 | 74% | | | | |

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

**Table 9.1 (continued)**
**CT Outcomes Cases with Blood Sample by Estimated Volume (in ml)**
**After Accounting for Approved Core and Ancillary Studies**

| | | | | | Volume of Designated Blood Components (ml) | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 0* | | >0 - <.5 | | .5 - <1 | | 1 - <1.5 | | 1.5 - <2 | | 2 - <2.5 | | 2.5 - <3 | | 3 - <3.5 | | 3.5 - <4 | | 4+ | |
| Visit | Outcome | Total Ppts | No Draw | Blood Type | Ppt | % | Ppt | % | Ppt | % | Ppt | % | Ppt | % | Ppt | % | Ppt | % | Ppt | % | Ppt | % | Ppt | % |
| AV1 | Breast Cancer | 3220 | 199 | Serum | 203 | 6% | 1 | 0% | 2 | 0% | 26 | 1% | 47 | 1% | 78 | 2% | 215 | 7% | 456 | 14% | 317 | 10% | 1875 | 58% |
| | | | | Citrate | 208 | 6% | 1 | 0% | 3 | 0% | 37 | 1% | 2 | 0% | 198 | 6% | 4 | 0% | 2767 | 86% | | | | |
| | | | | EDTA | 234 | 7% | | | | | 12 | 0% | 8 | 0% | 220 | 7% | | | 2746 | 85% | | | | |
| | Breast Cancer, Invasive | 2608 | 173 | Serum | 177 | 7% | 1 | 0% | 2 | 0% | 22 | 1% | 35 | 1% | 76 | 3% | 144 | 6% | 423 | 16% | 302 | 12% | 1426 | 55% |
| | | | | Citrate | 180 | 7% | 1 | 0% | 2 | 0% | 34 | 1% | 1 | 0% | 158 | 6% | 4 | 0% | 2228 | 85% | | | | |
| | | | | EDTA | 202 | 8% | | | | | 10 | 0% | 7 | 0% | 180 | 7% | | | 2209 | 85% | | | | |
| | Breast Cancer, Non Inv | 647 | 26 | Serum | 26 | 4% | | | | | 5 | 1% | 12 | 2% | 2 | 0% | 73 | 11% | 38 | 6% | 18 | 3% | 473 | 73% |
| | | | | Citrate | 28 | 4% | | | 1 | 0% | 4 | 1% | 1 | 0% | 41 | 6% | | | 572 | 88% | | | | |
| | | | | EDTA | 33 | 5% | | | | | 2 | 0% | 1 | 0% | 40 | 6% | | | 571 | 88% | | | | |
| | CHD | 2571 | 265 | Serum | 266 | 10% | 1 | 0% | 2 | 0% | 21 | 1% | 9 | 0% | 57 | 2% | 82 | 3% | 324 | 13% | 62 | 2% | 1747 | 68% |
| | | | | Citrate | 289 | 11% | 12 | 0% | 9 | 0% | 116 | 5% | 51 | 2% | 251 | 1% | 4 | 0% | 1839 | 72% | | | | |
| | | | | EDTA | 298 | 12% | 5 | 0% | 13 | 1% | 46 | 2% | 99 | 4% | 257 | 1% | | | 1853 | 72% | | | | |
| | Clinical MI | 1983 | 170 | Serum | 170 | 9% | 1 | 0% | 2 | 0% | 19 | 1% | 8 | 0% | 45 | 2% | 64 | 3% | 260 | 13% | 43 | 2% | 1371 | 69% |
| | | | | Citrate | 193 | 1% | 9 | 0% | 7 | 0% | 93 | 5% | 41 | 2% | 197 | 1% | 4 | 0% | 1439 | 73% | | | | |
| | | | | EDTA | 198 | 1% | 5 | 0% | 8 | 0% | 39 | 2% | 78 | 4% | 203 | 1% | | | 1452 | 73% | | | | |
| | Colorectal Cancer | 832 | 75 | Serum | 75 | 9% | 1 | 0% | | | 8 | 1% | 4 | 0% | 7 | 1% | 18 | 2% | 66 | 8% | 67 | 8% | 586 | 70% |
| | | | | Citrate | 78 | 9% | 3 | 0% | 1 | 0% | 14 | 2% | 4 | 0% | 55 | 7% | 2 | 0% | 675 | 81% | | | | |
| | | | | EDTA | 84 | 1% | | | 1 | 0% | 5 | 1% | 4 | 0% | 60 | 7% | 1 | 0% | 677 | 81% | | | | |
| | DVT/PE | 695 | 63 | Serum | 64 | 9% | | | | | 2 | 0% | 4 | 1% | 14 | 2% | 40 | 6% | 98 | 14% | 52 | 7% | 421 | 61% |
| | | | | Citrate | 73 | 11% | 14 | 2% | 6 | 1% | 92 | 13% | 28 | 4% | 57 | 8% | 2 | 0% | 423 | 61% | | | | |
| | | | | EDTA | 70 | 1% | 2 | 0% | 2 | 0% | 23 | 3% | 8 | 1% | 164 | 24% | | | 426 | 61% | | | | |
| | Endometrial Cancer | 430 | 24 | Serum | 24 | 6% | | | | | 2 | 0% | 2 | 0% | 9 | 2% | 3 | 1% | 31 | 7% | 9 | 2% | 350 | 81% |
| | | | | Citrate | 28 | 7% | | | | | 9 | 2% | 1 | 0% | 21 | 5% | | | 371 | 86% | | | | |
| | | | | EDTA | 28 | 7% | | | | | 2 | 0% | 3 | 1% | 28 | 7% | | | 369 | 86% | | | | |
| | Hip Fracture | 1008 | 63 | Serum | 63 | 6% | 1 | 0% | 2 | 0% | 10 | 1% | 18 | 2% | 21 | 2% | 5 | 6% | 95 | 9% | 120 | 12% | 622 | 62% |
| | | | | Citrate | 75 | 7% | 2 | 0% | 1 | 0% | 31 | 3% | 10 | 1% | 65 | 6% | 3 | 0% | 821 | 81% | | | | |
| | | | | EDTA | 79 | 8% | | | 2 | 0% | 13 | 1% | 6 | 1% | 80 | 8% | | | 828 | 82% | | | | |
| | Ovarian Cancer | 276 | 28 | Serum | 28 | 10% | | | | | 3 | 1% | 1 | 0% | 1 | 0% | 5 | 2% | 26 | 9% | 4 | 1% | 208 | 75% |
| | | | | Citrate | 29 | 11% | 1 | 0% | | | 3 | 1% | 3 | 1% | 22 | 8% | | | 218 | 79% | | | | |
| | | | | EDTA | 31 | 11% | | | | | 1 | 0% | 2 | 1% | 26 | 9% | | | 216 | 78% | | | | |
| | Stroke | 1742 | 165 | Serum | 168 | 10% | 3 | 0% | | | 16 | 1% | 10 | 1% | 36 | 2% | 74 | 4% | 234 | 13% | 91 | 5% | 1110 | 64% |
| | | | | Citrate | 179 | 1% | 11 | 1% | 7 | 0% | 167 | 1% | 44 | 3% | 282 | 16% | 39 | 2% | 1013 | 58% | | | | |
| | | | | EDTA | 191 | 11% | | | | | 34 | 2% | 15 | 1% | 264 | 15% | | | 1238 | 71% | | | | |

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

**Table 9.2**
**OS Outcomes Cases with Blood Sample by Estimated Volume (in ml)**
**After Accounting for Approved Core and Ancillary Studies**

| Visit | Outcome | Total Ppts | No Draw | Blood Type | Volume of Designated Blood Components (ml) | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 0* | | >0 - <.5 | | .5 - <1 | | 1 - <1.5 | | 1.5 - <2 | | 2 - <2.5 | | 2.5 - <3 | | 3 - <3.5 | | 3.5 - <4 | | 4+ | |
| | | | | | Ppt | % | Ppt | % | Ppt | % | Ppt | % | Ppt | % | Ppt | % | Ppt | % | Ppt | % | Ppt | % | Ppt | % |
| Base-line | Breast Cancer | 4735 | 9 | Serum | 29 | 1% | 8 | 0% | 6 | 0% | 39 | 1% | 32 | 1% | 198 | 4% | 267 | 6% | 610 | 13% | 1042 | 22% | 2504 | 53% |
| | | | | Citrate | 51 | 1% | 5 | 0% | 7 | 0% | 45 | 1% | 60 | 1% | 355 | 7% | 919 | 19% | 3293 | 70% | | | | |
| | | | | EDTA | 123 | 3% | 55 | 1% | 277 | 6% | 683 | 14% | 89 | 2% | 355 | 7% | 696 | 15% | 2457 | 52% | | | | |
| | Breast Cancer, Invasive | 3933 | 8 | Serum | 26 | 1% | 8 | 0% | 5 | 0% | 29 | 1% | 28 | 1% | 186 | 5% | 256 | 7% | 567 | 14% | 864 | 22% | 1964 | 50% |
| | | | | Citrate | 44 | 1% | 5 | 0% | 6 | 0% | 38 | 1% | 55 | 1% | 311 | 8% | 816 | 21% | 2658 | 68% | | | | |
| | | | | EDTA | 108 | 3% | 55 | 1% | 277 | 7% | 674 | 17% | 67 | 2% | 279 | 7% | 528 | 13% | 1945 | 49% | | | | |
| | Breast Cancer, Non-Invasive | 834 | 1 | Serum | 3 | 0% | | | 2 | 0% | 11 | 1% | 6 | 1% | 13 | 2% | 11 | 1% | 47 | 6% | 183 | 22% | 558 | 67% |
| | | | | Citrate | 7 | 1% | | | 1 | 0% | 7 | 1% | 6 | 1% | 46 | 6% | 109 | 13% | 658 | 79% | | | | |
| | | | | EDTA | 16 | 2% | | | | | 13 | 2% | 22 | 3% | 81 | 10% | 174 | 21% | 528 | 63% | | | | |
| | CHD | 2968 | 3 | Serum | 9 | 0% | 9 | 0% | 15 | 1% | 74 | 2% | 42 | 1% | 285 | 10% | 76 | 3% | 298 | 10% | 376 | 13% | 1784 | 60% |
| | | | | Citrate | 62 | 2% | 28 | 1% | 36 | 1% | 236 | 8% | 143 | 5% | 687 | 23% | 383 | 13% | 1393 | 47% | | | | |
| | | | | EDTA | 65 | 2% | 21 | 1% | 29 | 1% | 207 | 7% | 192 | 6% | 775 | 26% | 287 | 10% | 1392 | 47% | | | | |
| | Clinical MI | 2276 | 2 | Serum | 6 | 0% | 7 | 0% | 12 | 1% | 58 | 3% | 37 | 2% | 229 | 10% | 62 | 3% | 237 | 10% | 341 | 15% | 1287 | 57% |
| | | | | Citrate | 51 | 2% | 23 | 1% | 33 | 1% | 186 | 8% | 125 | 5% | 543 | 24% | 281 | 12% | 1034 | 45% | | | | |
| | | | | EDTA | 49 | 2% | 17 | 1% | 23 | 1% | 167 | 7% | 162 | 7% | 623 | 27% | 233 | 10% | 1002 | 44% | | | | |
| | Colorectal Cancer | 1026 | 1 | Serum | 8 | 1% | 5 | 0% | 11 | 1% | 12 | 1% | 55 | 5% | 93 | 9% | 127 | 12% | 234 | 23% | 320 | 31% | 161 | 16% |
| | | | | Citrate | 13 | 1% | 3 | 0% | 5 | 0% | 20 | 2% | 34 | 3% | 152 | 15% | 400 | 39% | 399 | 39% | | | | |
| | | | | EDTA | 37 | 4% | 16 | 2% | 30 | 3% | 56 | 5% | 446 | 43% | 318 | 31% | 9 | 1% | 114 | 11% | | | | |
| | DVT/PE | 90 | 0 | Serum | | | | | | | | | 1 | 1% | 8 | 9% | | | 3 | 3% | 7 | 8% | 71 | 79% |
| | | | | Citrate | | | | | | | 1 | 1% | 2 | 2% | 9 | 10% | 2 | 2% | 76 | 84% | | | | |
| | | | | EDTA | 3 | 3% | | | | | 7 | 8% | 2 | 2% | 11 | 12% | 3 | 3% | 64 | 71% | | | | |
| | Endometrial Cancer | 642 | 1 | Serum | 5 | 1% | | | 3 | 0% | 11 | 2% | 3 | 0% | 37 | 6% | 53 | 8% | 143 | 22% | 274 | 43% | 113 | 18% |
| | | | | Citrate | 8 | 1% | | | | | 12 | 2% | 13 | 2% | 70 | 11% | 178 | 28% | 361 | 56% | | | | |
| | | | | EDTA | 18 | 3% | | | 15 | 2% | 22 | 3% | 17 | 3% | 57 | 9% | 323 | 50% | 190 | 30% | | | | |
| | Hip Fracture | 1428 | 2 | Serum | 5 | 0% | 4 | 0% | 11 | 1% | 53 | 4% | 75 | 5% | 164 | 11% | 143 | 10% | 134 | 9% | 77 | 5% | 762 | 53% |
| | | | | Citrate | 16 | 1% | 2 | 0% | 1 | 0% | 15 | 1% | 24 | 2% | 136 | 10% | 91 | 6% | 1143 | 80% | | | | |
| | | | | EDTA | 35 | 2% | 1 | 0% | 6 | 0% | 42 | 3% | 48 | 3% | 149 | 10% | 103 | 7% | 1044 | 73% | | | | |
| | Ovarian Cancer | 407 | 0 | Serum | 1 | 0% | | | 2 | 0% | 6 | 1% | 6 | 1% | 8 | 2% | 16 | 4% | 130 | 32% | 164 | 40% | 74 | 18% |
| | | | | Citrate | 4 | 1% | 1 | 0% | 1 | 0% | 2 | 0% | 3 | 1% | 23 | 6% | 20 | 5% | 353 | 87% | | | | |
| | | | | EDTA | 6 | 1% | | | 6 | 1% | 8 | 2% | 10 | 2% | 37 | 9% | 207 | 51% | 133 | 33% | | | | |
| | Stroke | 2131 | 1 | Serum | 148 | 1% | 7 | 0% | 9 | 0% | 38 | 2% | 40 | 2% | 96 | 5% | 160 | 8% | 659 | 31% | 208 | 10% | 900 | 42% |
| | | | | Citrate | 25 | 1% | 15 | 1% | 22 | 1% | 180 | 8% | 304 | 14% | 547 | 26% | 70 | 3% | 968 | 45% | | | | |
| | | | | EDTA | 31 | 1% | 19 | 1% | 31 | 1% | 327 | 15% | 400 | 19% | 362 | 17% | 72 | 3% | 889 | 42% | | | | |

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

**Table 9.2 (continued)**
**OS Outcomes Cases with Blood Sample by Estimated Volume (in ml)**
**After Accounting for Approved Core and Ancillary Studies**

| | | | | | Volume of Designated Blood Components (ml) | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Total | No | Blood | 0* | | >0 - <.5 | | .5 - <1 | | 1 - <1.5 | | 1.5 - <2 | | 2 - <2.5 | | 2.5 - <3 | | 3 - <3.5 | | 3.5 - <4 | | 4+ | |
| Visit | Outcome | Ppts | Draw | Type | Ppt | % | Ppt | % | Ppt | % | Ppt | % | Ppt | % | Ppt | % | Ppt | % | Ppt | % | Ppt | % | Ppt | % |
| AV3 | Breast Cancer | 4735 | 797 | Serum | 800 | 17% | | | | | 10 | 0% | | | 30 | 1% | 1 | 0% | 81 | 2% | 100 | 2% | 3713 | 78% |
| | | | | Citrate | 842 | 18% | | | | | 23 | 0% | | | 50 | 1% | | | 3820 | 81% | | | | |
| | | | | EDTA | 883 | 19% | 4 | 0% | 153 | 3% | 59 | 1% | 16 | 0% | 139 | 3% | 71 | 1% | 3410 | 72% | | | | |
| | Breast Cancer, Invasive | 3933 | 688 | Serum | 691 | 18% | | | | | 10 | 0% | | | 29 | 1% | 1 | 0% | 69 | 2% | 85 | 2% | 3048 | 77% |
| | | | | Citrate | 726 | 18% | | | | | 20 | 1% | | | 42 | 1% | | | 3145 | 80% | | | | |
| | | | | EDTA | 757 | 19% | 4 | 0% | 153 | 4% | 56 | 1% | 16 | 0% | 114 | 3% | 65 | 2% | 2768 | 70% | | | | |
| | Breast Cancer, Non-Invasive | 834 | 113 | Serum | 113 | 14% | | | | | 1 | 0% | | | 1 | 0% | | | 12 | 1% | 15 | 2% | 692 | 83% |
| | | | | Citrate | 120 | 14% | | | | | 4 | 0% | | | 8 | 1% | | | 702 | 84% | | | | |
| | | | | EDTA | 130 | 16% | | | 1 | 0% | 3 | 0% | 1 | 0% | 27 | 3% | 6 | 1% | 666 | 80% | | | | |
| | CHD | 2968 | 787 | Serum | 789 | 27% | | | 1 | 0% | 6 | 0% | 2 | 0% | 16 | 1% | 13 | 0% | 75 | 3% | 93 | 3% | 1973 | 66% |
| | | | | Citrate | 805 | 27% | | | | | 8 | 0% | | | 95 | 3% | | | 2060 | 69% | | | | |
| | | | | EDTA | 832 | 28% | 4 | 0% | 9 | 0% | 58 | 2% | 19 | 1% | 521 | 18% | 69 | 2% | 1456 | 49% | | | | |
| | Clinical MI | 2276 | 491 | Serum | 492 | 22% | | | 1 | 0% | 4 | 0% | 2 | 0% | 14 | 1% | 11 | 0% | 55 | 2% | 74 | 3% | 1623 | 71% |
| | | | | Citrate | 504 | 22% | | | | | 7 | 0% | | | 78 | 3% | | | 1687 | 74% | | | | |
| | | | | EDTA | 526 | 23% | 4 | 0% | 5 | 0% | 48 | 2% | 12 | 1% | 432 | 19% | 54 | 2% | 1195 | 53% | | | | |
| | Colorectal Cancer | 1026 | 245 | Serum | 247 | 24% | | | 2 | 0% | | | 5 | 0% | 2 | 0% | 5 | 0% | 8 | 1% | 633 | 62% | 124 | 12% |
| | | | | Citrate | 250 | 24% | | | | | 2 | 0% | | | 13 | 1% | | | 761 | 74% | | | | |
| | | | | EDTA | 257 | 25% | 1 | 0% | | | 7 | 1% | 4 | 0% | 53 | 5% | 70 | 7% | 634 | 62% | | | | |
| | DVT/PE | 90 | 26 | Serum | 27 | 30% | | | | | 2 | 2% | | | | | | | 1 | 1% | 1 | 1% | 59 | 66% |
| | | | | Citrate | 29 | 32% | | | | | | | | | | | | | 61 | 68% | | | | |
| | | | | EDTA | 30 | 33% | | | | | | | | | 3 | 3% | | | 57 | 63% | | | | |
| | Endometrial Cancer | 642 | 103 | Serum | 103 | 16% | | | | | | | | | 5 | 1% | | | 16 | 2% | 17 | 3% | 501 | 78% |
| | | | | Citrate | 106 | 17% | | | | | 2 | 0% | | | 11 | 2% | | | 523 | 81% | | | | |
| | | | | EDTA | 111 | 17% | | | 1 | 0% | 2 | 0% | 1 | 0% | 20 | 3% | 7 | 1% | 500 | 78% | | | | |
| | Hip Fracture | 1428 | 282 | Serum | 286 | 20% | | | | | 2 | 0% | 1 | 0% | 12 | 1% | | | 20 | 1% | 24 | 2% | 1083 | 76% |
| | | | | Citrate | 294 | 21% | | | | | 7 | 0% | | | 12 | 1% | | | 1115 | 78% | | | | |
| | | | | EDTA | 304 | 21% | | | 2 | 0% | 8 | 1% | | | 55 | 4% | 5 | 0% | 1054 | 74% | | | | |
| | Ovarian Cancer | 407 | 128 | Serum | 129 | 32% | | | | | | | | | 2 | 0% | | | 24 | 6% | 86 | 21% | 166 | 41% |
| | | | | Citrate | 131 | 32% | | | | | 2 | 0% | | | 2 | 0% | | | 272 | 67% | | | | |
| | | | | EDTA | 133 | 33% | | | | | 1 | 0% | 1 | 0% | 10 | 2% | 2 | 0% | 260 | 64% | | | | |
| | Stroke | 2131 | 581 | Serum | 581 | 27% | | | | | 5 | 0% | | | 16 | 1% | 2 | 0% | 29 | 1% | 31 | 1% | 1467 | 69% |
| | | | | Citrate | 597 | 28% | | | | | 10 | 0% | | | 32 | 2% | | | 1492 | 70% | | | | |
| | | | | EDTA | 618 | 29% | | | 2 | 0% | 16 | 1% | 2 | 0% | 93 | 4% | 13 | 1% | 1387 | 65% | | | | |

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

**Table 9.3**
**CT and OS Outcomes Cases with DNA Available**
**Data as of 8-15-07**

| Outcome As of 8-15-07 | Ppts | No DNA Available[1] | | < 25 ug DNA Extracted, with Buffy Coat Available for Extraction[2] | | < 25 ug Extracted[3] | | > 25 ug Extracted[4] | |
|---|---|---|---|---|---|---|---|---|---|
| | | # | % | # | % | # | % | # | % |
| **CT** | | | | | | | | | |
| Breast Cancer | 3220 | 35 | 1.10% | 6 | 0.20% | 1018 | 31.60% | 2161 | 67.10% |
| Breast Cancer - Invasive | 2608 | 26 | 1.00% | 6 | 0.20% | 474 | 18.20% | 2102 | 80.60% |
| Breast Cancer - Non Invasive | 647 | 9 | 1.40% | 0 | 0.00% | 558 | 86.20% | 80 | 12.40% |
| CHD | 2571 | 26 | 1.00% | 12 | 0.50% | 1808 | 70.30% | 725 | 28.20% |
| Clinical MI | 1983 | 20 | 1.00% | 8 | 0.40% | 1391 | 70.10% | 564 | 28.40% |
| Colorectal Cancer | 832 | 7 | 0.80% | 1 | 0.10% | 678 | 81.50% | 146 | 17.50% |
| DVT/PE | 695 | 4 | 0.60% | 6 | 0.90% | 376 | 54.10% | 309 | 44.50% |
| Endometrial Cancer | 430 | 3 | 0.70% | 0 | 0.00% | 346 | 80.50% | 81 | 18.80% |
| Fracture - Hip | 1008 | 9 | 0.90% | 6 | 0.60% | 269 | 26.70% | 724 | 71.80% |
| Ovarian Cancer | 276 | 1 | 0.40% | 0 | 0.00% | 235 | 85.10% | 40 | 14.50% |
| Stroke | 1742 | 16 | 0.90% | 14 | 0.80% | 1045 | 60.00% | 667 | 38.30% |
| **OS** | | | | | | | | | |
| Breast Cancer | 4735 | 51 | 1.10% | 19 | 0.40% | 1493 | 31.50% | 3172 | 67.00% |
| Breast Cancer - Invasive | 3933 | 47 | 1.20% | 18 | 0.50% | 847 | 21.50% | 3021 | 76.80% |
| Breast Cancer - Non Invasive | 834 | 4 | 0.50% | 2 | 0.20% | 658 | 78.90% | 170 | 20.40% |
| CHD | 2968 | 43 | 1.40% | 23 | 0.80% | 507 | 17.10% | 2395 | 80.70% |
| Clinical MI | 2276 | 30 | 1.30% | 13 | 0.60% | 399 | 17.50% | 1834 | 80.60% |
| Colorectal Cancer | 1026 | 16 | 1.60% | 9 | 0.90% | 438 | 42.70% | 563 | 54.90% |
| DVT/PE | 90 | 1 | 1.10% | 0 | 0.00% | 56 | 62.20% | 33 | 36.70% |
| Endometrial Cancer | 642 | 5 | 0.8% | 0 | 0.00% | 264 | 41.10% | 373 | 58.10% |
| Fracture - Hip | 1428 | 16 | 1.10% | 6 | 0.40% | 300 | 21.00% | 1106 | 77.50% |
| Ovarian Cancer | 407 | 5 | 1.20% | 2 | 0.50% | 289 | 71.00% | 111 | 27.30% |
| Stroke | 2131 | 35 | 1.60% | 10 | 0.50% | 208 | 9.80% | 1878 | 88.10% |

[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 10.1**
**Approved and Proposed Core Studies[1]**

| Ref # | Title | Status | Study Pop | Blood | Analytes/Data | Used in Approved Publications |
|---|---|---|---|---|---|---|
| W1 | CT core analytes | Complete | CT, 6% subsample<br><br>*Baseline, Y1, Y3, and Y6 | Y | Citrate 1.05 ml: FVII Ag; FVIIC; fibrinogen<br><br>EDTA 1.05 ml: HDL-C; HDL-2; HDL-3; LDL-C; Lp(a); total cholesterol; triglyceride<br><br>Serum 1.05 ml: alpha-carotene; alpha-tocopherol; beta-carotene; beta-cryptoxanthine; gamma-tocopherol; glucose; insulin; lutein and zeaxanthin; lycopene; retinol | 204, 210, 222, 240, 273, 345, 347, 350, 447, 448, 449, 520, 521, 524 |
| W2 | OS-measurement precision study (OS-MPS) | Complete | OS, n = 1061<br><br>*Baseline and 3 month repeat | Y | Citrate 1.05 ml: FVII Ag; FVIIC; fibrinogen<br><br>EDTA 1.05 ml: HDL-C; HDL-2; HDL-3; LDL-C; Lp(a); total cholesterol; triglyceride<br><br>Serum 1.05 ml: alpha-carotene; alpha-tocopherol; beta-carotene; beta-cryptoxanthine; gamma-tocopherol; glucose; insulin; lutein and zeaxanthin; lycopene; retinol | 442, 524 |
| W4 | National validation and quality control assurance of vitamin D absorption from CaD tablets for WHI | Complete | CaD, n=448 | Y | Serum 1.05 ml: 25-OH Vitamin $D_3$ | |
| W5 | Correlates of endogenous sex hormone concentrations in WHI | Complete | DM, n=300<br><br>*Baseline and Y1 | Y | Serum 3.05 ml: albumin; androstenedione; bioavailable estradiol; DHEA; DHEAS; dihydrotestosterone; estradiol; estrone; estrone sulfate; progesterone; prolactin; SHBG; testosterone | 20, 280 |
| W6 | CVD biomarkers - Phase I | Funded | HT<br>Cases: n=402 CHD, 272 stroke, 223 VTE<br>Controls: n=877<br><br>*Baseline and Y1 | Y | Citrate 1.05 ml: ATIII; CRP; D-dimers; FIX conc; FVIII activity; fibrinogen; PAI-1 Ag; PAP; protein C; protein S free; protein S total; prothrombin Ag; F1+2; TAFI; vWF<br><br>DNA 3 ug: FXIII val34leu; FV Leiden; FV-HR2; MTHF reductase polymorphism; PAI-1; PT19911; PT20210; ESR1 Exon 1 +30; ESR1 IVS1 -1415; ESR1 IVS1 -1505; ESR1 IVS1 -354; ESR1 IVS1 -401; ESR beta - 1730 A/G; GP1ba M145T; integrin alpha 2 - 807 C/T; platelet glycoprotein IIIa - P1(A1), (A2) | 204, 210, 222, 273, 345, 347, 350, 380, 429, 445, 526, 589 |

**Table 10.1 (continued)**
**Approved and Proposed Core Studies[1]**

| Ref # | Title | Status | Study Pop | Blood | Analytes/Data | Used in Approved Publications |
|---|---|---|---|---|---|---|
| W6 (Con't) | CVD Biomarkers - Phase I | Funded | HT<br>Cases: n=402 CHD, 272 stroke, 223 VTE<br>Controls: n=877<br><br>*Baseline and Y1 | Y | EDTA 1.3 ml: HDL-C; HDL size; large HDL; medium HDL; small HDL; HDL particles (total); LDL-C; LDL size; large LDL; medium LDL; small LDL (total); LDL particles (total); very small LDL; VLDL size; large VLDL/chylomicrons; medium VLDL;small VLDL; VLDL particles (total); VLDL trig; trig; Lp(a); E-selectin; HDL-C; HDL-2; HDL-3; homocysteine; IL-6; LDL-C; total cholesterol; triglyceride<br><br>Serum 0.05 ml: MMP9 | |
| W7 | Genome-wide scan on breast dancer, CHD, and stroke | Funded | OS/HT<br>Phase I-II (OS)<br>Cases: n=1,800 breast cancer, 1,800 CHD, 1,721 stroke<br>Controls: n=same<br><br>Phase III (HT)<br>Cases: n=345 breast cancer, 319 CHD, 494 stroke<br>Controls: n=same | Y | DNA 2 ug: genome-wide scan | |
| W8 | Nutritional biomarkers study (NBS) | Funded | DM, n=544, with 111 of these in repeat sample | Y | NBS 24 hr urine: vol; nitrogen g/day; nitrogen g/L; sodium; potassium<br><br>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<br><br>Serum 0.2 ml: alpha-carotene, alpha-tocopherol, beta-carotene, folate, gamma-tocopherol, total cholesterol | 464, 624, 646 |
| W9 | Biological markers of the effect of HT on risk of fractures in the Women's Health Initiative Clinical Trial | Funded | HT<br>Cases: n=750*<br>Controls: n=750<br>*All hip + non-spine to reach 750 | Y | Serum 0.65 ml: estradiol; SHBG<br><br>Serum 0.35 ml: PINP; CTx | |

**Table 10.1 (continued)**
**Approved and Proposed Core Studies[1]**

| Ref # | Title | Status | Study Pop | Blood | Analytes/Data | Used in Approved Publications |
|---|---|---|---|---|---|---|
| W10 | Biological markers of the effect of HT on risk of breast cancer in the Women's Health Initiative Clinical Trial | Funded | HT<br>Cases: n=758<br>Controls: n=758 | Y | Serum 0.95 ml: estradiol, estrone sulfate, estrone, SHBG at Baseline and Year 1; progesterone and testosterone at Baseline only | |
| W11 | CVD biomarkers - Phase II: strokes after Feb 2001 | Funded | HT<br><br>Cases: n=316]<br>Controls: n=316<br>*Baseline and Y1 | Y | Citrate 0.9 ml: free TFPI; TFPI activity; total TFPI; APC-ETP<br><br>DNA 1 ug: ESR1 Exon 1 +30; ESR1 IVS1 -1415; ESR1 IVS1 -1505; ESR1 IVS1 -354; ESR1 IVS1 -401; estrogen receptor beta - 1730 A/G; GP1ba M145T; integrin alpha 2 - 807 C/T; platelet glycoprotein IIIa - P1(A1), (A2)<br><br>Serum 0.25 ml: glucose; insulin | 435 |
| W14 | CVD biomarkers - Phase I: additional assays | Funded | HT<br>Cases: n=390 CHD, 270 stroke,220 VTE<br>Controls: n=390 CHD, 270 stroke, 220 VTE<br>*Baseline and Y1 | Y | Citrate 0.95 ml: free TFPI; TFPI activity; total TFPI<br><br>Serum 0.25 ml: glucose; insulin | |
| W15 | CaD Vitamin D levels in CaD participants with colorectal cancer or fractures | Funded | CaD<br>Cases: n=1,830<br>Controls: n=1,830 | Y | Serum 0.2 ml: 25-OH-Vitamin $D_3$ | 450, 451, 581 |
| W18 | HT hormone pretest | Funded | HT, n=200<br>*Baseline and Y1 | Y | Serum 0.95 ml: estradiol, estrone, SHBG on both E-Alone and E+P samples; progesterone and testosterone on E+P only samples. | |
| W19 | WHI HT proteomic pilot Study | Funded | OS | Y | Serum 0.55 ml: proteomics | |
| W20 | WHI-EDRN pilot study for the identification of circulating biomarkers for colon cancer in pre-clinical specimens | Funded | OS<br>Cases: n=2952<br>Controls: n=2952 | Y | EDTA 0.55 ml: proteomics | |
| W21 | Cancer genetic markers of susceptibility (CGEMS) | Funded | CaD | Y | DNA 4 ug: genome-wide scan | |

**Table 10.1 (continued)**
**Approved and Proposed Core Studies[1]**

| Ref # | Title | Status | Study Pop | Blood | Analytes/Data | Used in Approved Publications |
|---|---|---|---|---|---|---|
| W22 | Vitamin D in 6% blood subsample of CaD | Proposed | CaD<br>Cases: n=357<br>Controls: n=357 | Y | Serum 0.2 ml: 25-OH Vitamin $D_3$ | |
| W23 | Genotyping to explore CaD intervention effect on hip fracture | Dropped | CaD<br>Cases: n=1,376<br>Controls: n=1,376 | Y | DNA 1 ug: 3 SNPs of the Vit D receptor (VDR) gene: Bsm I, Apa I, Taq I; 4 SNPs in the non-coding region of CYP27B1; 4 SNPs of the calcium sensing receptor (CASR): CA repeat; A986; R990G; Q1011E | |
| W24 | CaD Vitamin D and breast cancer | Funded | HT (E-Alone)<br>n = 1,141 aged 50-59 | Y | Serum 0.2 ml: 25-OH Vitamin $D_3$ | |
| W25 | WHI coronary artery calcification study in E-Alone (WHI-CACS) | Funded | DM | N | Coronary artery calcification | 503, 506 |
| W26 | Food grouping in WHI by FHCRC Nutrition Shared Resource group | Funded | OS; n=450 | N | 4DFR food group codes | |
| W27 | AS218-Nutrition and physical activity assessment study (NPAAS) lab assays | Funded | OS/CT, participants aged 65+ | Y | NPAAS 24 hr urine: vol; nitrogen g/day, nitrogen g/L<br><br>NPAAS 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<br><br>Serum 0.2 ml: alpha-carotene, alpha-tocopherol, beta-carotene, folate, gamma-tocopherol, total cholesterol | |
| W28 | Medicare claims data pilot | Funded | OS/CT<br>Cases: n=279<br>Controls: n=279 | N | Medicare claims data for 2 years on all WHI participants aged 65+. | |
| W29 | NCI pancreatic cancer cohort consortium | Funded | DM, n=166 | Y | DNA 4 ug: genome-wide scan | |
| W30 | Dietary assessment study | Complete | DM, n=160 | N | 4DFR nutrient analyses; repeat 24 hr recalls; repeat FFQs | |

**Table 10.1 (continued)**
**Approved and Proposed Core Studies[1]**

| Ref # | Title | Status | Study Pop | Blood | Analytes/Data | Used in Approved Publications |
|---|---|---|---|---|---|---|
| W31 | 4DFR and ovarian cancer | Complete | CT/OS | N | 4DFR analyses for DM other cancer paper | 469 |
| W32 | Form 125 –Hospital-ization coding | On Hold | DM | N | Diagnosis codes for text written on WHI Form 125 – Hospitalization | |
| W33 | 4DFR and DM breast cancer | Complete | OS/CT<br>Cases: n=1,328 CT, 268 OS<br>Controls: 1,596 | N | 4DFR analyses for DM breast cancer paper | 448 |
| W34 | Extension of WHI stroke genome-wide association study (W7) | Funded | | Y | DNA 1 ug: 5,400 SNPs | |

[1] Core studies are conducted using internal WHI Funds included in the Clinical Coordinating Center budget. Studies are developed and monitored by a study-wide Core Resources Working Group. NHLBI conducts additional peer review of proposed uses beyond those specified in the study protocol (certain subsamples) and pilot projects.

**Table 11.1**
**All Ancillary Studies**

| AS | Title | PIs | Status | Study dates | Study Population* | Blood Study |
|---|---|---|---|---|---|---|
| 1 | Arterial disease artherosclerosis prevention Trial (ADAPT) | Anc: Crouse<br>Whi: Burke | Dropped | | DM | N |
| 2 | Prostate, lung, colorectal, and ovarian cancer screening trial (PLCO-OS) | Anc: Weissfeld<br>Whi: Kuller | Dropped | | OS/CT | N |
| 3 | PLCO offer to WHI-partners (PLCO-Partners) | Anc: Weissfeld<br>Whi: Kuller | Dropped | | OS/CT | N |
| 4 | Dietary modification and prostate cancer in WHI husbands | Anc: Shikany<br>Whi: Oberman | Dropped | | DM | N |
| 5 | Explanations for the cevelopment of fat distaste | Anc: Green<br>Whi: Bowen | Complete | 04/01/95-<br>09/30/96 | DM | N |
| 6 | Incidence and Impact of Arthritis in Older Women | Anc: Hughes<br>Whi: Greenland | Dropped | | OS/CT | N |
| 7 | Effect of HRT on cardiovascular morbidity and mortality in postmenopausal women with a low ankle/arm BPI | Anc: Kuller<br>Whi: Kuller | Dropped | | HRT | N |
| 8 | Partner's health study | Anc: Langer<br>Whi: Langer | Dropped | | | N |
| 9 | Oral bone loss | Anc: Jeffcoat<br>Whi: Lewis | Complete | 05/29/95-<br>11/30/04 | OS<br>450 Ppts@Birming | N |
| 10 | Urinary estrogen metabolites and breast cancer risk | Anc: Meilahn<br>Whi: Kuller | Dropped | | DM | N |
| 11 | Validation and exploration of sleep and mood predictors | Anc: Kripke<br>Whi: Langer | Complete | 08/01/95-<br>07/31/99 | OS | N |
| 12 | Empowerment/nutritional counseling | Anc: Mouton<br>Whi: Lasser | Dropped | | DM | N |
| 13 | Prevalence and correlates of lumbar spinal stenosis | Anc: Vogt<br>Whi: Kuller | Complete | | CT | N |
| 14 | High density lipoprotein metabolism | Anc: Going<br>Whi: Moon | Complete | 07/01/94-<br>06/30/96 | OS | N |
| 15 | The relationship between osteopenia and periodontitis | Anc: Wactawski-Wende<br>Whi: Trevisan | Complete | 09/16/96-<br>09/15/01 | OS<br>1468 Ppts@Buffalo | N |
| 16 | Lower extremity atherosclerotic disease | Anc: McDermott<br>Whi: Greenland | Dropped | | OS | N |

**Table 11.1 (continued)**
**All Ancillary Studies**

| AS | Title | PIs | Status | Study dates | Study Population* | Blood Study |
|---|---|---|---|---|---|---|
| 17 | Domestic violence in older women | Anc: Mouton<br>Whi: Lasser | Complete | 10/25/94-10/24/96 | OS | N |
| 18 | WHT:FSMP DM follow-up | Anc: Grizzle<br>Whi: Bowen | Dropped | | DM | N |
| 19 | Coagulation proteins, anticardiolipin antibodies and stroke in women | Anc: Orencia<br>Whi: Greenland | Dropped | | OS/CT | N |
| 20 | Coronary screening of postmenopausal women using EBCT | Anc: Detrano<br>Whi: Chlebowski | Dropped | | OS | N |
| 21 | Effect of DM, HRT and CaD admin on progression of coronary atherosclerosis assessed by EBCT | Anc: Detrano<br>Whi: Chlebowski | Dropped | | CT | N |
| 22 | Vascular compliance as a predictor of cardiovascular disease in postmenopausal women | Anc: Robinson<br>Whi: Grimm | Dropped | | CT | N |
| 23 | Non-steroidal anti-inflammatory drugs and cancers of the breast and colon | Anc: Harris<br>Whi: Jackson | Dropped | | OS/CT | N |
| 24 | Cross-ethnic comparisons of skeletal health of postmenopausal women in San Diego county | Anc: Schneider<br>Whi: Langer | Complete | 01/03/95-01/02/97 | OS | N |
| 25 | Ankle-arm blood pressure index measurement | Anc: Masaki<br>Whi: Curb | Complete | 02/01/96-01/01/98 | OS | N |
| 26 | HRT and knee/hip osteoarthritis | Anc: Cerhan<br>Whi: Wallace | Dropped | | HRT | N |
| 27 | Vitamin D, calcium, and breast cancer | Anc: Hulka<br>Whi: Sheps | Dropped | | OS/CT | Y |
| 28 | Perspectives on aging | Anc: Smoller<br>Whi: Smoller | Dropped | | OS/CT | N |
| 29 | HRT and cardiovascular biomarkers related to oxidation status and platelet function | Anc: Gaziano<br>Whi: Manson | Dropped | | HRT | N |
| 30 | The role of endocrine factors in the etiology of lung cancer in women | Anc: Kabat<br>Whi: Smoller | Dropped | | OS | N |
| 31 | Eye care use | Anc: Kleinstein<br>Whi: Oberman | Complete | | OS | N |
| 32 | Recruitment techniques in getting minority women to participate in breast cancer clinical trials | Anc: Boe<br>Whi: Langer | Dropped | | OS/CT | N |
| 33 | The association of HRT with abdominal and total body fat in postmenopausal women | Anc: Mayo<br>Whi: Oberman | Complete | 07/31/95-03/31/96 | OS | N |

**Table 11.1 (continued)**
**All Ancillary Studies**

| AS | Title | PIs | Status | Study dates | Study Population* | Blood Study |
|---|---|---|---|---|---|---|
| 34 | Ethnic differences in hip bone geometry by DXA and QCT | Anc: Nelson<br>Whi: Hendrix | Complete | 12/01/96-<br>12/31/02 | HRT<br>311 Ppts@Detroit | N |
| 35 | Risk factors for fatigue in women ages 50 to 75 | Anc: Hartz<br>Whi: Kotchen | Dropped | | CT | N |
| 36 | HRT and changes in mammographic density | Anc: Hulka<br>Whi: Heiss | Complete | 01/31/98-<br>12/31/02 | HRT<br>857 Ppts@19 clinics<br>Breast Cancer: | N |
| 37 | Lipid markers of atherosclerotic disease in post menopausal women | Anc: Manson<br>Whi: Manson | Dropped | | OS | Y |
| 38 | Hemostatic/thrombotic and genetic markers for coronary disease in postmenopausal women | Anc: Ridker<br>Whi: Manson | Dropped | | OS | Y |
| 39 | The effects of HRT on the development and progression of dementia (WHIMS) | Anc: Shumaker<br>Whi: Shumaker | Complete | 06/01/96-<br>05/31/05 | HRT<br>7528 Ppts@48 clinics | N |
| 40 | Ethnic and age differences in use of mammography | Anc: Smoller<br>Whi: Smoller | Complete | | OS | N |
| 41 | Metabolism of lipoprotein and HRT | Anc: Morrisett<br>Whi: Foreyt | Dropped | | OS | N |
| 42 | Impact of insurance status on health outcomes and health services utilization in the WHI | Anc: Hsia<br>Whi: Miller | Dropped | 11/01/96-<br>10/31/99 | OS | N |
| 43 | Decrease of bone mass in older women | Anc: Goodman<br>Whi: Judd | Dropped | | CT | N |
| 44 | Estrogen and vaginal pH | Anc: Schaeffer<br>Whi: Greenland | Dropped | | HRT | N |
| 45 | Response set biases in dietary self-report in the WHI DM | Anc: Herbert<br>Whi: Herbert | Dropped | | DM | N |
| 46 | Prostate and colorectal cancer in WHI dietary arm husbands | Anc: Oberman<br>Whi: Oberman | Dropped | | DM | N |
| 47 | Effect of diet intervention on motivation to make other health-related changes | Anc:<br>Whi: Langer | Complete | 05/01/96-<br>04/30/97 | DM | N |
| 48 | Prostate cancer survey of spouses of WHI screened women | Anc: Smoller<br>Whi: Smoller | Complete | 02/01/96-<br>06/30/96 | OS/CT | N |
| 49 | Applying creative self-monitoring in the WHI | Anc: Rahmani<br>Whi: Rahmani | Dropped | | DM | N |

**Table 11.1 (continued)**
**All Ancillary Studies**

| AS | Title | PIs | Status | Study dates | Study Population* | Blood Study |
|---|---|---|---|---|---|---|
| 50 | Nutrition practice guidelines for maintaining low-fat dietary change in post menopausal women | Anc: Burrows<br>Whi: Grimm | Complete | 10/01/96-<br>09/30/97 | DM | N |
| 51 | Cross-sectional and longitudinal evaluation of bone quality | Anc: LeBlanc<br>Whi: Foreyt | Dropped | | OS/CT | N |
| 52 | Genetic polymorphisms in the hormonal etiology of breast cancer | Anc: McTiernan<br>Whi: McTiernan | Dropped | | OS<br>Breast Cancer: | N |
| 53 | A prospective study of diet and hormones in the development of prostate cancer | Anc: Kabat<br>Whi: Smoller | Dropped | | OS/CT | N |
| 54 | Women and minority recruitment / retention: a community-based Intervention | Anc: Fouad<br>Whi: Oberman | Dropped | | DM | N |
| 55 | Predictors of participation among latinos in clinical trials | Anc: Talavera<br>Whi: Talavera | Dropped | | OS/CT | N |
| 56 | Behavioral and psychosocial predictors of dietary change in postmenopausal women | Anc: Pleuss<br>Whi: Burke | Complete | 09/01/96-<br>08/31/98 | DM | N |
| 57 | Hispanic women's advocacy and retention strategies | Anc: Ritenbaugh<br>Whi: Ritenbaugh | Complete | 09/01/96-<br>08/31/98 | OS | N |
| 58 | Enrollment of hispanic women in prevention trials | Anc: Trapido<br>Whi: Baum | Dropped | | OS/CT | N |
| 59 | Prevalence and natural history of autoimmune thyroid disease (AITD) in postmenopausal women | Anc: Zakarija<br>Whi: Greenland | Dropped | | OS/CT | N |
| 60 | Fat intake in husbands of WHI dietary arm participants | Anc: Shikany<br>Whi: Oberman | Complete | 12/01/96-<br>12/01/96 | DM | N |
| 61 | Longitudinal assessment of memory functioning in the WHI clinical trial | Anc: Ober<br>Whi: Robbins | Analysis | 09/01/96-<br>08/31/09 | HRT | N |
| 62 | Prevention of age-related maculopathy in the WHI HRT CT: WHI-SE | Anc: Haan<br>Whi: Robbins | Analysis | 01/01/99-<br>01/01/07 | HRT<br>4430 Ppts@21 clinics | N |
| 63 | Development and evaluation of eating style index | Anc: Haines<br>Whi: Heiss | Complete | 10/01/96-<br>06/30/99 | OS | N |
| 64 | Examine mammography sensitivity in WHI women | Anc: Foreyt<br>Whi: Foreyt | Dropped | | CT | N |
| 65 | Benign breast disease | Anc: Rohan<br>Whi: Rohan | Complete | 07/01/98-<br>08/30/00 | DM<br>101 Ppts@12 clinics | N |

**Table 11.1 (continued)**
**All Ancillary Studies**

| AS | Title | PIs | Status | Study dates | Study Population* | Blood Study |
|---|---|---|---|---|---|---|
| 66 | Quantitative, patient-specific serially comparable (QPS) mammography | Anc: Morrisett<br>Whi: Foreyt | Dropped | | OS/CT | N |
| 67 | Prevalence and natural history of autoimmune thyroid disease in postmenopausal women | Anc: Zakarija<br>Whi: O'Sullivan | Funded | 03/31/97-02/28/10 | OS | N |
| 68 | Coronary artery calcification detected with Ultrafast CT as an indication of CAD in OS participants | Anc: Hsia<br>Whi: Hsia | Complete | 01/01/97-12/31/05 | OS<br>735 Ppts@2 clinics | N |
| 69 | Birth place and CVD risk in women | Anc: Wylie-Rosett<br>Whi: Smoller | Dropped | | OS/CT | N |
| 70 | The prevalence and prognostic importance of myocardial ischemia during daily life, and its relationship to migraine status: WHI | Anc: Sheps<br>Whi: Heiss | Complete | 09/01/97-08/31/00 | OS | N |
| 71 | Assessing stages of change in postmenopausal women enrolled in the Dietary Modification arm if the WHI | Anc: Brewer<br>Whi: Applegate | Dropped | | DM | N |
| 72 | Ethnicity, body composition, bone density and breast cancer | Anc: Chen<br>Whi: Ritenbaugh | Analysis | 09/01/97-08/30/02 | OS | N |
| 73 | Psychosocial and cultural determinants of NIDDM in Latinas | Anc: Ritenbaugh<br>Whi: Langer | Complete | 05/01/97-04/30/98 | OS | N |
| 74 | The effectiveness of individual versus group behavioral strategies to increase participants adherence | Anc: Wodarski<br>Whi: Trevisan | Complete | 07/01/97-09/30/97 | DM | N |
| 75 | Adherence to dietary modification in the WHI | Anc: Rosal<br>Whi: Ockene | Analysis | 09/01/97-08/30/02 | DM | N |
| 76 | Tailored messages to enhance adherence of older women to dietary programs for breast cancer control | Anc: Chlebowski<br>Whi: Chlebowski | Complete | 09/01/97-08/13/98 | DM | N |
| 77 | HRT decision project | Anc: Kerner<br>Whi: Langer | Dropped | | OS/CT | N |
| 78 | Community strategy to retain women enrolled in research | Anc: Fouad<br>Whi: Oberman | Complete | 07/01/97-09/30/97 | CT | N |
| 79 | How a low fat diet is related to adiposity and body fat distribution: cross-sectional and longitudinal evaluation | Anc: Wylie-Rosett<br>Whi: Smoller | Dropped | | OS/CT | N |
| 80 | Combine effect of HRT and heritable prothrombotic mutations on the risk of deep venous thrombosis (DVT) and pulmonary embolus (PE) | Anc: Psaty<br>Whi: Psaty | Dropped | | HRT | N |
| 81 | Androgeneic hair growth in postmenopausal women | Anc: Freeman<br>Whi: Smoller | Dropped | | OS | N |
| 82 | Extension of bone mineral density assessment in WHI Native American women | Anc: Chen<br>Whi: Ritenbaugh | Complete | 07/01/97-06/30/01 | OS | N |

**Table 11.1 (continued)**
**All Ancillary Studies**

| AS | Title | PIs | Status | Study dates | Study Population* | Blood Study |
|---|---|---|---|---|---|---|
| 83 | Thrombotic, inflammatory and genetic markers for coronary heart disease in postmenopausal women: a WHI umbrella study | Anc: Ridker<br>Whi: Manson | Complete | 09/01/99-08/31/03 | OS<br>CHD:650<br>Controls:650 | Y |
| 84 | Estrogen, vitamin E and cognitive change in women | Anc: Dunn<br>Whi: Van Horn | Funded | 09/01/01-08/31/06 | OS/CT<br>546 Ppts@2 clinics | N |
| 85 | Brain imaging with fluorometatyrosine in post-menopausal women on or off hormonal replacement therapy - implications for schizophrenia | Anc: Nordahl<br>Whi: | Dropped | | | N |
| 86 | A pilot study to determine the sensitivity of Form 39 toi impaired executive control function (ECF) as measured by the CLOX: an executive clock-drawing task | Anc: Polk<br>Whi: Schenken | Complete | | HRT | N |
| 87 | The effect of dietary change on blood flavonoid and F2-isoprostane levels | Anc: Simon<br>Whi: Hendrix | Dropped | | DM | N |
| 88 | Cholesterol distribution in lipoprotein particles in WHI DM Intervention participants consuming a low-fat dietary pattern compared to Comparison participants consuming their usual fat intake | Anc: Tinker<br>Whi: Grimm | Dropped | | DM | N |
| 89 | Effect of HRT on plasma homocysteine concentration | Anc: Manson<br>Whi: Manson | Dropped | | HRT | N |
| 90 | WHI sex hormone and genetic risk factors for hip fracture | Anc: Cummings<br>Whi: Cummings | Funded | 04/01/03-03/31/07 | OS<br>Fracture - Hip:400<br>Controls:400<br>*same as AS181 | Y |
| 91 | Alterations in calcium and calcitropic hormone levels in 4 ethnic groups in response to CaD supplementation: possible effect modulation by VDR phenotype | Anc: Lester<br>Whi: | Dropped | | CT | N |
| 92 | Fasting glucose in baseline plasma from all CT participants | Anc: Howard<br>Whi: Howard | Tabled | | CT | N |
| 93 | The epidemiology of venous disease | Anc: Criqui<br>Whi: Langer | Complete | 03/11/98-06/30/99 | OS | N |
| 94 | The effect of lowfat Dietary Modification on markers of bone turnover and bone mineral density | Anc: Jackson<br>Whi: Jackson | Dropped | | OS/CT | N |
| 95 | Work organization, psychological distress, and health among minority older women | Anc: Rodriguez<br>Whi: Curb | Complete | 12/01/97-12/01/97 | OS | N |

**Table 11.1 (continued)**
**All Ancillary Studies**

| AS | Title | PIs | Status | Study dates | Study Population* | Blood Study |
|---|---|---|---|---|---|---|
| 96 | Longitudinal insulin sensitivity and postmenopausal HRT | Anc: Cottrell<br>Whi: | Dropped | | OS/CT | N |
| 97 | Modeling serum markers for cost-effective ovarian cancer screening | Anc: Anderson<br>Whi: Anderson | Funded | 09/30/01-<br>06/30/09 | OS<br>Ovarian Cancer:240<br>Controls:480 | Y |
| 98 | Bone mineral density as a predictor for periodontitis | Anc: Wactawski-Wende<br>Whi: Trevisan | Funded | 04/01/02-<br>03/30/07 | OS<br>969 Ppts@Buffalo | N |
| 99 | GENNID study | Anc: Chlebowski<br>Whi: Chlebowski | Complete | 12/01/98-<br>03/31/00 | OS/CT | N |
| 100 | Genetic, biochemical and behavioral determinants of obesity | Anc: Hays<br>Whi: Hays | Funded | 01/01/99-<br>04/30/04 | OS<br>797 Ppts@3 clinics | N |
| 101 | Women's Health oral history project | Anc: Allen<br>Whi: Allen | Dropped | | | N |
| 102 | Quality of life improvements and willingness to pay: an investigation of selective estrogen receptor modulators | Anc: Fouad<br>Whi: Oberman | Complete | 09/01/98-<br>10/01/98 | OS | N |
| 103 | Effects of hormone replacement therapy on cognitive aging: Women's Health Initiative study of cognitive aging (WHISCA) | Anc: Shumaker<br>Whi: Shumaker | Funded | 04/01/99-<br>06/30/08 | HRT<br>2266 Ppts@15 clinics | N |
| 104 | Tamoxifen prevention: Is it acceptable to women at risk? | Anc: Melnikow<br>Whi: Robbins | Complete | 07/01/99-<br>06/30/02 | OS | N |
| 105 | Carotenoids in age-related eye disease study | Anc: Mares-Perlman<br>Whi: Sarto | Complete | 06/01/00-<br>04/30/04 | OS<br>2007 Ppts@4 clinics<br>Eye:1350<br>Controls:1350 | Y |
| 106 | Gene-diet interactions in human breast cancer risk | Anc: Hu<br>Whi: Paskett | Dropped | | OS/CT | N |
| 107 | Hashimoto's thyroiditis in postmenopausal women | Anc: Zakarija<br>Whi: O'Sullivan | Not Approved | 12/01/02-<br>11/30/05 | OS | Y |
| 108 | Gene-environment effects and colorectal cancer | Anc: Lin<br>Whi: Chlebowski | Complete | 04/01/03-<br>07/31/07 | OS<br>Colorectal Cancer:50<br>Controls:150 | Y |

**Table 11.1 (continued)**
**All Ancillary Studies**

| AS | Title | PIs | Status | Study dates | Study Population* | Blood Study |
|---|---|---|---|---|---|---|
| 110 | Sex steroid hormones and risk of coronary heart disease: a nested case control study | Anc: Rexrode<br>Whi: Manson | Complete | 09/01/00-<br>07/31/05 | OS<br>CHD:385<br>Controls:385<br>*79 matched cases-controls and 92 cases (but not controls) overlap with AS83. | Y |
| 112 | Motivators and barriers to exercise in older women | Anc: Haan<br>Whi: Haan | Dropped | | OS | N |
| 113 | Some aspects of mediterranean diet in relation to risk of chronic diseases among postmenopausal women | Anc: Hakim<br>Whi: Bassford | Complete | 08/01/99-<br>07/31/02 | OS | N |
| 114 | Effects of hormone replacement therapy on cardiac function and ischemia | Anc: Haan<br>Whi: Robbins | Dropped | | HRT | N |
| 115 | Diabetes In postmenopausal women | Anc: Howard<br>Whi: Howard | Dropped | | OS/CT<br>Type 2 Diabetes: | N |
| 116 | National validation and quality assurance of vitamin D absorption from CaD tablets | Anc: Garland<br>Whi: Langer | Dropped | | CaD | N |
| 117 | Risk factors for dry eye syndrome in postmenopausal women | Anc: Nichols<br>Whi: Jackson | Analysis | 02/01/01-<br>01/01/04 | OS<br>217 Ppts@Columbus | N |
| 118 | Accuracy of food portion estimation among postmenopausal women | Anc: Coy<br>Whi: Hubble | Complete | 12/01/99-<br>04/01/00 | DM | N |
| 119 | The longevity consortium | Anc: Langer<br>Whi: Langer | Dropped | | OS/CT | N |
| 120 | Epidemiology of cervical and lumbar stenosis | Anc: Vogt<br>Whi: Kuller | Dropped | | OS | N |
| 121 | Hyperinsulinemia and ovarian cancer | Anc: Modugno<br>Whi: Kuller | Complete | 09/01/02-<br>08/31/04 | OS<br>Ovarian Cancer:225<br>Controls:225<br>*originally a subset of AS97 | Y |
| 122 | Feasibility study of computerized tailored dietary feedback | Anc: Glanz<br>Whi: Curb | Complete | 03/10/00-<br>09/01/00 | DM | N |
| 123 | Genetic and ethnic determinants of nicotine addiction in postmenopausal women | Anc: David<br>Whi: Assaf | Dropped | | OS/CT | N |

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**Table 11.1 (continued)**
**All Ancillary Studies**

| AS | Title | PIs | Status | Study dates | Study Population* | Blood Study |
|---|---|---|---|---|---|---|
| 123 | Genetic and ethnic determinants of nicotine addiction in postmenopausal women | Anc: David<br>Whi: Assaf | Dropped | | OS/CT | N |
| 124 | Sociocultural influences on motivation for and maintenance of health-related dietary change among women | Anc: Namie<br>Whi: Langer | Complete | 06/01/00-<br>12/01/00 | DM | N |
| 125 | Osteoporosis in caribbean hispanic women | Anc: Cohen<br>Whi: Smoller | Dropped | | OS/CT | N |
| 126 | Stroke risk factors and molecular markers in postmenopausal women | Anc: Smoller<br>Whi: Smoller | Complete | 08/01/03-<br>07/31/06 | OS<br>Stroke:1100<br>Controls:1100 | Y |
| 127 | CHD risk perception study | Anc: Barnhart<br>Whi: Smoller | Funded | 05/15/02-<br>04/30/07 | OS | N |
| 128 | Mismatch repair gene associated malignancies in women | Anc: Weber<br>Whi: Smoller | Expired | 04/01/04-<br>03/31/08 | OS<br>Colorectal Cancer:1025<br>Endometrial Cancer:710<br>Ovarian Cancer:405<br>Controls:1000<br>*sharing ovarian cases with AS97 | Y |
| 129 | Association of diabetes and insulin-like growth factor-I (IGF-I) with risks of colorectal, breast, and endometrial cancer | Anc: Strickler<br>Whi: Smoller | Analysis | 01/15/02-<br>12/31/05 | OS<br>Breast Cancer:900<br>Colorectal Cancer:500<br>Endometrial Cancer:300<br>Controls:900<br>*same as AS152 | Y |
| 130 | Randomized controlled trial of fat reduction, calcium/Vitamin D supplementation, hormone replacement therapy, and risk of proliferative forms of benign breast disease | Anc: Rohan<br>Whi: Smoller | Analysis | 07/01/01-<br>07/31/07 | CT<br>3901 Ppts@49 clinics<br>Breast Cancer:<br>Controls:0 | N |
| 131 | Sex steroid hormones, inflammatory cytokines and the risk of rheumatoid arthritis: a nested case control study | Anc: Shadick<br>Whi: Manson | Dropped | | OS | Y |
| 132 | A prospective study of genetic and biochemical predictors of Type 2 diabetes mellitus | Anc: Liu<br>Whi: Manson | Funded | 08/01/02-<br>07/03/08 | OS<br>Type 2 Diabetes:2150<br>Controls:2150 | Y |
| 133 | Biochemical and genetic predictors of incident hypertension in white and black women | Anc: Sesso<br>Whi: Manson | Funded | 08/01/04-<br>07/31/08 | OS<br>Hypertension:800<br>Controls:800 | Y |

**Table 11.1 (continued)**
**All Ancillary Studies**

| AS | Title | PIs | Status | Study dates | Study Population* | Blood Study |
|---|---|---|---|---|---|---|
| 134 | Serum estrogen hormone metabolites, hormone replacement therapy and the risk of breast cancer | Anc: Modugno<br>Whi: Kuller | Complete | 07/01/02-<br>05/31/04 | OS<br>Breast Cancer:200<br>Controls:200 | Y |
| 135 | Natural history of pelvic organ prolapse in WHI women | Anc: Nygaard<br>Whi: Wallace | Analysis | 02/01/02-<br>06/30/07 | HRT | N |
| 136 | The natural history of female pelvic organ prolapse | Anc: Handa<br>Whi: Robbins | Dropped | | HRT | N |
| 137 | Postmenopause CHD risk: platelet genes and hormone therapy | Anc: Bray<br>Whi: Hays | Funded | 09/27/03-<br>08/31/07 | OS<br><br>CHD:1060<br>Controls:2120 | Y |
| 138 | The study of tamoxifen, raloxifene, and cognition (Co-STAR) | Anc: Shumaker<br>Whi: Shumaker | Dropped | | HRT | N |
| 139 | Follow-up of healthy breast cancer survivors in the WHI Observational Study | Anc: Paskett<br>Whi: Burke | Complete | 02/01/02-<br>01/31/03 | OS | N |
| 140 | Air pollution and electrocardiographic abnormalities | Anc: Whitsel<br>Whi: Heiss | Funded | 09/01/03-<br>05/31/08 | CT | N |
| 141 | Periodontal disease and subclinical cardiovascular disease in post-menopausal women | Anc: Dorn<br>Whi: Trevisan | Complete | 06/01/01-<br>03/16/05 | OS | N |
| 142 | Thrombosis-related genes in population subgroups narrowly defined by race, ethnicity, and place of birth | Anc: Kaplan<br>Whi: Smoller | Dropped | | OS | Y |
| 143 | Treatment of elevated cholesterol among US postmenopausal women | Anc: Kaplan<br>Whi: Smoller | Dropped | | OS | Y |
| 144 | Interactions of polymorphisms in selected genes of thrombogenic & thrombolytic systems with hormone replacement therapy as risk factors for atherothrombotic events in postmenopausal women | Anc: Liu<br>Whi: Liu | Dropped | | OS | Y |
| 145 | Pancreatic cancer | Anc: Whitcomb<br>Whi: Kuller | Dropped | | OS | Y |
| 146 | A prospective study of pancreatic cancer pathogenesis | Anc: Fuchs<br>Whi: Manson | Complete | 03/01/03-<br>12/31/04 | OS<br>Pancreatic Cancer:106<br>Controls:318 | Y |
| 147 | Gene-gene and gene-environment interactions and breast cancer risk | Anc: Eng<br>Whi: Jackson | Dropped | | OS | Y |

**Table 11.1 (continued)**
**All Ancillary Studies**

| AS | Title | PIs | Status | Study dates | Study Population* | Blood Study |
|---|---|---|---|---|---|---|
| 148 | Relationship between monoclonal hemopoiesis and other molecular abnormalities and the development of leukemia in older women | Anc: Preisler<br>Whi: Black | Expired | | OS<br>Leukemia:59<br>Controls:177 | Y |
| 149 | Gene-environment interactions and human breast cancer risk | Anc: Hu<br>Whi: Paskett | Dropped | 06/01/04-<br>05/31/06 | OS<br>Breast Cancer:800<br>Controls:800 | Y |
| 150 | Effect of airborne particulate matter and other air pollutants on the incidence of cardiovascular events in the Women's Health Initiative Observational Study | Anc: Kaufman<br>Whi: Anderson | Analysis | 05/01/02-<br>05/31/06 | OS/CT<br>CHD: | N |
| 151 | Behavioral management of urinary incontinence in African-American women | Anc: Ruff<br>Whi: Howard | Dropped | | OS | N |
| 152 | Growth factor genes and female breast, colorectal, and endometrial cancers | Anc: Ho<br>Whi: Smoller | Funded | 08/01/03-<br>07/31/07 | OS<br>Breast Cancer:900<br>Colorectal Cancer:500<br>Endometrial Cancer:300<br>Controls:900<br>*Same as AS129 | Y |
| 153 | Longitudinal changes in hip geometry and skeletal muscle | Anc: Chen<br>Whi: Bassford | Funded | 08/15/03-<br>06/30/08 | OS<br>47 Ppts@Tucson<br>Fracture - Hip: | N |
| 154 | Serum and DNA precursors of colon cancer | Anc: Garland<br>Whi: Langer | Not Approved | 09/01/02-<br>08/30/03 | OS<br>Colon cancer:400<br>Controls:400 | Y |
| 155 | Carotenoids, transforming growth factors, and breast cancer risk | Anc: Rohan<br>Whi: Smoller | Dropped | | OS<br>Breast Cancer:3500<br>Controls:3500 | Y |
| 156 | The effect of domestic violence on health care costs and utilization | Anc: Mouton<br>Whi: Schenken | PO Approved | 11/01/02-<br>09/30/05 | OS | N |
| 157 | Prediction of CHD among postmenopausal women using NMR spectroscopy lipoproteins | Anc: Kuller<br>Whi: Kuller | Dropped | | OS | Y |
| 158 | Potential mediators of the association of depression with CVD | Anc: Wylie-Rosett<br>Whi: Smoller | Dropped | | OS | Y |
| 159 | The insulin-like growth factor (IGF) system and coronary heart disease | Anc: Kaplan<br>Whi: Smoller | Dropped | | OS | Y |

**Table 11.1 (continued)**
**All Ancillary Studies**

| AS | Title | PIs | Status | Study dates | Study Population* | Blood Study |
|---|---|---|---|---|---|---|
| 160 | An assessment of symptoms and symptom self-management for women abruptly stopping hormone replacement study pills | Anc: Valanis<br>Whi: Ritenbaugh | Complete | 07/01/02-<br>08/17/02 | HRT E+P | N |
| 161 | Bone mass response to termination of Estrogen + Progestin | Anc: Cauley<br>Whi: Kuller | Funded | 07/10/02-<br>10/01/02 | HRT E+P | N |
| 162 | Interactive telephone strategy to maintain diet change | Anc: Beresford<br>Whi: Beresford | Tabled | 07/01/03-<br>06/30/08 | CT | N |
| 163 | Hormone use following the WHI E+P trial termination: a pilot study | Anc: Hays<br>Whi: Hays | Complete | 01/01/03-<br>12/01/04 | HRT E+P | N |
| 164 | The IGF system and coronary heart disease | Anc: Kaplan<br>Whi: Smoller | Expired | 01/01/06-<br>12/31/06 | OS<br>CHD:350<br>Controls:350 | Y |
| 165 | Subclinical thyroid dysfunction and risk of myocardial infarction and stroke | Anc: Hartmann<br>Whi: Heiss | Analysis | 09/01/04-<br>07/31/08 | OS<br>CHD:800<br>Stroke:591<br>Controls:3136 | Y |
| 166 | Estrogen replacement therapy and autoantibodies | Anc: Mackay<br>Whi: Smoller | Dropped | | OS | Y |
| 167 | Sex hormones, risk factors, and risk of ER+ and ER- breast cancer | Anc: Cummings<br>Whi: Cummings | Funded | 01/01/05-<br>12/31/06 | OS<br>Breast Cancer:400<br>Controls:600 | Y |
| 168 | Plasma inflammatory markers and colorectal cancer | Anc: Ho<br>Whi: Smoller | Dropped | | OS | Y |
| 169 | Risk factors for hemorrhagic stroke among postmenopausal women | Anc: Kaplan<br>Whi: Smoller | Expired | 04/01/06-<br>07/30/10 | OS<br>Stroke:357<br>Controls:757 | Y |
| 170 | WHI nutrition and diabetes study (WHINDS) | Anc: Margolis<br>Whi: Margolis | Dropped | 01/01/04-<br>12/31/06 | DM | N |
| 171 | Analysis of heart rate variability from ultra-short records: the WHI study | Anc: Michael<br>Whi: Ritenbaugh | Complete | 01/01/03-<br>06/01/03 | CT | N |
| 172 | Estrogen receptor polymorphisms and cardiovascular effects of HRT | Anc: Herrington<br>Whi: Burke | Dropped | | CT | N |
| 173 | Relationship of biomarkers and genetic markers to risk of congestive heart failure | Anc: Chae<br>Whi: Manson | Not Approved | | OS<br>CHF:656<br>Controls:1312 | Y |

**Table 11.1 (continued)**
**All Ancillary Studies**

| AS | Title | PIs | Status | Study dates | Study Population* | Blood Study |
|---|---|---|---|---|---|---|
| 174 | Proinflammatory markers and colorectal cancer | Anc: Ho<br>Whi: Smoller | Not Approved | | OS<br>Colorectal Cancer:500<br>Controls:900 | Y |
| 175 | Physical function determinants in minority women | Anc: Nicholas<br>Whi: Bassford | Funded | 12/01/03-<br>09/01/06 | OS | N |
| 176 | Long term breast and colorectal cancer survivors in the OS | Anc: Rahmani<br>Whi: Smoller | Dropped | | OS | N |
| 177 | Relative risk differences between FFQs and food records | Anc: Subar<br>Whi: Patterson | Complete | 09/30/03-<br>09/30/04 | DM | N |
| 178 | Mammographic density and invasive breast cancer | Anc: Pisano<br>Whi: Heiss | Analysis | 03/12/04-<br>02/28/08 | CT<br>793 Ppts@34 clinics<br>Breast Cancer: | N |
| 179 | Frailty in WHI: drugs, inflammatory and genetic markers | Anc: LaCroix<br>Whi: LaCroix | Funded | 09/15/05-<br>07/31/08 | OS<br>Frailty-disability:900<br>Controls:900<br>*Changed from 600 frailty cases + 600 disability cases + 600 controls to 900 frailty cases + 900 controls | Y |
| 180 | Macrovascular complications of diabetes in postmenopausal women | Anc: Li<br>Whi: Johnson | Expired | 12/01/05-<br>11/30/09 | OS<br>Type 2 Diabetes:3164 | Y |
| 181 | Estradiol, cytokines, and bone turnover: effects on hip fracture | Anc: Cauley<br>Whi: Kuller | Analysis | 07/01/05-<br>06/30/08 | OS<br>Fracture - Hip:400<br>Controls:400<br>*same as AS90 | Y |
| 182 | Genetic and epigenetic markers of lung cancer risk in post-menopausal women | Anc: Schlecht<br>Whi: Smoller | Dropped | 04/01/07-<br>03/30/10 | OS<br>Cancer of Lung:720<br>Controls:1440 | Y |
| 183 | WHIMS MRI study | Anc: Shumaker<br>Whi: Shumaker | Analysis | 07/01/04-<br>06/30/06 | HRT<br>Stroke: | N |
| 184 | Measures for changes in skeletal muscle mass | Anc: Chen<br>Whi: Bassford | Dropped | | OS/CT | N |
| 185 | An assessment of symptoms and symptom self-management for women abruptly stopping hormone replacement study pills (extension of AS160) | Anc: Ritenbaugh<br>Whi: Ritenbaugh | Complete | 03/19/04-<br>09/30/04 | HRT E alone | N |

**Table 11.1 (continued)**
**All Ancillary Studies**

| AS | Title | PIs | Status | Study dates | Study Population* | Blood Study |
|---|---|---|---|---|---|---|
| 186 | Plasma fatty acids and risk of non-Hodgkin's lymphoma in the Women's Health Initiative Observational Study: a nested case-control study | Anc: Chiu<br>Whi: Van Horn | Not Approved | | OS<br>Lymphoma, Non Hodgkins:290<br>Controls:870 | Y |
| 187 | Serum fatty acids and salicylic acid in relation to incidence of ischemic stroke in postmenopausal women | Anc: He<br>Whi: Van Horn | Not Funded | 04/01/07-03/31/09 | OS<br>Stroke:1050<br>Controls:1050<br>*shares cases and controls with AS 126 | Y |
| 188 | Inflammation and the risk of hormonally-linked cancer | Anc: Modugno<br>Whi: Kuller | Dropped | 07/01/07-06/30/10 | OS<br>Breast Cancer:500<br>Endometrial Cancer:500<br>Ovarian Cancer:350<br>Controls:1250<br>*Maximize case/control overlap with AS129. Extra 750 breast cancer cases for DNA analyses | Y |
| 189 | Biochemical and anthropometric heterogeneity among morbid obese women in the Women's Health Initiative Observational Study | Anc: Mackey<br>Whi: Kuller | Funded | 05/01/06-04/30/09 | OS<br>CHD:150<br>Controls:1300 | Y |
| 190 | Insulin resistance and vitamin D | Anc: Hsia<br>Whi: Hsia | Not Approved | | CaD<br>Insulin Resistance: | Y |
| 191 | Cytokines, hormones and sarcopenia in older women (includes AS199) | Anc: Chen<br>Whi: Bassford | Funded | 10/01/07-09/30/12 | OS<br>Sarcopenia:800<br>Controls:2000<br>*Identification of cases done in AS153, same info for carry over from 199 | Y |
| 192 | Estrogen and progesterone-related genes and colorectal cancer risk | Anc: Zhang<br>Whi: Manson | Funded | 07/01/06-08/31/10 | OS<br>Colorectal Cancer:644<br>Controls:1288<br>*Requests 10% blind duplicates (96 pairs) | Y |

**Table 11.1 (continued)**
**All Ancillary Studies**

| AS | Title | PIs | Status | Study dates | Study Population* | Blood Study |
|---|---|---|---|---|---|---|
| 193 | Immune dysregulation in the pathogenesis of non Hodgkin's lymphoma | Anc: DeRoos<br>Whi: LaCroix | Not Approved | | OS<br>Lymphoma, Non Hodgkins:500<br>Controls:1000<br>*300 OS cases, 600 OS controls; 200 CT cases, 400 CT controls | Y |
| 194 | Genetic epidemiology of hip fracture in WHI & SOF | Anc: Zmuda<br>Whi: Kuller | Not Approved | | OS<br>Fracture - Hip:700<br>Controls:1400 | Y |
| 195 | Candidate pathways in colorectal carcinogenesis: one-carbon metabolism and inflammation | Anc: Ulrich<br>Whi: Prentice | Submitted | 11/01/07-10/31/11 | OS<br>Colorectal Cancer:1000<br>Controls:1500<br>*Same cases/controls as AS 206 | Y |
| 196 | Heart failure evaluation in post-menopausal women: the Women's Health Initiative study | Anc: Klein<br>Whi: Van Horn | Funded | 07/01/07-06/30/08 | HRT | N |
| 197 | Validity of self-reported diabetes mellitus in the Women's Health Initiative | Anc: Margolis<br>Whi: Margolis | Funded | 07/01/07-06/30/09 | CT<br>224 Ppts@Minneapo | N |
| 198 | Women's thoughts and feelings about participating In a clinical trial | Anc: Furniss<br>Whi: Lasser | PO Approved | | HRT | N |
| 199 | Genetic factors of muscle loss (added to AS191) | Anc: Chen<br>Whi: Bassford | Funded | | OS<br>Sarcopenia:800<br>Controls:2000<br>*Combined with AS191 | Y |
| 200 | Women's Health Initiative cancer survivor cohort: biological, psychosocial, and behavioral predictors of survival | Anc: Paskett<br>Whi: Jackson | Not Approved | | OS<br>Breast Cancer:<br>*3129 OS cases and 498 CT cases - breast, colorectal, endometrial, and ovarian cancers | Y |
| 201 | Effect of hormone therapy on angiotensin II and microalbuminuria among postmenopausal women | Anc: Agarwal<br>Whi: Bonds | Not Approved | | HRT<br>Microalbuminuria:820<br>Controls:820<br>*120 samples for blood measurements | Y |

**Table 11.1 (continued)**
**All Ancillary Studies**

| AS | Title | PIs | Status | Study dates | Study Population* | Blood Study |
|---|---|---|---|---|---|---|
| 202 | Insulin/IGF and risk of benign bread disease (BBD): a cohort study | Anc: Rohan<br>Whi: Smoller | Not Approved | | CT<br>Benign Breast Disease:1000<br>Controls:1700 | Y |
| 203 | Infection of Helicobacter pylori, other Helicobacter species and the risk of pancreatic cancer among postmenopausal women | Anc: Ye<br>Whi: Margolis | Not Approved | | OS<br>Pancreatic Cancer:310<br>Controls:620<br>*420 CT (140 cases/280 controls, 510 OS (170 cases/ 340 controls) | Y |
| 204 | Genetic susceptibility of chronic kidney disease | Anc: Vupputuri<br>Whi: Heiss | Not Approved | | OS<br>Kidney Disease:2278<br>*CT 3836 (959 cases/ 2877controls); OS 5276 (1319 cases/3957 controls) | Y |
| 205 | Genome-wide scan of cardiovascular disease and breast cancer and combined postmenopausal hormone therapy | Anc: Prentice<br>Whi: Grimm | Tabled | | OS/CT<br>Breast Cancer: | Y |
| 206 | Selenium, genetic variation in selenoenzymes and colorectal cancer | Anc: Peters<br>Whi: Prentice | Funded | 07/01/06-06/30/09 | OS<br>Colorectal Cancer:805<br>Controls:805<br>*Same cases/controls as AS195; controls include 100 Y3 samples | Y |
| 207 | IGF and multiple myeloma | Anc: Colditz<br>Whi: Manson | Submitted | 08/01/07-05/31/10 | OS/CT<br>Multiple Myeloma:151<br>Controls:302 | Y |
| 208 | Proi and anti-inflammatory cytokines and colorectal cancer | Anc: Ho<br>Whi: Smoller | Submitted | 04/01/07-03/31/10 | OS<br>Colorectal Cancer:500<br>Controls:900<br>*same cases/controls as AS 129 | Y |
| 209 | Red blood cell omega-3 and trans fatty levels and the risk of coronary heart disease death | Anc: Harris<br>Whi: Wallace | Not Funded | 04/01/06-03/31/08 | OS<br>CHD:800<br>Controls:800 | Y |

**Table 11.1 (continued)**
**All Ancillary Studies**

| AS | Title | PIs | Status | Study dates | Study Population* | Blood Study |
|---|---|---|---|---|---|---|
| 210 | The effect of a low fat diet on lipid profiles and adipokines in post-menopausal women: potential modulation by select genetic variants | Anc: Thomson<br>Whi: Bassford | Not Approved | | DM | Y |
| 211 | Homocysteine levels, B vitamins and bone health in women | Anc: LeBoff<br>Whi: Manson | Expired | 12/01/07-11/30/10 | OS<br>Fracture (general):2500<br>Controls:2500<br>*2500 cases/2500 controls for EDTA plasma (B+Y3) and DNA; 400 cases/400 controls for serum and urine | Y |
| 212 | Biochemical antecedents of fracture in minority women (funded as BA09) | Anc: Cauley<br>Whi: Kuller | Dropped | 07/01/07-06/30/11 | OS<br>Fracture (general):1320<br>Controls:1320 | Y |
| 213 | Assays for early detection of cancer | Anc: Hendrix<br>Whi: Hendrix | Not Approved | | OS<br>Ovarian Cancer:200<br>Controls:200 | Y |
| 214 | A prospective study of pancreatic cancer pathogenesis - extension | Anc: Fuchs<br>Whi: Manson | Submitted | 07/01/07-06/30/12 | OS<br>Pancreatic Cancer:200<br>Controls:400 | Y |
| 215 | UGTs, NSAIDs, and breast cancer risk in the WHI Observational Study | Anc: Lampe<br>Whi: Prentice | Expired | 12/01/05-11/30/09 | OS<br>Breast Cancer:3398<br>Controls:3398<br>*all ppts diagnosed with breast cancer at least one year after their enrollment plus matched controls | Y |
| 216 | Decision-making about cancer screening among older women | Anc: Messina<br>Whi: Lane | Funded | 07/01/06-06/30/08 | OS/CT<br>1300 Ppts@Stonybrk | N |
| 217 | Validation of the self-report of rheumatoid arthritis and systemic lupus erythematosus: The Women's Health Initiative | Anc: Wallitt<br>Whi: Howard | Funded | 07/01/04-06/01/06 | CT | N |
| 218 | WHI nutrition and physical activity assessment study (NPAAS) | Anc: Prentice<br>Whi: Neuhouser | Funded | 07/12/06-06/30/09 | OS<br>84 Ppts@9 clinics | N |
| 219 | Diet and eye health in the WHI: end of trial study: pilot study | Anc: Mares<br>Whi: Sarto | Funded | 01/01/06-12/31/06 | DM<br>400 Ppts@Madison | N |

**Table 11.1 (continued)**
**All Ancillary Studies**

| AS | Title | PIs | Status | Study dates | Study Population* | Blood Study |
|---|---|---|---|---|---|---|
| 220 | Neighborhoods, women, and coronary heart disease: a prospective study | Anc: Bird<br>Whi: Margolis | Funded | 07/01/07-<br>04/30/10 | OS/CT<br>CHD: | N |
| 221 | Dietary modification, calcium/vitamin D supplementation, and change in breast density | Anc: Rohan<br>Whi: Smoller | Not Funded | 04/15/05-<br>04/14/10 | ppts in DM & CaD | N |
| 222 | Developmental research of air pollution as a cause of common cancers | Anc: DeRoos<br>Whi: LaCroix | Not Approved | | OS/CT | N |
| 223 | Women's Health Initiative cancer survivor cohort: biological, psychosocial, and behavioral predictors of survival: pilot study | Anc: Paskett<br>Whi: Jackson | Funded | 10/01/05-<br>09/01/07 | OS/CT | N |
| 224 | Genome-wide association study for nonsynonymous NSPs in colon cancer | Anc: Peters<br>Whi: Prentice | Funded | 07/02/07-<br>05/31/12 | OS<br>Colon cancer:930<br>Controls:930<br>*Shares controls and genotyping data with BA03 where possible. | Y |
| 225 | Potential gene-environment interaction on the association between chronic air pollution exposure and incident MI in the WHI-OS | Anc: Sullivan<br>Whi: Beresford | Not Approved | | OS | N |
| 226 | Ambient Air Pollution and Sleep Disturbance in Postmenopausal Women | Anc: Chen<br>Whi: Heiss | Submitted | 09/01/07-<br>08/31/12 | OS/CT | N |
| 227 | Risk factors and biomarkers for Parkinson's disease | Anc: Ascherio<br>Whi: Manson | Proposed | | OS/CT | Y |
| 228 | Obesity, diet, physical activity and medicare costs | Anc: Yan<br>Whi: Van Horn | PO Approved | 01/01/07-<br>12/31/11 | OS/CT | N |
| 229 | Genome wide, case-control analysis of SNP associations with cardiovascular disease in African American women | Anc: Carlson<br>Whi: LaCroix | Dropped | 09/20/06-<br>09/20/09 | OS<br>CHD:1825<br>Controls:1825 | Y |
| 230 | Markers of inflammation and renal function and hte risk of coronary heart disease and mortality in women with diabetes | Anc: Rajpathak<br>Whi: Smoller | Not Approved | 10/20/08-<br>10/20/10 | OS<br>CHD:764<br>Controls:1736<br>*note - he wants 764 CHD cases and 500 death cases, 382/250 of which respectively are baseline diabetes | Y |

**Table 11.1 (continued)**
**All Ancillary Studies**

| AS | Title | PIs | Status | Study dates | Study Population* | Blood Study |
|---|---|---|---|---|---|---|
| 231 | Relationship between circulating nutrient biomarkers and death from coronary heart disease or myocardial infarct | Anc: Lichtenstein<br>Whi: Van Horn | Proposed | 09/01/07-<br>08/31/09 | OS<br>CHD:1200<br>Controls:1200 | Y |
| 232 | Carotenoids and incidence and progression of age-related eye disease in women | Anc: Mares-Perlman<br>Whi: Sarto | Not Funded | 10/01/07-<br>08/31/09 | OS<br>Eye:500<br>Controls:1000 | Y |
| 233 | WHIMS (AS39) extension | Anc: Shumaker<br>Whi: Shumaker | Analysis | 12/13/03-<br>06/30/08 | HRT<br>2879 Ppts@31 clinics | N |
| 234 | Adipokines, inflammation and energy balance in postmenopausal women | Anc: Neuhouser<br>Whi: Prentice | Not Approved | 11/01/07-<br>10/31/10 | DM | 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<br>Whi: Kotchen | Funded | 11/01/06-<br>06/30/08 | CT | N |
| 236 | Choline/betaine habitual intake and chronic disease endpoints | Anc: Siega-Riz<br>Whi: Heiss | Funded | 10/01/07-<br>09/01/08 | OS/CT | N |
| 237 | The hypothalamic-pituitary-adrenal (HPA) axis and postmenopausal breast cancer risk | Anc: Dorgan<br>Whi: Lasser | Submitted | 04/01/08-<br>03/31/11 | OS<br>Breast Cancer:3992<br>Controls:3992 | Y |
| 238 | Genetic and biochemical predictors of Type 2 DM in women | Anc: Liu<br>Whi: Nathan | Submitted | 08/01/08-<br>07/31/11 | OS<br>Type 2 Diabetes:1800<br>Controls:2500 | Y |
| 239 | Biomarkers related to energy balance and renal cell cancer | Anc: Cho<br>Whi: Manson | Not Approved | 03/01/08-<br>02/28/12 | OS/CT<br>Renal Cancer:182<br>Controls:546 | Y |
| 240 | Microalbuminuria and cardiovascular risk in the WHI | Anc: Hsia<br>Whi: Hsia | Tabled | 02/01/07-<br>01/31/08 | OS/CT<br>CHD:5500<br>Controls:0 | Y |
| 241 | Dietary relationships to inflammatory bowel disease (IBD) in older women | Anc: Tamboli<br>Whi: Wallace | Not Approved | 04/01/07-<br>04/01/08 | OS | N |
| 242 | DNA repair, telomere length and cutaneous malignant melanoma | Anc: Han<br>Whi: Manson | Submitted | 01/01/08-<br>12/31/10 | OS<br>Melanoma - Skin:277<br>Controls:277 | Y |
| 243 | Validation of direct measures of physical activity: an ancillary study to the Women's Health Initiative (WHI) Nutrition and Physical Activity Assessment Study (NPAAS) | Anc: Sternfeld<br>Whi: Caan | Funded | 04/15/07-<br>12/31/08 | OS | N |

**Table 11.1 (continued)**
**All Ancillary Studies**

| AS | Title | PIs | Status | Study dates | Study Population* | Blood Study |
|---|---|---|---|---|---|---|
| 244 | Women's Health Initiative memory study epidemiology of cognitive health (WHIMS-ECOH) | Anc: Shumaker<br>Whi: Vitolins | D&A Approval | 10/01/07-09/30/12 | HRT | N |
| 245 | Ghrelin, adiposity-derived hormones, and colorectal cancer | Anc: Lin<br>Whi: Manson | Not Approved | 03/01/08-02/28/12 | OS<br>Colorectal Cancer:1000<br>Controls:1000 | Y |
| 246 | Prospective study of hormones, autoantibodies and biomarkers and risk of systemic lupus erythematosus in women | Anc: Costenbader<br>Whi: Manson | Not Approved | 07/01/08-06/01/13 | OS/CT<br>Death - other cause:547<br>Controls:1641 | Y |
| 247 | Genetic factors associated with the risk of Parkinson Disease in the multiethnic cohort of the WHI | Anc: Saunders-Pullman<br>Whi: Wassertheil-Smoller | Not Approved | 01/01/08-12/31/10 | OS/CT<br>Death - other cause:1376<br>Controls:450 | Y |
| 248 | Hormone therapy, changes in subpopulations of triglyceride-rich lipoproteins and HDL, and development of CHD in women. | Anc: Lamon-Fava<br>Whi: Wassertheil-Smoller | Not Approved | 07/01/08-06/30/12 | OS/CT<br>CHD:444<br>Controls:444 | Y |
| 249 | The epidemiology of alcohol metabolism genes, alcohol and Women's Health Outcomes | Anc: Freiberg<br>Whi: Kuller | Submitted | 07/01/08-06/30/13 | OS/CT<br>MI:1800<br>Benign Breast Disease:4500<br>Controls:10942 | Y |
| 250 | Genetic contributions to cognitive decline in normal and pathological aging in older post-menopausal women and modification by hormone therapy | Anc: Driscoll<br>Whi: Shumaker | Not Approved | 07/01/08-07/01/10 | HRT | Y |
| 251 | Acute cardiovascular events and air pollution | Anc: Whitsel<br>Whi: Heiss | PO Approved | 07/01/08-06/30/11 | OS/CT | N |
| 252 | Environmental determinants of cognitive aging in WHIMS | Anc: Chen<br>Whi: Heiss | Not Approved | 07/01/08-06/30/13 | CT | N |
| 253 | Serum selenium and pancreatic cancer risk | Anc: Stolzenberg<br>Whi: LaCroix | Proposed | | OS/CT | Y |
| 254 | Telomere and its biochemical and genetic regulators as predictors for clinical diabetes in women | Anc: Liu<br>Whi: Nathan | Proposed | 07/01/08-07/01/10 | OS/CT | Y |
| 255 | Androgens and CHD in women with type 2 diabetes | Anc: Rajpathak<br>Whi: Smoller | Proposed | 01/01/08-08/31/10 | OS | Y |

*Number of clinics includes number of satellite sites.

**Table 11.2**
**Broad Agency Announcement Activities**

| BAA | Title | PI | Institution |
|---|---|---|---|
| 1 | Ancestry Association Analyses of WHI Traits | Dr. Michael Seldin | University of California, Davis |
| 2 | High-Dimensional Genotype in Relation to Breast Cancer and WHI Clinical Trial Interventions | Dr. Ross Prentice | Fred Hutchinson Cancer Research Center |
| 3 | Genome-wide Association Study to Identify Genetic Components of Hip Fracture | Dr. Rebecca Jackson | Ohio State University Research Foundation |
| 4 | Proteomics and the Health Effects of Postmenopausal Hormone Therapy | Dr. Ross Prentice | Fred Hutchinson Cancer Research Center |
| 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 |
| 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 |
| 7 | Endogenous Estradiol and the Effects of Estrogen Therapy on Major Outcomes of WHI | Dr. Steve Cummings | California Pacific Medical Center |
| 8 | Predictive Value of Nutrient Biomarkers for CHD Death | Dr. Alice Lichtenstein | Tufts University |
| 9 | Biochemical Antecedents of Fracture in Minority Women | Dr. Jane Cauley | University of Pittsburgh |
| 10 | Adipokines and Risk of Obesity-Related Diseases | Dr. Gloria Ho | Albert Einstein College of Medicine |
| 11 | Physical Activity, Obesity, Inflammation and CHD in a Multi-Ethnic Cohort of Women | Dr. I-Min Lee | Brigham and Women's Hospital |
| 12 | Hormone Therapy, Estrogen Metabolism and Risk of Breast Cancer or Hip Fracture in the WHI Hormone Trial | Dr. Lewis Kuller | University of Pittsburgh |

**Table 11.3**
**Approved BAAs and Ancillary Studies Using Blood Specimens by Outcome**

| Disease | Ref ID # | Title | PIs | Status | Study Dates | Study Population | Blood Usage |
|---|---|---|---|---|---|---|---|
| Breast Cancer | 129 | Association of Diabetes and Insulin-Like Growth Factor-I (IGF-I) with Risks of Colorectal, Breast, and Endometrial Cancer | Anc: Strickler<br>WHI: Smoller | Complete | 02/01/02-12/31/05 | OS<br>Breast Cancer: 900<br>Colorectal Cancer: 500<br>Endometrial Cancer: 300<br>Controls: 900<br>*same as AS152 | Serum 0.6 ml: total estradiol, glucose; insulin, IGF free; IGFBP-3; IGF-I |
| Breast Cancer | 134 | Serum Estrogen Hormone Metabolites, Hormone Replacement Therapy and the Risk of Breast Cancer | Anc: Modugno<br>WHI: Kuller | Complete | 07/01/02-06/30/04 | OS<br>Breast Cancer: 200<br>Controls: 200 | Serum 0.25 ml: 16a-OH estrone; 2-OH estrone |
| Breast Cancer | 149 | Gene-Environment Interactions and Human Breast Cancer Risk | Anc: Hu<br>WHI: Paskett | Expired<br>Approval ends 6-04 | 06/01/04-05/31/06 | OS<br>Breast Cancer: 800<br>Controls: 800 | DNA 1 ug: SNPs of DNA repair genes with amino acid substitutions: X-ray repair cross complementing group 1 (XRCC1 Arg194Trp and Arg399Gln), X-ray repair cross complementing group 3 (XRCC3 Thr241Met), apurinic/apyrimidinic endonuclease (APE Asp148Glu), and xeroderma pigmentosum complementation groups D and F (XPD, Lys751GLU; XPF, Arg415Glu) |
| Breast Cancer | 152 | Growth Factor Genes and Female Breast, Colorectal, and Endometrial Cancers | Anc: Ho<br>WHI: Smoller | Funded | 08/01/03-07/31/07 | OS<br>Colorectal Cancer: 500<br>Endometrial Cancer: 300<br>Controls: 900<br>*Same as AS129 | DNA 3 ug: IGF-1; IGFBP-3; insulin, insulin receptor substrate 1; ERK1, ERK2, PIK3R1, AKT1, AKT2 |
| Breast Cancer | 155 | Carotenoids, Transforming Growth Factors, and Breast Cancer Risk | Anc: Rohan<br>WHI: Smoller | Dropped | | OS<br>Breast Cancer: 3,500<br>Controls: 3,500 | DNA 3 ug: polymorphisms in genes for TGF-beta 1 and 2 in genes for TGF-beta receptor types I and III<br>Serum 0.65 ml: Baseline (3,500) and AV3 (170) cases/controls: TGF-beta 1, carotenoids |
| Breast Cancer | 167 | Sex Hormones, Risk Factors, and Risk of ER+ and ER- Breast Cancer | Anc: Cummings<br>WHI: Cummings | Funded | 01/01/05-12/31/06 | OS<br>Breast Cancer: 400<br>Controls: 600 | Serum 0.95 ml: estradiol; free estradiol; bioavailable estradiol; SHBG; testosterone; free testosterone |
| Breast Cancer | 188 | Inflammation and the Risk of Hormonally-Linked Cancer | Anc Modugno<br>WHI: Kuller | Dropped | 07/01/07-06/30/10 | OS<br>Breast Cancer: 500<br>Endometrial Cancer: 500<br>Ovarian Cancer: 350<br>Controls: 1,250<br>Maximize case/control overlap with AS129. Extra 750 breast cancer cases for DNA analyses | DNA 1 ug: TNFa-308 (AA);IL-6 -597/-572/-373/-174;IL-1B-31 (TT); IL-1B-511 (TT); IL1RNVNTR*2; TGFa1 29 (CC); TGFaR1*6A; IL-10-1082/-819/-592 (GCC/GCC); Il-8-251-A-T; IGF-1 (CA)n 192/192<br>EDTA 0.35 ml: IL-1 cluster, IL-2, IL-4, IL-5, IL-6, IL-8, IL-10, IL-12p40, IL-13, IL-15, IL-17, TNFa, IFNs, FGF, GCSF, GMCSF, EGF, VEGF, MCP, MIPs, eot, sIL-6r I; sIL-2r; EGFR, and TNFa SRI and II; CRP<br>Serum 0.25 ml: estradiol |

**Table 11.3 (continued)**
**Approved BAAs and Ancillary Studies Using Blood Specimens by Outcome**

| Disease | Ref ID # | Title | PIs | Status | Study Dates | Study Population | Blood Usage |
|---|---|---|---|---|---|---|---|
| Breast Cancer | 215 | UGTs, NSAIDs, and Breast Cancer Risk in the WHI Observational Study | Anc: Lampe<br>WHI: Prentice | Expired<br>Approval ends 6-07 | 12/01/05-11/30/09 | OS<br>Breast Cancer: 3,398<br>Controls: 3,398<br>*all ppts diagnosed with breast cancer at least one year after enrollment | DNA 0.4 ug: UGT1A1*28, UGT1A3(W11R), UGT1A3(V47A), UGT1A3(M270V), UGT1A6*2, UGT1A6*3, UGT1A7*2, UGT1A7*3, UGT1A7*4, UGT1A8*2, UGT1A8*3, UGT1A9(T[10]), UGT1A9*3, UGT2B4(D458E), UGT2B7(H268Y), CYP2C9*2, CYP2C9*3 |
| Breast Cancer | 237 | The Hypothalamic-Pituitary-Adrenal (HPA) Axis and Postmenopausal Breast Cancer Risk | Anc: Dorgan<br>WHI: Lasser | Approved<br>Approval ends 11-09 | 04/01/08-03/31/11 | OS<br>Breast Cancer: 3,992<br>Controls: 3,992<br>*serum on subset of 1992 cases/controls | DNA 1 ug: NR3C1 (N363S, BclI, ER22/23EK, TthIII, htSNPs), FKBP5 (rs1360780, htSNPs), NR3C2 (htSNPs), CRH (AflIII, CviJI, BsmA1, XmnI, htSNPs) , CRHR1 (htSNPs), AVP (htSNPs), ARVPR1b (htSNPs), ADRA2A (C-1291G, htSNPs), GABRA6 (AlwNI, htSNPs), OPRM1 (A118G, htSNPs), POMC (C1032G, C8246T, C3755T, G-2353A, htSNPs), MC2R (SacI, htSNPs), CYP11A1 (5? UTR (tttta)n , htSNPs), StAR (htSNPs), CYP17A1 (T-34C, htSNPs), CYB5A (htSNPs), CYP21A2 (V281L, I172N, htSNPs), CYP11B1 (Nla111, BsoBI, G225A, htSNPs), CYP11B2 (C-344T, G5937A, A4550C, A2713G, Int2C, htSNPs), HSD11B1 (G-2940A, G94T, htSNPs), HSD11B2 (htSNPs), SERPINA6 (intron 1 (GTTT)n, htSNPs)<br>Serum 0.085 ml: DHEAS |
| Breast Cancer | BA02 | High-Dimensional Genotype in Relation to Breast Cancer and WHI Clinical Trial Interventions | BAA: Prentice | Funded | 01/15/07-01/14/09 | OS<br>Breast Cancer: 2,242<br>Controls: 2,242 | DNA 2 ug: 10,000 SNPs |
| Breast Cancer | BA04 | Proteomics and the Health Effects of Postmenopausal Hormone Therapy | BAA: Prentice | Funded | 01/15/07-01/14/09 | OS<br>Breast Cancer: 800<br>CHD: 800<br>Stroke: 800<br>Controls: 2,400 | EDTA 0.01 ml: proteomics<br>* Excludes breast cancer cases in BA05-Proteomics (PI Li) |
| Breast Cancer | BA05 | Identification and Validation of Circulating Biomarkers for the Early Detection of Breast Cancer in Pre-Clinical Specimens | BAA: Li | Funded | 01/15/07-01/14/09 | OS<br>Breast Cancer: 930<br>Controls: 930<br>*cases 6-19 months after Baseline or Year 3 blood draw | EDTA 0.35 ml: proteomics using 3 platforms |

**Table 11.3 (continued)**
**Approved BAAs and Ancillary Studies Using Blood Specimens by Outcome**

| Disease | Ref ID # | Title | PIs | Status | Study Dates | Study Population | Blood Usage |
|---|---|---|---|---|---|---|---|
| Breast Cancer | BA06 | Interaction Effects of Genes in the Inflammatory Pathway and Dietary, Supplement, and Medication Exposures on General Cancer Risk | BAA: Xu | Funded | 01/15/07-01/14/09 | OS<br>Breast Cancer: 841<br>Colorectal Cancer: 601<br>Lung Cancer: 558<br>Controls: 2,000<br>*Case and control: 500 each in Whites, up to 500 in Blacks | Citrate 0.25 ml: CRP, TNFalpha<br><br>DNA 3 ug: 9,000 SNPs in about 1,000 genes for immunity and inflamation |
| Breast Cancer | BA07 | Endogenous Estradiol and the Effects of Estrogen Therapy on Major Outcomes of WHI | BAA: Cummings | Funded | 01/15/07-01/14/09 | HT<br>Breast Cancer: 567<br>CHD: 753<br>Fracture - Hip: 227<br>Fracture-Spine: 204<br>PD/MCI: 310<br>Stroke: 534<br>VTE: 422<br>Controls: 830; Random 400, QA: 346 | Serum 0.65 ml: estradiol, SHBG<br>*Breast cancer: uses results from core study W10-HT Breast Cancer<br>*Hip fracture: uses results from core study W9-HT Hip Fracture |
| Breast Cancer | BA10 | Adipokines and Risk of Obesity-Related Disease | BAA: Ho | Funded | 01/15/07-01/14/09 | OS<br>Breast Cancer: 900<br>Colorectal Ca: 500<br>Endometrial Ca :300<br>Stroke: 970<br>Controls: 1,870<br>*Same as AS126 and AS129 | Citrate 0.2 ml: adiponectin, leptin, resistin, hepatocyte growth factor (HGF) on AS126 samples<br>Citrate 0.35 ml: adiponectin, leptin, resistin, hepatocyte growth factor (HGF); CRP, IL-6, TNFa, PAI-1 on AS129 samples |
| Breast Cancer | BA12 | Hormone Therapy, Estrogen Metabolism and Risk of Breast Cancer or Hip Fracture in the WHI Hormone Trial | BAA: Kuller | Funded | 01/15/07-01/14/09 | HT<br>Breast Cancer: 900<br>Fracture - Hip: 370<br>Controls: 1,800 | Serum 0.2 ml: 16a-OHE-1, 2-OHE-1 (Baseline + Year 3 for 1500 in HT active treatment arms, Baseline only for 1570 in HT placebo arms)<br>* Breast cancer controls from core study W10-HT Breast Cancer<br>* Hip fracture controls from core study W9-HT Hip Fracture |
| CHD | 083 | Thrombotic, Inflammatory and Genetic Markers for Coronary Heart Disease in Postmenopausal Women: A WHI Umbrella Study | Anc: Ridker<br>WHI: LaCroix | Complete | 09/01/99-08/31/03 | OS<br>CHD: 650<br>Controls: 650 | Citrate 1 ml: D-dimers; tPA<br>EDTA 1 ml: Lp(a); CRP; HDL-C; homocysteine; IL-6; LDL-C; sICAM; total cholesterol; triglyceride |

**Table 11.3 (continued)**
**Approved BAAs and Ancillary Studies Using Blood Specimens by Outcome**

| Disease | Ref ID # | Title | PIs | Status | Study Dates | Study Population | Blood Usage |
|---|---|---|---|---|---|---|---|
| CHD | 110 | Sex Steroid Hormones and Risk of Coronary Heart Disease: A Nested Case Control Study | Anc: Rexrode<br>WHI: Manson | Complete | 09/01/00-08/31/03 | OS<br>CHD: 385<br>Controls: 385<br>*79 matched case-control pairs and 92 cases (but not controls) overlap with AS83. | Citrate 1 ml: FVII Ag; FVIIC; fibrinogen<br>EDTA 1 ml: Lp(a); HDL-C; HDL-2; HDL-3; LDL-C; total cholesterol; triglyceride<br>Serum 1.25 ml: glucose; insulin; DHEAS; estradiol; estrone-sulfate; SHBG; testosterone |
| CHD | 137 | Postmenopause CHD Risk: Platelet Genes and Hormone Therapy | Anc: Bray<br>WHI: Hays | Funded | 09/27/03-08/31/07 | OS<br>CHD: 1,060<br>Controls: 2,120 | DNA 3 ug: GPIIIa (integrin beta3); integrin alpha2 (platelet GPIa); GPI b alpha; ER beta; ER alpha; alpha2-adrenergic receptor; beta 3 subunit of G protein; GPVI |
| CHD | 164 | The IGF System and Coronary Heart Disease | Anc: Kaplan<br>WHI: Smoller | Expired<br>Approval ends 6-05 | | OS<br>CHD: 350<br>Controls: 350 | Serum 0.2 ml: total IGF-I, IGFBP-3 |
| CHD | 165 | Subclinical Thyroid Dysfunction and Risk of Myocardial Infarction and Stroke | Anc: Hartmann<br>WHI: Heiss | Funded | 09/01/04-07/31/07 | OS<br>CHD: 800<br>Stroke: 591<br>Controls: 3,136 | Serum 0.3 ml: TSH on all samples<br>Serum 0.25 ml: Anti-thyroid peroxidase autoantibodies; free thyroxine on selected samples |
| CHD | 189 | Biochemical and Anthropometric Heterogeneity among Morbid Obese Women in the Women's Health Initiative Observational Study | Anc: Mackey<br>WHI: Kuller | Funded | 05/01/06-04/30/09 | OS<br>CHD: 150<br>Controls: 1,300 | EDTA 0.2 ml: NMR lipoproteins<br>Serum 0.57 ml: adiponectin; ghrelin; glucose; insulin; leptin |
| CHD | 209 | Red Blood Cell Omega-3 and Trans Fatty Levels and the Risk of Coronary Heart Disease Death | Anc: Harris<br>WHI: Wallace | Not Funded<br>Approval ends 10-07 | | Ppts: OS<br>CHD: 800<br>Controls: 800<br>*cases are CHD deaths | RBC 0.3 ml: EPA, DHA, ALA, trans fatty acids |
| CHD | 229 | Genome Wide, Case-Control Analysis of SNP Associations with Cardiovascular Disease in African American Women | Anc: Carlson<br>WHI: LaCroix | Not Funded<br>Approval ends 10-08 | 09/01/06-09/01/09 | OS<br>CHD: 1,825<br>Controls: 1,825 | DNA: 1 ug: affymetrix gene chip mapping 1 million SNP genotypes per sample |
| CHD | BA04 | Proteomics and the Health Effects of Postmenopausal Hormone Therapy | BAA: Prentice | Funded | 01/15/07-01/14/09 | OS<br>Breast Cancer: 800<br>CHD: 800<br>Stroke: 800<br>Controls: 2,400 | EDTA 0.01 ml: Proteomics<br>* Excludes breast cancer cases in BA05-Li proteomics study |

**Table 11.3 (continued)**
**Approved BAAs and Ancillary Studies Using Blood Specimens by Outcome**

| Disease | Ref ID # | Title | PIs | Status | Study Dates | Study Population | Blood Usage |
|---|---|---|---|---|---|---|---|
| CHD | BA07 | Endogenous Estradiol and the Effects of Estrogen Therapy on Major Outcomes of WHI | BAA: Cummings | Funded | 01/15/07-01/14/09 | HT<br>Breast Cancer: 567<br>CHD: 753<br>Fracture - Hip: 227<br>Fracture-Spine: 204<br>PD/MCI: 310<br>Stroke: 534<br>VTE: 422<br>Controls: 830; Random 400, QA: 346 | Serum 0.65 ml: estradiol, SHBG<br>*Breast cancer: uses results from core study W10-HT Breast Cancer<br>*Hip fracture: uses results from core study W9-HT Hip Fracture |
| CHD | BA08 | Predictive Value of Nutrient Biomarkers for CHD Death | BAA: Lichtenstein | Funded | 01/15/07-01/14/09 | OS<br>CHD: 1,200<br>Controls: 1,200 | Citrate 0.75 ml: PL fatty acid profile (PL EPA, PL DHA,PL TFA), phylloquinone (Vit K), 2,3-dihydrophylloquinone (dK) |
| CHD | BA11 | Physical Activity, Obesity, Inflammation and CHD in a Multi-Ethnic Cohort of Women | BAA: Lee | Funded | 01/15/07-01/14/09 | OS<br>CHD: 600<br>Controls: 1,200<br>*Baseline+Year 3: all Black, Hispanic, Asian, White up to 600 cases; 300 of each ethnicity for controls | EDTA 0.8 ml: CRP, IL-6, IL-1b, TNF-R1, TNF-R2, leptin, adiponectin, resistin, cholesterol, HDL, LDL, triglyceride, glucose |
| Colorectal Cancer | 108 | Gene-environment Effects and Colorectal Cancer | Anc: Lin<br>WHI: Chlebowski | Complete | 04/01/03-03/31/04 | OS<br>Colorectal Cancer: 50<br>Controls: 150 | DNA 1 ug: hematopoietic prostaglandin D synthase - val187ile; post-transcriptional gene silencing |
| Colorectal Cancer | 128 | Mismatch Repair Gene Associated Malignancies in Women | Anc: Weber<br>WHI: Smoller | Expired<br>Approval ends 9-03 | | OS<br>Colorectal Cancer: 1,025<br>Endometrial Cancer: 710<br>Ovarian Cancer: 405<br>Controls: 1,000 | DNA 3 ug/case: DNA mismatch repair genes: hMSH2, hMLH1, hMSH6. Experimental methods for cases: DHPLC, Automated DNA sequencing. 1 ug/control: Experimental methods for controls: pyrosequencing |
| Colorectal Cancer | 129 | Association of Diabetes and Insulin-Like Growth Factor-I (IGF-I) with Risks of Colorectal, Breast, and Endometrial Cancer | Anc: Strickler<br>WHI: Smoller | Complete | 02/01/02-12/31/05 | OS<br>Breast Cancer: 900<br>Colorectal Cancer: 500<br>Endometrial Cancer: 300<br>Controls: 900<br>*same as AS152 | Serum 0.6 ml: total estradiol, glucose; insulin, IGF free; IGFBP-3; IGF-I |

**Table 11.3 (continued)**
**Approved BAAs and Ancillary Studies Using Blood Specimens by Outcome**

| Disease | Ref ID # | Title | PIs | Status | Study Dates | Study Population | Blood Usage |
|---|---|---|---|---|---|---|---|
| Colorectal Cancer | 152 | Growth Factor Genes and Female Breast, Colorectal, and Endometrial Cancers | Anc: Ho<br>WHI: Smoller | Funded | 08/01/03-07/31/07 | OS<br>Breast Cancer: 900<br>Colorectal Cancer: 500<br>Endometrial Cancer: 300<br>Controls: 900 | DNA 3 ug: IGF-1; IGFBP-3; insulin, insulin receptor substrate 1; ERK1, ERK2, PIK3R1, AKT1, AKT2 |
| Colorectal Cancer | 192 | Estrogen and progesterone-related genes and colorectal cancer risk | Anc: Zhang<br>WHI: Manson | Funded | 07/01/06-06/30/10 | OS<br>Colorectal Cancer: 800<br>Controls: 1,600 | DNA 2 ug: ESR1 (PVII; Xbal); ESR2 (CA repeat; G1730A); PGR (G+331A); CYP1A1 (MspI; Ile462Val); CYP1B1 (Leu432Val; Asn453Ser); CYP17A1 (T-34C); CYP19A1 ([TTTA]n repeat; G240A); COMT (Val158Met); HSD17B2 (Ser312Gly); 100 SNPs for haplotype analyses |
| Colorectal Cancer | 195 | Candidate pathways in colorectal carcinogenesis: one-carbon metabolism and inflammation | Anc: Ulrich<br>WHI: Prentice | Submitted<br>Approval ends 6-07 | 03/01/06-02/28/11 | OS<br>Colorectal Cancer: 1,000<br>Controls: 1,500<br>*Same cases/controls as AS 206 | DNA 0.8 ug: Candidate polymorphisms in one-carbon metabolism (MTHFR, thymidylate synthase, reduced folate carrier, trifunctional enzyme, gamma-glutamyl-hydrolase, methionine synthase, methionine synthase reductase, serine hydroxyl-methyl-transferase, holo-transcobalamin II, DNA methyltransferase, alcohol dehydrogenase II) and in prostaglandin synthesis/pro-inflammatory cytokines (Cyclooxygenases 1 and 2, 5-Lipoxygenase, Prostacyclin synthase, TGFb, CRP, TNFa, IL-6); global DNA methylation<br>EDTA 0.85 ml: homocysteine, folate, pyridoxal-5-phosphate (vitamin B6), vitamin B12, and holotranscobalamin II<br>RBC 0.25 ml: RBC folate<br>Serum 0.25 ml: CRP, serum-amyloid A, creatinine |
| Colorectal Cancer | 206 | Selenium, Genetic Variation in Selenoenzymes and Colorectal Cancer | Anc: Ulrich<br>WHI: Prentice | Funded | 07/01/06-06/30/09 | OS<br>Colorectal Cancer: 805<br>Controls: 805 Baseline, 100 Y3<br>*Same cases/controls as AS195 | DNA: 0.8 ug: about 40 tagging polymorphisms in the following 6 selenoenzypes: GPX1, GPX2, GPX3, GPX4, TXNRD1, SEPP1<br>Serum 0.13 ml: selenium |
| Colorectal Cancer | 208 | Proinflammatory Markers and Colorectal Cancer | Anc: Ho<br>WHI: Smoller | Not Funded<br>Approval ends 7-07 | 04/01/07-03/31/10 | OS<br>Colorectal Cancer: 500<br>Controls: 900<br>*same cases/controls as AS 129 | DNA 1 ug: TNF, TNFRSF1A, TNFRSF1B, NFKBIB, NFKBIB, IKBKB, IL-1B, IL-1R1, IL-1RN, IL-6, IL-6ST, STAT3, IFNG, IFNGR2, STAT1<br>EDTA 0.55 ml: IL-1b, IFN-gamma, TNF-R1, TNF-R2, IL-1Ra |

**Table 11.3 (continued)**
**Approved BAAs and Ancillary Studies Using Blood Specimens by Outcome**

| Disease | Ref ID # | Title | PIs | Status | Study Dates | Study Population | Blood Usage |
|---|---|---|---|---|---|---|---|
| Colorectal Cancer | 224 | Genome-wide Association Study for Nonsynonymous NSPs in Colon Cancer | Anc: Peters<br>WHI: Prentice | Funded | 04/01/07-8/01/0 | OS<br>Colorectal Cancer: 930<br>Controls: 930 | DNA 1 ug: genome wide scan of 20,000 nonsynonymous SNPs |
| Colorectal Cancer | BA06 | Interaction Effects of Genes in the Inflammatory Pathway and Dietary, Supplement, and Medication Exposures on General Cancer Risk | BAA: Xu | Funded | 01/15/07-01/14/09 | OS<br>Breast Cancer: 841<br>Colorectal Cancer: 601<br>Lung Cancer: 558<br>Controls: 2,000<br>*Both case and control: 500 each in Whites, up to 500 in Blacks | Citrate 0.25 ml: CRP, TNFalpha<br>DNA 3 ug: 9,000 SNPs in about 1,000 genes for immunity and inflamation |
| Colorectal Cancer | BA10 | Adipokines and Risk of Obesity-Related Disease | BAA: Ho | Funded | 01/15/07-01/14/09 | OS<br>Breast Cancer: 900<br>Colorectal Ca: 500<br>Endometrial Ca :300<br>Stroke: 970<br>Controls: 1,870<br>*Same as AS126 and AS129 | Citrate 0.2 ml: adiponectin, leptin, resistin, hepatocyte growth factor (HGF) on AS126 samples<br>Citrate 0.35 ml: adiponectin, leptin, resistin, hepatocyte growth factor (HGF); CRP, IL-6, TNFa, PAI-1 on AS129 samples |
| Diabetes | 238 | Genetic and Biochemical Predictors of Type 2 DM in Women | Anc: Liu<br>WHI: Nathan | Approved<br>Approval ends 11-09 | 01/01/08-01/01/12 | OS<br>Diabetes Melitus: 1,800<br>Controls: 2,500 | DNA 1 ug: hormone-metabolizing genes (i.e., CYP19, AR, ESR1, and SHBG) and genes coding for adipokines (i.e., adiponectin, resistin, leptin, and leptin receptor)<br>EDTA 0.65 ml: total testosterone, free testosterone, SHBG, DHEAS, estradiol, leptin, leptin receptor, resistin, adiponectin<br>RBC 0.20 ml: HbA1c |
| Diabetes, Type 2 | 132 | A Prospective Study of Genetic and Biochemical Predictors of Type 2 Diabetes Mellitus | Anc: Liu<br>WHI: Manson | Funded | 08/01/02-07/30/07 | OS<br>Type 2 Diabetes: 1,800<br>Controls: 1,800 | DNA 3 ug: adiopocyte 2; calpain 10 gene; E-selectin 128Arg polymorphisms; NOS3; peroxisome proliferator activated receptor; TNFa G308A; uncoupling protein 2<br>EDTA 0.75 ml: CRP; E-selectin; glucose; insulin, IL-6; sICAM; TNFa; VCAM-1 |
| Diabetes, Type 2 | 180 | Macrovascular Complications of Diabetes in Postmenopausal Women | Anc: Li<br>WHI: Johnson | Expired<br>Approval ends 6-06 | | OS<br>Cases: 3,164 | DNA 1 ug: AGT, AGTR1, ACE, NOS3, GNB3, ADRB2, PPARG, RETN, TNF, UCP3 |

**Table 11.3 (continued)**
**Approved BAAs and Ancillary Studies Using Blood Specimens by Outcome**

| Disease | Ref ID # | Title | PIs | Status | Study Dates | Study Population | Blood Usage |
|---|---|---|---|---|---|---|---|
| Endometrial Cancer | 128 | Mismatch Repair Gene Associated Malignancies in Women | Anc: Weber<br>WHI: Smoller | Expired<br>Approval ends 9-03 | 04/01/04-03/31/08 | OS<br>Colorectal Cancer: 1,025<br>Endometrial Cancer: 710<br>Ovarian Cancer: 405<br>Controls: 1,000 | DNA 3 ug/case: DNA mismatch repair genes: hMSH2, hMLH1, hMSH6. Experimental methods for cases: DHPLC, Automated DNA sequencing. 1 ug/control: Experimental methods for controls: pyrosequencing |
| Endometrial Cancer | 129 | Association of Diabetes and Insulin-Like Growth Factor-I (IGF-I) with Risks of Colorectal, Breast, and Endometrial Cancer | Anc: Strickler<br>WHI: Smoller | Complete | 02/01/02-12/31/05 | OS<br>Breast Cancer: 900<br>Colorectal Cancer: 500<br>Endometrial Cancer: 300<br>Controls: 900<br>*same as AS152 | Serum 0.6 ml: total estradiol, glucose; insulin, IGF free; IGFBP-3; IGF-I |
| Endometrial Cancer | 152 | Growth Factor Genes and Female Breast, Colorectal, and Endometrial Cancers | Anc: Ho<br>WHI: Smoller | Funded | 08/01/03-07/31/07 | OS<br>Breast Cancer:900<br>Colorectal Cancer:500<br>Endometrial Cancer:300<br>Controls:900 | DNA 3 ug: IGF-1; IGFBP-3; insulin, insulin receptor substrate 1; ERK1, ERK2, PIK3R1, AKT1, AKT2 |
| Endometrial Cancer | 188 | Inflammation and the Risk of Hormonally-Linked Cancer | Anc: Modugno<br>WHI: Kuller | Dropped | 07/01/07-06/30/10 | OS<br>Breast Cancer: 500<br>Endometrial Cancer: 500<br>Ovarian Cancer: 350<br>Controls: 1,250<br>Maximize case/control overlap with AS129. Extra 750 breast cancer cases for DNA analyses | DNA 1 ug: TNFa-308 (AA);IL-6 -597/-572/-373/-174;IL-1B-31 (TT); IL-1B-511 (TT); IL1RNVNTR*2; TGFa1 29 (CC); TGFaR1*6A; IL-10-1082/-819/-592 (GCC/GCC); Il-8-251-A-T; IGF-1 (CA)n 192/192<br>EDTA 0.35 ml: IL-1 cluster, IL-2, IL-4, IL-5, IL-6, IL-8, IL-10, IL-12p40, IL-13, IL-15, IL-17, TNFa, IFNs, FGF, GCSF, GMCSF, EGF, VEGF, MCP, MIPs, eot, sIL-6r I; sIL-2r; EGFR, and TNFa SRI and II; CRP<br>Serum 0.25 ml: estradiol |
| Endometrial Cancer | BA10 | Adipokines and Risk of Obesity-Related Disease | BAA: Ho | Funded | 01/15/07-01/14/09 | OS<br>Breast Cancer: 900<br>Colorectal Ca: 500<br>Endometrial Ca :300<br>Stroke: 970<br>Controls: 1,870<br>*Same as AS126 and AS129 | Citrate 0.2 ml: adiponectin, leptin, resistin, hepatocyte growth factor (HGF) on AS126 samples<br>Citrate 0.35 ml: adiponectin, leptin, resistin, hepatocyte growth factor (HGF); CRP, IL-6, TNFa, PAI-1 on AS129 samples |

**Table 11.3 (continued)**
**Approved BAAs and Ancillary Studies Using Blood Specimens by Outcome**

| Disease | Ref ID # | Title | PIs | Status | Study Dates | Study Population | Blood Usage |
|---|---|---|---|---|---|---|---|
| Eye Disease | 105 | Carotenoids in Age-Related Eye Disease Study | Anc: Mares-Perlman<br>WHI: Sarto | Complete | 06/01/00-04/30/04 | OS<br>Eye: 1,350<br>Controls: 1,350 | Serum 0.6 ml: total cholesterol; triglyceride; alpha-carotene; beta-carotene (all trans, 13cis, 9cis-); cryptoxanthine (alpha + beta); lutein cis isomer 1, 2; and 3; lycopene (all trans, 13 cis, 15 cis, 5 cis, 9 cis- all trans; total [trans + cis]); retinol; tocopherol (total, alpha, delta, gamma); zeaxanthin; zeaxanthin cis isomer; retinyl palmitate;<br>12/04 add CRP, 25-OH Vit D |
| Eye Disease | 232 | Carotenoids and Incidence and Progression of Age-Related Eye Disease in Women | Anc: Mares-Perlman<br>WHI: Sarto | Submitted<br>Approval ends 7-09 | 10/01/07-09/30/12 | OS | DNA 1 ug: CFH, FB and PLEKHA1 gene variants |
| Fracture – General | 211 | Homocysteine Levels, B Vitamins and Bone Health in Women | Anc: LeBoff<br>WHI: Manson | Expired<br>Approval ends 7-07 | 12/01/07-11/30/10 | OS<br>Fracture (general): 2,500<br>Controls: 2,500<br>*2,500 cases/2,500 controls for EDTA plasma (B+Y3) and DNA; 400 cases/400 controls for serum and urine | DNA 1 ug: MTHFR C677T and A1298C; CBS G919A and T833C; MTR A2756; MTRR G66A<br>EDTA 0.55 ml: homocysteine<br>Serum 1.05 ml: BSAP, osteocalcin, OPG, RANKL, TRACP<br>Urine 0.55 ml: N-telopeptides |
| Fracture – General | 212 | Biochemical Antecedents of Fracture in Minority Women | Anc: Cauley<br>WHI: Kuller | Dropped | 07/01/07-06/30/11 | OS<br>Fracture (general): 1,320<br>Controls: 1,320 | EDTA 0.25 ml: PTH<br>Serum 1.1 ml: estradiol, testosterone, SHBG; 25-OH Vitamin D; PINP, CTx |
| Fracture – General | BA09 | Biochemical Antecedents of Fracture in Minority Women | BAA: Cauley | Funded | 01/15/07-01/14/09 | Ppts: OS<br>Fracture (general): 1,210<br>Controls: 1,210<br>*Exclude spine fx | EDTA 0.2 ml: PTH<br>Serum 1.92 ml: estradiol, testosterone, SHBG, Vit D, IGF, CTx, PINP, cystatin C, IL-6, TNFa-R1, TNFa-R2 |
| Fracture - Hip | BA07 | Endogenous Estradiol and the Effects of Estrogen Therapy on Major Outcomes of WHI | BAA: Cummings | Funded | 01/15/07-01/14/09 | HT<br>Breast Cancer: 567<br>CHD: 753<br>Fracture - Hip: 227<br>Fracture-Spine: 204<br>PD/MCI: 310<br>Stroke: 534<br>VTE: 422<br>Controls: 830; Random 400, QA: 346 | Serum 0.65 ml: estradiol, SHBG<br>*Breast cancer: uses results from core study W10-HT Breast Cancer<br>*Hip fracture: uses results from core study W9-HT Hip Fracture |

**Table 11.3 (continued)**
**Approved BAAs and Ancillary Studies Using Blood Specimens by Outcome**

| Disease | Ref ID # | Title | PIs | Status | Study Dates | Study Population | Blood Usage |
|---|---|---|---|---|---|---|---|
| Fracture – Hip | 090 | WHI Sex Hormone and Genetic Risk Factors for Hip Fracture | Anc: Cummings<br>WHI: Cummings | Funded | 04/01/04-03/31/07 | OS<br>Fracture – Hip: 400<br>Controls: 400<br>*same as AS181 | DNA 3 ug: apolipoprotein-E4; collagen Ialpha1 Sp1 polymorphism; TGF-Beta Leu10Pro; androgen receptor (AR); aromatase (CYP19); ESR1; ESR2; LDL receptor-related protein 5 (LRP5); SHBG;Vitamin D receptor start codon polymorphism (VDRFOK1)<br>Serum 1.35 ml: estradiol; IGF-I; SHBG; testosterone; cystatin-C; homocysteine, TSH |
| Fracture – Hip | 181 | Estradiol, Cytokines, and Bone Turnover: Effects on Hip Fracture | Anc: Cauley<br>WHI: Kuller | Funded | 07/01/05-06/30/08 | OS<br>Fracture – Hip: 400<br>Controls: 400<br>*same as AS90 | Serum 0.85 ml: 25-OH Vitamin D; PINP; CTx; IL-6; osteoprotegerin; TNFa SR1; TNFa SR2 |
| Fracture – Hip | BA01 | Ancestry Association Analyses of WHI Traits | BAA: Seldin | Funded | 01/15/07-01/14/09 | OS/CT<br>Fracture – Hip: 1,800<br>Controls: 1,800<br>*Hip fractures: Whites; 400 low/400 high BMD in Blacks;<br>all Blacks 14,618;<br>all Hispanics 6,484 | DNA 2 ug: Ancestry Informative Markers: 1,536 AIMS in Black low/high BMD; 768 AIMS in White hip fractures; 96 AIMS in Blacks and Hispanics |
| Fracture – Hip | BA03 | Genome-wide Association Study to Identify Genetic Components of Hip Fracture | BAA: Jackson | Funded | 01/15/07-01/14/09 | OS/CT<br>Fracture – Hip: 2,250<br>Controls: 2,250<br>*Stage I: 750 non-minority cases/controls, Stage II: 2,250 cases/controls | DNA 2.5 ug: Stage I: 317,000 haplotype tagging SNPs; Stage II: top 1% genes (about 3,000) |
| Fracture – Hip | BA12 | Hormone Therapy, Estrogen Metabolism and Risk of Breast Cancer or Hip Fracture in the WHI Hormone Trial | BAA: Kuller | Funded | 01/15/07-01/14/09 | HT<br>Breast Cancer: 900<br>Fracture - Hip: 370<br>Controls: 1,800 | Serum 0.2 ml: 16a-OHE-1, 2-OHE-1 (Baseline + Year 3 for 1,500 in HT active treatment arms, Baseline only for 1,570 in HT placebo arms)<br>* Breast cancer controls from core study W10-HT Breast Cancer<br>* Hip fracture controls from core study W9-HT Hip Fracture |
| Frailty-disability | 179 | Frailty in WHI: Drugs, Inflammatory and Genetic Markers | Anc: LaCroix<br>WHI: LaCroix | Funded | 09/15/05-07/31/08 | OS<br>Frailty: 900<br>Controls: 900 | Citrate 0.75 ml: D-dimers; FVIII act; fibrinogen; tPA<br>DNA 2 ug: ACE gene insertion (I) polymorphism; two promotor polymorphisms (-174G/C and -572G/C ) of the IL-6 gene<br>EDTA 0.3 ml: CRP; IL-6 |

**Table 11.3 (continued)**
**Approved BAAs and Ancillary Studies Using Blood Specimens by Outcome**

| Disease | Ref ID # | Title | PIs | Status | Study Dates | Study Population | Blood Usage |
|---|---|---|---|---|---|---|---|
| Hyperten-sion | 133 | Biochemical and Genetic Predictors of Incident Hypertension in White and Black Women | Anc: Sesso<br>WHI: Manson | Funded | 08/01/04-07/31/08 | OS<br>Hypertension: 800<br>Controls: 800 | DNA 2 ug: CRP, sICAM-1, IL-6, TNFa; IL-1b; MMP-9; adiponectin, PPAR-gamma2; TNF-R2<br>EDTA 0.85 ml: adiponectin, CRP; glucose, ICAM-1, IL-1b; IL-6; TNF-R2; HDL-C, total cholesterol |
| Leukemia | 148 | Relationship between Monoclonal Hemopoiesis and other Molecular Abnormalities and the Development of Leukemia in Older Women | Anc: Priesler<br>WHI: Black | Expired<br>Approval ends 8-04 | | OS<br>Leukemia: 59<br>Controls: 177 | DNA 3 ug: clonality of hemopoiesis, presence of N-ras mutation and methylation of the of p15 gene |
| Lung Cancer | 182 | Genetic and Epigenetic Markers of Lung Cancer Risk in Post-menopausal Women | Anc: Schlecht<br>WHI: Smoller | Submitted<br>Approval ends 7-08 | 04/01/07-03/30/10 | OS<br>Lung Cancer: 720<br>Controls: 1,440 | Citrate 0.3 ml: Folate, B12, B6, homocysteine<br>DNA 1 ug: Dnmt1; Dnmt3b; MSS; MS; MTHFR |
| Lung Cancer | BA06 | Interaction Effects of Genes in the Inflammatory Pathway and Dietary, Supplement, and Medication Exposures on General Cancer Risk | BAA: Xu | Funded | 01/15/07-01/14/09 | OS<br>Breast Cancer: 841<br>Colorectal Cancer: 601<br>Lung Cancer: 558<br>Controls: 2,000<br>*Both case and control: 500 each in Whites, up to 500 in Blacks | Citrate 0.25 ml: CRP, TNFalpha<br>DNA 3 ug: 9,000 SNPs in about 1,000 genes for immunity and inflamation |
| Multiple Myeloma | 207 | IGF and Multiple Myeloma | Anc: Colditz<br>WHI: Manson | Submitted<br>Approval ends 4-08 | 04/01/07 – | OS<br>Multiple Myeloma: 151<br>Controls: 302 | DNA 1 ug: htSNPs on 5 genes in IGF pathway; IGF1, IGF-1receptor, IGFBP-1, OGFBP-2, IGFBP-3<br>EDTA 0.7 ml: C-peptide, IGF-1, IGFBP-3, ALS, MGUS |
| Other – Blacks, Hispanics | BA01 | Ancestry Association Analyses of WHI Traits | BAA: Seldin | Funded | 01/15/07-01/14/09 | OS/CT<br>Fracture – Hip: 1,800<br>Controls: 1,800<br>*Hip fractures: Whites; 400 low/400 high BMD in Blacks;<br>all Blacks 14,618;<br>all Hispanics 6,484 | DNA 2 ug: Ancestry Informative Markers: 1,536 AIMS in Black low/high BMD; 768 AIMS in White hip fractures; 96 AIMS in Blacks and Hispanics |

**Table 11.3 (continued)**
**Approved BAAs and Ancillary Studies Using Blood Specimens by Outcome**

| Disease | Ref ID # | Title | PIs | Status | Study Dates | Study Population | Blood Usage |
|---|---|---|---|---|---|---|---|
| Other – BMD | BA01 | Ancestry Association Analyses of WHI Traits | BAA: Seldin | Funded | 01/15/07-01/14/09 | OS/CT<br>Fracture – Hip: 1,800<br>Controls: 1,800<br>*Hip fractures: Whites; 400 low/400 high BMD in Blacks;<br>all Blacks 14,618;<br>all Hispanics 6,484 | DNA 2 ug: Ancestry Informative Markers: 1,536 AIMS in Black low/high BMD; 768 AIMS in White hip fractures; 96 AIMS in Blacks and Hispanics |
| Ovarian Cancer | 097 | Modeling serum markers for cost-effective ovarian cancer screening | Anc: Anderson<br>WHI: Anderson | Funded | 09/30/01-06/30/09 | OS<br>Ovarian Cancer: 240<br>Controls: 480 | Serum 350 ul: cancer antigen 125; macrophage colony-stimulating factor; ovarian tumor marker |
| Ovarian Cancer | 121 | Hyperinsulinemia and Ovarian Cancer | Anc: Modugno<br>WHI: Kuller | Complete | 09/01/02-08/31/04 | OS<br>Ovarian Cancer: 225<br>Controls: 225 | Serum 0.5 ml: glucose; insulin; IGFBP-1; IGFBP-3; IGF-I |
| Ovarian Cancer | 128 | Mismatch Repair Gene Associated Malignancies in Women | Anc: Weber<br>WHI: Smoller | Expired<br>Approval ends 9-03 | 04/01/04-03/31/08 | OS<br>Colorectal Cancer: 1,025<br>Endometrial Cancer: 710<br>Ovarian Cancer: 405<br>Controls: 1,000 | DNA 3 ug/case: DNA mismatch repair genes: hMSH2, hMLH1, hMSH6. Experimental methods for cases: DHPLC, Automated DNA sequencing. 1 ug/control: Experimental methods for controls: pyrosequencing |
| Ovarian Cancer | 188 | Inflammation and the Risk of Hormonally-Linked Cancer | Anc: Modugno<br>WHI: Kuller | Dropped | 07/01/07-06/30/10 | OS<br>Breast Cancer: 500<br>Endometrial Cancer: 500<br>Ovarian Cancer: 350<br>Controls: 1,250<br>Maximize case/control overlap with AS129. Extra 750 breast cancer cases for DNA analyses | DNA 1 ug: TNFa-308 (AA);IL-6 -597/-572/-373/-174;IL-1B-31 (TT); IL-1B-511 (TT); IL1RNVNTR*2; TGFa1 29 (CC); TGFaR1*6A; IL-10-1082/-819/-592 (GCC/GCC); Il-8-251-A-T; IGF-1 (CA)n 192/192<br>EDTA 0.35 ml: IL-1 cluster, IL-2, IL-4, IL-5, IL-6, IL-8, IL-10, IL-12p40, IL-13, IL-15, IL-17, TNFa, IFNs, FGF, GCSF, GMCSF, EGF, VEGF, MCP, MIPs, eot, sIL-6r I; sIL-2r; EGFR, and TNFa SRI and II; CRP<br>Serum 0.25 ml: estradiol |
| Pancreatic Cancer | 146 | A Prospective Study of Pancreatic Cancer Pathogenesis | Anc: Fuchs<br>WHI: Manson | Complete | 03/01/03-12/31/04 | OS<br>Pancreatic Cancer: 106<br>Controls: 318 | DNA 3 ug: N-acetyltransferase-1; N-acetyltransferase-2; CYP1A1, GSTM1, MTHFR-667, MTHFR-1287<br>EDTA 0.7 ml: C-Peptide; Folate; Homocysteine; IGFBP-1; IGFBP-3; IGF-I; IGF-II; Insulin; Pyridoxal-5'-phosphate; Vitamin B12 |

**Table 11.3 (continued)**
**Approved BAAs and Ancillary Studies Using Blood Specimens by Outcome**

| Disease | Ref ID # | Title | PIs | Status | Study Dates | Study Population | Blood Usage |
|---|---|---|---|---|---|---|---|
| Pancreatic Cancer | 214 | A Prospective Study of Pancreatic Cancer Pathogenesis - Extension | Anc: Fuchs<br>WHI: Manson | Submitted<br>Approval ends 7-07 | 07/01/07-06/30/12 | OS<br>Pancreatic Cancer: 200<br>Controls:400 | DNA 1 ug: IRS1, IRS2, IGF1, IGF2, IGF1R, IGF2R, GH1, GHR, IGFBP1, IGFBP3, ACDC, IL1B, IL1RN, IL6, IL8, IL10, TNF, TGFB1, PPARD, NFKB1, NFKB1A, NFKBIL1, PTGS1, PTGS2, VDR<br>EDTA 1.3 ml: C-peptide, insulin, proinsulin, adiponectin, leptin, CRP, IL-6, TNFa-RII, H. pylori whole cell and CagA antibodies, gastrin, carotenoids, retinol, 25-OH Vitamin D<br>RBC 0.2 ml: Hb A1 |
| Probable Dementia/ Mild Cognitive Impair-ment (PD/MCI) | BA07 | Endogenous Estradiol and the Effects of Estrogen Therapy on Major Outcomes of WHI | BAA: Cummings | Funded | 01/15/07-01/14/09 | HT<br>Breast Cancer: 567<br>CHD: 753<br>Fracture - Hip: 227<br>Fracture-Spine: 204<br>PD/MCI: 310<br>Stroke: 534<br>VTE: 422<br>Controls: 830; Random 400, QA: 346 | Serum 0.65 ml: estradiol, SHBG<br>*Breast cancer: uses results from core study W10-HT Breast Cancer<br>*Hip fracture: uses results from core study W9-HT Hip Fracture |
| Sarco-penia | 191 and 199 | Cytokines, Hormones and Sarcopenia in Older Women | Anc: Chen<br>WHI: Bassford | Funded | 07/01/07-06/30/12 | OS<br>Sarcopenia: 800<br>Controls: 2,000<br>*Identification of cases done in AS153 | DNA 0.5 ug: IL-6 (3 marker SNPs and 1 minisatellite); IL1beta, IL1alpha, and IL1ra gene cluster (5 SNPs); TNF-alpha (4 sites); IGF-1 (8 tag snps); GH1 (3 SNPs)<br>EDTA .35 ml: CRP, insulin, leptin, acid labile subunit (ALS), IL-1a, IL-1b, IL-1ra, IL-6, IL-6sR, IL-10, TNFa, TNFRII, IGF-1, IGFBP-1, IGFBP-3 |
| Stroke | 126 | Stroke Risk Factors and Molecular Markers in Postmenopausal Women | Anc: Smoller<br>WHI: Smoller | Complete | 08/01/03-07/31/06 | OS<br>Stroke: 1,100<br>Controls: 1,100 | Citrate 1.25 ml: D-dimers; FVII Ag; FVIIC; fibrinogen; PAI-1 Ag; F1+2; TNFa; tPA<br>EDTA 1.52 ml: Lp-PLA2; HDL particles (total); HDL Size; HDL-C; IDL; LDL particles (total); LDL size; large HDL; large LDL; large VLDL/chylomicrons; medium HDL; medium small LDL; medium VLDL; small HDL; small LDL (total); small VLDL; triglyceride; VLDL particles (total); VLDL size; VLDL-TG; very small LDL; Lp(a); CRP; glucose; HDL-C; homocysteine; insulin; IL-6; neopterin; total cholesterol; triglyceride; VCAM-1<br>11-06: added adiponectin |

**Table 11.3 (continued)**
**Approved BAAs and Ancillary Studies Using Blood Specimens by Outcome**

| Disease | Ref ID # | Title | PIs | Status | Study Dates | Study Population | Blood Usage |
|---|---|---|---|---|---|---|---|
| Stroke | 165 | Subclinical Thyroid Dysfunction and Risk of Myocardial Infarction and Stroke | Anc: Hartmann<br>WHI: Heiss | Funded | 09/01/04-07/31/07 | OS<br>CHD: 800<br>Stroke: 591<br>Controls: 3,136 | Serum 0.3 ml: TSH<br>Serum 0.25 ml: anti-thyroid peroxidase autoantibodies; free thyroxine on selected samples |
| Stroke | 169 | Risk Factors for Hemorrhagic Stroke Among Postmenopausal Women | Anc: Kaplan<br>WHI: Smoller | Expired<br>Approval ends 6-06 | 04/01/06-07/30/10 | OS<br>Stroke: 357<br>Controls: 757 | Citrate 0.6 ml: fibrinogen, vWF; elastase, MMP-2, MMP-3, MMP-9, MMP-12, MMP activity, MMP-2/TIMP-1 complex (activated MMP2), MMP-9/TIMP-2 complex (activated MMP-9), TIMP-1<br>DNA 1 ug: ApoE<br>EDTA 0.95 ml: HDL-C, total cholesterol, LDL-C, triglycerides, glucose, CRP |
| Stroke | 187 | Serum Fatty Acids and Salicylic Acid in Relation to Incidence of Ischemic Stroke in Postmenopausal Women | Anc: He<br>WHI: Van Horn | Submitted<br>Approval ends 10-07 | 04/01/07-03/31/09 | OS<br>Stroke: 1,050<br>Controls: 1,050<br>shares cases and controls *with AS 126 | Serum 0.65 ml: fatty acids: myristic acid, palmitic acid, trans-elaidic acid, trans-linoleic acid; alpha-linolenic acid, eicosapentaenoic acid, docasahexaenoic acid; salicylic acid |
| Stroke | BA04 | Proteomics and the Health Effects of Postmenopausal Hormone Therapy | BAA: Prentice | Funded | 01/15/07-01/14/09 | OS<br>Breast Cancer: 800<br>CHD: 800<br>Stroke: 800<br>Controls: 2,400 | EDTA 0.01 ml: Proteomics<br>* Excludes breast cancer cases in BA05-Li proteomics study |
| Stroke | BA07 | Endogenous Estradiol and the Effects of Estrogen Therapy on Major Outcomes of WHI | BAA: Cummings | Funded | 01/15/07-01/14/09 | HT<br>Breast Cancer: 567<br>CHD: 753<br>Fracture - Hip: 227<br>Fracture-Spine: 204<br>PD/MCI: 310<br>Stroke: 534<br>VTE: 422<br>Controls: 830; Random 400, QA: 346 | Serum 0.65 ml: estradiol, SHBG<br>*Breast cancer: uses results from core study W10-HT Breast Cancer<br>*Hip fracture: uses results from core study W9-HT Hip Fracture |
| Stroke | BA10 | Adipokines and Risk of Obesity-Related Disease | BAA: Ho | Funded | 01/15/07-01/14/09 | OS<br>Breast Cancer: 900<br>Colorectal Ca: 500<br>Endometrial Ca :300<br>Stroke: 970<br>Controls: 1,870<br>*Same as AS126 and AS129 | Citrate 0.2 ml: adiponectin, leptin, resistin, hepatocyte growth factor (HGF) on AS126 samples<br>Citrate 0.35 ml: adiponectin, leptin, resistin, hepatocyte growth factor (HGF); CRP, IL-6, TNFa, PAI-1 on AS129 samples |

**Table 11.3 (continued)**
**Approved BAAs and Ancillary Studies Using Blood Specimens by Outcome**

| Disease | Ref ID # | Title | PIs | Status | Study Dates | Study Population | Blood Usage |
|---|---|---|---|---|---|---|---|
| VTE | BA07 | Endogenous Estradiol and the Effects of Estrogen Therapy on Major Outcomes of WHI | BAA: Cummings | Funded | 01/15/07-01/14/09 | HT<br>Breast Cancer: 567<br>CHD: 753<br>Fracture - Hip: 227<br>Fracture-Spine: 204<br>PD/MCI: 310<br>Stroke: 534<br>VTE: 422<br>Controls: 830; Random 400, QA: 346 | Serum 0.65 ml: estradiol, SHBG<br>*Breast cancer: uses results from core study W10-HT Breast Cancer<br>*Hip fracture: uses results from core study W9-HT Hip Fracture |

**Table 11.4**
**Recruitment to Ancillary Studies Requiring Separate Consents by Field Centers**
Data as of August 15, 2007

| | 9 | 15 | 34 | 36 | 39 | 62 | 65 | 68 | 84 | 98 | 100 | 103 | 105 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 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 Studyof Cognitive Aging(WHISCA) | Carotenoids in Age-Related Eye Disease Study |
| **Total** | **450** | **1468** | **311** | **857** | **7528** | **4430** | **101** | **735** | **546** | **969** | **797** | **2266** | **2007** |

**Table 11.4 (continued)**
**Recruitment to Ancillary Studies Requiring Separate Consents by Field Centers**
Data as of August 15, 2007

| | 117 | 130 | 153 | 178 | 197 | 216 | 218 | 219 | 233 | W25 | W30 | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Risk Factors for Dry Eye Syndrome in Postmenopausal Women | Randomized Controlled Trial of Fat Reduction, Calcium/ Vitamin 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 | WHI Coronary Artery Calcification Study in E-Alone | Dietary Assessment Study | |
| **Total** | **217** | **3901** | **47** | **793** | **224** | **1299** | **210** | **400** | **2879** | **1141** | **134** | **33710** |

**Table 11.5**
**Participant Enrollment in WHI Ancillary Studies**
**Requiring Separate Consents**

Data as of August 15, 2007

| CT+OS | | | |
|---|---|---|---|
| | **Ppts** | **%** | |
| CT+OS | 161808 | | |
| Not Enrolled in Ancillary Studies | 137849 | 85.19 | |
| Enrolled in Ancillary Studies | 23959 | 14.81 | |
| **Number of Studies** | **Ppts** | **%** | **Enrollments** |
| 1 | 17273 | 10.67 | 17273 |
| 2 | 4429 | 2.74 | 8858 |
| 3 | 1652 | 1.02 | 4956 |
| 4 | 536 | 0.33 | 2144 |
| 5 | 67 | 0.04 | 335 |
| 6 | 2 | 0.00 | 12 |
| **Total** | **23959** | **14.81** | **33578** |

| Extension | | | |
|---|---|---|---|
| | **Ppts** | **%** | |
| Consented to Extension | 115403 | | |
| Not Enrolled in Ancillary Studies | 95624 | 82.86 | |
| Enrolled in Ancillary Studies | 19779 | 17.14 | |
| **Number of Studies** | **Ppts** | **%** | **Enrollments** |
| 1 | 13798 | 11.96 | 13798 |
| 2 | 3838 | 3.33 | 7676 |
| 3 | 1546 | 1.34 | 4638 |
| 4 | 529 | 0.46 | 2116 |
| 5 | 66 | 0.06 | 330 |
| 6 | 2 | 0.00 | 12 |
| **Total** | **19779** | **17.14** | **28570** |

**Table 11.6**
**Ancillary Study and BAA PI List**

| Investigator | | PI for Ancillary Study # | Sponsoring WHI PI for Ancillary Study # | Supporting CCC PI for Ancillary Study # |
|---|---|---|---|---|
| Last Name | First Name | | | |
| Agarwal | Mamta | 201 | | |
| Allen | Catherine | 101 | 101 | |
| Anderson | Garnet | 97 | 97, 150 | 97, 121, 129, 140, 150, BA6, BA11 |
| Applegate | Bill | | 71 | |
| Ascherio | Albert | 227 | | |
| Assaf | Annlouise | | 123 | |
| Barnhart | Janice | 127 | | |
| Bassford | Tamsen | | 113, 153, 175, 184, 191, 199, 210 | |
| Baum | Marianna | | 58 | |
| Beresford | Shirley | 162 | 162, 225 | |
| Bird | Cloe | 220 | | |
| Black | Henry | | 148 | |
| Boe | Kathryn | 32 | | |
| Bonds | Denise | | 201 | |
| Bowen | Deborah | | 5, 18 | 39 |
| Bray | Paul | 137 | | |
| Brewer | Amy | 71 | | |
| Burke | Greg | | 1, 56, 139, 172 | |
| Burrows | Beth | 50 | | |
| Caan | Bette | | 243 | |
| Carlson | Chris | 229 | | |
| Cauley | Jane | 212, 161, 181, BA9 | | |
| Cerhan | James | 26 | | |
| Chae | Claudia | 173 | | |
| Chen | Chu | 199 | | 164 |
| Chen | Jiu-Chiuan | 252 | | |
| Chen | Zhao | 72, 82, 153, 184, 191, 226 | | |
| Chiu | Brian | 186 | | |
| Chlebowski | Rowan | 76, 99 | 20, 21, 76, 99, 108 | |
| Cho | Eunyong | 239 | | |
| Cochrane | Barbara | | | 110, 133, 134, 146, 149, 167, 182, 192, 196, 214, 223 |
| Cohen | Ellen | 125 | | |
| Colditz | Graham | 207 | | |
| Costenbader | Karen | 246 | | |
| Cottrell | Daryl | 96 | | |
| Coy | Christine | 118 | | |
| Criqui | Michael | 93 | | |
| Crouse | John | 1 | | |
| Cummings | Steve | 90, 167, BA7 | 90, 167 | |
| Curb | David | | 25, 95, 122 | |
| David | Sean | 123 | | |
| DeRoos | Anneclaire | 193, 222 | | |
| Detrano | Robert | 20, 21 | | |
| Dorgan | Joanne | 237 | | |
| Dorn | Joan | 141 | | |
| Driscoll | Ira | 250 | | |
| Dunn | Julie | 84 | | |
| Eng | Charis | 147 | | |
| Foreyt | John | 64 | 41, 51, 64, 66 | |

**Table 11.6 (continued)**
**Ancillary Study and BAA PI List**

| Investigator | | PI for Ancillary Study # | Sponsoring WHI PI for Ancillary Study # | Supporting CCC PI for Ancillary Study # |
|---|---|---|---|---|
| Last Name | First Name | | | |
| Fouad | Mona | 54, 78, 102 | | |
| Freeman | Ruth | 81 | | |
| Freiberg | Matthew | 249 | | |
| Fuchs | Charles | 146, 214 | | |
| Furniss | Kathleen | 198 | | |
| Garland | Cedric | 116, 154 | | |
| Gaziano | Michael | 29 | | |
| Glanz | Karen | 122 | | |
| Going | Scott | 14 | | |
| Goodman | William | 43 | | |
| Green | Pamela | 5 | | |
| Greenland | Phil | | 6, 16, 19, 44, 59 | |
| Grimm | Richard | | 22, 50, 88, 205 | |
| Grizzle | Jim | 18 | | |
| Haan | Mary | 62, 112, 114 | 112 | |
| Haines | Pam | 63 | | |
| Hakim | Iman | 113 | | |
| Han | Jiali | 242 | | |
| Handa | Victoria | 136 | | |
| Harris | Randall | 23 | | |
| Harris | William | 209 | | |
| Hartmann | Katherine | 165 | | |
| Hartz | Arthur | 35 | | |
| Hays | Jennifer | 100, 163 | 100, 137, 163 | |
| He | Ka | 187 | | |
| Heiss | Gerardo | | 36, 63, 70, 140, 165, 178, 204, 226, 236, 251, 252 | |
| Hendrix | Susan | 213 | 34, 87, 213 | |
| Herbert | James | 45 | 45 | |
| Herrington | David | 172 | | |
| Ho | Gloria | 152, 168, 174, 208, BA10 | | |
| Howard | Barbara | 92, 115 | 92, 115, 151, 217 | |
| Hsia | Judith | 42, 68, 190, 240 | 68, 190, 240 | |
| Hu | Jennifer | 106, 149 | | |
| Hubble | Allan | | 118 | |
| Hughes | Susan | 6 | | |
| Hulka | Barbara | 27, 36 | | |
| Hunt | Julie | | | 220, 226, 249 |
| Jackson | Rebecca | 94, BA3 | 23, 94, 117, 147, 200, 223, BA3 | |
| Jeffcoat | Marjorie | 9 | | |
| Johnson | Karen | | 180 | |
| Judd | Howard | | 43 | |
| Kabat | Geoffrey | 30, 53 | | |
| Kaplan | Robert | 142, 143, 159, 164, 169 | | |
| Kaufman | Joel | 150 | | |
| Kerner | David | 77 | | |
| Kerwin | Diana | 235 | | |
| Klein | Liviu | 196 | | |
| Kleinstein | Robert | 31 | | |
| Kooperberg | Charles | | | 90, 126, 169, BA10, BA12 |
| Kotchen | Jane | | 35, 235 | |

**Table 11.6 (continued)**
**Ancillary Study and BAA PI List**

| Investigator | | PI for Ancillary Study # | Sponsoring WHI PI for Ancillary Study # | Supporting CCC PI for Ancillary Study # |
|---|---|---|---|---|
| Last Name | First Name | | | |
| Kripke | Daniel | 11 | | |
| Kuller | Lew | 7, 157, BA12 | 2, 3, 7, 10, 13, 120, 121, 134, 145, 157, 161, 181, 188, 189, 194, 212, 249 | |
| LaCroix | Andrea | 179 | 179, 193, 222, 229, 253 | 83, 137, 153, 165, 179,181, 191, 199, 211, 212, 229, BA3, BA7, BA9 |
| Lamon-Fava | Stafania | 248 | | |
| Lampe | Johanna | 215 | | |
| Lane | Dorothy | | 216 | |
| Langer | Robert | 8, 119 | 8, 11, 24, 32, 47, 73, 77, 93, 116, 119, 124, 154 | |
| Lasser | Norm | | 12, 17, 198, 237 | |
| LeBlanc | Adrian | 51 | | |
| LeBoff | Meryl | 211 | | |
| Lee | I-Minn | BA11 | | |
| Lester | Gayle | 91 | | |
| Lewis | Beth | | 9, R1 | |
| Li | Rongling | 180, BA5 | | |
| Lichtenstein | Alice | 231, BA8 | | |
| Lin | Henry | 108 | | |
| Lin | Jennifer | 245 | | |
| Liu | James | 144 | | |
| Liu | Simin | 132, 238, 254 | | |
| Lund | Bernedine | | | 195, 206, 224 |
| Mackay | Meggan | 166 | | |
| Mackey | Rachel | 189 | | |
| Manson | JoAnn | 37, W25 | 29, 37, 38, 83, 89, 110, 131, 132, 133, 146, 173, 192, 207, 211, 214, 227, 242, 245, 246, BA11 | |
| Manson | JoAnn | 89 | 239 | |
| Mares | Julie | 219 | | |
| Mares-Perlman | Julie | 105, 232 | | |
| Margolis | Karen | 170, 197 | 170, 197, 203, 220 | |
| Masaki | Kamal | 25 | | |
| Mayo | Charlotte | 33 | | |
| McDermott | Mary | 16 | | |
| McTiernan | Anne | 52 | 52 | 36, 178 |
| Meilahn | Elaine | 10 | | |
| Melnikow | Joy | 104 | | |
| Messina | Catherine | 216 | | |
| Michael | Yvonne | 171 | | |
| Miller | Vallery | | 42 | |
| Modugno | Francesmary | 121, 134, 188 | | |
| Moon | Tom | | 14 | |
| Morrisett | Joel | 41, 66 | | |
| Mouton | Charles | 12, 17, 156 | | |
| Namie | Joylin | 124 | | |
| Nathan | Lauren | | 238, 254 | |
| Nelson | Dorothy | 34 | | |
| Neuhouser | Marian | 234 | 218 | 130, 162, 188, 207, 236, BA8 |

**Table 11.6 (continued)**
**Ancillary Study and BAA PI List**

| Investigator | | PI for Ancillary Study # | Sponsoring WHI PI for Ancillary Study # | Supporting CCC PI for Ancillary Study # |
|---|---|---|---|---|
| Last Name | First Name | | | |
| Nicholas | J. | 175 | | |
| Nichols | Kelley | 117 | | |
| Nordahl | Thomas | 85 | | |
| Nygaard | Ingrid | 135 | | |
| O'Sullivan | Mary Jo | | 67, 107 | |
| Ober | Beth | 61 | | |
| Oberman | Albert | 46 | 4, 31, 33, 46, 54, 60, 78, 102 | |
| Ockene | Judith | | 75 | |
| Orencia | Anthony | 19 | | |
| Parra-Medina | Deborah | | | |
| Paskett | Electra | 139, 200, 223 | 106, 149 | |
| Patterson | Ruth | | 177 | 65, 108, 128 |
| Peters | Ulrike | 206, 224 | | |
| Pisano | Etta | 178 | | |
| Pleuss | Joan | 56 | | |
| Polk | M.J. | 86 | | |
| Preisler | Harvey | 148 | | |
| Prentice | Ross | 205, 218, BA2, BA4 | 195, 206, 215, 224, 234 | 84, BA1, BA2, BA4, BA5 |
| Psaty | Bruce | 80 | 80 | |
| Rahmani | Yasmin | 49, 176 | 49 | |
| Rajpathak | Swapnil | 230 | | |
| Rahmani | Yasmin | 49, 176 | 49 | |
| Rajpathak | Swapnil | 230, 255 | | |
| Rexrode | Kathryn | 110 | | |
| Ridker | Paul | 38, 83 | | |
| Ritenbaugh | Cheryl | 57, 73, 185 | 57, 72, 82, 160, 171, 185 | |
| Robbins | John | | 61, 62, 104, 114, 136, BA1 | |
| Robinson | Jennifer | 22 | | |
| Rodriguez | Beatriz | 95 | | |
| Rohan | Tom | 65, 130, 155, 202, 221 | 65 | |
| Rosal | Milagros | 75 | | |
| Ruff | Coralese | 151 | | |
| Sarto | Gloria | | 105, 219, 232 | |
| Saunders-Pullman | Rachel | 247 | | |
| Schaeffer | Anthony | 44 | | |
| Schenken | Robert | | 86, 156 | |
| Schlecht | Nicolas | 182 | | |
| Schneider | Diane | 24 | | |
| Seldin | Michael | BA1 | | |
| Sesso | Howard | 133 | | |
| Shadick | Nancy | 131 | | |
| Sheps | David | 70 | 27 | |
| Shikany | James | R1, 4, 60 | | |
| Shumaker | Sally | 39, 103, 138, 183, 233, 244 | 39, 103, 138, 183, 233, 250 | |
| Siega-Riz | Anna Maria | 236 | | |
| Simon | Michael | 87 | | |

**Table 11.6 (continued)**
**Ancillary Study and BAA PI List**

| Investigator | | PI for Ancillary Study # | Sponsoring WHI PI for Ancillary Study # | Supporting CCC PI for Ancillary Study # |
|---|---|---|---|---|
| **Last Name** | **First Name** | | | |
| Smoller | Sylvia | 28, 40, 48, 126, | 28, 30, 40, 48, 53, 69, 79, 81, 125, 126, 127, 128, 129, 130, 142, 143, 152, 155, 158, 159, 164, 166, 168, 169, 174, 176, 182, 202, 208, 221, 230, 247, 248, 255, BA10 | |
| Sternfeld | Barbara | 243 | | |
| Stolzenberg | Rachael | 253 | | |
| Strickler | Howard | 129 | | |
| Subar | Amy | 177 | | |
| Sullivan | Jeffrey | 225 | | |
| Talavera | Gregory | 55 | 55 | |
| Tamboli | Cyrus | 241 | | |
| Thomson | Cynthia | 210 | | |
| Tinker | Lesley | 88 | | 105, 115, 132, 152, 180, 187, 189, 208, 209, 218, 219, 232, 237, 238, R1 |
| Trapido | Edward | 58 | | |
| Trevisan | Maurizio | | 15, 75, 98, 141 | |
| Ulrich | Cornelia | 195 | | |
| Valanis | Barbara | 160 | | |
| Van Horn | Linda | | 84, 186, 187, 196, 228, 231 | |
| Vitolins | Mara | 244 | | |
| Vogt | Molly | 13, 120 | | |
| Vupputuri | Suma | 204 | | |
| Wactawski-Wende | Jean | 15, 98 | | |
| Wallace | Robert | | 26, 135, 209, 241 | |
| Wallitt | Brian | 217 | | |
| Wang | C.Y. | | | 9 |
| Weber | Tom | 128 | | |
| Weissfeld | Joel | 2, 3 | | |
| Whitcomb | David | 145 | | |
| Whitsel | Eric | 140, 251 | | |
| Wodarski | Lois | 74 | | |
| Wylie-Rosett | Judith | 69, 79, 158 | | |
| Xu | Jianfeng | BA6 | | |
| Yan | Lijing | 228 | | |
| Ye | Weimin | 203 | | |
| Zakarija | Margita | 59, 67, 107 | | |
| Zhang | Shumin | 192 | | |
| Zmuda | Joseph | 194 | | |

**Table 12.1**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 1 | Informed consent in the Women's Health Initiative clinical trial and observational study | **McTiernan**, Rossouw, Manson, Franzi, Taylor, Carleton, Johnson, Nevitt | 11 | Gen | J Womens Health 1995;4(5):519-529 |
| 4 | The Women's Health Initiative: Overview of the nutrition component | **Tinker**, Burrows, Henry, Patterson, VanHorn, Rupp | 11 | Gen | Nutrition and Women's Health 1996;510-542 |
| 5 | Women's Health Initiative: Why now? What is it? What's new? | **Matthews**, Shumaker, Bowen, Langer, Hunt, Kaplan, Klesges, Ritenbaugh | 11 | Gen | Am Psychol 1997;52(2):101-116 |
| 6 | Low-fat diet practices of older women: Prevalence and implications for dietary assessment | **Patterson**, Kristal, Coates, Tylavsky, Ritenbaugh, VanHorn, Caggiula, Snetselaar | 11 | Gen | J Am Diet Assoc 1996;7:670-679 |
| 7 | The evolution of the Women's Health Initiative: Perspectives from the NIH | **Rossouw**, Finnegan, Harlan, Pinn, Clifford, McGowan | 11 | Gen | J Am Med Womens Assoc 1995;50(2):50-55 |
| 8 | Design of the WHI clinical trial and observational study: The WHI Study Group | **Prentice**, Rossouw, Furberg, Johnson, Henderson, Cummings, Manson, Freedman, Oberman, Kuller, Anderson | 11 | Gen | Control Clin Trials 1998;19:61-109 |
| 9 | Approaches to monitoring the results of long-term disease prevention trials: Examples from the Women's Health Initiative | **Freedman**, Anderson, Kipnis, Prentice, Wang, Rossouw, Wittes, DeMets | 11 | CT | Control Clin Trials 1996;Dec 17(6):509-525 |
| 11 | The role of randomized controlled trials in assessing the benefits and risks of long-term hormone replacement therapy: Example of the Women's Health Initiative | **Prentice**, Rossouw, Johnson, Freedman, McTiernan | 11 | CT | Menopause 1996;3(2):71-76 |
| 12 | Factors associated with insurance status among participants in the WHI | **Hsia**, Sofaer, Kiefe, Zapka, Bowen, Mason, Limacher, Pettinger, Lillington | 11 | Gen | J Womens Health Gend Based Med 2000;9(8):881-889 |
| 13 | Depression and cardiovascular sequelae in postmenopausal women | **Wassertheil-Smoller**, Shumaker, Ockene, Talavera, Greenland, Cochrane, Robbins, Aragaki, Dunbar | 11 | Gen | Arch Intern Med 2004;164:289-298 |

Status codes are found on page 11-51

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 16 | Differences between estimated caloric requirements and self-reported caloric intake in the WHI | **Hebert**, Patterson, Gorfine, Ebbeling, St. Jeor, Chlebowski | 11 | Gen | Ann Epidemiol 2003;13:1-9 |
| 17 | Sexual orientation and health: Comparisons in the Women's Health Initiative sample | **Valanis**, Bowen, Bassford, Whitlock, Charney, Carter | 11 | CT | Arch Fam Med 2000;9(9):843-53 |
| 19 | Ethnic, socioeconomic, and lifestyle correlates of obesity in U.S. women: The Women's Health Initiative | **Manson**, Lewis, Kotchen, Allen, Johnson, Stefanick, Foreyt, Klesges, Tinker, Noonan, Perri, Hall | 11 | Gen | Clin J Womens Health 2001;Dec 1(5):225-34 |
| 20 | Relation of demographic factors, menstrual history, reproduction and medication use to sex hormones in postmenopausal women | **McTiernan**, Wu, Barnabei, Chen, Hendrix, Modugno, Rohan, Stanczyk, Wang | 11 | CT | Breast Cancer Res Treat, 2007 May [Epub] |
| 21 | Hypertension and its treatment in postmenopausal women: Baseline data from the Women's Health Initiative | **Wassertheil-Smoller**, Anderson, Psaty, Black, Manson, Wong, Francis, Grimm, Kotchen, Langer, Lasser | 11 | OS | Hypertension 2000;36:780-789 |
| 22 | Pelvic organ prolapse in the WHI: Gravity and gravidity | **Hendrix**, Clark, Nygaard, Aragaki, Barnabei, McTiernan | 11 | CT | Am J Obstet Gynecol 2002;186:1160-6 |
| 24 | Estimation of the correlation between nutrient intake measures under restricted sampling | **Wang**, Anderson, Prentice | 11 | Gen | Biometrics 1999; 55:711-717 |
| 25 | Estrogen and progestin use and the QT interval in postmenopausal women | **Kadish**, Greenland, Limacher, Frishman, Daugherty, Parker, Schwartz | 11 | CT | Ann Noninvasive Electrocardiol 2004;9(4):366-74 |
| 26 | Special populations recruitment for the WHI: Successes and limitations | **Fouad**, Corbie-Smith, Curb, Howard, Mouton, Simon, Talavera, Thompson, Wang, White, Young | 11 | Gen | Control Clin Trials 2004;335-352 |
| 27 | The effects of insurance coverage and ethnicity on mammography utilization in a postmenopausal population | **Bush**, Langer | 11 | Gen | West J Med 1998;168:236-40 |
| 35 | Measurement characteristics of the WHI food frequency questionnaire | **Patterson**, Kristal, Carter, Tinker, Bolton, Agurs-Collins | 11 | Gen | Ann Epidemiol 1999;9(3):178-197 |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 40 | The health impact of domestic violence in older women | **Mouton**, Furniss, Lasser, Rovi | 11 | OS | J Womens Health Gend Based Med 1999;8(9):1173-1179 |
| 41 | Cross-sectional correlates of fasting hyperinsulinaemia in post-menopausal women of different ethnic origin | **Pradhan**, Manson, Hendrix, Johnson, Wagenknecht, Haan, Weidner, LaCroix, Cook | 11 | Gen | Diabet Med. 2006 Jan;23(1):77-85 |
| 43 | Sleep complaints of postmenopausal women | **Kripke**, Brunner, Freeman, Hendrix, Jackson, Masaki, Carter | 11 | CT | Clin J Womens Health 2001;1(5):244-252 |
| 51 | Relationship of social support and social burden to repeated breast cancer screening in the Women's Health Initiative | **Messina**, Lane, Glanz, Smith, Taylor, Frishman, Powell | 11 | Gen | Health Psychol 2004;23(6):582-594 |
| 55 | Factor structure and measurement invariance of the Women's Health Initiative insomnia rating scale | **Levine**, Kaplan, Kripke, Bowen, Naughton, Shumaker | 11 | Gen | Psychol Assess 2003;15(2):123-136 |
| 59 | Risk factors for kidney stones in postmenopausal women in the southern United States | **Hall**, Pettinger, Oberman, Watts, Johnson, Paskett, Limacher, Hays | 11 | Gen | Am J Med Sci 2001;322(1):1-7 |
| 60 | WHIMS: A trial of the effect of estrogen therapy in preventing and slowing the progression of dementia | **Shumaker**, Reboussin, Espeland, Rapp, McBee, Dailey, Bowen, Terrell, Jones | 11 | WHIMS | Control Clin Trials 1998;19:604-621 |
| 62 | Self-reported urogential symptoms in postmenopausal women: Women's Health Initiative | **Pastore**, Carter, Hulka, Wells | 11 | Gen | Maturitas 2004;49(4):292-303 |
| 63 | The importance of health insurance as a determinant of cancer screening: Evidence from the WHI | **Hsia**, Kemper, Kiefe, Zapka, Sofaer, Pettinger, Bowen, Limacher, Lillington, Mason | 11 | OS | Prev Med 2000;31:261-270 |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 66 | Walking compared with vigorous exercise for the prevention of cardiovascular events in women | **Manson**, Greenland, LaCroix, Stefanick, Mouton, Oberman, Perri, Sheps, Pettinger, Siscovick | 11 | OS | N Engl J Med 2002;347(10) |
| 67 | Yogurt consumption is associated with healthy behavior in postmenopausal women | **Mossavar-Rahmani**, Garland, Caan, Hebert, Wodarski, Vitolins, Himes, Parker | 11 | OS | Clin J Womens Health 2002;2(3):128-134 |
| 69 | Correlates of serum lypocene in older women | **Casso**, White, Patterson, Agurs-Collins, Kooperberg, Haines | 11 | CT | Nutr Cancer 2000;36:163-69 |
| 70 | Correlates of serum alpha- and gamma-tocopherol in the WHI | **White**, Kristal, Shikany, Wilson, Chen, Mares-Perlman, Masaki, Caan | 11 | CT | Ann Epidemiol 2001;11:136-144 |
| 71 | The Women's Health Initiative: Goals, rationale, and current status | **Liu** | 11 | Gen | Menopausal Medicine 1998;6(2):1-4 |
| 72 | Postmenopausal bone loss and its relationship to oral bone loss | **Jeffcoat**, Lewis, Reddy, Wang, Redford | 11 | Gen | Periodontol 2000; June23(1):94-102 |
| 76 | Differences in eating pattern labels between maintainers and nonmaintainers in the WHI | **Hopkins**, Burrows, Bowen, Tinker | 11 | CT | J Nutr Educ 2001;33:278-283 |
| 78 | Lack of a relationship between antioxidants and BMD: Results from the WHI | **Wolf**, Cauley, Stone, Nevitt, Simon, Jackson, LaCroix, Lewis, Wactawski-Wende, LeBoff | 11 | Gen | Am J Clin Nutr 2005;82:581-588 |
| 80 | Insulin resistance and weight gain in postmenopausal women of diverse ethnic groups | **Howard**, Adams-Campbell, Allen, Black, Pasaro, Rodriguez, Safford, Stevens, Wagenknecht, Snetselaar | 11 | Gen | Int Journal Obesity 2004;28(8):1039-1047 |
| 83 | Recreational physical activity and the risk of breast cancer in postmenopausal women | **McTiernan**, Kooperberg, White, Wilcox, Coates, Adams-Campbell, Woods, Ockene | 11 | Gen | JAMA 2003;290:1331-1336 |
| 84 | Research staff turnover and participant adherence in the WHI | **Jackson**, Berman, Huber, Snetselaar, Granek, Boe, Milas, Spivak, Chlebowski | 11 | CT | Control Clin Trials 2003;24:422-435 |
| 85 | The Women's Health Initiative: Rationale, design and progress report | **Johnson**, Anderson, Barad, Stefanick | 11 | CT | J of the British Menopause Society 1995;155-159 |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 86 | The effects of physical and emotional status on adherence to a low-fat dietary pattern in the Women's Health Initiative | **Tinker**, Perri, Patterson, Bowen, McIntosh, Parker, Sevick, Wodarski | 11 | CT | J Am Diet Assoc 2002;102:789-800 |
| 88 | Estimating normal hemogram values for postmenopausal women | **Assaf**, Carleton, Miller, Coccio | 11 | Gen | Clin J Womens Health 2000;1(1):23-28 |
| 91 | Compliance with national cholesterol education program dietary and lifestyle guidelines among older women with self-reported hypercholesterolemia: The WHI | **Hsia**, Rodabough, Rosal, Cochrane, Howard, Snetselaar, Frishman, Stefanick | 11 | OS | Am J Med 2002;113;384-92 |
| 92 | Comparison of self-report, hospital discharge codes, and adjudication of cardiovascular events in the WHI | **Heckbert**, Kooperberg, Safford, Psaty, Hsia, McTiernan, Gaziano, Frishman, Curb | 11 | Gen | Am J Epidemiol 2004;160:1152-1158 |
| 93 | Fat intake in husbands of participants in the dietary modification component of the Women's Health Initiative | **Shikany** | 11 | Gen | Nutr Res 2002;22:577-586 |
| 95 | The effects of widowhood on physical and mental health, health behaviors, and health outcomes: The Women's Health Initiative | **Wilcox**, Evenson, Aragaki, Wassertheil-Smoller, Mouton, Loevinger | 11 | OS | Health Psychol 2003;22(5):513-522 |
| 98 | Antioxidant supplement use in the Women's Health Initiative participants | **Shikany**, Patterson, Agurs-Collins, Anderson | 11 | Gen | Prev Med 2003;36(3):379-387 |
| 99 | Risk factor clustering in the insulin resistance syndrome and its relationship to cardiovascular disease in postmenopausal white, black, ` ispanic, and Asian/Pacific Islander women | **Howard**, Criqui, Curb, Rodabough, Safford, Santoro, Wilson, Wylie-Rosette | 11 | OS | Metabolism 2003;52(3):362-71 |
| 100 | Frequency and predictive value of a mammographic recommendation for short-interval follow-up | **Yasmeen**, Romano, Pettinger, Chlebowski, Robbins, Lane, Hendrix | 11 | Gen | JNCI 2003;95(6):429-436 |
| 102 | Association between cardiovascular outcomes and antihypertensive drug treatment in older women | **Wassertheil-Smoller**, Psaty, Greenland, Oberman, Kotchen, Mouton, Black, Aragaki, Trevisan | 11 | OS | JAMA 2004;292:2849-2859 |
| 103 | The Women's Health Initiative: Recruitment complete - looking back and looking forward (guest editorial) | **Rossouw**, Hurd | 11 | CT | J Womens Health 1999;8:3-5 |
| 104 | Promoting adherence and retention to clinical trials in special populations: A Women's Health Initiative workshop | **Wilcox**, Shumaker, Bowen, Naughton, Rosal, Ludlam, Dugan, Hunt, Stevens | 11 | Gen | Control Clin Trials. 2001 Jun;22(3):279-89 |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 105 | Retention of under-served women in clinical trials: a focus group study | **Johnson**, Williams, Nagy, Fouad | 11 | CT | Ethn Dis. 2003 Spring;13(2):268-78. |
| 107 | Vigorous leisure activity through women's adult life: The Women's Health Initiative | **Evenson**, Wilcox, Pettinger, Brunner, King, McTiernan | 11 | OS | Am J Epidemiol 2002;156:945-953 |
| 108 | Cross-sectional geometry, bone strength, and bone mass in the proximal femur in black and white postmenopausal women | **Nelson**, Barondess, Hendrix, Beck | 11 | CT | J Bone Miner Res 2000;15(10):1992-1997 |
| 109 | Recruitment of women to the WHI: The case of Embajadoras in Arizona | **Larkey**, Staten, Ritenbaugh, Hall, Buller, Bassford, Altimari | 11 | Gen | Control Clin Trials 2002;23:289-298 |
| 111 | Effects of fat content on fat hedonics: cognition or taste? | **Bowen**, Green, Vizenor, Vu, Kreuter, Rolls | 11 | OS | Physiol Behav. 2003 Feb;78(2):247-53. |
| 112 | Results of an adjunct dietary intervention program in the Women's Health Initiative | **Bowen**, Ehret, Pedersen, Snetselaar, Johnson, Tinker, Hollinger, Lichty, Sivertsen, Ocken, Staats, Beedoe | 11 | OS | J Am Diet Assoc 2002;102:1631-1637 |
| 113 | Prior oral contraception and postmenopausal fracture: A Women's Health Initiative observational cohort study | **Barad**, Kooperberg, Wactawski-Wende, Liu, Hendrix, Watts | 11 | Gen | Fertil Steril 2005; 84(2):374-383 |
| 115 | Prevalence and 3-year incidence of abuse among postmenopausal women | **Mouton**, Rodabough, Rovi, Hunt, Talamantes, Brzyski, Burge | 11 | OS | Am J Public Health 2004;94(4):605-612 |
| 120 | Obesity, body size, and risk of postmenopausal breast cancer: The Women's Health Initiative | **Morimoto**, White, McTiernan, Chlebowski, Hays, Stefanick, Margolis, Manson, Kuller, Chen, Muti, Lopez | 11 | OS | Cancer Causes Control 2002;13:741-751 |
| 122 | Does statin use reduce risk of osteoporotic fracture or improve bone density in postmenopausal women? Results from the Women's Health Initiative observational study | **LaCroix**, Cauley, Pettinger, Hsia, Bauer, McGowan, Chen, Lewis, McNeeley, Pasaro, Jackson | 11 | OS | Ann Intern Med 2003;129:97-104 |
| 126 | Influences on older women's adherence to a low-fat diet in the Women's Health Initiative | **Rosal**, Kearney, Ockene, Churchill | 11 | CT | Psychosom Med 2002;64(3):450-7 |
| 128 | Inflammatory biomarkers, hormone replacement therapy, and incident coronary heart disease: Prospective analysis from the Women's Health Initiative observational study | **Pradhan**, Manson, Rossouw, Siscovick, Mouton, Wallace, Jackson, Pettinger, Ridker | 11 | OS | JAMA 2002;288:980-987 |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 129 | Thrombotic markers for coronary heart disease in women | **Pradhan**, LaCroix, Trevisan, Lewis, Langer, Hsia, Oberman, Kotchen, Ridker | 11 | OS | Circulation 2004;110:292-300 |
| 130 | Cross-sectional analysis of association between hormone replacement therapy and thrombotic and inflammatory markers for CHD in women | **Langer**, Manson, LaCroix, Lewis, Hendrix, Rossouw, Pradhan, Ridker | 11 | OS | Thromb Haemost 2005;93:1108-16 |
| 132 | Association of nonmelanoma skin cancer with second malignancy: The Women's Health Initiative observational study | **Rosenberg**, Greenland, Khandekar, Ascensao, Lopez | 11 | Gen | Cancer 2004;100:130-138 |
| 134 | Additional self-monitoring tools in the dietary modification component of the Women's Health Initiative | **Mossavar-Rahmani**, Henry, Rodabough, Bragg, Brewer, Freed, Kinzel, Soule, Vosburg | 11 | CT | J Am Diet Assoc 2004;104:76-85 |
| 135 | Radiographic measurements, bone mineral density and the Singh Index in the proximal femur of white and African-American postmenopausal women | **Barondess**, Singh, Hendrix, Nelson | 11 | | Dis Mon. 2002 Oct;48(10):637-46. |
| 137 | Recruitment of hispanic women to the Women's Health Initiative: The case of Embajadoras in Arizona | **Larkey**, Staten, Ritenbaugh, Buller, Bassford, Altimari | 11 | | Control Clin Trials. 2002 Jun;23(3):289-98 |
| 138 | Baseline experience with the Modified Mini-Mental State exam: The Women's Health Initiative Memory Study | **Rapp**, Espeland, Hogan, Jones, Dugan | 11 | WHIMS | Aging Ment Health. 2003 May;7(3):217-23 |
| 139 | Cholesteryl ester transfer protein and lecithin:cholesterol acyltransferase activities in hispanic and anglo postmenopausal women: associations with total and regional body fat | **Greaves**, Going, Fernandez, Milliken, Lohman, Bassford, McNamara | 11 | OS | Metabolism. 2003 Mar;52(3):282-9. |
| 140 | Usefulness of prior hysterectomy as an independent predictor of Framingham Risk Score (The WHI) | **Hsia**, Barad, Margolis, Rodabough, McGovern, Limacher, Oberman, Wassertheil-Smoller | 11 | Gen | Am J Cardiol 2003;92:264-269 |
| 142 | Coronary artery calcification in black and white women | **Khurana**, Rosenbaum, Howard, Adams-Campbell, Detrano, Klouj, Hsia | 11 | OS | Am Heart J 2003;145:724-729 |
| 144 | Risk of cardiovascular disease by hysterectomy status, with and without oophorectomy: The WHI observational study | **Howard**, Kuller, Langer, Manson, Allen, Assaf, Cochrane, Larson, Lasser, Rainford, VanHorn, Stefanick, Trevisan | 11 | OS | Circulation 2005;111:1462-1470 |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 145 | Breast cancer and nonsteroidal anti-inflammatory drugs: Prospective results from the Women's Health Initiative | **Harris**, Chlebowski, Jackson, Frid, Ascensao, Anderson, Loar, Rodabough, White, McTiernan | 11 | OS | Cancer Res 2003;63:6096-6101 |
| 148 | Incidence of cytologial abnormalities on cervical cytology with aging in the WHI estrogen plus progestin trial | **Yasmeen**, Romano, Pettinger, Johnson, Hubbell, Lane, Hendrix | 11 | CT | Obstet Gynecol. 2006 Aug;108(2):410-9 |
| 149 | A community-based study of postmenopausal white women with back and leg pain: health status and limitations in physical activity | **Vogt**, Lauerman, Chirumbole, Kuller | 11 | OS | J Gerontol A Biol Sci Med Sci. 2002 Aug;57(8):M544-50. |
| 155 | Changes in food sources of dietary fat in response to an intensive low-fat dietary intervention: Early results from the Women's Health Initiative | **Patterson**, Kristal, Rodabough, Caan, Lillington, Mossavar-Rahmani, Simon, Snetselaar, VanHorn | 11 | CT | J Am Diet Assoc 2003;103(4):454-459 |
| 163 | Ethnicity and breast cancer: Factors influencing differences in incidence and outcome | **Chlebowski**, Chen, Anderson, Rohan, Aragaki, Lane, Dolan, Paskett, McTiernan, Hubbell, Adams-Campbell, Prentice | 11 | OS | JNCI 2005;97(6):439-448 |
| 164 | Leukocyte count as a predictor of cardiovascular events and mortality in postmenopausal women | **Margolis**, Manson, Greenland, Rodabough, Bray, Safford, Grimm, Howard, Assaf, Prentice | 11 | OS | Arch Intern Med 2005;165:500-508 |
| 166 | Habitual tea consumption and risk of osteoporosis: A prospective study in the WHI observational study | **Chen**, Pettinger, Ritenbaugh, LaCroix, Robbins, Caan, Barad, Hakim | 11 | OS | Am J Epidemiol 2003;158:772-781 |
| 169 | Reliability and validity of the Women's Health Initiative insomnia rating scale | **Levine**, Kaplan, Kripke, Bowen, Naughton, Shumaker | 11 | Gen | Psychol Assess. 2003 Jun;15(2):137-48 |
| 171 | Prevalence and correlates of panic attacks in postmenopausal women: Results from an ancillary study to the Women's Health Initiative | **Smoller**, Pollack, Wassertheil-Smoller, Barton, Hendrix, Jackson, Dicken, Oberman, Sheps | 11 | Gen | Arch Intern Med 2003;163:2041-2050 |
| 174 | Statin use and breast cancer: Prospective results from the Women's Health Initiative | **Cauley**, McTiernan, Rodabough, LaCroix, Bauer, Margolis, Paskett, Vitolins, Furberg, Chlebowski | 11 | OS | J Natl Cancer Inst. 2006 May 17;98(10):700-7 |
| 176 | Predicting Risk of Estrogen Receptor Positive Breast Cancers in Postmenopausal Women | **Chlebowski**, Anderson, Lane, Aragaki, Rohan, Yasmeen, Sarto, Rosenberg, Hubbell | 11 | Gen | In press, JNCI |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 177 | Validity of self-reports of fractures among postmenopausal women in a prospective study results from the Women's Health Initiative | **Chen**, Kooperberg, Pettinger, Bassford, Cauley, LaCroix, Lewis, Kipersztok, Borne, Jackson | 11 | Gen | Menopause 2004;11(3):264-274 |
| 179 | Progression and remission of pelvic organ prolapse: A longitudinal study of menopausal women | **Handa**, Garret, Hendrix, Gold, Robbins | 11 | CT | Am J Obstet Gynecol 2004;190:27-32 |
| 183 | Panic attacks, chest pain and ischemia in postmenopausal women | **Smoller**, Pollack, Wassertheil-Smoller, Brunner, Curb, Torner, Oberman, Hendrix, Hsia, Sheps | 11 | Gen | Psychosom Med. 2006 Nov-Dec;68(6):824-32. Epub 2006 Nov 13. |
| 186 | Physical activity and diabetes risk in postmenopausal women | **Hsia**, Wu, Allen, Oberman, Lawson, Torrens, Safford, Limacher, Howard | 11 | Gen | Am J Prev Med 2005;28(1):19-25 |
| 187 | Postmenopausal Hormone Therapy and Cardiovascular Disease | **Rossouw** | 11 | OS | Evidence Based Cardiology, 2nd Ed. S. Yusuf (Ed.): 2002 BMJ Press. |
| 188 | Electrocardiographic abnormalities that predict coronary heart disease events and mortality in postmenopausal women: The Women's Health Initiative | **Rautaharju**, Kooperberg, Larson, LaCroix | 11 | CT | Circulation. 2006 Jan 31;113(4):473-80 |
| 189 | Dietary adherence in the WHI dietary modification trial | **The Writing Group for the Women's Health Initiative Investigators** | 11 | CT | J Am Diet Assoc 2004;104(4):654-658 |
| 190 | Prevalence and determinants of electrocardiographic left ventricular hypertrophy among a multiethnic population of postmenopausal women (The Women's Health Initiative) | **Oberman**, Prineas, Larson, LaCroix, Lasser | 11 | CT | Circulation. 2006 Jan 31;113(4):473-80 |
| 192 | Bone mineral density of American Indian and Alaska Native women: Results from the Women's Health Initiative study | **Wampler**, Chen, Jacobsen, Henderson, Howard, Rossouw | 11 | Gen | Menopause 2005; 12(5):492-494 |
| 196 | Predictors of dietary change and maintenance in the Women's Health Initiative (WHI) Dietary Modification (DM) Trial | **Tinker**, Rosal, Young, Perri, Patterson, VanHorn, Assaf, Bowen, Ockene, Hays, Wu | 11 | CT | J Am Diet Assoc. 2007 Jul;107(7):1155-65. |
| 197 | Predictors of angina pectoris vs myocardial infarction from the WHI observational study | **Hsia**, Aragaki, Bloch, LaCroix, Wallace | 11 | OS | Am J Cardiol 2004;93(6):673-678 |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 198 | The Women's Health Initiative: Aspects of the management and coordination | **Cochrane**, Lund, Anderson, Prentice | 11 | Gen | Diversity in Health Care Research: Strategies for Multisite, Multidisciplinary and Multi-ethnic Projects. J. W. Hawkins, L. A. Haggerty (eds.): 2003 pp.181-207 Springer |
| 200 | Expression and ambivalence over expression of negative emotion: Psychometric analysis in the Women's Health Initiative | **Michael**, Perrin, O'Connor, Cochrane, Wisdom, Brzyski, Ritenbaugh | 11 | Gen | J Women Aging 2005;17(1/2):5-18 |
| 201 | Normal standards for QT and QT subintervals derived from a large ethnically diverse population of women aged 50 to 79 years (the Women's Health Initiative [WHI]) | **Rautaharju**, Prineas, Kadish, Larson, Hsia, Lund | 11 | Gen | Am J Cardiol. 2006 Mar 1;97(5):730-7. Epub 2006 Jan 11 |
| 202 | Depressive symptoms and heart rate variability in postmenopausal women: An ancillary study to the Women's Health Initiative | **Sheps**, Kim, McGorray, Bartholomew, Marsh, Dicken, Wassertheil-Smoller, Curb, Oberman, Barton, McMahon | 11 | Gen | Arch Intern Med 2005;165(11):1239-44 |
| 203 | Influence of estrogen plus progestin on breast cancer and mammography in healthy postmenopausal women | **Chlebowski**, Hendrix, Langer, Stefanick, Gass, Lane, Rodabough, Gilligan, Cyr, Thomson, Khandekar, Petrovich, McTiernan | 11 | CT | JAMA 2003;289:3243-3253 |
| 204 | Effect of estrogen plus progestin on stroke in postmenopausal women: The Women's Health Initiative: A randomized trial | **Wassertheil-Smoller**, Hendrix, Limacher, Heiss, Kooperberg, Baird, Kotchen, Curb, Black, Rossouw, Aragaki, Safford, Stein, Laowattana, Mysiw | 11 | CT | JAMA 2003;289(20):2673-84 |
| 206 | Fracture risk among breast cancer survivors | **Chen**, Maricic, Bassford, Pettinger, Ritenbaugh, Lopez, Barad, Gass, LeBoff | 11 | Gen | Arch Intern Med 2005;165:552-558 |
| 208 | The effects of estrogen plus progestin on the risk of fracture and bone mineral density: The Women's Health Initiative clinical trial | **Cauley**, Robbins, Chen, Cummings, Jackson, LaCroix, LeBoff, Lewis, McGowan, Neuner, Pettinger, Stefanick, Wactawski-Wende, Watts | 11 | CT | JAMA 2003;290:1729-1738 |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 209 | Obesity, hormone therapy, estrogen metabolism and risk of postmenopausal breast cancer | **Modugno**, Kip, Cochrane, Kuller, Klug, Rohan, Chlebowski, Lasser, Stefanick | 11 | OS | Int J Cancer. 2006 Mar 1;118(5):1292-301 |
| 210 | Estrogen plus progestin and the risk of coronary heart disease | **Manson**, Hsia, Johnson, Rossouw, Assaf, Lasser, Trevisan, Black, Heckbert, Detrano, Strickland, Wong, Crouse, Stein, Cushman | 11 | CT | N Engl J Med 2003;349:523-34 |
| 211 | Effects of estrogen plus progestin on health-related quality of life | **Hays**, Ockene, Brunner, Kotchen, Manson, Patterson, Aragaki, Shumaker, Brzyski, LaCroix, Granek, Valanis | 11 | CT | N Engl J Med 2003;348:1839-1854 |
| 212 | Effect of oestrogen plus progestin on the incidence of diabetes in postmenopausal women: Results from the WHI hormone trial | **Margolis**, Bonds, Rodabough, Tinker, Phillips, Allen, Bassford, Burke, Torrens, Howard | 11 | CT | Diabetologia 2004;47(7):1175-1187 |
| 216 | Effects of combination estrogen plus progestin hormone treatment on cognition and affect | **Resnick**, Maki, Rapp, Espeland, Brunner, Coker, Granek, Hogan, Ockene, Shumaker | 11 | CT | J Clin Endocrinol Metab. 2006 May;91(5):1802-10. Epub 2006 Mar 7 |
| 220 | The Women's Health Initiative: Implications for practice | **Furniss** | 11 | CT | Adv Nurse Pract. 2002 Nov;10(11):53-5. |
| 221 | Effects of estrogen plus progestin on gynecologic cancers and associated diagnostic procedures: The WHI randomized trial | **Anderson**, Judd, Kaunitz, Barad, Beresford, Pettinger, Liu, McNeeley, Lopez | 11 | CT | JAMA 2003;290:1739-1748 |
| 222 | Estrogen plus progestin and risk of venous thrombosis | **Cushman**, Kuller, Prentice, Rodabough, Psaty, Stafford, Sidney, Rosendaal | 11 | CT | JAMA 2004;292(13):1573-1580 |
| 224 | Estimation of dependence between paired correlated failure times in the presence of covariate measurement error | **Gorfine**, Hsu, Prentice | 11 | OS | J R Stat Soc [Ser B] 2003;65(3):633-661 |
| 225 | Estrogen plus progestin and the incidence of dementia and mild cognitive impairment in postmenopausal women: The Women's Health Initiative Memory Study: A randomized controlled trial | **Shumaker**, Legault, Rapp, Thal, Wallace, Ockene, Hendrix, Jones, Assaf, Jackson, Kotchen, Wassertheil-Smoller, Wactawski-Wende | 11 | CT | JAMA 2003;289:2651-2662 |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 226 | The effect of estrogen with progestin treatment on global cognitive function in postmenopausal women: Results from the Women's Health Initiative Memory Study | **Rapp**, Espeland, Shumaker, Henderson, Brunner, Manson, Gass, Stefanick, Lane, Hays, Johnson, Coker, Dailey, Bowen | 11 | CT | JAMA.2003;289:2663-2672 |
| 229 | Menopausal symptoms and treatment-related effects of estrogen and progestin in the WHI | **Barnabei**, Cochrane, Aragaki, Nygaard, Williams, McGovern, Young, Wells, O'Sullivan, Chen, Schenken, Johnson | 11 | CT | Obstet Gynecol 2005;105(5):1063-1073 |
| 230 | Use of electric blankets and association with prevalence of endometrial cancer | **Abel**, Hendrix, McNeeley, O'Leary, Mossavar-Rahmani, Johnson, Kruger | 11 | OS | Eur J Cancer Prev. 2007 Jun;16(3):243-50 |
| 232 | Women's Health Initiative: Statistical aspects and early results | **Prentice**, Anderson | 11 | Gen | Encyclopedia of Biostatistics, 2nd edition, Armitage P, Colton T, eds), 2005 |
| 233 | Estrogen plus progestin and colorectal cancer in postmenopausal women | **Chlebowski**, Wactawski-Wende, Ritenbaugh, Hubbell, Ascensao, Rodabough, Rosenberg, Taylor, Harris, Chen, Adams-Campbell, White | 11 | CT | N Engl J Med 2004;350:991-1004 |
| 234 | Postmenopausal hormone therapy and body composition: A substudy of the estrogen and progestin trial of the Women's Health Initiative | **Chen**, Bassford, Green, LeBoff, LaCroix, Margolis, Jackson, Cauley, Stefanick | 11 | CT | Am J Clin Nutr 2005;82:651-6 |
| 235 | Hormone replacement therapy and risk of cardiovascular disease: Implications of the results of the WHI | **Kuller** | 11 | CT | Arterioscler Thromb Vasc Biol 2003;23:11-16 |
| 237 | The Women's Health Initiative Study of Cognitive Aging (WHISCA): A randomized clinical trial of the effects of hormone therapy on age associated cognitive decline | **Resnick**, Coker, Maki, Rapp, Espeland, Shumaker | 11 | CT | Clinical Trials 2004; 1: 440-450 |
| 240 | Risks and benefits of estrogen plus progestin in healthy post-menopausal women: Principal results of the Women's Health Initiative randomized controlled trial. | **The Writing Group for the Women's Health Initiative Investigators** | 11 | CT | JAMA 2002;288(3):321-333 |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 242 | Estrogen deficiency symptom management in breast cancer survivors in the changing context of menopausal hormone therapy | **Chlebowski**, Kim, Col | 11 | CT | Semin Oncol 2003;30(6):776-88 |
| 243 | Combined postmenopausal hormone therapy and cardiovascular disease: Toward resolving the discrepancy between observational studies and the Women's Health Initiative clinical trial | **Prentice**, Langer, Stefanick, Howard, Pettinger, Anderson, Barad, Curb, Kotchen, Kuller, Limacher, Wactawski-Wende | 11 | CT | Am J Epidemiol 2005;162:404-414 |
| 246 | WHI response to Goodman, Goldzieher and Ayala's critique of the Women's Health Initiative report on the risks and benefits of estrogen plus progestin | **Hendrix**, Prentice | 11 | CT | Menopausal Medicine 2003;11:1-4 |
| 248 | Progression of coronary calcification in healthy postmenopausal women | **Hsia**, Klouj, Prasad, Burt, Adams-Campbell, Howard | 11 | OS | BMC Cardiovasc Disord 2004;4:21 |
| 249 | Effects of estrogen with and without progestin on urinary incontinence | **Hendrix**, Cochrane, Nygaard, Handa, Barnabei, Iglesia, Aragaki, Naughton, Wallace, McNeeley | 11 | CT | JAMA 2005;293:935-948 |
| 250 | Hormone therapy and age-related macular degeneration: the Women's Health Initiative Sight Exam Study | **Haan**, Klein, Klein, Deng, Hendrix, Seddon, Musch, Kuller, Hyman, Wallace | 11 | CT | Arch Ophthalmol. 2006 Jul;124(7):988-92. |
| 253 | Cardiovascular disease, its risk factors and treatment, and age-related macular degeneration: Women's Health Initiative Sight Exam ancillary study | **Klein**, Deng, Klein, Hyman, Seddon, Frank, Wallace, Hendrix, Kuppermann, Langer, Kuller, Brunner, Johnson, Thomas, Haan | 11 | CT | Am J Ophthalmol. 2007 Mar;143(3):473-83. Epub 2007 Jan 10. |
| 265 | Comparing SF-36 scores of participants in the Women's Healthy Eating and Living Study, Women's Health Initiative, and Medical Outcomes Study | **Yost**, Haan, Levine, Gold | 11 | Gen | Qual Life Res 2005;14:1251–1261 |
| 271 | Factors associated with treatment initiation after screening and diagnosis of osteoporosis | **Brennan**, Wactawski-Wende, Crespi, Dmochowski | 11 | CT | Am J Epidemiol 2004;160:475-483 |
| 272 | Effect of estrogen therapy on gallbladder disease | **Cirillo**, Wallace, Rodabough, Greenland, LaCroix, Limacher, Larson | 11 | CT | JAMA 2005;293(3):330-339 |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 273 | Effects of conjugated equine estrogen in postmenopausal women with hysterectomy. The Women's Health Initiative randomized controlled trial | **The Women's Health Initiative Steering Committee** | 11 | CT | JAMA 2004;291:1701-1712 |
| 274 | Association between self-reported alcohol intake and changes in cognition: Results from the Women's Health Initiative Memory Study (WHIMS) | **Espeland**, Gu, Masaki, Langer, Coker, Stefanick, Ockene, Rapp | 11 | CT | Am J Epidemiol 2005;161(3):228-238 |
| 277 | Estrogen plus progestin and the risk of peripheral arterial disease: The WHI | **Hsia**, Criqui, Rodabough, Langer, Resnick, Phillips, Allison, Bonds, Masaki, Caralis, Kotchen | 11 | CT | Circulation 2004;109(5):620-626 |
| 279 | Symptom experience after discontinuing use of estrogen plus progestin | **Ockene**, Barad, Cochrane, Larson, Gass, Manson, Barnabei, Lane, Brzyski, Rosal, Wylie-Rosette, Hays | 11 | CT | JAMA 2005;294(2):183-193 |
| 280 | Diet, physical activity, energy balance and endogenous sex hormone concentrations in the WHI | **McTiernan**, Wu, Chen, Chlebowski, Mossavar-Rahmani, Modugno, Perri, Stanczyk, VanHorn, Wang | 11 | CT | Obesity (Silver Spring). 2006 Sep;14(9):1662-77 |
| 282 | Improving dietary self-monitoring and adherence with hand-held computers: A pilot study | **Glanz**, Murphy, Moylan, Evensen, Curb | 11 | CT | Am J Health Promot. 2006 Jan-Feb;20(3):165-70 |
| 285 | Estrogen plus progestin influence on mammogram density in healthy postmenopausal women in the Women's Health Initiative | **McTiernan**, Martin, Peck, Pisano, Wang, Aragaki, Chlebowski | 11 | CT | J Natl Cancer Inst 2005; 97:1366-1376 |
| 287 | Prior hormone therapy and breast cancer risk in the Women's Health Initiative randomized trial of estrogen plus progestin | **Anderson**, Chlebowski, Rossouw, Rodabough, McTiernan, Margolis, Aggerwal, Curb, Hendrix, Hubbell, Khandekar, Lane, Lasser, Lopez, Potter | 11 | CT | Maturitas. 2006 Sep 20;55(2):103-15. Epub 2006 Jul 11 |
| 288 | Insulin, physical activity, and caloric intake in postmenopausal women: Breast cancer implications | **Chlebowski**, Pettinger, Stefanick, Howard, Mossavar-Rahmani, McTiernan | 11 | Gen | J Clin Oncol 2004;22:4507-4513 |
| 289 | Cutaneous melanoma in postmenopausal women following nonmelanoma skin carcinoma: The Women's Health Initiative observational study | **Rosenberg**, Khandekar, Greenland, Rodabough, McTiernan | 11 | OS | Cancer. 2006 Feb 1;106(3):654-63 |
| 294 | Weighted estimators for proportional hazards regression with missing covariates | **Qi**, Wang, Prentice | 11 | OS | J American Statistical Association 2005; |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 298 | The association between aspirin use and the incidence of colorectal cancer in women | **Allison**, Garland, Chlebowski, Criqui, Langer, Wu, Roy, McTiernan, Kuller | 11 | OS | Am J Epidemiol. 2006 Sep 15;164(6):567-75. Epub 2006 Jul 17 |
| 302 | Frailty: Emergence and consequences in women aged 65 and older in the WHI observational study | **Woods**, LaCroix, Gray, Aragaki, Cochrane, Brunner, Masaki, Murray, Newman | 11 | Gen | J Am Geriatr Soc 2005;53(8):1321-30 |
| 303 | Statin use and incident frailty in women ages 65 and older: Prospective findings from the Women's Health Initiative Observational Study | **LaCroix**, Gray, Aragaki, Cochrane, Newman, Kooperberg, Black, Curb, Greenland, Woods | 11 | Gen | In press, J Gerontol |
| 307 | Predictors of optical density of lutein and zeaxanthin in retinas of older women in the Carotenoids in Age-Related Eye Disease Study, an ancillary study of the Women's Health Initiative | **Mares-Perlman**, Snodderly, Gruber, Moeller, Ficek, Klein, Wooten, Johnson, Chappel | 11 | OS | Am J Clin Nutr 2006;84:1107-1122 |
| 317 | Pelvic organ prolapse in older women: Prevalence and risk factors | **Nygaard**, Bradley, Brandt | 11 | CT | Obstet Gynecol 2004;104(3):489-497 |
| 322 | Postmenopausal Hormone Therapy and Risk of Cardiovascular Disease by Age and Years Since Menopause | **Rossouw**, Prentice, Manson, Wu, Barad, Barnabei, Ko, LaCroix, Margolis, Stefanick | 11 | CT | JAMA. 2007 Apr 4;297(13):1465-77. |
| 323 | Vaginal wall descensus and pelvic floor symptoms in older women | **Bradley**, Nygaard | 11 | OS | Obstet Gynecol. 2005 Oct;106(4):759-66. |
| 324 | Mortality and cardiac and vascular outcomes in extremely obese women | **McTigue**, Larson, Valoski, Burke, Kotchen, Lewis, Stefanick, VanHorn, Kuller | 11 | OS | JAMA. 2006 Jul 5;296(1):79-86 |
| 325 | Association between alcohol intake and domain-specific cognitive function in older women. | **Espeland**, Coker, Wallace, Rapp, Resnick, Limacher, Powell, Messina | 11 | CT | Neuroepidemiology. 2006;27(1):1-12. Epub 2006 May 24 |
| 326 | The association between osteoporosis and alveolar crestal height in postmenopausal women | **Wactawski-Wende**, Hausmann, Hovey, Trevisan, Grossi, Genco | 11 | CT | J Periodontol. 2005 Nov;76(11 Suppl):2116-24. |
| 327 | Effects of a 7-yr low-fat, high carbohydrate diet on body weight in postmenopausal women: The Women's Health Initiative dietary modification trial | **Howard**, Manson, Stefanick, Beresford, Frank, Jones, Rodabough, Snetselaar, Thomson, Tinker, Vitolins, Prentice | 11 | CT | JAMA. 2006 Jan 4;295(1):39-49 |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 328 | Prospective study of leukocyte count as a predictor of incident breast, colorectal, endometrial, and lung cancer and mortality in postmenopausal women | **Margolis**, Rodabough, Thomson, Lopez, McTiernan | 11 | OS | In press, Arch Int Med |
| 331 | Pelvic floor symptoms and lifestyle factors in older women. | **Bradley**, Kennedy, Nygaard | 11 | CT | J Womens Health (Larchmt). 2005 Mar;14(2):128-36. |
| 332 | Conjugated equine estrogens and global cognitive function in postmenopausal women: The Women's Health Initiative Memory Study | **Espeland**, Rapp, Shumaker, Brunner, Manson, Sherwin, Hsia, Margolis, Hogan, Wallace, Dailey, Freeman, Hays | 11 | WHIMS | JAMA 2004;291:2959-2968 |
| 336 | Conjugated equine estrogens and incidence of probable dementia and mild cognitive impairment in postmenopausal women: WHIMS | **Shumaker**, Legault, Kuller, Rapp, Thal, Lane, Stefanick, Hendrix, Lewis, Masaki, Coker | 11 | WHIMS | JAMA 2004;291:2947-2958 |
| 341 | Race/ethnicity, socioeconomic status, and lifetime morbidity burden in the Women's Health Initiative: A cross-sectional analysis | **Gold**, Michael, Whitlock, Hubbell, Mason, Rodriguez, Safford, Sarto | 11 | Gen | J Womens Health (Larchmt). 2006 Dec;15(10):1161-73 |
| 342 | Body mass index is not a good predictor of bone density: results from WHI, CHS, and EPIDOS | **Robbins**, Schott, Azari, Kronmal | 11 | OS | J Clin Densitom. 2006 Jul-Sep;9(3):329-34. |
| 343 | Effects of conjugated equine estrogens on breast cancer and mammography screening in postmenopausal women with hysterectomy | **Stefanick**, Anderson, Margolis, Hendrix, Rodabough, Paskett, Lane, Hubbell, Assaf, Sarto, Schenken, Yasmeen, Lessin, Chlebowski | 11 | CT | JAMA. 2006 Apr 12;295(14):1647-57 |
| 344 | Postmenopausal hormone therapy does not influence hospitalization for non-specific chest pain or its prognosis | **Robinson**, Wallace, Cochrane, Ko, Limacher, Ockene, Wassertheil-Smoller, Blanchette | 11 | Gen | J Womens Health (Larchmt). 2006 Dec;15(10):1151-60 |
| 345 | CEE and coronary heart disease: The Women's Health Initiative | **Hsia**, Langer, Manson, Kuller, Johnson, Hendrix, Pettinger, Heckbert, Greep, Crawford, Eaton, Kostis, Caralis, Prentice | 11 | CT | Arch Intern Med. 2006 Feb 13;166(3):357-65 |
| 346 | Estrogen Plus Progestin and Breast Cancer Detection with Mammography and Breast Biopsy | **Chlebowski**, Anderson, Pettinger, Lane, Langer, Gilligan, Walsh, Chen, McTiernan | 11 | CT | Submitted to Archives of Internal Medicine |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 347 | Effect of CEE & estrogen plus progestin on stroke in the WHI | **Hendrix**, Wassertheil-Smoller, Johnson, Howard, Kooperberg, Rossouw, Trevisan, Aragaki, Baird, Bray, Buring, Criqui, Herrington, Rapp, Torner | 11 | CT | Circulation. 2006 May 23;113(20):2425-34. Epub 2006 May 15 |
| 348 | Effects of conjugated equine estrogen on health-related quality of life in postmenopausal women with hysterectomy: Results from the Women's Health Initiative randomized clinical trial | **Brunner**, Ockene, Aragaki, Assaf, Brzyski, Gass, Granek, LaCroix, Mason, Matthews, Wallace, Woods | 11 | CT | Arch Intern Med 2005;165:1976-1986 |
| 350 | Hormone therapy and risk of venous thrombosis in the Women's Health Initiative trial of estrogen alone in women without a uterus | **Curb**, Prentice, Bray, Langer, VanHorn, Barnabei, Bloch, Cyr, Gass, Lepine, Rodabough, Sidney, Uwaifo, Rosendaal | 11 | CT | Arch Intern Med. 2006 Apr 10;166(7):772-80 |
| 352 | Body Size, Weight Cycling, and Risk of Renal Cell Carcinoma among Postmenopausal Women: The Women's Health Initiative (United States) | **Luo**, Margolis, Adami, Lopez, Lessin, Ye | 11 | Gen | Am J Epidemiol. 2007 Oct 1;166(7):752-9. Epub 2007 Jul 5. |
| 354 | Effects of conjugated equine estrogen on risk of fractures and bone mineral density in postmenopausal women with hysterectomy: Results from the Women's Health Initiative randomized trial | **Jackson**, Wactawski-Wende, LaCroix, Pettinger, Yood, Watts, Robbins, Lewis, Beresford, Ko, Naughton, Satterfield, Bassford | 11 | CT | J Bone Miner Res. 2006 Jun;21(6):817-28 |
| 357 | Effect of conjugated equine estrogen in women without a uterus on the incidence of diabetes in postmenopausal women | **Bonds**, Lasser, Qi, Brzyski, Caan, Heiss, Limacher, Liu, Mason, Oberman, O'Sullivan, Phillips, Prineas, Tinker | 11 | CT | Diabetologia. 2006 Mar;49(3):459-68. Epub 2006 Jan 27 |
| 359 | Risk of fracture in women with type 2 diabetes: The Women's Health Initiative observational study | **Bonds**, Larson, Schwartz, Strotmeyer, Robbins, Rodriguez, Johnson, Margolis | 11 | OS | J Clin Endocrinol Metab. 2006 Sep;91(9):3404-10. Epub 2006 Jun 27 |
| 361 | Effect of hormone therapy on risk of hip and knee joint replacement in the Women's Health Initiative | **Cirillo**, Wallace, Wu, Yood | 11 | CT | Arthritis Rheum. 2006 Oct;54(10):3194-204 |
| 363 | Air pollution and cardiovascular disease incidence in the Women's Health Initiative observational study | **Miller**, Siscovick, Sheppard, Shepherd, Sullivan, Anderson, Kaufman | 11 | CT | N Engl J Med. 2007 Feb 1;356(5):447-58. |
| 367 | The Women's Health Initiative: A potential resource for future studies of autoimmune diseases | **Howard** | 11 | Gen | Autoimmunity 2004;37(4):265-268 |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 368 | Postmenopausal hormone therapy in relation to cardiovascular disease and cognition | **Prentice** | 11 | CT | Proceedings of the Forty Seventh Study Group of the Royal College of Obstetricians and Gynecologists, 2004 |
| 369 | A prospective study of inflammatory cytokines and diabetes mellitus in a multiethnic cohort of postmenopausal women. | **Liu**, Tinker, Song, Rifai, Bonds, Cook, Heiss, Howard, Hotamisligil, Hu, Kuller, Manson | 11 | OS | Arch Intern Med. 2007 Aug 13-27;167(15):1676-85 |
| 370 | Benchmarks for designing two-Status studies using modified mini-mental state examinations: Experience from the Women's Health Initiative Memory Study | **Espeland**, Rapp, Robertson, Granek, Murphy, Albert, Bassford | 11 | CT | Clin Trials. 2006;3(2):99-106 |
| 371 | Associations between intermediate age-related macular degeneration and lutein and zeaxanthin in the Carotenoids in Age-related Eye Disease Study (CAREDS): ancillary study of the Women's Health Initiative | **Moeller**, Parekh, Tinker, Ritenbaugh, Blodi, Wallace, Mares-Perlman | 11 | OS | Arch Ophthalmol. 2006 Aug;124(8):1151-62 |
| 373 | Conjugated equine estrogens and peripheral arterial disease risk: The Women's Health Initiative | **Hsia**, Criqui, Herrington, Manson, Wu, Heckbert, Allison, McDermott, Robinson, Masaki | 11 | CT | Am Heart J. 2006 Jul;152(1):170-6 |
| 376 | Markers of endothelial activation as predictors of type 2 diabetes mellitus in a multi-racial cohort of women | **Song**, Manson, Tinker, Rifai, Cook, Hu, Hotamisligil, Ridker, Rodriguez, Margolis, Oberman, Liu | 11 | OS | Diabetes. 2007 Jul;56(7):1898-904. Epub 2007 Mar 27. |
| 378 | Expression and ambivalence over expression of negative emotion: Cross-sectional associations with psychosocial factors and health-related quality of life in postmenopausal women | **Michael**, Wisdom, Perrin, Bowen, Cochrane, Brzyski, Ritenbaugh | 11 | Gen | J Women Aging. 2006;18(2):25-40. |
| 385 | Development of a glycemic index database for food frequency questionnaires used in epidemiologic studies | **Neuhouser**, Tinker, Thomson, Caan, VanHorn, Snetselaar, Parker, Patterson, Robinson, Beresford, Shikany | 11 | CT | J Nutr. 2006 Jun;136(6):1604-9 |
| 387 | Predictive role of the resting electrocardiogram in the WHI hormone therapy trial | **Denes**, Larson, Lloyd-Jones, Prineas, Greenland | 11 | CT | JAMA. 2007 Mar 7;297(9):978-85 |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 88 | Accuracy of commercial geocoding: assessment and implications | **Whitsel**, Quibrera, Smith, Catellier, Liao, Henley, Heiss | 11 | CT | Epidemiol Perspect Innov. 2006 Jul 20;3:8 |
| 398 | Osteoporosis and rate of bone loss among postmenopausal survivors of breast cancer: Results from a subcohort of WHI observational study | **Chen**, Maricic, Pettinger, Ritenbaugh, Lopez, Barad, Gass, LeBoff, Bassford | 11 | OS | Cancer 2005;104(7):1520-1530 |
| 409 | Clinical Risk Factors for Fractures in Multi-ethnic Women: The Women's Health Initiative | **Cauley**, Wu, Wampler, Barnhart, Allison, Chen, Jackson, Robbins | 11 | OS | J Bone Miner Res. 2007 Jul 16; [Epub ahead of print] |
| 414 | Prehypertension and cardiovascular disease risk in the Women's Health Initiative | **Hsia**, Margolis, Eaton, Wenger, Allison, Wu, LaCroix, Black | 11 | CT | Circulation. 2007 Feb 20;115(7):855-60 |
| 415 | GIS approaches for the estimation of residential-level ambient PM concentrations. | **Liao**, Peuquet, Duan, Whitsel, Dou, Smith, Lin, Chen, Heiss | 11 | CT | Environ Health Perspect. 2006 Sep;114(9):1374-80. |
| 417 | Impact of cyclooxygenase inhibitors in the Women's Health Initiative hormone trials: Secondary analysis of a randomized trial | **Hsia**, Manson, Kuller, Pettinger, Choe, Langer, Limacher, Oberman, Ockene, O'Sullivan, Robinson | 11 | CT | PLoS Clin Trials. 2006 Sep 29;1(5):e26 |
| 418 | Linear measurement error models with restricted sampling | **Gorfine**, Lipshtat, Freedman, Prentice | 11 | CT | Biometrics. 2007 Mar;63(1):137-42 |
| 421 | Associations of serum alpha tocopherol status, current supplemental vitamin E and past supplemental and dietary vitamin E with cognitive impairments in older women | **Dunn**, Weintraub, Stoddard, Banks | 11 | Gen | Neurology. 2007 Feb 27;68(9):670-6 |
| 423 | Combined analysis of Women's Health Initiative observational and clinical trial data on postmenopausal hormone treatment and cardiovascular disease | **Prentice**, Langer, Stefanick, Howard, Pettinger, Anderson, Barad, Curb, Kotchen, Kuller, Limacher, Wactawski-Wende | 11 | Gen | Am J Epidemiol. 2006 Apr 1;163(7):589-99. Epub 2006 Feb 16 |
| 428 | Association of pelvic organ prolapse and fractures in postmenopausal women: analysis of baseline data from the Women's Health Initiative Estrogen plus Progestin Trial | **Pal**, Hailpern, Santoro, Freeman, Barad, Kipersztok, Barnabei, Wassertheil-Smoller | 11 | Gen | Menopause. 2007 Aug 9; [Epub ahead of print] |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 429 | Can Biomarkers Identify Women at Increased Stroke Risk? The Women's Health Initiative Hormone Trials | **Kooperberg**, Cushman, Hsia, Robinson, Aragaki, Lynch, Baird, Johnson, Kuller, Beresford, Rodriguez | 11 | Gen | PLoS Clin Trials. 2007 Jun 15;2(6):e28 |
| 438 | Walking Speed And Risk Of Incident Ischemic Stroke Among Postmenopausal Women | **McGinn**, Kaplan, Verghese, LaCroix, Rosenbaum, Psaty, Baird, Lynch, Wolf, Kooperberg, Larson, Wassertheil-Smoller | 11 | Gen | In press, Stroke |
| 440 | Monitoring and reporting of the Women's Health Initiative randomized hormone therapy trials | **Anderson**, Kooperberg, Gellar, Rossouw, Pettinger, Prentice | 11 | CT | Clin Trials. 2007;4(3):207-17. |
| 441 | Effect of calcium and vitamin D supplementation on weight change in postmenopausal women: Results from the WHI clinical trial of CaD supplementation | **Caan**, Neuhouser, Aragaki, Lewis, Jackson, LeBoff, Margolis, Powell, Uwaifo, Whitlock, Wylie-Rosette, LaCroix | 11 | CT | Arch Intern Med. 2007 May 14;167(9):893-902 |
| 447 | Low-fat dietary pattern and risk of cardiovascular disease: The Women's Health Initiative randomized controlled dietary modification trial | **Howard**, VanHorn, Hsia, Manson, Stefanick, Wassertheil-Smoller, Kuller, LaCroix, Langer, Lasser, Lewis, Limacher, Margolis, Mysiw, et al | 11 | CT | JAMA. 2006 Feb 8;295(6):655-66 |
| 448 | Low-fat dietary pattern and risk of invasive breast cancer: The Women's Health Initiative randomized controlled dietary modification trial. | **Prentice**, Caan, Chlebowski, Patterson, Kuller, Ockene, Margolis, Limacher, Manson, Parker, Paskett, Phillips, Robbins, Rossouw, et al | 11 | CT | JAMA. 2006 Feb 8;295(6):629-42 |
| 449 | Low-fat dietary pattern and risk of colorectal cancer: The Women's Health Initiative randomized controlled dietary modification trial. | **Beresford**, Johnson, Ritenbaugh, Lasser, Snetselaar, Black, Anderson, Assaf, Bassford, Bowen, Brunner, Brzyski, Caan, Chlebowski, et al | 11 | CT | JAMA. 2006 Feb 8;295(6):643-54 |
| 450 | Calcium plus vitamin D supplementation and the risk for fractures | **Jackson**, LaCroix, Gass, Wallace, Robbins, Lewis, Bassford, Beresford, Black, Blanchette, Bonds, Brunner, Brzyski, Caan, et al | 11 | CT | N Engl J Med. 2006 Feb 16;354(7):669-83 |
| 451 | Calcium plus vitamin D supplementation and the risk of colorectal cancer | **Wactawski-Wende**, Kotchen, Anderson, Assaf, Brunner, O'Sullivan, Margolis, Ockene, Phillips, Pottern, Prentice, Robbins, Rohan, Sarto, et al | 11 | CT | N Engl J Med. 2006 Feb 16;354(7):684-96 |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 452 | Macular Pigment Density and Age-Related Maculopathy in the Carotenoids in Age-Related Eye Disease Study An Ancillary Study of the Women's Health Initiative | **LaRowe**, Mares-Perlman, Snodderly, Klein, Wooten, Chappell | 11 | CT | Ophthalmology. 2007 Sep 12; [Epub ahead of print] |
| 469 | Low-Fat Dietary Pattern and Invasive Cancer Incidence: Further Results from the Women's Health Initiative Dietary Modification Trial | **Prentice**, Thomson, Hubbell, Caan, Anderson, Lessin, Lane, Yasmeen, Singh, Khandekar, Shikany, Satterfield, Chlebowski, Beresford | 11 | CT | In press, J Natl Cancer Inst |
| 471 | Calcium/vitamin D supplementation and the risk of cardiovascular disease: The Women's Health Initiative randomized trial | **Hsia**, Heiss, Ren, Allison, Dolan, Greenland, Heckbert, Johnson, Manson, Sidney, Trevisan | 11 | CT | Circulation. 2007 Feb 20;115(7):846-54 |
| 486 | Insulin sensitivity and insulin secretion determined by homeostasis model assessment and risk of diabetes in a multiethnic cohort of women: the Women's Health Initiative Observational Study | **Liu**, Howard, Kuller, Manson, Nathan, Rifai, Song, Tinker | 11 | OS | Diabetes Care. 2007 Jul;30(7):1747-52. Epub 2007 Apr 27 |
| 493 | Panic attacks and risk of Incident cardiovascular events in postmenopausal women in the Women's Health Initiative observational study | **Smoller**, Pollack, Wassertheil-Smoller, Jackson, Oberman, Wong, Sheps | 11 | OS | In press, Arch Gen Psychiatry; Expected publication 10/07 |
| 495 | Natural history of pelvic organ prolapse in older women | **Bradley**, Zimmerman, Qi, Nygaard | 11 | CT | Obstet Gynecol. 2007 Apr;109(4):848-54 |
| 504 | A comparison of two dietary instruments for evaluating the fat-breast cancer relationship | **Freedman**, Potischman, Kipnis, Midthune, Schatzkin, Thompson, Troiano, Prentice, Patterson, Carroll, Subar | 11 | CT | Int J Epidemiol. 2006 Aug;35(4):1011-21. Epub 2006 May 3. |
| 506 | Estrogen therapy and coronary-artery calcification | **Manson**, Allison, Rossouw, Carr, Langer, Hsia, Kuller, Cochrane, Hunt, Ludlam, Pettinger, Gass, Margolis, Nathan, Ockene | 11 | CT | N Engl J Med. 2007 Jun 21;356(25):2591-602 |
| 508 | Alcohol and folate consumption and risk of benign proliferative epithelial disorders of the breast | **Cui**, Page, Chlebowski, Beresford, Hendrix, Lane, Rohan | 11 | CT | Int J Cancer. 2007 Sep 15;121(6):1346-51 |
| 509 | Cigarette smoking and risk of benign proliferative epithelial disorders of the breast in the Women's Health Initiative | **Cui**, Page, Chlebowski, Hsia, Hubbell, Johnson | 11 | CT | Cancer Causes Control. 2007 May;18(4):431-8. Epub 2007 Feb 24 |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 518 | Baseline Monograph - foreword | **Rossouw**, Anderson, Oberman | 11 | Gen | Ann Epidemiol 2003;13:S1-S4 |
| 519 | Baseline Monograph - Implementation of the WHI study design | **Anderson**, Manson, Wallace, Lund, Hall, Davis, Shumaker, Wang, Stein, Prentice | 11 | Gen | Ann Epidemiol 2003;13:S5-S17 |
| 520 | The WHI recruitment methods and results | **Hays**, Hunt, Hubbell, Anderson, Limacher, Allen, Rossouw | 11 | OS | Ann Epidemiol 2003;13:S18-S77 |
| 521 | The WHI postmenopausal hormone trials | **Stefanick**, Cochrane, Hsia, Barad, Liu, Johnson | 11 | Gen | Ann Epidemiol 2003;13:S78-S86 |
| 522 | The WHI DM trial: Overview and baseline characteristics of participants | **Ritenbaugh**, Patterson, Chlebowski, Caan, Tinker, Howard, Ockene | 11 | Gen | Ann Epidemiol 2003;13:S87-S97 |
| 523 | The WHI CaD trial: Overview and baseline characteristics of participants | **Jackson**, LaCroix, Cauley, McGowan | 11 | Gen | Ann Epidemiol 2003;13:S98-S106 |
| 524 | The WHI observational study: Baseline characteristics of participants and reliability of baseline measures | **Langer**, White, Lewis, Kotchen, Hendrix, Trevisan | 11 | OS | Ann Epidemiol 2003;13:S107-S121 |
| 525 | Outcomes ascertainment and adjudication methods in the WHI | **Curb**, McTiernan, Heckbert, Kooperberg, Stanford, Nevitt, Johnson, Proulx-Burns, Pastore, Criqui, Daugherty | 11 | Gen | Ann Epidemiol 2003;13:S122-S128 |
| 527 | Predictors of change in calcium intake in postmenopausal women after osteoporosis screening | **McLeod**, McCann, Horvath, Wactawski-Wende | 11 | OS | J Nutr. 2007 Aug;137(8):1968-73 |
| 538 | Electrocardiographic predictors of incident congestive heart failure and all-cause mortality in postmenopausal women: The Women's Health Initiative | **Rautaharju**, Kooperberg, Larson, LaCroix | 11 | CT | Circulation. 2006 Jan 31;113(4):481-9 |
| 542 | Recruitment and consent into a brain magnetic resonance study: Results from the Women's Health Initiative Memory Study Magnetic Resonance Imaging Study (WHIMS-MRI) | **Jaramillo**, Felton, Andrews, Desiderio, Hallarn, Jackson, Coker, Robinson, Ockene, Espeland | 11 | WHIMS | Acad Radiol. 2007 May;14(5):603-12 |
| 550 | Common genetic variation in calpain-10 gene (CAPN10) and diabetes risk in a multi-ethnic cohort of American postmenopausal women | **Song**, You, Hsu, Sul, Wang, Tinker, Eaton, Liu | 11 | OS | In press, Hum Mol Genet; [Epub 2007 Sep 12] |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 635 | Validation of the self-report of rheumatoid arthritis and systemic lupus erythematosus: The Women's Health Initiative | **Walitt**, Constantinescu, Katz, Weinstein, Wang, Khorana, Hsia, Howard | 11 | OS | In press, Arthritis Care Res |
| 652 | Bacterial species in subgingival plaque and oral bone loss | **Brennan**, Genco, Wilding, Hovey, Trevisan, Wactawski-Wende | 11 | OS | J Periodontol. 2007 Jun;78(6):1051-1061 |
| 701 | Statistical issues Arising in the Women's Health Initiative | **Prentice**, Pettinger, Anderson | 11 | Gen | Biometrics. 2005 Dec; 61:899-941 |
| 154 | The role of dietary proteins in the disposition to fractures: A prospective analysis of postmenopausal women from the Women's Health Initiative Observational Study | **Barzel**, Aragaki, Ritenbaugh, LeBoff, Wylie-Rosette | 10 | OS | |
| 195 | Predictors of calcium/Vitamin D supplementation adherence in the Women's Health Initiative | **Brunner**, Cauley, Snetselaar, Jackson, Cochrane, Granek, Wactawski-Wende | 10 | CT | Submitted, Control Clin Trials |
| 218 | Psychosocial effects of physical and verbal abuse among postmenopausal women | **Mouton**, Rodabough, Rovi, Brzyski, Katerndahl | 10 | OS | Submitted, J of Gerontology |
| 275 | Prior use of hormone therapy and incident Alzheimer's Disease in the Women's Health Initiative Memory Study (WHIMS) | **Henderson**, Hogan, Espeland, Curb, Freeman, Johnson, Rapp, Wassertheil-Smoller, Stefanick, Wactawski-Wende | 10 | CT | Submitted, Arch Intern Med |
| 312 | Accuracy of food portion estimation among postmenopausal women | **Coy**, Frank, Lee, Meyskens | 10 | CT | Submitted, Am J Clin Nutr |
| 337 | Joint analyses of clinical trial and observational study data on E+P use and cancers of the breast | **Prentice**, Anderson, Chlebowski, Hendrix, Hubbell, Kooperberg, Kuller, Lane, Langer, Manson, McTiernan, O'Sullivan, Stefanick | 10 | Gen | |
| 362 | Effects of Postmenopausal Hormone Therapy on Rheumatoid Arthritis: The Women's Health Initiative Randomized Controlled trials | **Walitt**, Pettinger, Weinstein, Katz, Torner, Wasko, Howard | 10 | CT | |
| 372 | Factors Associated with Five Year Risk of Hip Fracture in Postmenopausal Women: From the Women's Health Initiative | **Robbins**, Aragaki, Cauley, Chen, Jackson, Kooperberg, Lewis, Stefanick, Wactawski-Wende, Watts | 10 | OS | Submitted, JAMA |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 383 | Circulating levels of insulin/glucose/igf-axis proteins and risk of postmenopausal ovarian, peritoneal and fallopian tube cancers | **Modugno**, Kip, Shikany, Rohan, Monk, Williams, Rosen, Anderson, Kuller | 10 | OS | In revision |
| 404 | Fracture Risk Increases after Cancer Diagnosis in Postmenopausal Women: Results from the Women's Health Initiative | **Chen**, Maricic, Aragaki, Mouton, Arendell, Lopez, Bassford, Chlebowski | 10 | Gen | Submitted, Arch Intern Med |
| 456 | Is DXA a useful tool for assessing skeletal muscle mass in older women? | **Chen**, Wang, Lohman, Heymsfield, Outwater, Nicholas, Bassford, LaCroix, Sherrill, Going | 10 | Gen | Submitted |
| 475 | Calcium, Vitamin D Supplementation and Physical Function in the Women's Health Initiative | **Brunner**, Cochrane, Jackson, Larson, Lewis, Limacher, Rosal, Shumaker, Wallace | 10 | CT | Submitted, J Am Diet Assoc |
| 479 | Homocysteine Levels and Risk of Hip Fracture in Postmenopausal Women | **LeBoff**, Narweker, LaCroix, Wu, Jackson, Lee, Bauer, Cauley, Kooperberg, Lewis, Thomas, Cummings | 10 | OS | Submitted, JAMA |
| 501 | Health Risks and Benefits Three Years After Stopping Intervention in the WHI E+P Trial | **Heiss**, Wallace, Anderson, Aragaki, Brzyski, Gass, LaCroix, Rossouw, Stefanick, Jackson, Johnson, Kooperberg, Kotchen, Kuller, Lane | 10 | CT | Submitted, JAMA |
| 541 | Low-fat dietary pattern and risk of treated type 2 diabetes mellitus in postmenopausal women | **Tinker**, Bonds, Beresford, Howard, Manson, Margolis, Ockene, Parker, Perri, Robinson, Rodriguez, Safford, Stevens, Wenger | 10 | CT | Submitted, Arch Intern Med |
| 554 | Genetic variation in the mitochondrial uncoupling protein 2 is associated with type 2 diabetes in the Women's Health Initiative observational study | **Hsu**, Niu, Song, Manson, Tinker, Kuller, Liu | 10 | OS | Submitted, Hum Mol Genet |
| 563 | Cystatin-c and risk for hip fracture in postmenopausal women | **LaCroix**, Lee, Wu, Cauley, Shlipak, Ott, Robbins, Curb, LeBoff, Bauer, Jackson, Kooperberg, Cummings | 10 | OS | Submitted, N Engl J Med |
| 603 | Lipoprotein-associated phospholipase A2 (Lp-PLA2) and the risk of stroke in postmenopasaul women: The Women's Health Initiative observational study | **Wassertheil-Smoller**, Kooperberg, McGinn, Kaplan, Hsia, Hendrix, Manson, Berger, Kuller, Allison, Baird | 10 | OS | Submitted, JAMA |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 620 | Calcium plus vitamin D supplementation and the risk of incident diabetes mellitus in the Women's Health Initiative | **DeBoer**, Tinker, Connelly, Curb, Howard, Kestenbaum, Larson, Manson, Margolis, Siscovick, Uwaifo, Weiss | 10 | CT | Submitted, Diabetes Care |
| 39 | Hormone replacement therapy and dietary fat intake influence on blood lipids and insulin in postmenopausal women | **Chlebowski**, Sparks, Stefanick, Howard, Mossavar-Rahmani, McTiernan | 9 | Gen | |
| 73 | Innovative strategies for monitoring and enhancing clinic performance in the WHI clinical trial: The creation of the Performance Monitoring Committee | **Pottern**, Naughton, Lund, Cochrane, Brinson, Kotchen, McTiernan, Shumaker | 9 | Gen | |
| 87 | Predictors of total hip replacement in a cohort of older women: Result from the WHI observational study | **Wallace**, Chang, Nevitt, LaCroix, Kaplan, Sturm | 9 | Gen | |
| 117 | Correlates of session completion and self-monitoring of food intake among minority participants enrolled in the Women's Health Initiative (WHI) dietary modification intervention during the first year of intervention | **Rosal**, Ockene, Mossavar-Rahmani, Margolis, Paskett, Thomson | 9 | CT | |
| 127 | Homocysteine and Incident Coronary Heart Disease: Prospective analysis from the Women's Health Initiative Observational Study | **Siscovick**, Manson, Trevisan, Wallace, Howard, Burke, Ridker | 9 | OS | |
| 147 | Association of hormone replacement therapy with body fat distribution in postmenopausal women | **Mayo**, Heimburger, Gower, Goran, Fouad, Redden, Oberman, Lewis, McGwin | 9 | CT | |
| 173 | A Prospective Study of the Relationship of Hypertension, Antihypertensive Treatment and Baseline Blood Pressure on Cognitive Decline and Dementia in Postmenopausal Women: the Women's Health Initiative Memory Study | **Johnson**, Espeland, Colenda, Fillit, Manson, Margolis, Masaki, Mouton, Prineas, Robinson, Wassertheil-Smoller | 9 | WHIMS | |
| 181 | The relationship between alcohol and folate intake and breast cancer risk in the WHI observational study | **Duffy**, Assaf, Cyr, Burkholder, Coccio, Rohan, McTiernan, Paskett, Lane, Chetty | 9 | OS | |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 215 | Influence of psychosocial stress on breast cancer incidence in Women's Health Initiative | **Michael**, Ritenbaugh, Carlson, Aickin, Weihs, Ockene, Bowen, Hays, Chlebowski | 9 | OS | |
| 308 | Association between dietary fats and age-related macular degeneration (AMD) in the Carotenoids in Age-Related Eye Disease Study (CAREDS), an ancillary study of the Women's Health Initiative | **Parekh**, Moeller, Blodi, Ritenbaugh, Chappel, Wallace, Mares-Perlman | 9 | OS | |
| 310 | Relationship of body fat level and distribution to age-related maculopathy in the Carotenoids in Age related Eye Disease Study (CAREDS) | **LaRowe**, Wallace, Gehrs, Chappel, Mares-Perlman | 9 | OS | |
| 314 | The Effect of Aspirin Treatment and Dose on All-Cause Mortality and Cardiovascular Events in Postmenopausal Women with Stable Cardiovascular Disease: The Women's Health Initiative Observational Study | **Berger**, Brown, Burke, Oberman, Kostis, Langer, Wong, Wassertheil-Smoller | 9 | OS | |
| 316 | Daily Coffee Consumption and Prevalence of Nonmelanoma Skin Cancer in Caucasian Women | **Abel**, Fernandez, Johnson, Jones, Mossavar-Rahmani, Rosenberg, Vitolins, Wong | 9 | OS | |
| 318 | The association of depressive symptoms with BMD and fracture: A prospective study from the WHI observational study | **Scholes**, Brunner, Ko, Robbins, Melville, Reed | 9 | OS | |
| 319 | The relationship between religion and cardiovascular morbidity and mortality in The Women's Health Initiative trial | **Schnall**, Brzyski, Goodwin, O'Sullivan, Swencionis, Tinker, VanHorn, Wassertheil-Smoller, Zemon | 9 | OS | |
| 339 | Validity of Diabetes Self-Reports in the Women's Health Initiative: Comparison with Medication Inventories and Fasting Glucose Values | **Margolis**, Qi, Brzyski, Bonds, Howard, Kempainen, Liu, Phillips, Robinson, Safford, Tinker | 9 | Gen | |
| 353 | Effects of conjugated equine estrogens on colorectal cancer in postmenopausal women with hysterectomy: The Women's Health Initiative randomized controlled trial. | **Ritenbaugh**, Stanford, Ascensao, Chlebowski, Frank, Garland, Lane, Mason, McNeeley, Shikany, Stefanick, Taylor, Wu | 9 | CT | |
| 386 | The Role of Antioxidants and Vitamin A in Ovarian Cancer: Results from the Women's Health Initiative Prospective Cohort | **Thomson**, Neuhouser, Shikany, Caan, Monk, Mossavar-Rahmani, Sarto, Parker, Modugno, Anderson | 9 | Gen | |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 390 | Identifying risk factors for cognitive change in the Women's Health Initiative Memory Study: a neural networks approach | **Bandelow**, Espeland, Coker, Henderson, Hogervorst, Resnick, Wallace | 9 | WHIMS | |
| 392 | Family History of Myocardial Infarction Predicts Incident Coronary Heart Disease in Postmenopausal Women with Diabetes: the Women's Health Initiative Observational Study | **Li**, Johnson, O'Sullivan, Robinson, Safford, Curb | 9 | OS | |
| 394 | The association between cigarette smoking and colorectal cancer in WHI | **Paskett**, Reeves, Rohan, Allison, Williams, Messina, Whitlock, Sato, Hunt | 9 | Gen | |
| 401 | Association of Depressive Symptoms with Cancer Screening and Cancer Status in Postmenopausal Women: The Women's Health Initiative | **Aggarwal**, Freund, Sato, Adams-Campbell, Lopez, Lessin, Ockene, Wallace, Williams, Bonds | 9 | OS | |
| 442 | Test-retest reliability of the Women's Health Initiative physical activity questionnaire | **Meyer**, Evenson, Morimoto, Siscovick, White | 9 | OS | |
| 444 | Associations between age-related nuclear cataract and lutein and zeaxanthin in the diet and serum in the Carotenoids in Age-Related Eye Disease Study (CAREDS), an ancillary study of the Women's Health Initiative | **Moeller**, Voland, Tinker, Blodi, Klein, Gehrs, Johnson, Snodderly, Wallace, Chappell, Mehta, Ritenbaugh, Mares-Perlman | 9 | OS | |
| 445 | Interaction of hormone therapy with lipid biomarkers for cardiovascular outcomes in women without cardiovascular disease | **Bray**, Larson, LaCroix, Manson, Limacher, Rossouw, Lasser, Lawson, Stefanick, Langer, Margolis | 9 | Gen | |
| 453 | Relationship between degree of obesity and quality of life and functioning in women of diverse racial-ethnic backgrounds | **McTigue**, Adams-Campbell, Bost, Hays, Kuller, Lynch, Manson, Sarto, Tinker, Vitolins | 9 | Gen | |
| 459 | A prospective evaluation of insulin and insulin-like growth factor I as risk factors for endometrial cancer amoung postmenopausal women | **Gunter**, Hoover, Yu, Wassertheil-Smoller, Manson, Li, Harris, Xue, Rohan, Einstein, Kaplan, Burk, Pollak, Howard | 9 | OS | |
| 460 | Insulin, Insulin-like Growth Factor-I, Endogenous Estradiol and Risk of Colorectal Cancer in Postmenopausal Women | **Gunter**, Hoover, Yu, Wassertheil-Smoller, Rohan, Manson, Howard, Wylie-Rosette, Anderson, Ho, Kaplan, Li, Xue, Harris, Burk | 9 | OS | |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 464 | Use of recovery biomarkers to calibrate nutrient consumption self-reports in the Women's Health Initiative | **Neuhouser**, Tinker, Shaw, Schoeller, Bingham, VanHorn, Beresford, Caan, Thomson, Satterfield, Kuller, Heiss, Smit, Sarto, Ockene | 9 | CT | |
| 470 | Calcium plus Vitamin D and Exogenous Estrogen Influence on Joint Symptoms | **Chlebowski**, Johnson, Wactawski-Wende, Cummings, Kooperberg, Hubbell, Hiatt, Vitolins, Lane, Yasmeen, Shikany, Khandekar, O'Sullivan, Rohan | 9 | CT | |
| 481 | Sex hormone-binding globulin, endogenous sex hormones, and risk of hip fracture: Women's Health Initiative Observational Study | **Lee**, LaCroix, Wu, Cauley, Jackson, Kooperberg, Robbins, Lewis, Bauer, Cummings | 9 | OS | |
| 492 | Cardiovascular Risk in Women with Non-Specific Chest Pain: Women's Health Initiative Hormone Trials | **Robinson**, Wallace, Limacher, Sato, Ren, Cochrane, Wassertheil-Smoller, Ockene, Blanchette, Ko | 9 | CT | |
| 496 | Bone density, Gail score and breast cancer risk - Results from the Women's Health Initiative | **Chen**, Arendell, Aickin, Cauley, Lewis, Chlebowski | 9 | Gen | |
| 503 | Oophorectomy, Hormone Therapy and Subclinical Coronary Artery Disease in Women with Hysterectomy: The Women's Health Initiative Coronary Artery Calcium Study | **Allison**, Manson, Langer, Carr, Rossouw, Pettinger, Phillips, Cochrane, Eaton, Greenland, Hendrix, Hsia, Hunt, Jackson, Johnson | 9 | CT | |
| 507 | A naturally occurring variant in hematopoietic prostaglandin D synthase affecting enzyme stability and a case-control study of colorectal neoplasia | **Tippen**, Levine, Materi, Park, Song, Keku, Dai, Huang, Zhou, Frankl, Hardy, Patterson, Chlebowski, Henderson, Kolonel | 9 | OS | Submitted |
| 514 | Selected antioxidants and risk of hormone receptor-defined invasive breast cancers among postmenopausal women in the Women's Health Initiative | **Cui**, Shikany, Liu, Yasmeen, Rohan | 9 | OS | |
| 549 | Semiparametric regression exploiting covariate independence in two-phase sampling | **Dai**, LeBlanc, Kooperberg | 9 | Gen | |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 585 | Low-fat dietary pattern and risk of benign proliferative breast disease: a randomized, controlled dietary modification trial | **Rohan**, Negassa, Caan, Chlebowski, Curb, Ginsberg, Lane, Neuhouser, Shikany, Wassertheil-Smoller, Page | 9 | CT | |
| 586 | Conjugated Equine Estrogen and Risk of Benign Proliferative Breast Disease: a Randomized, Controlled Trial | **Rohan**, Negassa, Chlebowski, Habel-Oakland, McTiernan, Wassertheil-Smoller, Page | 9 | CT | |
| 587 | Estrogen plus progestin and Risk of Benign Proliferative Breast Disease | **Rohan**, Negassa, Chlebowski, Lasser, McTiernan, Schenken, Wassertheil-Smoller, Page | 9 | CT | |
| 592 | Vaginal Descent and Pelvic Floor Symptoms in Postmenopausal Women: A Longitudinal Study | **Bradley**, Zimmerman, Wang, Nygaard | 9 | CT | |
| 602 | Inflammation and hemostasis biomarkers for predicting risk of ischemic stroke in postmenopausal women: The Women's Health Initiative Observational Study | **Kaplan**, McGinn, Baird, Hendrix, Kooperberg, Lynch, Rosenbaum, Johnson, Strickler, Wassertheil-Smoller | 9 | OS | |
| 610 | Prostaglandin H synthase 2 Val511Ala variant in African Americans: Suggestion of lower risk for colorectal cancer in four case-control studies | **Lin**, Levine, Materi, Park, Patterson, Goodman, Chlebowski, Sansbury, Keku, Henderson, Kolonel, Harris, Sandler, Haile | 9 | OS | Submitted |
| 613 | Obesity and risk of pancreatic cancer among postmenopausal women: the Women's Health Initiative (United States) | **Luo**, Margolis, Adami, LaCroix, Ye | 9 | Gen | |
| 632 | Clinical attachment loss, systemic bone density, and subgingival calculus in postmenopausal Women | **Brennan**, Genco, Hovey, Trevisan, Wactawski-Wende | 9 | OS | |
| 645 | Aortic aneurysm in postmenopausal women: findings from the Women's Health Initiative | **Lederle**, Larson, Margolis, Allison, Freiberg, Cochrane, Graettinger, Curb | 9 | Gen | |
| 664 | A Common Variant in the FTO Gene and Obesity and Diabetes Risk in a Multi-ethnic Cohort of Postmenopausal Women (Ancillary study of the WHI-OS | **Song**, You, Hsu, Howard, Langer, Manson, Nathan, Niu, Tinker, Liu | 9 | OS | |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 38 | Relationship of select dietary components and colorectal cancer among postmenopausal women: The Women's Health Initiative | **Frank**, Pettinger, Paskett, Wylie-Rosette, Agurs-Collins | 8 | Gen | |
| 74 | Baseline characteristics of the WHI observational study breast cancer survivor cohort | **Paskett**, Sherman, Andersen, Hays, McDonald, Naughton | 8 | OS | |
| 153 | The Relationship between Mood and Metabolic Syndrome Characteristics in Post Menopausal Women | **Wylie-Rosette**, Aragaki, Cochrane, Perri, Rosal, Rapp | 8 | CT | |
| 172 | Dietary Glycemic Index/Glycemic Load and CVD Risk Factors in the Women's Health Initiative Observational Study | **Shikany**, Tinker, Neuhouser, Ma, Patterson, Phillips, Liu, Redden | 8 | Gen | |
| 228 | Past hysterectomy as a risk factor for hypertension in the Women's Health Initiative observational study participants | **Barad** | 8 | OS | |
| 315 | Urethral lesions in a postmenopausal population | **Coughlin** | 8 | CT | |
| 330 | Effects of Estrogen With and Without Progestin and Obesity on Gastroesophageal Reflux Disease: The Women Health Initiative Randomized Controlled Trial | **Zheng**, Margolis, Liu, Tinker, Ye | 8 | CT | |
| 476 | Associations between dietary fat intake and late age related macular degeneration (ARM) for the Women's Health Initiative-Sight Exam (WHI-SE) Study Participants | **Kannan**, Haan, Blythe, Moore, Tong | 8 | CT | |
| 536 | The correlation of sexual satisfaction and cardiovascular disease in women in the WHI | **McCall-Hosenfeld**, Freund, Bonds | 8 | OS | |
| 553 | Association of Dopamine Genotypes with Physical Activity and Body Habitus in Post-menopausal Women | **Leddy**, Hovey, Salis, Brennan, Epstein, Wactawski-Wende | 8 | OS | |
| 555 | Genetic variation in the peroxisome proliferator-activated receptor y is associated with type 2 diabetes mellitus in the Women's Health Initiative observational study | **Song**, Manson, Tinker, Howard, Kuller, Nathan, Rifai, Liu | 8 | OS | |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 565 | The Prevalence of Self-Reported Osteoarthritis and Associated Risk Factors in Postmenopausal Women---Results from the Women's Health Initiative | **Wright**, Kershner Riggs, Lisse, Hunt, Chen | 8 | Gen | |
| 594 | Association between dietary fiber and inflammatory markers in an ethnically diverse cohort of postmenopausal women | **Ma**, Hebert, Li, Bertone-Johnson, Ockene, Olendzki, Pagoto, Rosal, Ockene, Tinker, Griffith, Liu | 8 | OS | |
| 614 | Incidence of Fractures in Multiethnic Women: The Women's Health Initiative | **Cauley**, Wampler, Barnhart, Wu, Allison, Chen, Hendrix, Robbins, Jackson | 8 | OS | |
| 631 | Body Mass Index and Lung Cancer Risk in the Women's Health Initiative | **Kabat**, Kim, Hunt, Chlebowski, Rohan | 8 | Gen | |
| 651 | Alcohol consumption, hypertension, and total mortality among black and white post-menopausal women: results from the Women's Health Initiative | **Freiberg**, Chang, Kraemer, Robinson, Adams-Campbell, Kuller | 8 | OS | |
| 677 | Calcium plus Vitamin D Supplementation and the Risk of Breast Cancer | **Chlebowski**, Johnson, Kooperberg, Pettinger, Wactawski-Wende, Rohan, Lane, O'Sullivan, Yasmeen, Hiatt, Schoen, Shikany, Vitolins, Khandekar, Hubbell | 8 | CT | |
| 79 | Databased tracking and statistical models of the clinical trial recruitment process | **Creech** | 7 | CT | |
| 81 | The prevalence of urinary incontinence in WHI women | **Hendrix**, Clark, Ling, Dugan, Salmieri, Hurtado, McNeeley, Laube, McTiernan, Francis | 7 | Gen | |
| 152 | The impact of magnesium intake on bone mass and risk of fracture in the Women's Health Initiative observational study | **Jackson**, LaCroix, Lewis, Wactawski-Wende, Cauley, Chen, Bassford | 7 | OS | |
| 175 | The effect of nutrient intake on blood pressure in the Women's Health Initiative at baseline | **Kotchen**, Kotchen | 7 | Gen | |
| 194 | Predictors of adherence to the hormone replacement therapy clinical trial in the Women's Health Initiative | **Cochrane**, Stefanick, Wallace, Granek, Lillington, Anderson, Woods, Naughton | 7 | CT | |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 283 | Hormone Therapy has no Detrimental Effects on the Rate of Cognitive Change in Postmenopausal Women: The WHIMS | **Royall**, Espeland, Colenda, Hays, Ockene, Palmer | 7 | OS | |
| 301 | Ace-inhibitor use and occurrence of frailty and disability in postmenopausal women | **Gray**, LaCroix, Woods, Cochrane, McDermott, Murray, Rodriguez, Black | 7 | Gen | |
| 358 | Estrogen only influence on mammogram density in healthy postmenopausal women in the Women's Health Initiative randomized trial | **Martin**, McTiernan, Pisano, Chlebowski, Heiss | 7 | CT | |
| 360 | Body Mass Index, Waist-Hip Ratio, and Cognitive Decline in Postmenopausal Women: Results from the WHIMS | **Kerwin**, Jaramillo, Chlebowski, Coker, Hoffman, Espeland, Kotchen, Kuller, Nicklas, Rainford, Vitolins | 7 | WHIMS | |
| 374 | Tamoxifen and coronary heart disease (CHD) risk | **Chlebowski**, Allison, Brzyski, Greep, Kooperberg, O'Sullivan, Robinson | 7 | Gen | |
| 377 | Medication utilization for the secondary prevention of cardiovascular disease in older women | **Robinson**, Wallace, Cochrane, Black, Ko, Masaki, O'Sullivan, Petrovich | 7 | Gen | |
| 380 | Coagulation factors, postmenopausal hormone replacement therapy and the risk of venous thrombosis: The Women's Health Initiative clinical trials of postmenopausal hormone therapy | **Cushman**, Rosendaal, Baird, Bray, Curb, Eaton, Heckbert, Howard, Phillips, Stafford | 7 | CT | |
| 406 | Effect of estrogen and estrogen plus progestin replacement therapy on the incidence of stroke in older women with atrial fibrillation | **Konety**, Robinson, Black, Frishman, Oberman, Sarto, Williams | 7 | CT | |
| 426 | Associations between Incident breast cancer and geographic location of residence in the Woman's Health Initiative observation study | **Millen**, Duffy, Freudenheim, Kuller, Lane, Langer, Lopez, McTiernan, Mossavar-Rahmani, Rosenberg, Wactawski-Wende | 7 | OS | |
| 467 | Low Fat Dietary Pattern, Fractures, and Bone Density: The Women's Health Initiative Dietary Modification Clinical Trial | **McTiernan**, Wactawski-Wende, Tylavsky, Jackson, Freeman, Hendrix, Watts | 7 | CT | |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 472 | Calcium plus Vitamin D Supplementation and Risk of Death in Postmenopausal Women: The WHI Calcium-Vitamin D Randomized Controlled Trial | **LaCroix**, Kotchen, Johnson, Ko, Brzyski, Gass, McGowan, Anderson, Manson, Cauley, Wactawski-Wende, Stefanick | 7 | CT | |
| 473 | Adverse effects of Calcium/Vitamin D Supplementation | **Wallace**, O'Sullivan, Wactawski-Wende, Masaki, Cochrane, Gass, Whitlock | 7 | CT | |
| 480 | Thyroid disease and risk for hip fracture in postmenopausal women | **Cummings**, Bauer, Cauley, Jackson, Kooperberg, LaCroix, LeBoff, Lee, Lewis, Thomas, Wu | 7 | OS | |
| 539 | Estrogen use and mild cognitive impairment: Baseline and retrospective data from the Cognitive Change in Women WHI Ancillary Study | **Dunn**, Stoddard, Harty, Gavett, Weintraub | 7 | CT | |
| 543 | Insulin-like growth hormone-1, risk factors, and risk for hip fracture in postmenopausal women | **Jackson**, Lee, Cummings | 7 | OS | |
| 544 | Menstrual history, oral contraceptive use, reproductive factors and risk of benign proliferative epithelial disorders of the breast | **Cui**, Page, Lane, Rohan | 7 | CT | |
| 560 | Effects of diuretic use on fracture incidence and bone mineral density in women with CHF: Findings from the WHI | **Carbone**, Bush, Johnson, LaCroix, Robbins, Thomas, Weber | 7 | CT | |
| 567 | Association between breast pain during hormone therapy and breast cancer | **Crandall**, Anderson, Aragaki, Cauley, Chlebowski, Cochrane, Hendrix, Kuller, Langer, McTiernan | 7 | CT | |
| 583 | Multivitamin-multimineral supplements and the risk of cancer and cardiovascular disease | **Neuhouser**, Thomson, Wassertheil-Smoller, Anderson, Lane, Manson, Patterson, Prentice, Rohan, Shikany, Thomas, VanHorn, LaCroix | 7 | CT | |
| 598 | Effects of conjugated equine estrogens on cognition and affect in surgically menopausal women: WHISCA | **Resnick**, Espeland, An, Coker, Jackson, Maki, Stefanick, Wallace | 7 | CT | |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 625 | Effects of postmenopausal hormone therapy on volumetric subclinical cerebrovascular disease: The Women's Health Initiative Memory Study Magnetic Resonance Imaging Study (WHIMS-MRI) | **Coker**, Hogan, Baird, Betterman, Bryan, Freeman, Kuller, Lao, Margolis, Shumaker, Stefanick, Wallace | 7 | WHIMS | |
| 626 | Effects of postmenopausal hormone therapy on regional brian volumes: The Women's Health Initiative Magnetic Resonance Imaging Study (WHIMS-MRI) | **Resnick**, Espeland, Jaramillo, Davatzikos, Hirsch, Murray, Ockene, Stefanick | 7 | WHIMS | |
| 634 | Vitamin D and the risk of hip fracture: The Women's Health Initiative | **Cauley**, Jackson, Lee, LaCroix, Ockene, Robbins, Sarto, Wactawski-Wende | 7 | OS | |
| 304 | The effect of E+P discontinuation on risk for fracture: The WHI | **Jackson**, Watts, Lewis, Chen, Neuner, Cauley, Mouton, Robbins, Greep, LaCroix, Stefanick, Caralis, O'Sullivan | 6 | Gen | |
| 366 | Association of vasomotor symptoms with cardiovascular outcomes | **Barad**, Allison, Barnabei, Brunner, Cochrane, Gass, Manson, Ockene, Robinson, Schatz, Stefanick, Woods, Rossouw | 6 | CT | |
| 375 | Past weight cycling as a cause of immune related cancers | **DeRoos**, Caan, McTiernan, Mossavar-Rahmani, Rosenberg, Thomson, Ulrich | 6 | OS | |
| 393 | BMI as a predictor of body image in older women, controlling for socio-demographic correlates | **Carrigan**, Robbins, Winward, Blanchette, Grosz, Hays, Hunt, Manson, Messina, Parker, Rosal | 6 | OS | |
| 395 | Hormone therapy, lean mass, falling and fracture risk among postmenopausal women: Results from the Women's Health Initiative hormone trials | **Chen**, Bassford, Cauley, Jackson, LaCroix, Lewis | 6 | CT | |
| 399 | Subtypes of mild cognitive impairment: Prevalence, course, and effect of hormone therapy | **Rapp**, Legault, Absher, Brunner, Henderson, Jones, Masaki, Thal | 6 | WHIMS | |
| 420 | Postmenopausal hormone use and the risk of nephrolithiasis: Results from the Women's Health Initiative | **Maalouf**, Welch, Robbins, Cochrane, Moe, Sakhaee | 6 | CT | |
| 551 | Selective serotonin reuptake inhibitor use and cardiovascular events in the Women's Health Initiative observational study | **Smoller**, Wassertheil-Smoller, Wang | 6 | OS | |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 558 | Cognitive function and physical performance in the Women's Health Initiative Memory Study | **Atkinson**, Espeland, Absher, Gass, Henderson, Johnson, Kostis, Lane, Mouton, Ockene, Rapp, Stefanick | 6 | WHIMS | |
| 628 | Time from menopause to hormone therapy initiation and the risks and benefits of postmenopausal hormone therapy (HT) : A combined CT and OS analysis | **Prentice**, Manson, Allison, Anderson, Brzyski, Jackson, Johnson, Kuller, Lane, Langer, Ockene, Pettinger, Rossouw, Sarto, Wactawski-Wende | 6 | Gen | |
| 18 | The relationship of dietary phytoestrogens to menopausal symptoms and major morbidity in postmenopausal women | **Assaf**, Cyr, Coccio, Hixson | 5 | CT | |
| 118 | Association between depressive symptomatology and physical activity in postmenopausal women | **Rosal**, Ockene, Haan, Brunner, Mouton, Lopez, Perri, Cochrane, Matthews, Jackson, Sato | 5 | Gen | |
| 141 | The association of food and nutrient intake with the incidence of stroke in the WHI observational study | **Beresford**, Shikany, St. Jeor, Torrens, Mossavar-Rahmani, Heiss, Patterson, VanHorn | 5 | OS | |
| 151 | History of estrogen and oral contraceptive use and cognitive function: Results from the Women's Health Initiative Memory Study | **Rapp**, Dailey, Gass, Wactawski-Wende, Hendrix, Hogan, Jones, Murphy, Shumaker | 5 | WHIMS | |
| 156 | Characteristics of Women with Systemic Lupus Erythematosus in the Women's Health Initiative Observational Study | **Assaf**, Cyr, Crowley, Coccio | 5 | OS | |
| 159 | Endogenous sex steroid hormone and risk of coronary heart disease in postmenopausal women | **Rexrode**, Manson, Kuller, McTiernan, Stefanick, Heckbert, White | 5 | OS | |
| 160 | Correlation of endogenous sex steroid hormones with inflammatory and thrombotic markers in postmenopausal women | **Rexrode**, Manson, Ridker, Cochrane, Ockene, Kotchen, Margolis, McGovern | 5 | OS | |
| 180 | Alcohol use and the risk of endometrial cancer in the Women's Health Initiative observational study | **Assaf**, Beresford, Ockene, Chen, Cyr, Coccio, Moulton, Duffy, Burkholder | 5 | OS | |
| 182 | The effect of moderate alcohol consumption on the incidence of ovarian cancer | **Assaf**, Coccio, Anderson, Caan, Kaunitz, DeSantis, Duffy, Burkholder | 5 | OS | |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 268 | The effects of estrogen plus progestin on the overall health of postmenopausal women as measured by a global index of disease events | **LaCroix**, Anderson, Beresford, Cauley, Chlebowski, Curb, Hendrix, Hubbell, Jackson, Margolis, O'Sullivan, Phillips, Wallace, Aragaki | 5 | CT | |
| 276 | Social support and cognitive functioning in post-menopausal women | **Messina**, Espeland, Jaramillo, Coker, Lane, Masaki, Phillips, Powell, Rosal, Shumaker | 5 | WHIMS | |
| 284 | The effect of estrogen and progestin on bone mineral density | **Jackson**, Cauley, Chen, LaCroix, Pettinger, Phillips, Robbins, Rodriguez, Tylavsky, Wactawski-Wende | 5 | CT | |
| 296 | Place of birth and migration within the United States and its effects on health behaviors and cardiovascular risk factors in postmenopausal women | **Johnson**, Connelly, Allison, Goldman, Langer, Limacher, Michael, Polanco-Paula, Sato | 5 | OS | |
| 309 | Correlates of dietary patterns in older women in the Carotenoids in Age related eye Disease Study (CAREDS) | **Moeller**, Ritenbaugh, Tinker, Moeller, Blodi, Chappel | 5 | OS | |
| 311 | Relationship of supplement use to age related maculopathy | **Gruber**, Mares-Perlman, Wallace, Moeller, Oxton, Chappel | 5 | OS | |
| 334 | Sexual function and the effect of discontinuation of E+P therapy among participants in WHI | **Gass**, Cochrane, Barad, Barnabei, Brzyski, Lane, LaValleur, Manson, Mouton, Ockene | 5 | CT | |
| 381 | Estimating ovarian cancer risk | **Anderson**, Chlebowski, Johnson, Kaunitz, Sato, Monk | 5 | Gen | |
| 410 | Stress as a factor contributing to advanced breast cancer Status at the time of diagnosis in underserved minority women | **Moshesh**, Eaton, Hunt, Paskett, Woods | 5 | Gen | |
| 422 | Occurrence of Second Malignancy Following Nonmelanoma Skin Cancer – A Prospective Observational Study from the Women's Health Initiative | **Rosenberg**, Greenland, Khandekar, McTiernan, Rodabough, Sharma | 5 | Gen | |
| 430 | Sleep quality and cardiovascular diseases of postmenopausal women | **Chen**, Brunner, Jain, Robinson, Stefanick | 5 | Gen | |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 435 | Association of diabetes-related phenotypes with genetic variants in the estrogen and progesterone receptor genes | **Mychaleckyj**, Bonds, Rodabough | 5 | CT | |
| 466 | Dietary modification, quality of life, and depression | **Assaf**, Beresford, Brunner, Bowen, Naughton, Petrovich, Granek, Whitlock, Phillips, Haines, DeCosimo, Robinson-O'Brien, Rosal, Wenger, Snetselaar | 5 | CT | |
| 468 | Effect of Calcium/Vitamin D Supplementation on Blood Pressure in Postmenopausal Women: Results from the Women's Health Initiative Clinical Trial of Calcium-Vitamin D Supplementation | **Margolis**, VanHorn, Kuller, Kristal, Kotchen, Black, Frank, Curb, Grimm, Allison, O'Sullivan, Torner, Beresford, Wassertheil-Smoller | 5 | CT | |
| 478 | Correlates of medication utilization for the secondary prevention of coronary heart disease in older women | **Robinson**, Wallace, Cochrane, Johnson, Safford | 5 | CT | |
| 482 | A prospective study of plasma folate, vitamin B6, vitamin B12, homocysteine and the risk of pancreatic cancer | **Fuchs**, Cochrane, Manson, Schernhammer, Thomson | 5 | OS | |
| 494 | The effect of lipid-lowering agents on the development of malignant melanoma: A prospective study from the Women's Health Initiative | **Rosenberg**, Levy, Greenland, McTiernan | 5 | Gen | |
| 498 | The effect of vitamin E intake on serum tocopherol concentrations: changes with age. | **Johnson**, Bragg | 5 | OS | |
| 526 | Biomarkers, Postmenopausal Hormone Therapy and the risk of Coronary Heart Disease: The Women's Health Initiative trials of postmenopausal hormone therapy | **Rossouw**, Bray, Cushman, Greenland, Hendrix, Hsia, Jones, Kooperberg, Robinson | 5 | CT | |
| 535 | Hormone-induced changes in lipoprotein subpopulations modulate CVD risk in the E alone and E+P trials | **Hsia**, Hendrix, Kuller, Lund, Otvos, Robinson, Rossouw, Wassertheil-Smoller | 5 | CT | |
| 546 | Predictors of incident dementia in postmenopausal women enrolled in a trial of hormone therapy: the Women's Health Initiative Memory Study (WHIMS) | **Coker**, Legault, Colenda, Greep, Limacher, Murray, Rainford, Vitolins, Wallace | 5 | WHIMS | |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 570 | The effect of treatment with calcium and vitamin D on the presences and extent of sublinical coronary atherosclerosis in women 50-59 years of age at enrollment in the WHI | **Manson**, Hsia, Allison, Carr, Cochrane, Hendrix, Hunt, Langer, Lewis, Margolis, Robinson, Thomas | 5 | CT | |
| 581 | Correlations between serum vitamin D, total vitamin D Intake, and estimates of sunlight exposure in the Women's Health Initiative nested case-control studies | **Millen**, Jackson, LaCroix, LeBoff, Liu, Mares-Perlman, Melamed, Robbins, Tylavsky, Wactawski-Wende | 5 | CT | |
| 589 | CVD biomarker responses to CEE and E+P | **Langer**, Brzyski, Johnson, Kuller, Mysiw, Manson, Neuhouser | 5 | CT | |
| 590 | Effect of lactation on cardiovascular disease | **Schwarz**, Cauley, Albano, Allison, Freiberg, Stuebe, Vista-Deck | 5 | Gen | |
| 597 | Prevalence of anticholinergic drug use and impact on cognition and function in older women | **Sink**, Espeland, Gass, Goff, Rapp, Sherwin, Thomas | 5 | WHIMS | |
| 624 | Biomarker calibrated energy and protein in relation to cancer risk | **Prentice**, Beresford, Caan, Neuhouser, Patterson, Satterfield, Shaw, Snetselaar, Stefanick, Thomas, Thomson, Tinker | 5 | Gen | |
| 630 | Postmenopausal hormone therapy and colorectal cancer in the WHI CT and OS | **Prentice**, Beresford, Chlebowski, Hubbell, Liu, Wactawski-Wende | 5 | Gen | |
| 639 | Psychiatric disorders and co-morbid adjudicated cognitive dysfunction among postmenopausal women: Results from the Women's Health Initiative Memory Study (WHIMS) | **Colenda**, Legault, DeBon, Hershey, Ockene, Phillips, Rapp, Sarto, Wallace, Whitmer | 5 | WHIMS | |
| 649 | Effects of low-fat dairy products and yogurt on diabetes incidence in post-menopausal women | **Margolis**, DeBoer, Howard, Liu, Manson, Mossavar-Rahmani, Phillips, Safford, Shikany, Tinker, Wei | 5 | OS | |
| 650 | Proton pump use and risk of fracture | **LaCroix**, Cauley, Chen, Gray, Manson, Robbins | 5 | Gen | |
| 665 | Ascertaining dementia related outcomes for deceased or proxy-dependent participants: an overview of WHIMS supplemental case ascertainment protocol (WHIMS-SCAP) | **Jaramillo**, Rapp, Absher, Espeland, Jones | 5 | WHIMS | |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 124 | Relationships between nutritional intake and measures of cognition | **Espeland**, Bowen, Haan, Brunner, Snetselaar, Dunn | 4 | WHIMS | |
| 185 | Correlates of dietary lutein in older women recruited to participate in the Carotenoids in Age-related Eye Disease Study (CAREDS) | **Mares-Perlman**, Allen, Wallace, Ritenbaugh, Tinker | 4 | OS | |
| 251 | Reproductive history and Age-Related Maculopathy in the Women's Health Initiative Sight Exam Study | **Haan**, Wallace, Hendrix, Seddon, Klein, Klein, Musch, Langer, Brunner, Wactawski-Wende | 4 | CT | |
| 252 | Dietary and supplement intake of antioxidants in relation to age related maculopathy endpoints in the Women's Health Initiative Sight Exam Study | **Haan**, Seddon, Gorin, Kuppermann | 4 | CT | |
| 256 | Inflammation and Age-Related Maculopathy in the Women's Health Initiative Sight Exam Study | **Klein**, Klein, Knudtson, Seddon, Wallace, Hyman | 4 | CT | |
| 259 | Alcohol, caffeine and Age-Related Maculopathy in the Women's Health Initiative Sight Exam Study | **Klein**, Seddon, Klein, Johnson, Tomany, Hyman, Musch, Johnson | 4 | CT | |
| 266 | Correlation of endogenous sex steroid hormones with fasting glucose and insulin levels, HOMA indices, and incident diabetes mellitus in postmenopausal women. | **Weinstein**, Rexrode, Ridker, Manson, Kuller, Hankinson, Cochrane | 4 | OS | |
| 267 | Adherence to dietary modifcation: A theoretical framework | **Rosal**, Ockene, Fletcher | 4 | CT | |
| 281 | Prevalence of ST segment depression on Holtor monitoring in women in the observational study relationship to HRT | **Sheps**, Smoller, Wassertheil-Smoller, Oberman, Hsia, Wong, Heiss, Ephross, McGorray | 4 | OS | |
| 340 | Postmenopausal Hormone Therapy and hip geometry | **Chen**, Cauley, Lewis | 4 | CT | |
| 356 | The cross-sectional relationship between relative body weight and cognitive function in older postmenopausal women participating in the Women's Health Initiative | **Kerwin**, Kotchen, Kooperberg, McTigue, Robinson, VanHorn, Coker, Espeland | 4 | CT | |
| 411 | Application of GIS to estimate residential daily ambient pollutant concentrations | **Liao**, Whitsel, Peuquet, Dou, Lin, Smith | 4 | CT | |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 427 | Statin use and cognition in postmenopausal women:The Women's Health Initiative Memory Study (WHIMS) | **Legault**, Fillit, Hsia, Limacher, Manson, Ockene, Robinson, Sherwin, Sink | 4 | CT | |
| 434 | The effect of physical activity frequency, duration, and intensity on cardiovascular outcomes in WHI observational study | **Meyer**, Evenson, Heiss, Manson | 4 | OS | |
| 446 | Hormone exposure and risk of Parkinson's disease | **Saunders-Pullman**, Bressman, Chiu, Hailpern, Lipton, Santoro, Wassertheil-Smoller | 4 | OS | |
| 463 | Glycemic load and risk of coronary heart disease in the Women's Health Initiative observational study | **Shikany**, Tinker, Liu, Allison, Hsia, Ma, Neuhouser, Uwaifo, VanHorn | 4 | OS | |
| 491 | Cause of death in women who die after hip fracture: WHI experience | **Robbins**, Pastore | 4 | OS | |
| 502 | Menopausal hormone therapy and risk of ovarian cancer | **Anderson**, Barnabei, Brzyski, Chlebowski, Hendrix, Lane, Monk, Ockene, Rodriguez, Sarto | 4 | CT | |
| 513 | Alcohol Consumption and the Risk of Cardiovascular Disease among Black and White Women: The Effects of Current and Lifetime Patterns of Alcohol Consumption among Participants from the Women's Health Initiative | **Freiberg**, Adams-Campbell, Allison, Beresford, Curb, Hunt, Kraemer, Kuller, Safford, Trevisan, Robinson | 4 | OS | |
| 528 | Ambient air pollution and ventricular repolarization: Environmental epidemiology of arrhythmogenesis in WHI,1999-2001 | **Whitsel**, Anderson, Catellier, Chen, Crooks, Liao, Peuquet, Prineas, Quibrera, Smith | 4 | CT | |
| 529 | Ambient air pollution, myocardial ischemia and infarction: The environmental epidemiology of arrhythmogenesis in WHI,1999-2001 | **Whitsel**, Anderson, Catellier, Chen, Crooks, Liao, Peuquet, Prineas, Quibrera, Smith | 4 | CT | |
| 552 | An application of mixed models in the analysis of periodontal data using a spatial covariance structure | **Cai**, Carter, Hutson, Wactawski-Wende, Wilding | 4 | OS | |
| 575 | Effect of hormone therapy on physical performance in the Women's Health Initiative | **Michael**, Brzyski, Cochrane, Gold, Manson, McNeeley, Wallace, Woods | 4 | CT | |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 577 | Effect of a long-term, low-fat, high fruit and vegetable diet on retinal carotenoids in the Women's Health Initiative | **Moeller**, Mares-Perlman | 4 | CT | |
| 582 | Prediction and risk stratification of clinical diabetes in postmenopausal women | **Chao**, Liu, Bonds, Chen, Eaton, Margolis, Phillips, Rodriguez, Song, Tinker | 4 | OS | |
| 584 | Calcium plus vitamin D supplementation and risk of benign proliferative epithelial disorders of the breast | **Rohan**, Negassa, Page, Ceria, Chlebowski, Cochrane, Lane | 4 | CT | |
| 588 | Non-steroidal anti-inflammatory drugs and cognitive function in older women | **Dunn**, Gavett, Harty, Stoddard, Weintraub | 4 | Gen | |
| 591 | Hypertension, blood pressure and coronary artery calcium in postmenopausal women | **Allison**, Aragaki, Cochrane, Hsia, Hunt, Lawson, Lewis, Manson, Robinson, Thomas, Wassertheil-Smoller | 4 | CT | |
| 593 | Effect of genetic polymorphisms on coronary cardiac events among women in the Women's Health Initiative (WHI) study | **Bray**, Afshar-Kharghan, Hays, Hendrix, Herrington, Howard, Johnson, Kuller, LaCroix, Langer, Leal | 4 | OS | |
| 595 | Quality assurance and training in a low event long-term clinical trial (WHIMS) | **Dailey**, Felton, Summerville, Coker, Nance, Kidd | 4 | WHIMS | |
| 608 | Ambient air pollution, atrioventricular / ventricular conduction and their abnormalities: The Environmental Epidemiology of Arrhythmogenesis in WHI, 1999-2003 | **Liao**, Anderson, Duan, Lin, Peuquet, Prineas, Quibrera, Smith, Whitsel | 4 | CT | |
| 609 | Ambient air pollution, ectopy and arrhythmias: The Environmental Epidemiology of Arrhythmogenesis in WHI, 1999-2003 | **Liao**, Anderson, Duan, Lin, Peuquet, Prineas, Quibrera, Smith, Whitsel | 4 | CT | |
| 616 | Subjective and informant-reported memory complaints and cognitive function in non-demented older women | **Gavett**, Dunn, Harty, Stoddard, Weintraub | 4 | OS | |
| 621 | Factors associated with 3-year change in cognitive function in older women | **Dunn**, Gavett, Harty, Stoddard, Weintraub | 4 | OS | |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 644 | Association between reproductive history, adult weight stability and postmenopausal BMI and body composition | **Rosal**, Crawford, Bodenlos, Brzyski, Hardy, Hays, Hunt, Liu, Masaki, McNeeley, Moore-Simas, Phillips, Thomson, VanHorn | 4 | Gen | |
| 56 | Psychometric evaluation of the urinary incontinence scale | **Levine**, Shumaker, Naughton, Kaplan, Bowen | 3 | Gen | |
| 90 | Passive smoke exposure in childhood and adulthood and prevalent coronary heart disease in women enrolled in the WHI | **Frishman**, Wagenknecht, Wong, Ockene | 3 | OS | |
| 157 | Type 2 Diabetes and Change in Cognitive Functioning in WHIMS: The Effects of Diabetic Risk Factors and Treatment for Diabetes and Hypertension | **Coker**, Hogan, Hall, Mount, Ockene, Wallace | 3 | WHIMS | |
| 161 | Reproductive history and cognitive function in WHIMS | **Haan**, Frishman, Stefanick | 3 | WHIMS | |
| 205 | Risk factors for sarcopenia among a multiethnic cohort of postmenopausal women | **Chen**, Cauley, Lewis, Phillips, VanHorn, Wallace | 3 | Gen | |
| 207 | Comparisons between never smokers, former smokers and current smokers in the observational study of the WHI | **Brunner**, Johnson, Hunt, Paskett, Stevens, Ockene, Bowen | 3 | OS | |
| 223 | Physical activity and fracture in the Women's Health Initiative observational study | **Wactawski-Wende**, Cauley, Jackson, LeBoff, Chen, Robbins, Ockene, Rodriguez, LaCroix | 3 | OS | |
| 245 | Factors associated with self-reported severity of constipation in the Women's Health Initiative | **Morse**, Ockene, Nygaard, Crawford | 3 | Gen | |
| 297 | Racial/ethnic differences in menopausal symptoms in minority vs. White women in the observational study cohort of WHI at baseline | **Mossavar-Rahmani**, Cochrane, Brzyski, Schenken, Murphy, O'Sullivan, Potter, Kempainen | 3 | OS | |
| 299 | Association between hypertension and change in cognitive function in postmenopausal women: Results from the Women's Health Initiative Memory Study (WHIMS) | **Margolis**, Espeland, Johnson | 3 | WHIMS | |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 305 | Serum sex hormone levels and risk of hypertension in postmenopausal women | **Joffe**, Rexrode, Cochrane, Allison, Kotchen, O'Sullivan, Safford | 3 | OS | |
| 351 | Validation of the Gail Model for breast cancer risk in over age 70 women enrolled in WHI. | **Yasmeen**, Adams-Campbell, Barnabei, Chlebowski, Gilligan, Hendrix, Hubbell, Lopez, Melnikow, Sarto, Woods | 3 | Gen | |
| 355 | Spanish-language translation issues in clinical trials: The WHI experience | **Talavera**, Angelelli, Fernandez, Heinrich, Hunt, Mossavar-Rahmani | 3 | CT | |
| 364 | Hormone replacement therapy and chronic heart failure incidence and outcomes in post-menopausal women | **Greenland**, Chae, Howard, LaCroix, Limacher, Robinson, Wong | 3 | CT | |
| 384 | Frailty in WHI clinical trials participants: Comparison of self-report and physical performance measures | **Woods**, LaCroix, Brunner, Cochrane, O'Sullivan, Wallace | 3 | CT | |
| 412 | Validation of WHO model for absolute risk of fracture | **Cauley**, Watts, Chen, Cummings, Jackson, LeBoff, McGowan, O'Sullivan, Robbins, Wactawski-Wende | 3 | Gen | |
| 416 | Influence of testosterone supplementation on breast cancer | **Ness**, Cauley, Albano, McTiernan | 3 | OS | |
| 432 | Racial/ethnic-specific patterns of extreme obesity, mortality, and cardiovascular risk in the Women's Health Initiative | **McTigue**, Valoski, Kuller, Johnson, Robinson, Lewis, Garcia, Liu, Eaton, Rosal | 3 | Gen | |
| 433 | Hormone therapy and fracture: Biological mechanisms in the Women's Health Initiative hormone trial | **Cauley**, Assaf, Chen, Frank, Jackson, LaCroix, McGowan, Neuner, Robbins, Wactawski-Wende, Wallace, Zmuda | 3 | CT | |
| 436 | Long term health risks and quality of life after breast augmentation. | **Kuller**, Chang, Lane, McNeeley, Rubin, Valoski | 3 | Gen | |
| 439 | The effect of intentional and unintentional weight loss on stroke risk in the Women's Health Initiative observational study. | **Ostfeld**, Bobra, Kaplan, Kooperberg, Lo, Myrskyla, Mysiw, Rosenbaum, Wassertheil-Smoller | 3 | OS | |
| 443 | Statin use and lung cancer risk in non-smoking postmenopausal women | **Schlecht**, Wassertheil-Smoller, Johnson, Kamensky | 3 | OS | |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 457 | Elevated blood pressure and kidney cancer | **Kuller**, Chang, Curb, Fried, Liu, Tevisan | 3 | OS | |
| 458 | BMI and prognostic features of endometrial cancer | **Paskett**, Cunyun, Lane, McNeeley, Reeves | 3 | Gen | |
| 483 | A prospective study of plasma C-peptide, insulin-like growth factor binding protein-1, fasting insulin, and the risk of pancreatic cancer | **Michaud**, Cochrane, Fuchs, Liu, Manson | 3 | OS | |
| 484 | A prospective study of plasma insulin-like growth factor-1 (IGF-1), insulin-like growth factor-2 (IGF-2), insulin-like growth factor binding protein-3 (IGFBP-3) and the risk of pancreatic cancer | **Fuchs**, Cochrane, Manson, Rohan, Wolpin | 3 | OS | |
| 489 | Effects of obesity on the structural geometry of the proximal femur | **Beck** | 3 | OS | |
| **Ms ID** | **Title** | **Authors** | **Status** | **Data Focus** | **Reference** |
| 497 | Extreme obesity and Incident hypertension and diabetes: Racial and ethnic patterns in the WHI study. | **McTigue**, Kuller, Valoski, Safford | 3 | Gen | |
| 499 | Prospective analysis of association between use of statins or other lipid lowering agents and colorectal cancer risk | **Rosenberg**, Roy, Khandekar, Cauley, Greenland, Lane, Ockene | 3 | Gen | |
| 500 | Results from the long term stability, standardization and quality control for the core analytes at the central laboratory for the WHI program. | **Stein**, Chen, LaCroix, Lund, Rossouw, Miller | 3 | Gen | |
| 505 | Body image satisfaction in postmenopausal women | **Ginsberg**, Margolis, Gray, Tinker, Rosal, Manson, Sangi-Haghpeykar | 3 | OS | |
| 510 | Drinking pattern and alcohol type and the risk of coronary heart disease among women with self-reported diabetes | **Rajpathak**, Wassertheil-Smoller, Rohan, Wylie-Rosette, Freiberg, Liu, Robinson | 3 | OS | |
| 532 | Urinary incontinence in postmenopausal women with diabetes: the Women's Health Initative observational study | **Bonds**, Cochrane, Hendrix, Manson, Masaki, McNeeley, Rodriguez, Sarto, Wenger | 3 | OS | |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 533 | Reproductive history and lung cancer in women | **Schwartz**, Anderson, McNeeley | 3 | OS | |
| 534 | Menopausal symptoms: Effects of conjugated equine estrogens and its discontinuation in the Women's Health Initiative | **Brunner**, Barnabei, Gass, Hendrix, Ockene, Stefanick, Woods, Yasmeen | 3 | CT | |
| 540 | Interaction between family history of cardiovascular disease and diabetes for the risk of coronary heart disease and stroke in postmenopausal women without diabetes at baseline: The WHI observational study | **Li**, Johnson, Curb, Robinson, Snetselaar, Allison, Safford, Liu | 3 | OS | |
| 557 | Characteristics of the built environment in Seattle and weight change over time | **Littman**, Beresford | 3 | CT | |
| 559 | Tagging SNPs and haplotypes in 9 genes involved in insulin and IGF-I signaling and their associations with breast cancer risk | **Ho** | 3 | OS | |
| 562 | Anemia and fractures | **Chen**, Bassford, Thomson | 3 | Gen | |
| 571 | Cause of death in women who die after hip fracture: WHI | **Robbins**, Pastore, Masaki, Stefanick, Gass, Carbone, LaCroix | 3 | Gen | |
| 572 | Genetic variation in the adiopocyte fatty acid binding protein (aP2 or FABP4) gene is associated with type 2 diabetes in the WHI OS | **Liu**, Hsu, Papps, Song, Tinker | 3 | OS | |
| 573 | Common genetic variation in the endothelial nitric oxide synthase (NOS3) gene and type 2 diabetes in an ethnically diverse cohort of women | **Liu**, Hsu, Papps, Tinker | 3 | OS | |
| 574 | Dietary glycemic index/glycemic load and risk of breast cancer in the Women's Health Initiative observational study | **Shikany**, Chlebowski, Lane, Liu, Neuhouser, Rohan, Simon, Tinker | 3 | OS | |
| 576 | A prospective study of plasma insulin-like growth factor binding protein-1 (IGFBP-1) and risk of pancreatic cancer | **Fuchs**, Wolpin, Manson, Cochrane, Rohan | 3 | OS | |
| 578 | Depression and the risk of peripheral arterial disease: Results from the Women's Health Initiative observational study | **Cherr**, Wassertheil-Smoller, Trevisan | 3 | OS | |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 579 | Relative effects of tamoxifen, raloxifene, and estrogen therapy on cognition: Results from the Women's Health Initiative Study of Cognitive Aging (WHISCA) and the Cognition in the Study of Tamoxifen and Raloxifene (CoStar) Clinical Trials | **Espeland**, Jaramillo, Barad, Lane, Limacher, Resnick, Shumaker, Stefanick | 3 | WHIMS | |
| 596 | Family history of non-early-onset breast cancer and the incidence of breast cancer among women with breast-healthy lifestyles | **Gramling**, Cabral, Eaton, Harrigan, Hunt, Lash, Rothman, Stefanick | 3 | OS | |
| 599 | Estrogen and progesterone and the risk of Parkinson's disease in the clincial trial | **Saunders-Pullman**, Lipton, Wassertheil-Smoller, Tanner, Derby, Santoro | 3 | CT | |
| 600 | Does ANART score account for race/ethnic differences in cognitive function? | **Dunn**, Stoddard, Weintraub | 3 | OS | |
| 604 | Metabolic syndrome and incident stroke | **McGinn**, Wassertheil-Smoller, Wolf, Allison, Baird, Berger, Hsia, Kaplan, Kooperberg, Kuller, Rexrode, Rosenbaum | 3 | OS | |
| 605 | Glycemic index, glycemic load, and risk of pancreatic cancer among postmenopausal women | **Cui**, Liu, Neuhouser, Rohan, Shikany, Simon, Nirmal | 3 | Gen | |
| 607 | Race, psychosocial stress, and mammography: Prospective analysis in the Women's Health Initiative | **Michael**, Bowen, Carson, Chlebowski, Hubbell, Lane, Yasmeen | 3 | OS | |
| 617 | Evaluating predictivness curve of continuous biomarkers in case-control study | **Huang**, Prentice | 3 | CT | |
| 618 | Glycemic index, glycemic load, and risk of colorectal cancer among postmenopausal women | **Kabat**, Rohan, Shikany, Tinker, Neuhouser, Caan, Beresford | 3 | CT | |
| 619 | Association between type of dietary fat intake and incident atrial fibrillation: The Women's Health Initiative | **Berry**, Belin, Goldberger, Liu, Lloyd-Jones, Passman, Snetselaar, Tinker | 3 | CT | |
| 627 | Neighborhood environment and the risk of coronary heart disease in WHI participants | **Li**, Crawford, Ma, Ockene | 3 | Gen | |
| 629 | Dietary potassium intake and the risk of incident stroke and mortality | **Rajpathak**, Wassertheil-Smoller | 3 | OS | |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 633 | Vitamin A intake and the risk of fractures among participants of the Women's Health Inititiative | **Caire**, Chen, Ritenbaugh, Snetselaar, Wactawski-Wende | 3 | OS | |
| 636 | Effect of obesity on the natural history of pelvic organ prolapse | **Kudish**, Cochrane, Hendrix, Iglesia, McNeeley, Petrovich, Richter, Sokol | 3 | CT | |
| 642 | Thiazolidinedione (TZD) use and fracture risk in postmenopausal women with diabetes | **Schwartz**, Bonds, Cummings, Liu, Margolis, Palermo, Phillips, Vittinghoff | 3 | Gen | |
| 646 | The association of calibrated nutrient biomarkers, dietary assessment and cardiovascular disease risk: The Women's Health Intiative Nutrient Biomarker Study | **Johnson**, Prentice, Hsia, Kuller, Liu, Ockene, Sarto, Stefanick, Tinker, VanHorn | 3 | OS | |
| 647 | The new AHA CV risk classification scheme is a simple and clinically useful approach to risk stratification in women | **Hsia**, Cochrane, Freiberg, Graettinger, Howard, Liu, Lloyd-Jones, Manson, Robinson, Rosal, Wong | 3 | Gen | |
| 654 | Plasma adiponectin, gene polymorphisms on the adiponectin gene, and risk of hypertension in White and Black women | **Sesso**, Manson, Wang, Brunner, Cochrane, Cook, Kwiatkowski, Liu, Miller | 3 | OS | |
| 655 | Plasma inflammatory markers and the risk of developing hypertension in White and Black women | **Sesso**, Cochrane, Cook, Gaziano, Liu, Manson, Ridker, Rifai, Wang | 3 | OS | |
| 656 | Multi-marker risk assessment will yield a better assessment of cardiovascular risk in the Women's Health Initiative compared to a standard risk assessment incorporating major traditional risk factors alone | **Greenland**, Cochrane, Lasser, Limacher, Lloyd-Jones, Manson, Margolis, Robinson, Rossouw | 3 | OS | |
| 659 | Coronary heart disease (CHD) risk perception and its relation to health behaviors in the Women's Health Initiative | **Barnhart**, Walker, Wassertheil-Smoller | 3 | OS | |
| 660 | Common genetic variation in the CRP, IL-6, and TNF-0 genes and diabetes risk in an ethnically diverse cohort of women | **You**, Liu, Manson, Song, Tinker | 3 | OS | |
| 661 | Racial differences in Vitamin D levels: Results from the WHI | **Melamed**, Cauley, Chlebowski, Jacobs, LaCroix, LeBoff, Liu, Millen, Robbins, Tylavsky, Wactawski-Wende, Wassertheil-Smoller, Wylie-Rosette | 3 | CT | |

**Table 12.1 (continued)**
**Publications**

| Ms ID | Title | Authors | Status | Data Focus | Reference |
|---|---|---|---|---|---|
| 662 | Inflammatory biomarkers and risk of incident frailty in postmenopausal women | **LaCroix**, Cauley, Cochrane, Gray, Liu, Reiner, Tinker, Wactawski-Wende, Woods | 3 | OS | |
| 663 | Thrombosis biomarkers and risk of incident frailty in postmenopausal women | **Reiner**, Cochrane, Gray, LaCroix,. Woods | 3 | OS | |
| 670 | Long-term neurocognitive effects of sleep disturbance: Impacts on cognitive declines, and incidence of mild cognitive impairment and dementia | **Chen**, Espeland, Lovato, Brunner, Johnson, Kotchen, Manson, Mysiw, Phillips, Robinson, Sarto, Stefanick, Wallace | 3 | WHIMS | |
| 672 | Obesity Subtypes and Inflammation | **Wildman**, Wassertheil-Smoller, Kaplan, Connelly, Rajkovic, Mackey, Curb, Eaton, Manson, Tinker | 3 | OS | |
| 673 | Abuse, Frailty, and Mortality in Older Women | **Baker**, LaCroix, Cochrane, Wallace, Woods | 3 | Gen | |
| 676 | Hot flushes, dietary modification, and breast cancer | **Caan**, Stefanick, Aragaki, Hubbell, Ockene, Bueche, Chlebowski, Rajkovic, Tinker, Vitolins | 3 | CT | |

**Status:**

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

# Attachment A

# Women's Health Initiative Memory Study (WHIMS) Suite of Studies

# Progress Report

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

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

# Table of Contents

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

**Study Activities:**

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

**WHIMS Extension Enrollment Data:** Currently, there are 4,174 participants enrolled in the WHIMS Extension. Enrollment rates for the WHIMS Extension average 80 percent for eligible WHI Extension participants across all sites. The WHIMS Enrollment Report which shows the cumulative number of participants recruited at each clinical center is attached. (Attachment A)

**Supplemental Case Ascertainment (SCA) Protocol:** In February 2006, WHIMS Site Monitors began conducting informant interviews. To date, 336 informant contacts have been made which have resulted in 167 completed interviews. The SCAP status report is attached (Attachment B).

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

**Participating Clinical Centers/Field Centers:** There are 37 WHI Extension clinical centers participating in the WHIMS Extension. They are as follows:

| | |
|---|---|
| Atlanta Vanguard Clinical Center | Clinic ID# 19 |
| Birmingham Vanguard Clinical Center | Clinic ID# 12 |
| Boston Vanguard Clinical Center | Clinic ID# 14 |
| Buffalo Vanguard Clinical Center | Clinic ID# 15 |
| Chapel Hill Clinical Center | Clinic ID# 58 |
| Chicago Vanguard Clinical Center | Clinic ID# 16 |
| Evanston Hospital (Satellite) | Clinic ID# 20 |
| Chicago-Rush Clinical Center | Clinic ID # 59 & 60 |
| Cincinnati Clinical Center | Clinic ID# 61 |
| Columbus Clinical Center | Clinic ID# 50 |
| Davis Vanguard Clinical Center | Clinic ID# 30 |
| Detroit Clinical Center | Clinic ID# 62 |
| Gainesville Clinical Center | Clinic ID# 46 |
| George Washington University | Clinic ID# 44 |
| Honolulu Clinical Center | Clinic ID# 45 |
| Houston Clinical Center | Clinic ID# 47 |
| Iowa City Clinical Center | Clinic ID# 21 |
| Des Moines Clinical Center (Satellite) | Clinic ID# 73 |

| | |
|---|---|
| Irvine Clinical Center | Clinic ID# 63 |
| Los Angeles Clinical Center | Clinic ID# 68 |
| Madison Clinical Center | Clinic ID# 56 |
| MedStar Clinical Center | Clinic ID# 51 |
| Memphis Vanguard Clinical Center | Clinic ID# 24 |
| Milwaukee Clinical Center | Clinic ID# 43 |
| Minneapolis Clinical Center | Clinic ID# 25 |
| Nevada Clinical Center | Clinic ID# 65 |
| New Brunswick Clinical Center | Clinic ID# 72 |
| New York City Clinical Center | Clinic ID# 49 |
| Oakland Clinical Center | Clinic ID# 53 |
| Pawtucket Vanguard Clinical Center | Clinic ID# 23 |
| Pittsburgh Vanguard Clinical Center | Clinic ID# 28 |
| Portland Clinical Center | Clinic ID# 66 |
| San Antonio Clinical Center | Clinic ID# 67 |
| Stanford Clinical Center | Clinic ID# 42 |
| Stony Brook Clinical Center | Clinic ID# 57 |
| Torrance Clinical Center | Clinic ID# 55 |
| Tucson Vanguard Clinical Center | Clinic ID# 29 |
| Winston-Salem Clinical Center | Clinic ID# 71 |
| Worcester Clinical Center | Clinic ID# 48 |

**Findings to Date:** Phase 1 (Form 39) data collection ended on September 30, 2007; however clinical centers are continuing to enter data via the website through October 31, 2007. Findings will not be known until after this time.

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

Attachment A

# WHIMS Extension Enrollment
## Number enrolled by clinic
Generated at 12:09 ET on 22OCT07

| | | | | WHI Extension | | WHIMS Extension | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Contacted^^ | | Enrolled | | Enrolled | | Denied Consent | |
| Clinic | Number eligible for Extension^ | N | % | N | % | N | %^^^ | N | % |
| ALL CLINICS | 6564 | 6241 | 95.1% | 5216 | 83.6% | 4174 | 80.0% | 1043 | 20.0% |
| 11=Davenport | 38 | 38 | 100% | 28 | 73.7% | 24 | 85.7% | 4 | 14.3% |
| 12=Birmingham | 151 | 145 | 96.0% | 114 | 78.6% | 96 | 84.2% | 18 | 15.8% |
| 13=Greensboro | 31 | 31 | 100% | 26 | 83.9% | 21 | 80.8% | 5 | 19.2% |
| 14=Boston | 191 | 180 | 94.2% | 155 | 86.1% | 101 | 65.2% | 54 | 34.8% |
| 15=Buffalo | 148 | 148 | 100% | 133 | 89.9% | 117 | 88.0% | 17 | 12.8% |
| 16=Chicago | 9 | 9 | 100% | 7 | 77.8% | 5 | 71.4% | 2 | 28.6% |
| 19=Atlanta | 94 | 93 | 98.9% | 76 | 81.7% | 70 | 92.1% | 6 | 7.89% |
| 20=Chicago-Evanston | 19 | 18 | 94.7% | 17 | 94.4% | 13 | 76.5% | 4 | 23.5% |
| 21=Iowa City | 48 | 45 | 93.8% | 35 | 77.8% | 21 | 60.0% | 14 | 40.0% |
| 23=Pawtucket | 182 | 182 | 100% | 158 | 86.8% | 109 | 69.0% | 49 | 31.0% |
| 24=Memphis | 90 | 90 | 100% | 61 | 67.8% | 45 | 73.8% | 16 | 26.2% |
| 25=Minneapolis | 197 | 197 | 100% | 161 | 81.7% | 126 | 78.3% | 35 | 21.7% |
| 26=Newark | 103 | 100 | 97.1% | 82 | 82.0% | 74 | 90.2% | 8 | 9.76% |
| 27=Phoenix | 89 | 88 | 98.9% | 59 | 67.0% | 49 | 83.1% | 10 | 16.9% |
| 28=Pittsburgh | 139 | 139 | 100% | 125 | 89.9% | 108 | 86.4% | 17 | 13.6% |
| 29=Tucson | 136 | 127 | 93.4% | 86 | 67.7% | 57 | 66.3% | 29 | 33.7% |
| 30=Davis | 199 | 194 | 97.5% | 164 | 84.5% | 120 | 73.2% | 44 | 26.8% |
| 42=Stanford | 240 | 239 | 99.6% | 214 | 89.5% | 193 | 90.2% | 21 | 9.81% |
| 43=Milwaukee | 232 | 232 | 100% | 193 | 83.2% | 148 | 76.7% | 45 | 23.3% |

| | | | | WHI Extension | | WHIMS Extension | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Contacted^^ | | Enrolled | | Enrolled | | Denied Consent | |
| Clinic | Number eligible for Extension^ | N | % | N | % | N | %^^^ | N | % |
| 44=George Wash. | 165 | 149 | 90.3% | 126 | 84.6% | 116 | 92.1% | 10 | 7.94% |
| 45=Honolulu | 86 | 71 | 82.6% | 62 | 87.3% | 58 | 93.5% | 4 | 6.45% |
| 46=Gainesville | 134 | 133 | 99.3% | 128 | 96.2% | 101 | 78.9% | 27 | 21.1% |
| 47=Houston | 109 | 109 | 100% | 67 | 61.5% | 59 | 88.1% | 8 | 11.9% |
| 48=Worcester | 263 | 261 | 99.2% | 247 | 94.6% | 197 | 79.8% | 50 | 20.2% |
| 49=New York | 244 | 239 | 98.0% | 200 | 83.7% | 164 | 82.0% | 36 | 18.0% |
| 50=Columbus | 264 | 264 | 100% | 213 | 80.7% | 139 | 65.3% | 74 | 34.7% |
| 51=Medlantic | 149 | 140 | 94.0% | 126 | 90.0% | 114 | 90.5% | 12 | 9.52% |
| 53=Oakland | 172 | 172 | 100% | 142 | 82.6% | 116 | 81.7% | 26 | 18.3% |
| 54=Jacksonville | 81 | 79 | 97.5% | 70 | 88.6% | 62 | 88.6% | 8 | 11.4% |
| 55=Torrance | 56 | 51 | 91.1% | 40 | 78.4% | 24 | 60.0% | 16 | 40.0% |
| 56=Madison | 143 | 141 | 98.6% | 125 | 88.7% | 98 | 78.4% | 27 | 21.6% |
| 57=Stony Brook | 231 | 231 | 100% | 198 | 85.7% | 153 | 77.3% | 45 | 22.7% |
| 58=Chapel Hill | 223 | 216 | 96.9% | 177 | 81.9% | 147 | 83.1% | 30 | 16.9% |
| 59/60=Chicago-Rush | 132 | 76 | 57.6% | 76 | 100% | 71 | 93.4% | 5 | 6.58% |
| 61=Cincinnati | 148 | 148 | 100% | 128 | 86.5% | 118 | 92.2% | 10 | 7.81% |
| 62=Detroit | 111 | 107 | 96.4% | 75 | 70.1% | 63 | 84.0% | 12 | 16.0% |
| 63=Irvine | 176 | 152 | 86.4% | 129 | 84.9% | 87 | 67.4% | 42 | 32.6% |
| 65=Nevada | 185 | 113 | 61.1% | 113 | 100% | 112 | 99.1% | 1 | 0.88% |
| 66=Portland | 179 | 171 | 95.5% | 150 | 87.7% | 130 | 86.7% | 20 | 13.3% |
| 67=San Antonio | 98 | 50 | 51.0% | 38 | 76.0% | 38 | 100% | 0 | 0.00% |
| 68=Los Angeles | 209 | 209 | 100% | 150 | 71.8% | 102 | 68.0% | 48 | 32.0% |
| 69=Fall River | 123 | 122 | 99.2% | 114 | 93.4% | 96 | 84.2% | 18 | 15.8% |

| | | | | WHI Extension | | WHIMS Extension | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Contacted^^ | | Enrolled | | Enrolled | | Denied Consent | |
| Clinic | Number eligible for Extension^ | N | % | N | % | N | %^^^ | N | % |
| 70=Pauline | 42 | 42 | 100% | 30 | 71.4% | 28 | 93.3% | 2 | 6.67% |
| 71=Bowman Gray | 34 | 34 | 100% | 23 | 67.6% | 13 | 56.5% | 10 | 43.5% |
| 72=New Brunswick | 185 | 180 | 97.3% | 149 | 82.8% | 126 | 84.6% | 23 | 15.4% |
| 73=Des Moines | 286 | 286 | 100% | 226 | 79.0% | 145 | 64.2% | 81 | 35.8% |

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

^^Completed WHIMS Extension consent form

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

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

## Attachment B

*WHIMS SCAP Call Status*

*Based on Data Entered as of 10/22/2007 at 12:14 PM*

| | Clinical Center Contacts | | | | CCC Contacts | | | | | | | CCC Call Status | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Eligible | Contacted | Call Outcome | | Attempts | | | | | Total Contacts | | | | | | | | |
| Clinic | N | N | Agreed | Refused | Not Yet Attempted | 1 | 2 | 3 | 4 | Participant | Phone | DQ Completed | Declined | No Answer | Phone Disconnected | Unable to Locate | Other | Left a message (4th attempt only) |
| ALL CLINICS | 733 | 558 | 390 | 168 | 54 | 110 | 42 | 28 | 156 | 336 | 902 | 167 | 9 | 116 | 19 | 4 | 6 | 15 |
| 11=Davenport | 4 | 3 | 3 | 0 | 0 | 2 | 1 | 0 | 0 | 3 | 4 | 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| 12=Birmingham | 25 | 24 | 15 | 9 | 3 | 4 | 1 | 3 | 4 | 12 | 31 | 10 | 0 | 1 | 1 | 0 | 0 | 0 |
| 13=Greensboro | 2 | 2 | 2 | 0 | 0 | 0 | 0 | 0 | 2 | 2 | 8 | 1 | 0 | 1 | 0 | 0 | 0 | 0 |
| 14=Boston | 13 | 10 | 10 | 0 | 0 | 3 | 2 | 2 | 3 | 10 | 25 | 5 | 0 | 1 | 1 | 0 | 1 | 2 |
| 15=Buffalo | 13 | 13 | 12 | 1 | 4 | 1 | 2 | 1 | 4 | 8 | 24 | 3 | 1 | 3 | 0 | 0 | 1 | 0 |
| 16=Chicago | 3 | 1 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| 19=Atlanta | 8 | 8 | 7 | 1 | 0 | 3 | 0 | 0 | 4 | 7 | 19 | 2 | 0 | 2 | 2 | 0 | 1 | 0 |
| 20=Chicago-Evanston | 1 | 1 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| 21=Iowa City | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 23=Pawtucket | 26 | 26 | 19 | 7 | 3 | 13 | 1 | 2 | 0 | 16 | 21 | 10 | 2 | 2 | 0 | 2 | 0 | 0 |
| 24=Memphis | 10 | 10 | 9 | 1 | 0 | 2 | 1 | 1 | 5 | 9 | 27 | 4 | 0 | 3 | 2 | 0 | 0 | 0 |
| 25=Minneapolis | 16 | 16 | 15 | 1 | 1 | 3 | 3 | 1 | 7 | 14 | 40 | 6 | 1 | 6 | 0 | 0 | 0 | 1 |
| 26=Newark | 11 | 2 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 27=Phoenix | 15 | 8 | 7 | 1 | 0 | 2 | 3 | 1 | 1 | 7 | 15 | 5 | 0 | 0 | 1 | 1 | 0 | 0 |
| 28=Pittsburgh | 19 | 19 | 16 | 3 | 1 | 3 | 1 | 2 | 9 | 15 | 47 | 11 | 0 | 3 | 0 | 0 | 0 | 1 |
| 29=Tucson | 18 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 30=Davis | 28 | 14 | 14 | 0 | 4 | 2 | 2 | 3 | 3 | 10 | 27 | 8 | 0 | 0 | 1 | 0 | 0 | 1 |
| 42=Stanford | 39 | 39 | 29 | 10 | 5 | 11 | 5 | 1 | 7 | 24 | 52 | 16 | 1 | 7 | 0 | 0 | 0 | 0 |
| 43=Milwaukee | 24 | 8 | 6 | 2 | 0 | 4 | 0 | 0 | 2 | 6 | 12 | 2 | 0 | 4 | 0 | 0 | 0 | 0 |
| 44=George Wash. | 21 | 21 | 19 | 2 | 0 | 4 | 3 | 1 | 11 | 19 | 57 | 9 | 0 | 6 | 1 | 1 | 0 | 2 |
| 46=Gainesville | 18 | 16 | 11 | 5 | 0 | 7 | 0 | 0 | 4 | 11 | 23 | 3 | 0 | 4 | 4 | 0 | 0 | 0 |
| 47=Houston | 6 | 5 | 4 | 1 | 0 | 1 | 0 | 1 | 2 | 4 | 12 | 3 | 0 | 1 | 0 | 0 | 0 | 0 |
| 48=Worcester | 39 | 38 | 36 | 2 | 2 | 8 | 4 | 4 | 18 | 34 | 100 | 16 | 0 | 14 | 0 | 0 | 1 | 3 |

| | Clinical Center Contacts | | | | CCC Contacts | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Eligible | Contacted | Call Outcome | | Attempts | | | | | Total Contacts | | CCC Call Status | | | | | | | |
| Clinic | N | N | Agreed | Refused | Not Yet Attempted | 1 | 2 | 3 | 4 | Participant | Phone | DQ Completed | Declined | No Answer | Phone Disconnected | Unable to Locate | Other | Left a message (4th attempt only) |
| 49=New York | 29 | 18 | 15 | 3 | 0 | 2 | 0 | 0 | 13 | 15 | 54 | 2 | 0 | 11 | 0 | 0 | 2 | 0 |
| 50=Columbus | 26 | 26 | 8 | 18 | 6 | 1 | 0 | 0 | 1 | 2 | 5 | 0 | 1 | 1 | 0 | 0 | 0 | 0 |
| 51=Mediantic | 26 | 13 | 8 | 5 | 2 | 0 | 0 | 0 | 6 | 6 | 24 | 0 | 0 | 6 | 0 | 0 | 0 | 0 |
| 53=Oakland | 13 | 12 | 9 | 3 | 1 | 6 | 1 | 1 | 0 | 8 | 11 | 7 | 0 | 0 | 1 | 0 | 0 | 0 |
| 54=Jacksonville | 4 | 4 | 3 | 1 | 0 | 1 | 0 | 0 | 2 | 3 | 9 | 1 | 0 | 0 | 1 | 0 | 0 | 1 |
| 55=Torrance | 5 | 3 | 1 | 2 | 0 | 0 | 0 | 0 | 1 | 1 | 4 | 0 | 0 | 1 | 0 | 0 | 0 | 0 |
| 56=Madison | 15 | 14 | 10 | 4 | 3 | 1 | 3 | 1 | 2 | 7 | 18 | 6 | 0 | 1 | 0 | 0 | 0 | 0 |
| 57=Stony Brook | 28 | 25 | 12 | 13 | 1 | 1 | 3 | 0 | 7 | 11 | 35 | 3 | 0 | 5 | 1 | 0 | 0 | 2 |
| 58=Chapel Hill | 27 | 26 | 15 | 11 | 8 | 0 | 1 | 0 | 6 | 7 | 26 | 1 | 0 | 6 | 0 | 0 | 0 | 0 |
| 59/60=Chicago-Rush | 13 | 12 | 4 | 8 | 0 | 1 | 0 | 0 | 3 | 4 | 13 | 0 | 1 | 3 | 0 | 0 | 0 | 0 |
| 61=Cincinnati | 15 | 15 | 12 | 3 | 0 | 9 | 0 | 2 | 1 | 12 | 19 | 10 | 0 | 0 | 1 | 0 | 0 | 1 |
| 62=Detroit | 12 | 3 | 2 | 1 | 0 | 1 | 0 | 1 | 0 | 2 | 4 | 2 | 0 | 0 | 0 | 0 | 0 | 0 |
| 63=Irvine | 13 | 11 | 5 | 6 | 0 | 3 | 0 | 0 | 2 | 5 | 11 | 2 | 1 | 2 | 0 | 0 | 0 | 0 |
| 65=Nevada | 34 | 5 | 5 | 0 | 0 | 0 | 0 | 0 | 5 | 5 | 20 | 0 | 0 | 5 | 0 | 0 | 0 | 0 |
| 66=Portland | 25 | 14 | 5 | 9 | 0 | 2 | 1 | 0 | 2 | 5 | 12 | 2 | 0 | 1 | 2 | 0 | 0 | 0 |
| 67=San Antonio | 13 | 4 | 4 | 0 | 0 | 0 | 0 | 0 | 4 | 4 | 16 | 0 | 0 | 4 | 0 | 0 | 0 | 0 |
| 69=Fall River | 14 | 13 | 12 | 1 | 2 | 4 | 1 | 0 | 5 | 10 | 26 | 5 | 0 | 5 | 0 | 0 | 0 | 0 |
| 70=Pauline | 9 | 8 | 5 | 3 | 2 | 2 | 1 | 0 | 0 | 3 | 4 | 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| 71=Bowman Gray | 2 | 2 | 2 | 0 | 0 | 0 | 0 | 0 | 2 | 2 | 8 | 0 | 0 | 2 | 0 | 0 | 0 | 0 |
| 72=New Brunswick | 30 | 29 | 6 | 23 | 5 | 0 | 0 | 0 | 1 | 1 | 4 | 0 | 0 | 1 | 0 | 0 | 0 | 0 |
| 73=Des Moines | 19 | 17 | 10 | 7 | 0 | 1 | 2 | 0 | 7 | 10 | 33 | 5 | 0 | 4 | 0 | 0 | 0 | 1 |

**Attachment C**

# WHIMS SUITE OF STUDIES PUBLICATIONS AND ANCILLARY STUDIES COMMITTEE
## November, 2006


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## WHIMS Cerebral Magnetic Resonance Imaging (WHIMS-MRI) Sub-Study

**Study activities:**

The following key tasks have been completed during the no-cost extension: central reading, data analysis, data archiving, and development of manuscripts. A plan for dissemination of study data has been developed. A meeting was held at WFUHS for the purpose of discussing data analyses, development of study manuscripts and dissemination of study data. The WHIMS-MRI Working Group serves as an advisory group for the study. Regular conference calls were held with the Working Group to discuss data, dissemination and publications.

**WHIMS-MRI Data, Dissemination and Publications Meeting**

The WHIMS-MRI Data, Dissemination and Publications Meeting was held Tuesday, February 27, 2007 at Wake Forest University Health Sciences, Winston-Salem, NC. This meeting convened scientists across multiple clinical centers for discussion of newly emerging MRI research data and collaboration on dissemination of the study results to the scientific literature, study participants and the public at large.

The overall goals of the meeting were to:

- disclose and discuss preliminary WHIMS-MRI study results;
- plan and facilitate WHIMS-MRI publications and allow break-out sessions for writing groups;
- plan dissemination of WHIMS-MRI findings;
- discuss opportunities for future research and funding; and
- facilitate the networking of investigators from WHIMS-MRI clinical centers who are conducting research in cognition and MRI.

Conference materials were placed on the WHIMS-MRI website at the following address: https://www.phsapps.wfubmc.edu/whims/index.cfm

**Committee and Administrative Activity:**

**WHIMS-MRI Working Group/Data Analysis Sub-committee:** Conference calls were held on November 20 and December 18, 2006, and January 22, 2007. Primary issues discussed included the following: data analysis; timeline and venues for presenting data; publications; MRI data flow and archiving of images at WFUHS.

**Coordinating Center Archiving of Images:** Image data for 1411 completed scans have been received at Wake Forest University from the University of Pennsylvania. The image data are transmitted to WFU for central archival.

**Data/Analysis:** Data from the central reading of 1411 scans have been received at Wake Forest University. Data analyses to support study publications is underway

**Number of Participants Enrolled:**

**WHIMS-MRI Enrollment Report** (Attachment A): Clinical centers contacted 2344 of 2859 (82%) potential enrollees. 1528 women across the clinical sites consented to enroll in the WHIMS-MRI study. Of the 2344 women contacted, only 3.4% were ineligible due to absolute contraindications and 31% refused.

**Number of Completed Scans** (Attachment B): A total of 1426 subjects were recruited for MRI. 1425 participants completed the MRI scan. One participant was unable to complete the scan; however, some of the data from this scan were usable.

**Clinical Centers/Field Centers participating:**

| | |
|---|---|
| Chapel Hill Clinical Center | Clinic ID# 58 |
| Columbus Clinical Center | Clinic ID# 50 |
| Davis Vanguard Clinical Center | Clinic ID# 30 |
| Gainesville/Jacksonville Clinical Centers | Clinic ID# 46/54 |
| Des Moines Clinical Center (Satellite) | Clinic ID# 73 |
| Los Angeles Clinical Center | Clinic ID# 68 |
| Milwaukee Clinical Center | Clinic ID# 43 |
| Minneapolis Clinical Center | Clinic ID# 25 |
| Nevada Clinical Center | Clinic ID# 65 |
| New York City Clinical Center | Clinic ID# 49 |
| Pittsburgh Vanguard Clinical Center | Clinic ID# 28 |
| Stanford Clinical Center | Clinic ID# 42 |
| Worcester Clinical Center | Clinic ID# 48 |

**Summary of Findings to date:** Data analyses and study manuscripts are currently underway. Manuscripts for the primary and key secondary outcomes have been approved by the WHIMS PASC and the WHI P & P/PO.

**Publications**:

**Development of Manuscripts:** This was a primary objective during the no-cost extension. The WHIMS-MRI Data, Dissemination and Publications Meeting was held Tuesday, February 27, 2007 at Wake Forest University Health Sciences, Winston-Salem, NC. This meeting convened scientists across participating clinical centers for discussion of newly emerging MRI research data and collaboration on dissemination of the study results to the scientific literature, study participants and the public at large. This meeting was instrumental in progress towards development of manuscripts. Writing group members were convened to view and discuss the data.

Attachment A

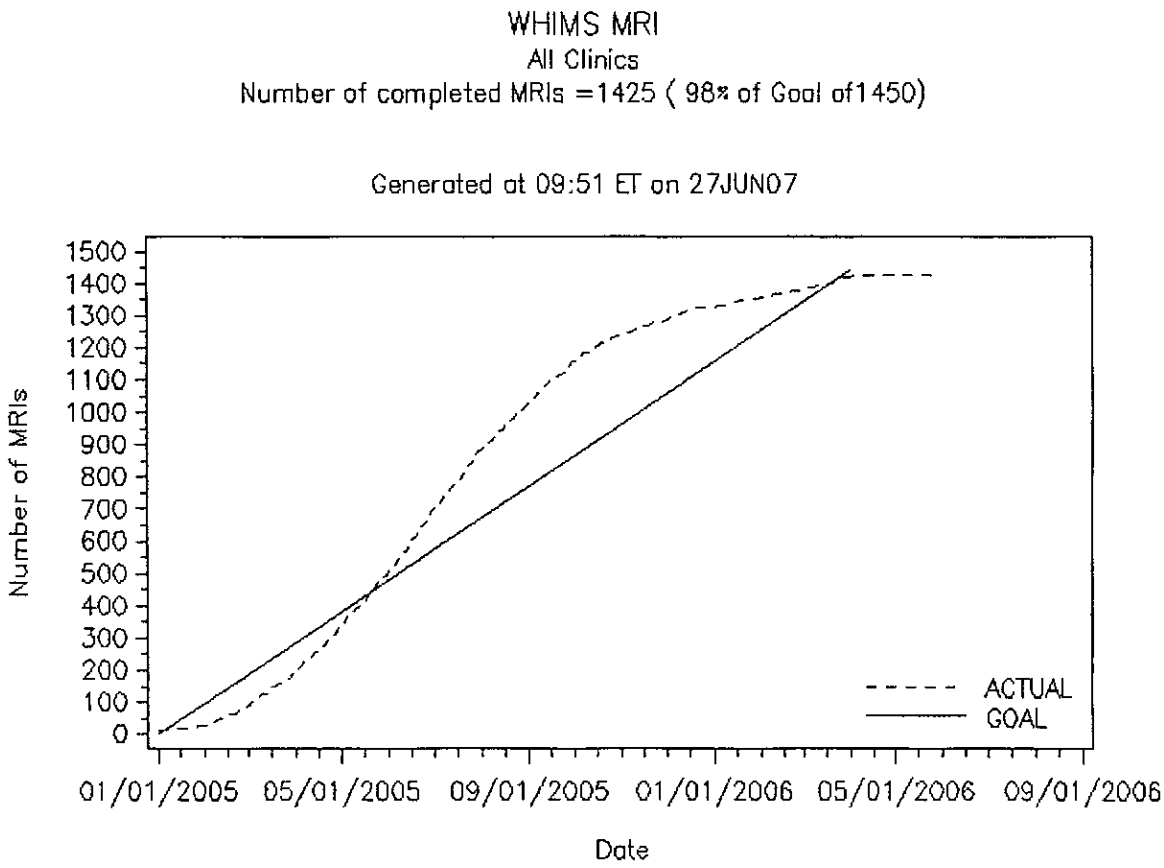
# *WHIMS MRI Screening*
## *Number screened by clinic*
*Generated at 14:48 ET on 27JUN07*

| | | | Ineligible due to absolute contraindication | | Refusal | | Missing screening status | | Eligible with additional follow-up | | Eligible and willing (MRI tech cleared device/condition) | | Eligible and willing | | Consented | | Consented and WHISCA participant | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clinic | Potential Enrollees^ | Contacted | N | % | N | % | N | % | N | % | N | % | N | % | N | %^^ | N | % |
| ALL CLINICS | 2851 | 2344 | 80 | 3.41% | 730 | 31.14% | 0 | 0.00% | 0 | 0.00% | 189 | 8.06% | 1345 | 57.38% | 1528 | 65.19% | 1166 | 76.31% |
| 25=Minneapolis | 194 | 160 | 15 | 9.38% | 39 | 24.38% | 0 | 0.00% | 0 | 0.00% | 23 | 14.38% | 83 | 51.88% | 106 | 66.25% | 77 | 72.64% |
| 28=Pittsburgh | 138 | 138 | 2 | 1.45% | 44 | 31.88% | 0 | 0.00% | 0 | 0.00% | 18 | 13.04% | 74 | 53.62% | 92 | 66.67% | 0 | 0.00% |
| 30=Davis | 189 | 128 | 6 | 4.69% | 14 | 10.94% | 0 | 0.00% | 0 | 0.00% | 8 | 6.25% | 100 | 78.13% | 109 | 85.16% | 82 | 75.23% |
| 42=Stanford | 229 | 151 | 7 | 4.64% | 13 | 8.61% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 131 | 86.75% | 127 | 84.11% | 98 | 77.17% |
| 43=Milwaukee | 222 | 120 | 5 | 4.17% | 7 | 5.83% | 0 | 0.00% | 0 | 0.00% | 16 | 13.33% | 92 | 76.67% | 108 | 90.00% | 104 | 96.30% |
| 46=Gainesville | 134 | 134 | 0 | 0.00% | 58 | 43.28% | 0 | 0.00% | 0 | 0.00% | 1 | 0.75% | 75 | 55.97% | 76 | 56.72% | 67 | 88.16% |
| 48=Worcester | 254 | 186 | 5 | 2.69% | 40 | 21.51% | 0 | 0.00% | 0 | 0.00% | 9 | 4.84% | 132 | 70.97% | 141 | 75.81% | 127 | 90.07% |
| 49=New York | 243 | 216 | 5 | 2.31% | 87 | 40.28% | 0 | 0.00% | 0 | 0.00% | 51 | 23.61% | 73 | 33.80% | 121 | 56.02% | 81 | 66.94% |
| 50=Columbus | 264 | 263 | 5 | 1.90% | 99 | 37.64% | 0 | 0.00% | 0 | 0.00% | 40 | 15.21% | 119 | 45.25% | 159 | 60.46% | 137 | 86.16% |
| 54=Jacksonville | 81 | 79 | 4 | 5.06% | 23 | 29.11% | 0 | 0.00% | 0 | 0.00% | 6 | 7.59% | 46 | 58.23% | 52 | 65.82% | 38 | 73.08% |
| 58=Chapel Hill | 222 | 188 | 4 | 2.13% | 75 | 39.89% | 0 | 0.00% | 0 | 0.00% | 15 | 7.98% | 94 | 50.00% | 108 | 57.45% | 86 | 79.63% |
| 65=Nevada | 187 | 99 | 9 | 9.09% | 12 | 12.12% | 0 | 0.00% | 0 | 0.00% | 1 | 1.01% | 77 | 77.78% | 79 | 79.80% | 52 | 65.82% |
| 68=Los Angeles | 210 | 198 | 7 | 3.54% | 88 | 44.44% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 103 | 52.02% | 103 | 52.02% | 88 | 85.44% |
| 73=Des Moines | 284 | 284 | 6 | 2.11% | 131 | 46.13% | 0 | 0.00% | 0 | 0.00% | 1 | 0.35% | 146 | 51.41% | 147 | 51.76% | 129 | 87.76% |

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

*^^ Denominator is # Contacted*

Attachment B



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

**Study Activities:**

As an ancillary study to the Women's Health Initiative Memory Study (WHIMS) Extension, WHISCA and now the WHISCA Extension conducted annual neuropsychological testing of participants enrolled at the 14 clinical sites through September 30, 2007. Annual assessments three, four, and five (Year 4, Year 5, and Year 6 including baseline) were completed; annual assessment six and seven (Year 7 and Year 8 including baseline) were ongoing at all sites; annual assessment eight (Year 9 including baseline) were begun at most sites. With the three additional years of testing provided by the current Extension, the WHISCA Extension is funded through June, 2008; data collection will end in September 30, 2007. All women continue to be followed off study medication due to early closure of the WHI E+P and WHI E-Alone HT trials. There have been 103 technicians certified through the life of the study with 23 technicians currently active. The smaller number reflects the reduction in clinic staff for the Extension. All fourteen clinical sites have at least one certified technician. All of the original WHISCA clinics are participating in the Extension with one exception; the University of Florida combined the clinical sites at Gainesville and Jacksonville into one clinical site at Gainesville. Technicians from the Gainesville clinic are conducting all of the test administrations. IRB approval for the Extension has been received from all 14 clinical sites.

**Number of Participants Enrolled:** Enrollment for the original contract period was completed June 30, 2001. The total enrollment for WHISCA has been revised to n=2304 (from n=2302) women. During data cleaning, two additional participants were added to the total enrollment making final enrollment 2304. The enrollment data for one participant was inadvertently omitted from the data entry process and was discovered when the technician attempted to enroll the participant for the Extension. The other participant had all data collected; however the data was not recorded by the clinical site. All follow-up data are now complete in the data base. Enrollment for the Extension is now at 1230 or 88% of projected enrollment. To date 1879 participants are reported to be at full follow-up status, leaving 273 participants who are alive but are not making clinic visits. There have been 152 participant deaths since the beginning of the study.

**Clinical Sites Participating:** There are 14 clinical centers:

| | |
|---|---|
| Chapel Hill Clinical Center | Clinic ID# 58 |
| Chicago-Rush Clinical Center | Clinic ID # 59 & 60 |
| Columbus Clinical Center | Clinic ID# 50 |
| Davis Vanguard Clinical Center | Clinic ID# 30 |
| Des Moines Clinical Center (Satellite) | Clinic ID# 73 |
| Gainesville/Jacksonville Clinical Centers | Clinic ID# 46/54 |
| Los Angeles Clinical Center | Clinic ID# 68 |
| Milwaukee Clinical Center | Clinic ID# 43 |
| Minneapolis Clinical Center | Clinic ID# 25 |
| Nevada Clinical Center | Clinic ID# 65 |

| | |
|---|---|
| New York City Clinical Center | Clinic ID# 49 |
| Pittsburgh Vanguard Clinical Center | Clinic ID# 28 |
| Stanford Clinical Center | Clinic ID# 42 |
| Worcester Clinical Center | Clinic ID# 48 |

**Findings to date:** With the WHI Estrogen plus Progestin and the WHI Estrogen Alone trials terminated early (July 9, 2002 and February 29, 2004 respectively) by the WHI DSMB, both the original WHISCA and the WHISCA Extension have continued to conduct annual neuropsychological testing of participants off study medication. Findings will not be known until after the September 30, 2007 study stop date.

**Publications:** The WHISCA Publications and Presentations (P & P) Committee was established with two representatives each from the WHISCA-CCC, WHISCA Principal Investigators, and the NIA. This
committee was combined with the WHIMS Suite of Studies PASC which is composed of Investigators from the WHIMS, WHIMS-MRI, and WHISCA studies. This revision reflects the renewed effort to encourage the development of manuscripts from a wider group.

The quarterly newsletter is now distributed online to all WHISCA PIs and technicians, the NIA, and the WHISCA-CCC.

# WHIMS Suite of Studies

## Publications and Ancillary Studies Committee

## Progress Report

## September, 2007

| | |
|---|---|
| **WHIMS Paper #2a**<br>**WHI Paper #173** | **A Prospective Study of the Relationship to Hypertension, Antihypertensive Treatment & Baseline Blood Pressure on Cognitive Decline and Dementia in Postmenopausal Women: Results from the WHIMS** |

| | | | |
|---|---|---|---|
| Writing Group Members: | Chair: | Karen Johnson | (Memphis) |
| | CCC facilitator: | Mark Espeland | (CCC) |
| | Primary data analyst: | Mark Espeland | (CCC) |
| | Other members: | Chris Colenda | (Former EAB) |
| | | Howard Fillit | (Former EAB) |
| | | JoAnn Manson | (Boston) |
| | | Karen Margolis | (Minneapolis) |
| | | Kamal Masaki | (Honolulu) |
| | | Charles Mouton | (San Antonio) |
| | | Ron Prineas | (WHI-CFC) |
| | | Jennifer Robinson | (Iowa) |
| | | Sylvia Smoller | (NYC) |
| Status: | ***As of 9/07 resubmitted draft manuscript approved for publication by the WHIMS PASC and the WHI P&P/PO.** | | |

| | |
|---|---|
| **WHIMS Paper #8**<br>**WHI Paper #157** | **Type 2 Diabetes and Change in Cognitive Functioning in WHIMS: The Effects of Diabetic Risk Factors and Treatment for Diabetes and Hypertension** |

| | | | |
|---|---|---|---|
| Writing Group Members: | Chair: | Laura Coker | (CCC) |
| | CCC facilitator: | Patricia Hogan | (CCC) |
| | Primary data analyst: | Patricia Hogan | (CCC) |
| | Other members: | Kathleen Hall | (Minneapolis) |
| | | David Mount | (CCC) |
| | | Judith Ockene | (Worcester) |
| | | Robert Wallace | (Iowa) |
| Status: | ***As of 9/07 the chair plans to revise this proposal using longitudinal data. Once revised, the proposal will be re-opened for study-wide writing group nominations. The Chair will develop a similar proposal using WHISCA longitudinal data.** | | |

| **WHIMS Paper #11**<br>**WHI Paper #595** | **Quality Assurance and Training in a Low Event Long-Term Clinical Trial (WHIMS)** | | |
|---|---|---|---|
| Writing Group Members: | Chair: | Maggie Dailey | (CCC) |
| | CCC facilitator: | Debbie Felton | (CCC) |
| | Other members: | Laura Coker | (CCC) |
| | | Kristin Kidd | (CCC) |
| | | Pam Nance | (CCC) |
| | | Cheryl Summerville | (CCC) |
| Status: | ***As of 9/07 manuscript proposal submitted and approved by the WHIMS PASC and the WHI P&P/PO. The group has met and begun drafting a manuscript.** | | |

| **WHIMS Paper #38**<br>**WHI Paper #275** | **Prior Use of HT and Incident Alzheimer's Disease in The WHIMS** | | |
|---|---|---|---|
| Writing Group Members: | Chair: | Victor Henderson | (EAB) |
| | CCC facilitator: | Patricia Hogan | (CCC) |
| | Primary data analyst: | Patricia Hogan | (CCC) |
| | Other members: | David Curb | (Honolulu) |
| | | Mark Espeland | (CCC) |
| | | Ruth Freeman | (NYC) |
| | | Karen Johnson | (Memphis) |
| | | Steve Rapp | (CCC) |
| | | Sylvia Smoller | (NYC) |
| | | Marcia Stefanick | (Stanford) |
| | | Jean W-Wende | (Buffalo) |
| Status: | ***As of 9/07 the manuscript is under revision.** | | |

| **WHIMS Paper #39**<br>**WHI Paper #276** | **Social Support and Cognitive Functioning in Post-Menopausal Women** | | |
|---|---|---|---|
| Writing Group Members: | Chair: | Catherine Messina | (S-Brook) |
| | CCC facilitator: | Mark Espeland | (CCC) |
| | Primary data analyst: | Sarah Jaramillo | (CCC) |
| | Other members: | Laura Coker | (CCC) |
| | | Dorothy Lane | (S-Brook) |
| | | Kamal Masaki | (Honolulu) |
| | | Lawrence Phillips | (Atlanta) |
| | | Lynda Powell | (Ch-Rush) |
| | | Milagros Rosal | (Worcester) |
| | | Sally Shumaker | (CCC) |
| Status: | ***As of 9/07 manuscript proposal and analysis underway.** | | |

| | | | |
|---|---|---|---|
| **WHIMS Paper #40**<br>**WHI Paper #283** | **Hormone Therapy has no Detrimental Effects on the Rate of Cognitive Change in Postmenopausal Women: The WHIMS** | | |
| Writing Group Members: | Chair: | Donald Royall | (San Antonio) |
| | CCC facilitator: | Mark Espeland | (CCC) |
| | Primary data analyst: | Mark Espeland | (CCC) |
| | Other members: | Chris Colenda | (Former EAB) |
| | | Jennifer Hays | (Houston) |
| | | Judith Ockene | (Worcester) |
| | | Ray Palmer | (San Antonio) |
| Status: | ***As of 3/07 nothing new to report.** As of 11/06 the draft manuscript had been revised and re-circulated to the writing group members for review and comment. Once revised, the draft manuscript will be reviewed by the WHIMS PASC and the WHI P&P/PO. | | |

| | | | |
|---|---|---|---|
| **WHIMS Paper #46**<br>**WHI Paper #360** | **Body Mass Index, Waist-Hip Ratio, and Cognitive Decline in Postmenopausal Women: Results from the WHIMS** | | |
| Writing Group Members: | Chair: | Diana Kerwin | (Milwaukee) |
| | CCC facilitator: | Sarah Jaramillo | (CCC) |
| | Primary data analyst: | Sarah Jaramillo | (CCC) |
| | Other members: | Rowan Chlebowski | (Torrance) |
| | | Laura Coker | (CCC) |
| | | Raymond Hoffmann | (Milwaukee) |
| | | Mark Espeland | (CCC) |
| | | Jane Kotchen | (Milwaukee) |
| | | Lew Kuller | (Pittsburgh) |
| | | Barb Nicklas | (WFUSM) |
| | | Monique Rainford | (MedStar) |
| | | Mara Vitolins | (W-S) |
| Status: | ***As of 9/07 a revised draft manuscript was reviewed and approved by PASC, upcoming planned submission to the WHI P&P/PO. Journal submission to follow WHI P&P/PO approval.** | | |

| | | | |
|---|---|---|---|
| **WHIMS Paper #47**<br>**WHI Paper #546** | **Predictors of Incident Dementia in Postmenopausal Women Enrolled in a Trial of HT: WHIMS** | | |
| Writing Group Members: | Chair: | Laura Coker | (CCC) |
| | CCC facilitator: | Claudine Legault | (CCC) |
| | Primary data analyst: | Claudine Legault | (CCC) |
| | Other members: | Chris Colenda | (Former EAB) |
| | | Nancy Greep | (Irvine) |
| | | Marian Limacher | (G-ville) |
| | | Anne Murray | (Minneap) |
| | | Monique Rainford | (MedStar) |
| | | Mara Vitolins | (W-S) |
| | | Bob Wallace | (Iowa) |
| Status: | ***As of 9/07 the writing group members had met by conference call, with data analyses and development of depression scale underway.** | | |

| | | | |
|---|---|---|---|
| **WHIMS Paper #49**<br>**WHI Paper #390** | **Identifying Risk Factors for cognitive change in the WHIMS: a Neural Networks Approach** | | |
| Writing Group Members: | Chair: | Stephan Bandelow | (Oxford) |
| | CCC facilitator: | Mark Espeland | (CCC) |
| | Primary data analyst: | Mark Espeland | (CCC) |
| | Other members: | Laura Coker | (CCC) |
| | | Victor Henderson | (EAB) |
| | | Eef Hogervorst | (Oxford) |
| | | Susan Resnick | (NIA) |
| | | Bob Wallace | (Iowa) |
| Status: | ***As of 6/07 the writing group members met and shortened the length of the final manuscript to meet journal requirements. Writing group members will research the appropriate target journal.** | | |

| | | | |
|---|---|---|---|
| **WHIMS Paper #50**<br>**WHI Paper #399** | **Subtypes of Mild Cognitive Impairment: Prevalence, Course and Effect of Hormone Therapy** | | |
| Writing Group Members: | Chair: | Steve Rapp | (CCC) |
| | CCC facilitator: | Claudine Legault | (CCC) |
| | Primary data analyst: | Claudine Legault | (CCC) |
| | Other members: | John Absher | (Adj. Com.) |
| | | Bob Brunner | (Nevada) |
| | | Victor Henderson | (EAB) |
| | | Bev Jones | (Adj. Com.) |
| | | Kamal Masaki | (Honolulu) |
| | | Leon Thal | (EAB) |
| Status: | ***As of 9/07 analyses are being finalized with plans to circulate the draft manuscript to the writing group.** | | |

| | | | |
|---|---|---|---|
| **WHIMS Paper #51**<br>**WHI Paper #427** | **Statin Use and Cognition in Postmenopausal Women: the WHIMS** | | |
| Writing Group Members: | Chair: | Claudine Legault | (CCC) |
| | CCC facilitator: | Claudine Legault | (CCC) |
| | Primary data analyst: | Claudine Legault | (CCC) |
| | Other members: | Howard Fillit | (Former EAB) |
| | | Judy Hsia | (GWU) |
| | | Marian Limacher | (G-ville) |
| | | JoAnn Manson | (Boston) |
| | | Ira Ockene | (Worcester) |
| | | Jennifer Robinson | (Iowa) |
| | | Barbara Sherwin | (EAB) |
| | | Kaycee Sink | (WFUSM) |
| Status: | ***As of 9/07 a conference call had been conducted to discuss data analysis.** | | |

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| **WHIMS Paper #52**<br>**Paper#5**<br>**WHI Paper #** | **Associations Between Body Mass Index and WHISCA Domain-Specific Cognitive Function Among Women Enrolled in the WHISCA** | | |
| Writing Group Members: | Chair: | Diana Kerwin | (Milwaukee) |
| | CCC facilitator: | Mark Espeland | (CCC) |
| | Primary data analyst: | Sarah Jaramillo | (CCC) |
| | Other members: | | |
| Status: | ***As of 6/07 the chair is meeting with the data analyst and facilitator to identify the variables needed for analysis. This is in response to the manuscript proposal review by PASC.** | | |

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| **WHIMS Paper #54**<br>**WHI Paper #558** | **Cognitive Function and Physical Performance in the WHIMS** | | |
| Writing Group Members: | Chair: | Hal Atkinson | (WFUSM) |
| | CCC facilitator: | Mark Espeland | (CCC) |
| | Primary data analyst: | Mark Espeland | (CCC) |
| | Other members: | John Absher | (WFUSM) |
| | | Margery Gass | (Cincinnati) |
| | | Victor Henderson | (EAB) |
| | | Karen Johnson | (Memphis) |
| | | John Kostis | (Newark) |
| | | Dorothy Lane | (S-Brook) |
| | | Charles Mouton | (MedStar) |
| | | Judy Ockene | (Worcester) |
| | | Steve Rapp | (CCC) |
| | | Marcia Stefanick | (Stanford) |
| Status: | ***As of 9/07 preliminary analyses have been done. Writing group members will convene in August to begin drafting the manuscript. Abstract approved for presentation at the GSA by PASC & P&P.** | | |

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| **WHIMS Paper #55**<br>**WHISCA/CoStar #1**<br>**Paper #579** | **Relative Effects of Tamoxifen, Raloxifene, and Estrogen Therapy on Cognition: Results from the WHI WHISCA and CoStar Trials** | | |
| Writing Group Members: | Chair: | Mark Espeland | (CCC) |
| | CCC facilitator: | Mark Espeland | (CCC) |
| | Primary data analyst: | Sarah Jaramillo | (CCC) |
| | Other members: | David Barad | (NYC) |
| | | Dorothy Lane | (S-brook) |
| | | Marian Limacher | (G-ville) |
| | | Susan Resnick | (NIA) |
| | | Sally Shumaker | (CCC) |
| | | Marcia Stefanick | (Stanford) |
| Status: | ***As of 9/07 manuscript proposal approved by WHIMS PASC and the WHI P&P/PO. WHISCA writing group members finalized, CoStar members are under review.** | | |

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| **WHIMS Paper #56**<br>**Paper #6**<br>**Paper #598** | **Effects of Conjugated Equine Estrogens on WHISCA Cognition and Affect in Surgically Menopausal WHI Women: WHISCA** | | |
| Writing Group Members: | Chair: | Susan Resnick | (NIA) |
| | CCC facilitator: | Mark Espeland | (CCC) |
| | Primary data analyst: | Mark Espeland | (CCC) |
| | Other members: | Yang An | (NIA) |
| | | Laura Coker | (CCC) |
| | | Rebecca Jackson | (Columbus) |
| | | Pauline Maki | (NIA) |
| | | Marcia Stefanick | (Stanford) |
| | | Bob Wallace | (Iowa) |
| Status: | *** As of 9/07 members are working on a draft manuscript. A conference call is planned for October to finalize the draft.** | | |

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| **WHIMS Paper #57**<br>**WHI Paper #597** | **Prevalence of Anticholinergic Drug Use and Impact on Cognition and Function in Older Women** | | |
| Writing Group Members: | Chair: | Kaycee Sink | (CCC) |
| | CCC facilitator: | Mark Espeland | (CCC) |
| | Primary data analyst: | Mark Espeland | (CCC) |
| | Other members: | Margery Gass | (Cincinnati) |
| | | David Goff | (WFUSM) |
| | | Steve Rapp | (CCC) |
| | | Barbara Sherwin | (EAB) |
| | | Asha Thomas | (MedStar) |
| Status: | *** As of 9/07 preliminary analyses are underway. The writing group members will convene soon to begin drafting a manuscript.** | | |

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| **WHIMS Paper #58**<br>**WHI Paper #** | **COX-2 Inhibitor Use and Cognitive Function: Interaction with Postmenopausal Hormone Therapy (WHIMS)** | | |
| Writing Group Members: | Chair: | TBN | |
| | CCC facilitator: | Mark Espeland | (CCC) |
| | Primary data analyst: | Mark Espeland | (CCC) |
| | Other members: | | |
| Status: | ***As of 6/07 the chair has stepped down (Judy Hsia). A replacement is forthcoming.** The manuscript proposal has been reviewed by the WHIMS PASC, with requested revisions. Once revised, the proposal will be reviewed by the WHI P&P/PO. | | |

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| **WHIMS Paper #59**<br>**WHI Paper #612** | **Impact of Prehypertension on Cognitive Function: (WHIMS)** | | |
| Writing Group Members: | Chair: | TBN | |
| | CCC facilitator: | Mark Espeland | (CCC) |
| | Primary data analyst: | Mark Espeland | (CCC) |
| | Other members: | | |
| Status: | ***As of 6/07 the chair has stepped down (Judy Hsia). A replacement is forthcoming.** The manuscript proposal has been reviewed by the WHIMS PASC and approved. The proposal was reviewed by the WHI P&P/PO on their 10/12/06 call with requested revisions and resubmission. | | |

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| **WHIMS Paper #60**<br>**MRI Paper #2**<br>**Paper #625** | **Effects of Postmenopausal HT on Volumetric WHIMS-Subclinical Cerebrovascular Disease: the WHIMS-WHI MRI.** | | |
| Writing Group Members: | Chair: | Laura Coker | (CCC) |
| | CCC facilitator: | Patricia Hogan | (CCC) |
| | Primary data analyst: | Patricia Hogan | (CCC) |
| | Other members: | Alyson Baird | (NIH) |
| | | Kerstin Betterman | (WFUSM) |
| | | Nick Bryan | (UPenn) |
| | | Ruth Freeman | (NYC) |
| | | Lew Kuller | (P-burgh) |
| | | Zhiqiang Lao | (UPenn) |
| | | Karen Margolis | (Minneapolis) |
| | | Sally Shumaker | (CCC) |
| | | Marcia Stefanick | (Stanford) |
| | | Bob Wallace | (Iowa) |
| Status: | ***As of 9/07 the proposal was approved by WHIMS PASC and the WHI P&P/PO. The group is drafting a manuscript.** | | |

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| **WHIMS Paper #61**<br>**WHIMS-MRI Paper #3**<br>**WHI Paper # 626** | **Effects of Postmenopausal HT on Regional Brain Volumes: the WHIMS-MRI** | | |
| Writing Group Members: | Chair: | Susan Resnick | (NIA) |
| | CCC facilitator: | Mark Espeland | (CCC) |
| | Primary data analyst: | Sarah Jaramillo | (CCC) |
| | Other members: | Christos Davatzikos | (UPenn) |
| | | Calvin Hirsch | (Davis) |
| | | Anne Murray | (Minneapolis) |
| | | Judy Ockene | (Worcester) |
| | | Marcia Stefanick | (Stanford) |
| Status: | ***As of 9/07 the proposal was approved by the WHIMS PASC and the WHI P&P/PO. The group is drafting a manuscript.** | | |

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| **WHIMS Paper #62**<br>**WHIMS-MRI #4**<br>**WHI Paper #** | **Associations that Cognitive Domains (WHISCA battery) have with MRI Outcomes: the WHIMS-MRI** | | |
| Writing Group Members: | Chair: | Bob Brunner | (Nevada) |
| | CCC facilitator: | Mark Espeland | (CCC) |
| | Primary data analyst: | Patricia Hogan | (CCC) |
| | Other members: | Yang An | (NIA) |
| | | Victor Henderson | (Stanford) |
| | | Abass Jawad | (UPenn) |
| | | Jerry Mysiw | (Columbus) |
| | | Steve Rapp | (CCC) |
| | | Susan Resnick | (NIA) |
| | | Sally Shumaker | (CCC) |
| | | Jeff Williamson | (WFUSM) |
| Status: | ***As of 9/07 the writing group has been formed. The proposal is currently under review by WHIMS PASC with review deadline of 10/11/07. Once approved, the proposal will be submitted to the WHI P&P/PO for their review.** | | |

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| **WHIMS Paper #63**<br>**MRI Paper #5**<br>**WHI Paper #** | **Differences in MRI Outcomes Associated with WHIMS-Cognitive Decline, Mild Cognitive Impairment and Probable Dementia** | | |
| Writing Group Members: | Chair: | Steve Rapp | (CCC) |
| | CCC facilitator: | Sarah Jaramillo | (CCC) |
| | Primary data analyst: | Sarah Jaramillo | (CCC) |
| | Other members: | Bob Brunner | (Nevada) |
| | | Rebecca Jackson | (Columbus) |
| | | Jane Kotchen | (Milwaukee) |
| | | Dorothy Lane | (S-Brook) |
| | | Claudine Legault | (CCC) |
| | | Marian Limacher | (G-ville) |
| | | Elias Melham | (UPenn) |
| | | Evi Parmpi | (UPenn) |
| | | Jennifer Robinson | (Iowa) |
| Status: | ***As of 9/07 the writing group has been formed and a proposal is forthcoming.** | | |

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| **WHIMS Paper #64**<br>**WHIMS-MRI Paper #6**<br>**WHI Paper #696** | **The Relationship of Hypertension, Blood Pressure and Blood Pressure Control with MRI Outcomes** | | |
| Writing Group Members: | Co-Chairs: | Lew Kuller | (P-burgh) |
| | | Karen Margolis | (Minneapolis) |
| | CCC facilitator: | Sarah Jaramillo | (CCC) |
| | Primary data analyst: | Sarah Jaramillo | (CCC) |
| | Other members: | Nick Bryan | (UPenn) |
| | | Diana Kerwin | (Milwaukee) |
| | | Marian Limacher | (G-ville) |
| | | Gul Moonis | (UPenn) |
| | | Jennifer Robinson | (Iowa) |
| | | Sylvia Smoller | (NYC) |
| | | Jeff Williamson | (WFUSM) |
| Status: | ***As of 9/07 the manuscript proposal has been approved by the WHIMS PASC and WHI P&P/PO. The group has begun drafting a manuscript.** | | |

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| **WHIMS Paper #65**<br>**WHIMS-MRI Paper #7**<br>**WHI Paper #** | **Do MRI Outcomes Predict Subsequent Declines in Global and Domain Specific Cognition: the WHIMS-MRI** |

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| Writing Group Members: | Chair: | Susan Resnick | (NIA) |
| | CCC facilitator: | Sarah Jaramillo | (CCC) |
| | Primary data analyst: | Sarah Jaramillo | (CCC) |
| | Other members: | Laura Coker | (CCC) |
| | | Christos Davatzikos | (UPenn) |
| | | Satoru Haysaka | (WFUSM) |
| | | Diana Kerwin | (Milwaukee) |
| | | Zhiqiang Lao | (UPenn) |
| | | Carol Murphy | (C-Hill) |
| | | Jerry Mysiw | (Columbus) |
| | | Lauren Nathan | (UCLA) |

Status: ***As of 9/07 the writing group has been formed and a proposal is forthcoming.**

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| **WHIMS Paper #66**<br>**WHI Paper #639** | **Psychiatric Disorders and Co-Morbid Adjudicated Cognitive Dysfunction Among Postmenopausal Women: Results from the WHIMS** |

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| Writing Group Members: | Chair: | Chris Colenda | (CCC) |
| | CCC facilitator: | Claudine Legault | (CCC) |
| | Primary data analyst: | Claudine Legault | (CCC) |
| | Other members: | Maggie DeBon | (Memphis) |
| | | Linda Hershey | (Buffalo) |
| | | Judith Ockene | (Worcester) |
| | | Lawrence Phillips | (Atlanta) |
| | | Steve Rapp | (CCC) |
| | | Gloria Sarto | (Madison) |
| | | Robert Wallace | (Iowa) |
| | | Rachel Whitmer | (Oakland) |

Status: ***As of 9/07 analysis and draft manuscript underway.**

| **WHIMS Paper #67**<br>**WHI Paper #670** | **Long-term Neurocognitive Effects of Sleep Disturbance: Impacts on Cognitive Declines, and Incidence of Mild Cognitive Impairment and Dementia** |
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| Writing Group Members: | Chair: | JC Chen | (Chapel Hill) |
| | CCC facilitator: | Mark Espeland | (CCC) |
| | Primary data analyst: | Laura Lovato | (CCC) |
| | Other members: | Robert Brunner | (Nevada) |
| | | Karen Johnson | (Memphis) |
| | | Jane Kotchen | (Milwaukee) |
| | | JoAnn Manson | (Boston) |
| | | Jerry Mysiw | (Columbus) |
| | | Lawrence Phillips | (Atlanta) |
| | | Jennifer Robinson | (Iowa) |
| | | Gloria Sarto | (Madison) |
| | | Marcia Stefanick | (Stanford) |
| | | Robert Wallace | (Iowa) |

Status: ***As of 9/07 the manuscript proposal was reviewed and approved by PASC & the WHI P&P/PO. Writing group nominations have been finalized and data analyses are underway.**

| **WHIMS Paper #68**<br>**WHI Paper #665** | **Ascertaining Dementia Related Outcomes for Deceased or Proxy-Dependent Participants: An Overview of the WHIMS Supplemental Case Ascertainment Protocol (SCAP)** |
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| Writing Group Members: | Chair: | Sarah Jaramillo | (CCC) |
| | CCC facilitator: | Sarah Jaramillo | (CCC) |
| | Primary data analyst: | Sarah Jaramillo | (CCC) |
| | Other members: | John Absher | (WFUSM) |
| | | Mark Espeland | (CCC) |
| | | Bev Jones | (WFUSM) |
| | | Steve Rapp | (CCC) |

Status: ***As of 9/07 the manuscript proposal was reviewed and approved by PASC & the WHI P&P/PO. Writing group nominations have been finalized and data analyses are underway.**

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| **WHIMS Paper #69**<br>**WHI Paper #683** | **Influence of Educational Attainment on Relationships Between Neuropathology and Cognitive Function: The WHIMS** | | |
| Writing Group Members: | Chair: | Mark Espeland | (CCC) |
| | CCC facilitator: | Mark Espeland | (CCC) |
| | Primary data analyst: | Mark Espeland | (CCC) |
| | Other members: | JoAnn Manson | (Boston) |
| | | Steve Rapp | (CCC) |
| Status: | ***As of 9/07 the manuscript proposal was reviewed and approved by PASC and WHI P&P/PO. The proposal has been opened studywide for writing group nominations with a nomination deadline of 10/22/07.** | | |

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| **WHIMS Paper #70**<br>**WHIMS-MRI Paper #8**<br>**WHI Paper #680** | **Mixed Distribution Risk Factors Models for Ischemic Lesion Prevalence and Extent: The WHIMS-MRI** | | |
| Writing Group Members: | Chair: | Mark Espeland | (CCC) |
| | CCC facilitator: | Mark Espeland | (CCC) |
| | Primary data analyst: | Mark Espeland | (CCC) |
| | Other members: | Yang An | (NIA) |
| | | Susan Resnick | (NIA) |
| | | Janet Tooze | (WFUSM) |
| Status: | ***As of 9/07 the manuscript proposal was reviewed and approved by PASC and WHI P&P/PO. The proposal has been opened studywide for writing group nominations with a nomination deadline of 10/22/07.** | | |

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| **WHIMS Paper #71**<br>**WHISCA Paper #6**<br>**WHI Paper #695** | **Application of Hidden Markov Models for Longitudinal Measures of Cognition Collected by the WHISCA** | | |
| Writing Group Members: | Chair: | Edward Ip | (CCC) |
| | CCC facilitator: | Claudine Legault | (CCC) |
| | Primary data analyst: | Claudine Legault | (CCC) |
| | Other members: | Allison Snow-Jones | (WFUSM) |
| | | Steve Rapp | (CCC) |
| | | Peter Zhang | (WFUSM) |
| Status: | ***As of 9/07 the manuscript proposal has been approved by the WHIMS PASC. The proposal will be reviewed by the WHI P&P/PO on their 10/11/07 call.** | | |

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Espeland, M.A., Gu, L., Masaki, K.H., Langer, R.D., Coker, L.H.; Stefanick, M.L., Ockene, J., Rapp, S.R. Association between reported alcohol intake and changes in cognition: results from the Women's Health Initiative Memory Study (WHIMS). **American Journal of Epidemiology**, 2005; 161 (3): 228-238

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Espeland, M.A., Rapp, S.R., Shumaker, S.A., Brunner, R.L., Manson, J.E., Sherwin, B.B., Hsia, J., Margolis, K.L., Hogan, P.E., Wallace, R., Dailey, M., Freeman, R., Hays, J. Conjugated equine estrogens and global cognitive function in postmenopausal women: the Women's Health Initiative Memory Study. **The Journal of the American Medical Association**, 2004, 291:2959-2968.

Shumaker, S.A., Legault, C., Rapp, S.R., Thal, L., Wallace, R.B., Ockene, J.K., Hendrix, S.L., Jones, B.N., Assaf, A.R., Jackson, R.D., Kotchen, J.M., Wassertheil-Smoller, S. & Wactawski-Wende, J. Estrogen plus progestin and the incidence of dementia and mild cognitive impairment in postmenopausal women: the Women's Health Initiative Memory Study. **The Journal of the American Medical Association**, 2003, 289:2651-2662.

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Schneider, L.S. Estrogen and dementia: insights from the women's health initiative memory study. **Journal of the American Medical Association**, 2004, 291: (24).

**WHIMS Suite of Studies**
**Presentations-Submitted/Confirmed**

| Conference Date | Title | City | Speaker Candidates | Current Decision | Submitted | Confirmed |
|---|---|---|---|---|---|---|
| June 27, 2003 | National Surgical Adjuvant Breast & Bowel Project | Orlando, Florida | Rapp | Yes | Yes | Yes |
| September 17-20, 2003 | North American Menopause Society | Miami Beach, Florida | Shumaker Legault | Yes | Yes | Yes |
| September 30, 2003 | University of Utah OB-GYN Grand Rounds | Salt Lake City, Utah | Rapp | Yes | Yes | Yes |
| October 3, 2003 | University of North Carolina at Chapel Hill/GCRC | Chapel Hill, NC | Legault Shumaker | Yes | Yes | Yes |
| October 29-31, 2003 | 9th Annual Graylyn Conference on Women's Health | Winston-Salem, NC | Shumaker Rapp | Yes | Yes | Yes |
| November 21-25, 2003 | Gerontological Society of America | San Diego, California | Shumaker Rapp | Yes | Yes | Yes |
| December 6-11 2003 | American College of Neuropsycho-pharmacology | San Juan, Puerto Rico | Rapp | Yes | Yes | Yes |
| February, 2004 | International Society of Hypertension | Sao Paulo, Brazil | Rapp | Yes | Yes | Yes |
| March 7-10, 2004 | American College of Cardiology | New Orleans, LA | Smoller | Yes | Yes | Yes |

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|---|---|---|---|---|---|---|
| March 17-20, 2004 | International Congress of Women's Health | Bethesda, Maryland | Shumaker | Yes | Yes | Yes |
| March 24-27, 2004 | Society of Behavioral Medicine | Baltimore, MD | Shumaker Ockene | Yes | Yes | Yes |
| April 21-24, 2004 | The Women's Health and Menopause Conference | Florence, Italy | Legault | Yes | Yes | Yes |
| May 1-6, 2004 | American Psychiatric Association | New York, NY | Shumaker | Yes | Yes | Yes |
| November 19-23, 2004 | Gerontological Society of America | Washington, DC | Coker Legault Rapp | Yes | Yes | Yes |

**WHIMS Suite of Studies**
**Presentations-Submitted/Confirmed**

| Conference Date | Title | City | Speaker Candidates | Current Decision | Submitted | Confirmed |
|---|---|---|---|---|---|---|
| April 9, 2005 | American Academy of Neurology | Miami, Florida | Shumaker | Yes | Yes | Yes |
| May 22-25, 2005 | Society for Clinical Trials | Portland, Oregon | Espeland | Yes | Yes | Yes |
| June 2, 2005 | University of Michigan OB-GYN Grand Rounds | Ann Arbor, Michigan | Shumaker | Yes | Yes | Yes |
| October 27, 2005 | 10th Annual Graylyn Conference on Women's Cognitive Health | Winston-Salem, NC | Espeland | Yes | Yes | Yes |
| May 21-24, 2006 | Society for Clinical Trials Meeting | Orlando, FL | Andrews | Yes | Yes | Yes |
| May 21-24, 2006 | Society for Clinical Trials Meeting | Orlando, FL | Jaramillo | Yes | Yes | Yes |
| May 21-24, 2006 | Society for Clinical Trials Meeting | Orlando, FL | Desiderio | Yes | Yes | Yes |
| November, 2006 | Gerontological Society of America | Dallas, TX | Rapp | Yes | Yes | Yes |
| March 27, 2007 | Society of Toxicology | Charlotte, NC | Legault | Yes | Yes | Yes |
| May 2, 2007 | American Academy of Neurology | Boston, MA | Henderson | Yes | Yes | Yes |
| May 20-23, 2007 | Society of Clinical Trials | Montreal, Canada | Jaramillo | Yes | Yes | Yes |
| June 9-12, 2007 | International Conference on Prevention of Dementia | Washington, DC | Rapp | Yes | Yes | Yes |

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|---|---|---|---|---|---|---|
| October 24-26, 2007 | 11th Annual Graylyn Conference on Women's Cognitive Health | Winston-Salem, NC | Coker<br>Davatzikos<br>Rapp<br>Resnick | Yes | Yes | Yes |
| November, 2007 | Gerontological Society of America | San Francisco, CA | Atkinson | Yes | Yes | Yes |
| April, 2008 | American Academy of Neurology | Chicgo, IL | Coker<br>Espeland<br>Resnick | Yes | Pending | Pending |