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# OS Objectives, Hypotheses, and Biomarkers

# SECTION 1-A5
# PROTOCOL APPENDIX 5

# WOMEN'S HEALTH INITIATIVE OBSERVATIONAL STUDY
# OVERVIEW OF OBJECTIVES AND HYPOTHESES

## 1-A5.1 Objectives

The objective of the Observational Study (OS) is to provide information complementary to that obtained from the Clinical Trial (CT). Measurement of baseline characteristics, remeasurement after three years, storage of frozen blood specimens, and ascertainment of clinical events in a large cohort of postmenopausal women allow the following specific objectives to be formulated:

1) Prediction of risk of outcome on the basis of:
   - Questionnaires and interview data
   - Physical exam findings
   - Laboratory data

2) Extension of results in the CT to related exposures and regimens

3) Assessment of temporal relationships between risk factors and disease occurrence

4) Documentation of variation in the incidence of cardiovascular disease, cancer, osteoporosis and fracture in postmenopausal women on the basis of geographic region and other demographic characteristics, and an evaluation of the extent to which differences among demographic subgroups in the prevalence of identified risk factors account for such variation. *Table 2-A5.1 - Cumulative Number of Events For 100,000 Women Age 50-79 Years At Baseline* presents estimates of the number of events of various types at 3, 6, and 9 years of follow-up.

## 1-A5.2 Hypotheses

These hypotheses include those of high priority that have been stated to date. This is not an exhaustive listing and future hypotheses will be added as they are developed. *Table 1-A5.2 - Summary of Exposure/Disease Hypotheses* summarizes the general exposure/disease hypotheses of interest initially.

**Disease-Related Hypotheses Classified by Predictive Factors**

1) **Diet**

   a) Antioxidant intake (vitamins C and E, carotenoids, selenium, zinc) predicts decreased risk of cancer, coronary heart disease (CHD), and stroke.

   b) Fiber intake is associated with lower risk of colorectal cancer, breast cancer, and other cancers, as well as CHD and stroke.

   c) Alcohol intake predicts decreased risk of cardiovascular disease, and increased risk of breast and colorectal cancer.

   d) Alcohol intake during adolescence increases risk of breast cancer during adulthood.

   e) Intake of vitamins B6, B12, and folate is associated with decreased risk of CHD and stroke. Folate intake predicts reduced risk of colorectal cancer.

   f) Coffee and caffeine are related to increased risk of CHD and stroke, as well as fracture.

g) Coffee and caffeine predict reduced risk of breast and ovarian cancer and increased risk of colorectal cancer.

h) Salt, alcohol, and calcium intake are predictors of hypertension.

i) Intake of vitamin D and calcium predicts lower risk of CHD and stroke, as well as cancer.

j) Dietary fat and fatty acid intake is related to breast, endometrial and other cancers. Different types of dietary fat may have different effects on the risk of breast and other cancers. Dietary fat may also have an effect on breast cancer survival.

k) Dietary fat and subtypes are related to risk of cardiovascular disease. Trans fatty acids increase risk of CHD and stroke; oleic acid may decrease these risks. Fish and omega-3 FA's predict reduced risks. Dietary fat and subtypes also predict total mortality.

l) Excessive intake of alcohol is associated with decreased bone density and increased risk of fractures.

m) Other dietary factors such as intake of excessive carbonated beverages may reduce bone density and increase fracture incidence, possibly secondary to high phosphoric acid content. Similarly, high levels of phosphate in the diet may predispose to bone loss, possibly as a result of increased parathyroid hormone levels.

n) High protein intake may increase bone loss and fracture due to associated increased calcium excretion.

o) Increased dietary fiber, magnesium, potassium, calcium, and antioxidant vitamins, as well as reduced dietary fat, decrease the occurrence of non-insulin-dependent diabetes mellitus (NIDDM).

p) Frequency of eating alters the risk of colorectal cancer.

2) **Physical Activity**

a) Physical activity independent of adiposity predicts lower risk of CHD and stroke.

b) Physical activity predicts increased bone mineral density and decreased risk of fracture.

c) Regular physical activity reduces the incidence of NIDDM.

d) Physical activity decreases the risk of breast and colorectal cancer.

e) Physical activity decreases total mortality.

3) **Body Habitus**

a) Weight, adipose distribution, weight cycling are predictors of CHD, stroke, and cancer.

b) Height is a predictor of cardiovascular disease and cancer.

c) Weight gain since early adulthood (age 18) is related to breast, endometrial and colorectal cancer, as well as CHD and stroke.

d) Body weight is related to breast cancer survival.

e) Lower weight is related to decreased bone density and osteoporosis-related fractures.

f) Body fat distribution and weight change predict risk of NIDDM.

g) Predictors of weight gain in adulthood include decreased physical activity, increased percentage of energy from fat, weight cycling, and obesity in late adolescence.

h) Blood pressure is associated with waist-hip ratio (WHR) and weight gain.

i) Some determinants of the variance in waist-hip ratio are modifiable (physical activity, dietary fat, smoking, alcohol, hormone therapy). These and other variables can also be assessed as predictors of change in WHI at the three-year visit.

j) Higher birth weight is associated with breast cancer.

4) **Reproductive factors**

a) Reproductive factors including increased age at first birth, lower parity, early age at menarche, late menopause, oligomenorrhea, and infertility may be associated with breast, endometrial, ovarian and colorectal cancer.

b) Reproductive factors including age at menopause and parity predict risk of CHD and stroke.

c) Several reproductive variables including parity and lactation are predictors of bone density and osteoporosis-related fractures.

d) Lactation is associated with decreased risk of breast and other cancers. Having been breast fed as an infant may also predict a reduced risk of breast cancer.

e) Tubal ligation and hysterectomy reduce risk of ovarian cancer.

5) **Medications**

a) Non-steroidal anti-inflammatory drugs (NSAIDs) may prevent CHD and stroke events, colorectal cancer, and may decrease dementia in arthritis patients.

b) Antioxidant drugs may prevent tissue damage when an acute coronary or cerebrovascular occlusion occurs.

c) Multivitamin and mineral supplement use may decrease risk of cancer, CHD, stroke, and osteoporotic fractures.

d) Past oral contraceptive use:

1) may be associated with increased risk of breast cancer and decreased risk of ovarian and endometrial cancer (variables of interest would include duration, age at first use, use before first full-term pregnancy).

2) is not associated with increased risk of CHD and stroke.

3) is a predictor of bone density and osteoporosis-related fractures.

e) Past use of diethylstilbestrol (DES) is associated with increased risk of breast cancer.

f) Hormone replacement therapy (HRT) predicts CHD, stroke, cancer, and fracture risk. Dosage, type, duration, and regimen used can be examined.

g) Higher endogenous estrogen levels is related to benefit from HRT with regard to fracture risk.

h) Medications such as thiazide diuretics are predictors of osteoporosis-related fractures. Also of interest are glucocorticoids, lasix, dilantin and tamoxifen. Further, thyroxine replacement therapy, particularly when associated with suppression of thyroid stimulating hormone, may be a determinant of bone density and fracture risk.

i) Antacids with high levels of calcium are related to fracture risk.

j) Class of antihypertensive medication may modify the risk of CHD and stroke.

k) Cimetidine increases breast cancer risk (via effects on estrogen metabolism).

6) **Smoking**

a) Cigarette smoking is a predictor of reduced bone density and osteoporosis-related fractures.

b) Smoking increases risk of CHD, stroke, diabetes, cataracts, colorectal cancer, disability, and total mortality.

c) Smoking is a risk factor for asthma in postmenopausal women.

d) Exposure to passive smoking is a risk factor for CHD, stroke, cancer and fractures.

7) Pathology

a) Mammographic patterns of dysplasia, as well as benign breast disease histologic subtypes are predictors of breast cancer.

8) **Medical History**

a) History of high cholesterol is related to CHD and stroke events.

b) History of high blood pressure is related to CHD and stroke.

c) History of benign breast disease alters breast cancer risk (depending on histologic subtype).

d) History of polyps is associated with risk of colorectal cancer.

e) History of atrial fibrillation is associated with CHD and cerebrovascular events.

f) Breast implants increase risk of breast cancer.

g) Breast implants increase risk of collagen vascular disorders.

9) **Family History**

a) The magnitude of the increase in risk of cancer, CHD, stroke, and fractures is associated with a positive family history. Also any modifying effect of age at diagnosis in family members can be examined.

10) **Behavioral/Psychosocial/Functional**

a) Participants with greater social support, less depression, or fewer life events, will have fewer chronic diseases, fewer hospitalizations, and lower mortality.

b) Moderators of stress predict recurrence of disease.

c) Physical function measures assessed at baseline (hand grip, chair stands, timed gait) predict risk of osteoporosis/fractures, CHD, stroke, disability, and total mortality.

11) **Environmental/Occupational Exposures**

a) Sun exposure (assessed by residential history) is associated with CHD, stroke, cancer and fracture risk.

b) Organochlorine residues from pesticides increase risk of breast cancer.

c) Talc use predicts ovarian cancer.

d) Electric blankets/waterbed use predicts increased risk of breast and other cancers.

e) Work as a cosmetologist increases risk of breast cancer.

12) **Special Populations**

a) Black women have similar fracture rates to other women, after adjusting for leanness.

b) CHD, stroke, cancer and fracture risks are not geographically-related when adjusted for other risk factors.

c) CHD, stroke, cancer and fracture risks are not ethnically-related when adjusted for other risk factors.

13) **Biological Markers**

"Nested" case-control or case-cohort analyses can be performed to assess prediagnostic blood measurements as predictors of subsequent disease. These hypotheses are summarized in in *Table 1-A5.3 - Biomarker Hypotheses and Plasma/Serum Volume Required.*

a) Endogenous sex hormones (estradiol, estrone, prolactin, progesterone, androgens) are predictors of cardiovascular disease, cancer, and osteoporosis.

1) Serum total estradiol, percent free estradiol, percent bioavailable estradiol, estrone, and estrone sulfate are associated with increased risk of breast cancer and decreased risk of CHD/stroke/fractures.

2) Serum progesterone is associated with increased risk of breast cancer.

3) Androgens such as androstenedione, testosterone, dehydroepiandrosterone (DHEA), and dehydroepiandrosterone sulfate (DHEA-S) are associated with increased risk of breast cancer and CHD/stroke and decreased risk of fractures.

4) Peptides such as prolactin are associated with increased risk of breast cancer.

b) Plasma lipids (total cholesterol and subfractions, apo B, Lp(a), plasma omega-3 fatty acids, and trans fatty acids) are predictors of cardiovascular disease in postmenopausal women. Lp(a) may predict acute MI, sudden death and stroke. The role of plasma lipids as predictors of cancer and total mortality can also be examined.

c) Insulin has powerful growth-promoting properties and may increase bone density and reduce risk of fracture. Growth hormone secretion, and its consequent metabolic functions, decrease with age and replacement hormone has been used in elders to promote muscle mass and physical function. In addition, the declining production of adrenal steroids dehydroepiandrosterone (DHEA) and 11B-hydroxyandrosterone has been related to lower bone density and offers promise as predictors of bone loss and fracture.

d) Fasting hyperinsulinemia is a predictor of future occurrence of NIDDM in nondiabetic women and of increased risk of CHD/stroke in both nondiabetic women and diabetic women without prior hypoglycemic therapy. Potentially modifiable determinants of fasting hyperinsulinemia, including physical activity level, body mass index, diet composition, postmenopausal hormone therapy, smoking, and other variables, could also be explored. Further, the role of glycemic control (as measured by serum fructosamine) could be examined as a predictor of CHD/stroke events in both nondiabetic and diabetic women.

e) Endogenous estrogen levels are associated with dietary fat intake.

f) Plasma antioxidants (vitamin C, vitamin E, carotenoids, ubiquinol, zinc, selenium) are associated with risk of breast cancer, ovarian cancer, endometrial cancer, colorectal cancer, CHD, and stroke. Levels of antioxidants will be affected by smoking.

g) Plasma retinol and cholecalciferol are associated with reduced risk of breast and other cancers.

h) Blood levels of organochlorine residues are associated with increased breast cancer risk.

i) Hemostatic factors (TPA, PAI, fibrinogen, Factor II) are predictors of CHD and stroke and venous thromboembolic disease. Factor VII levels are associated with levels of Lp(a).

j) Serum levels of 25-hydroxyvitamin $D_3$ are associated with higher levels of HDL.

k) Other markers such as homocysteine, folate, iron/ferritin, vitamins B6 and B12, calcium, magnesium, anti-cardiolipin antibodies, sialic acid, ceruloplasmin level may be related to CHD and stroke.

14) **Genetic markers**

White blood cell DNA can be used to explore genetic markers for the prediction of cancer, CHD, stroke, diabetes, and osteoporosis.

Examples:

a) Estrogen-receptor gene

b) Vitamin D receptor gene

c) Colorectal cancer genes

d) P53

e) Glycogen synthase gene

**Quality of Life Hypotheses**

a) The influence of several baseline variables, including physical activity level, diet, body habitus, smoking and co-morbid conditions, can be examined in relation to quality of life in the cohort.

b) Use of hormone replacement therapy can be assessed in relation to quality of life.

c) Participants with greater social support who develop chronic diseases can be assessed in relation to quality of life.

**Outcome Research Hypotheses**

Functional Outcomes of Chronic Illness

This would require baseline and periodic testing for physical and cognitive functions; simple self-report and performance testing protocols are available. Social variables would include impact on women's employment, insurance availability, social networks and support, care-giving activities, family structure, and personal and family assets. This may be valuable for community-based health and social planning.

Risk Factors for Functional Severity and Impact of Chronic Conditions

The goal here is to determine whether "standard" vascular risk factors (e.g., diabetes, hypertension, smoking habits) and other social and hygienic behaviors predict whether illnesses are fatal vs. non-fatal, and among survivors, predict disease severity in terms of functional impact and use of medical services. This could be done for incident diabetes mellitus, myocardial infarction, stroke, hip and spine fracture and also for various common neoplasms and neurologic illnesses.

**Table 1-A5.1**
**Cumulative Number of Events For 100,000 Women Age 50-79 Years At Baseline**

| Average Years of Follow-Up | 3 | 6 | 9 |
|---|---|---|---|
| Total Deaths | 5,000 | 11,100 | 18,200 |
| CHD | 1,900 | 4,200 | 6,700 |
| CVD | 4,000 | 8,500 | 13,800 |
| Breast Cancer | 1,000 | 2,000 | 3,100 |
| Colorectal Cancer | 500 | 1,100 | 1,900 |
| Composite Fracture | 3,300 | 7,000 | 11,200 |
| Diabetes | 1,500 | 3,330 | 5,460 |

**Table 1-A5.2**
**Summary of Exposure/Disease Hypotheses**

| | CHD | Stroke | Breast Cancer | Colorectal Cancer | Fractures | Diabetes |
|---|---|---|---|---|---|---|
| Diet | X | X | X | X | X | X |
| Physical Activity | X | X | X | X | X | X |
| Body Habitus | X | X | X | X | X | X |
| Reproductive | X | X | X | X | X | |
| Medications | X | X | X | X | X | |
| Smoking | X | X | | X | X | X |
| Pathology | X | | X | | | |
| Medical History | X | X | X | X | | |
| Family History | X | X | X | X | X | |
| Behavioral/ Psychosocial | X | X | X | X | X | X |
| Environmental | X | X | X | X | X | |
| Special Populations | X | X | X | X | X | X |
| Biological Markers | X | X | X | X | X | X |

**Table 1-A5.3**
**Biomarker Hypotheses and Plasma/Serum Volume Required**

| | Endpoints | | | | | |
|---|---|---|---|---|---|---|
| Biomarkers | Breast Cancer* | Colorectal Cancer | CHD/ Stroke | Fractures | Diabetes | Volume of Plasma/Serum Required |
| Endogenous estrogen levels (total estradiol,% bioavailable estradiol estrone, estrone-sulfate) | ↑ | | ↓ | ↓ | | 2.5 ml |
| Endogenous androgens (androstenedione, testosterone, free testos, DHT, DHEA, DHEA-S) | ↑ | | ↑ | ↓ | | 1.0 ml |
| Prolactin | ↑ | | | | | 0.25 ml |
| Progesterone | ↑ | | ↑ | ↓ | | 0.5 ml |
| Sex-hormone binding globulin | ↓ | | ↓ | | | 0.125 ml |
| Antioxidant vitamins (beta-carotene, other carotenoids, retinol, tocopherols, vitamin C) | ↓ | ↓ | ↓ | ↓ | ↓ | 1.0 ml |
| Cholecalciferol | ↓ | ↓ | ↓ | ↓ | | 1.0 ml |
| Organochlorine residues | ↑ | | | | | 1.0 ml |
| Genetic markers | ↑ or ↓ | ↑ or ↓ | ↑ or ↓ | ↑ or ↓ | ↑ or ↓ | |
| Lipids and lipoproteins (cholesterol, LDL, subtypes, HDL-2,HDL-3, VLDL, apolipoproteins) | ↑ or ↓ | | ↑ or ↓ | | | 0.5 ml |
| Fatty acids (poly-unsaturated and mono-unsaturated FA's) | ↓ | ↓ | ↓ | | | 0.5 ml |
| Trans fatty acids | | | ↑ | | | 0.5 ml |
| Marine oils (omega-3 FA's [EPA & DHA]) | ↓ | ↓ | ↓ | | | 0.5 ml |
| Lp(a) and isoforms | | | ↑ | | | 0.5 ml |
| Oxidized LDL | | | ↑ | | | 0.5 ml |
| Saturated FA's | ↑ | ↑ | ↑ | | ↑ | 0.5 ml |
| Homocysteine | | | ↑ | | | 0.5 ml |
| Folate, vitamin B6, vitamin B12 | ↓ | ↓ | ↓ | | | 0.5 ml |
| Selenium, zinc, ubiquinol | ↓ | ↓ | ↓ | ↓ | ↓ | 1.0 ml |
| Ferritin | ↑ | ↑ | ↑ | | ↑ | 0.5 ml |
| Calcium, magnesium | ↓ | ↓ | ↓ | ↓ | ↓ | 0.5 ml |
| Fasting insulin level | ↑ | ↑ | ↑ | ↓ | ↑ | 0.5 ml |
| C-peptide/pro-insulin | | | ↑ | | ↑ | 1.0 ml |
| Fibrinogen | | | ↑ | | | 0.5 ml |

**Table 1-A5.3 (Continued)**

| | Endpoints (continued) | | | | | |
|---|---|---|---|---|---|---|
| Biomarkers | Breast Cancer* | Colorectal Cancer | CHD/ Stroke | Fractures | Diabetes | Volume of Plasma/Serum Required |
| Tissue plasminogen activator (TPA) and PAI-1 | | | ↑ | | | 0.5 ml |
| Factors II and VII | | | ↑ | | | 0.5 ml |
| Anticardiolipin antibodies | | | ↑ | | | 0.5 ml |
| Serum fructosamine | | | ↑ | | ↑ | 0.5 ml |
| Ceruloplasmin | | | ↑ | | | 0.5 ml |
| C-reactive protein | | | ↑ | | | 0.5 ml |
| Sialic acid | | | ↑ | | | 0.5 ml |
| Chlamydia antibody titer | | | ↑ | | | 0.5 ml |
| Herpes Simplex Virus Types 1 and 2 antibody | | | ↑ | | | 0.5 ml |
| Cytomegalovirus antibody titer | | | ↑ | | | 0.5 ml |
| Thyroid stimulating hormone (TSH) | | | ↑ or ↓ | ↑ | | 0.5 ml |
| Parathyroid hormone (PTH) | | | | ↑ | | 0.2 ml |
| Bone-specific alkaline phosphatase (BsAP) | | | | ↑ | | 0.2 ml |
| Osteocalcin | | | | ↑ | | 0.2 ml |
| IGF - 1 IGF - BP3, and IGF II | | | | ↓ | | 0.25 ml |

The above hypotheses can also be tested for endometrial and ovarian cancer.

## 7.3 Data Analysis

Analyses of longer term intervention effects will employ the weighted (2-sided) log rank statistic as originally described (The Women's Health Initiative Study Group, 1998). Such a statistic can be written

$$T = \Sigma\, w_i\, (O_i - E_i)$$

where $w_i$ is the value of the weight function evaluated at the $i^{th}$ largest time from randomization to clinical outcome event among women in both groups, $O_i$ is one or zero depending on whether the outcome occurred in a woman in the treated group or not, and $E_i$ is the conditional expected value of $O_i$. If $V_i$ represents the conditional variance of $O_i$, then it follows that the variance ($\sigma^2$) of T is estimated by $\sigma^2 = \Sigma\, w_i^2 V_i$ and the test for differences between groups is then made by referring $T^2/\sigma^2$ to the 95th percentile of a chi-square distribution on one degree of freedom.

The weighting was intended to enhance test power under the expectation that intervention versus control disease incidence ratios increase in absolute value approximately linearly as a function of time since randomization. The weights $w_i$ were chosen to equal time from randomization up to a disease-specific maximum (three years for cardiovascular disease and fracture occurrence, 10 years for cancer occurrence and total mortality) and to be constant thereafter. Because this assumption was supported in some instances in the hormone trials and not in others, both weighted and unweighted statistics will be used, with unweighted statistics as the default test statistics unless a prior evidence had suggested otherwise (e.g., for effects on cancer incidence).

To examine post-intervention effects, weighted and unweighted time to event analyses will be conducted, typically using date of the close-out visit (or date of official notification of study closure for the HT trials) as the "time zero" for these analyses. Weights for post-intervention analyses will be defined to account for changing exposure to the interventions, lag-time and carry-over effects.

Analyses of intervention effects will typically be stratified on baseline age (50-54, 55-59, 60-69, 70-79), and self-reported prevalent disease (if applicable) for that outcome, and the categories of the other interventions. The primary HT comparisons will be examined separately based on baseline WHI hysterectomy status.

To assess potential selection bias among Extension Study participants relative to the initial trial cohort, comparisons of demographics, health history, adherence to intervention and key outcome event rates will be made between Extension Study enrollees and non-enrollees using data from the initial WHI database. Methods to account for non-representative enrollment using probability weighted tests may be employed if there is evidence of noteworthy selection in Extension Study enrollment.

All analyses of clinical trial results will be reported as two sided tests with acknowledgement of multiple testing issues, either by appropriate adjustment of p-values and confidence intervals or by an acknowledgement of the number of tests performed.

More detailed explanatory analyses will include tests for group differences with concomitant adjustment for covariates, as well as explanatory analyses that examine the extent to which an intervention benefit can be explained by changes in intermediate variables and outcomes (e.g., nutritional and biochemical measurements). These analyses will be conducted using relative risk regression methods, with appropriate account of measurement error in the intermediate variable measurements, using data obtained in a reliability substudy. Nested case-control and case-cohort sampling procedures (see next subsection) will be used in most such analyses since stored materials used to determine immediate variable values will not be routinely analyzed for the entire CT cohort.
Simple graphical displays and standard statistical methods will be used to present biochemical, bone density, and nutritional results by treatment group, clinic, and time since randomization during the course of the CT. Similar displays will describe the frequency and severity of adverse effects.

**Observational Study**
The ability to estimate relative risks reliably for the outcomes of interest in the OS as a function of baseline characteristics (exposures, behaviors or biologic measurements), or as a function of changes in such characteristics between baseline and three years is dependent on the accurate measurement of the characteristics (and outcomes) under study, and the accurate ascertainment and proper accommodation of all pertinent confounding factors. Even measurement error that is nondifferential in the sense that it is unrelated to disease risk given the 'true' characteristic values, can severely attenuate or otherwise distort relative risk estimates. Since many of the characteristics to be ascertained in the OS (e.g., nutrient intakes, blood cholesterol) are subject to noteworthy measurement error, a stratified 1% random subsample of the OS women had repeat baseline information and specimens obtained at between one and three months following their OS enrollment, and again at between one and three months following their three year clinic visit. This reliability subsample provides information of the reproducibility of the measurements taken (Langer et al, 2003), and can be used, under classical measurement error assumptions, to correct relative risk estimates for non-differential error in predictor and confounding variables. The 1% reliability sample was stratified on age, racial/ethnic group, and socioeconomic group. The size of the OS cohort, and the comprehensive set of measurements obtained allow a particularly thorough accommodation of confounding, by means of individual matching, stratification or regression modeling.

Relative risk regression methods (e.g., Cox, 1972) will also provide the primary data analytic tool for the OS. These methods, which can be thought of as an extension of classical person-year methods that avoids the assumption of constant disease risk for a study subject across the follow-up period, allow flexible modeling of the risks associated with the characteristics under study, as well as flexible accommodation of potential confounding factors, by means of stratification, matching, or regression modeling. Though less well developed they can also accommodate the types of reliability sample alluded to above (e.g., Pepe et al, 1989; Espeland et al, 1989; Lin et al, 1992), in order to produce 'deattenuated' relative risk estimates. Finally,

relative risk regression methods are also readily adapted to accommodate nested case-control (Liddell et al, 1977; Prentice and Breslow, 1978) and case-cohort (Prentice, 1986) sampling schemes.
Nested case-control sampling proceeds by selecting for each 'case' of a study outcome one or more 'control' women who have not developed the disease in question by the follow-up time at which the corresponding case was ascertained. Additional matching criteria in the OS will typically include baseline age, clinic, and date of enrollment, and depending on the analysis may also include racial/ethnic or socioeconomic group, or other factors. Nested case-control or case-cohort sampling provides the only practical approach to reducing the number of OS women whose blood specimens need be analyzed and processed, if the measurements of interest cannot be assumed to be stable over time. For example, certain of the antioxidant concentrations to be measured in blood specimens are known to substantially degrade over the course of a few months or years of storage, in which case the follow-up-time-matched aspect of the nested case-control approach is essential to valid relative risk estimation. For measurements that are stable over time, however, case-cohort sampling could provide an alternative that has some decided advantages. Case-cohort sampling involves the selection of a random, or a stratified random, sample of the cohort to serve as a comparison (control) group for the cases of all the outcomes under study.

Analyses that relate change in risk factors to disease risk have particular potential for gaining insight into disease mechanisms. For example, the OS provides a valuable forum for addressing the issue of whether or not the association between low blood cholesterol (e.g., <160 mg/dl) and excess non-cardiovascular mortality derives primarily from persons who have experienced major reductions in blood cholesterol over the preceding three years. In fact the OS is large enough that such analysis could be restricted to women with relatively low baseline blood cholesterol (e.g., lowest two quintiles) in order to avoid a complicated interpretation if the effect of interest happened to 'interact' with baseline cholesterol measurement. Furthermore the OS, by virtue of ascertaining a range on non-specific markers of debility or disease (e.g., serum albumin, hemoglobin; cancer biomarkers; baseline and follow-up disease prevalence by questionnaire and physical exam) may be able to examine whether the excess mortality associated with reduced blood cholesterol can be explained by the presence of recognized or latent disease. The careful accommodation of measurement error in predictor and confounding variables is particularly important in such risk-factor-change analyses.

Appendix 3 of the original WHI protocol provides power calculations for OS analyses as a function of disease rate, exposure frequency, relative risk, follow-up duration and, importantly, as a function of subsample sizes corresponding to racial/ethnic, age, and other important OS subgroups.

**Clinical Trial and Observational Study**
Separate analyses in both the CT and OS will be conducted according to self-reported baseline prevalence of the clinical outcome being analyzed. In fact, whenever applicable, relative risk analyses based on randomized CT comparisons will be accompanied by corresponding OS relative risk analyses. The comparability of these analyses is enhanced by the common aspects of baseline data collection procedures and outcome determination procedures in the CT and OS. Estimated relative risk functions from the two sources will take suitable account of prior

"exposure" histories and of measurement error in exposure assessment. Under circumstances in which careful analyses of this type lead to substantial agreement between CT and OS results, analyses will be conducted to extrapolate the relative risk results beyond those examined in the CT, using the OS. For many observational analyses, joint analyses of the CT/OS cohorts with stratification on cohort will also be a useful strategy for examining possible explanations for differences between relative risks in the CT and OS.

# Outcome Ascertainment Process

# Section 8

# Outcomes

## Introduction

The Women's Health Initiative (WHI) Extension Study (ES) outcomes are diverse and complex. The aim of the WHI Extension Study is to continue to assess the relationship of particular interventions on a broad range of health and illness conditions in women. Primary, subsidiary, and intermediate outcomes have been identified as important for the study. To ensure that the identified outcomes represent true disease states, detailed outcomes ascertainment procedures and diagnostic criteria for adjudication have been developed by study investigators. The standardized outcome procedures detailed below help ensure that the outcomes are ascertained in an unbiased manner.

The WHI Extension Study outcomes ascertainment and adjudication procedures are by and large the same as those used for the main WHI program. Outcomes ascertainment procedures performed by Field Center (FC) staff include the identification, investigation, and documentation of potential outcomes, and adjudication procedures include the review of assembled case packets by Physician Adjudicators.

All WHI Clinical Trial (CT) participants were unblinded to their treatment assignment before the close of the main WHI study (October 1, 2004 – March 31, 2005). While this information is located in the FC chart documentation and is readily accessible, the treatment assignment information should **not** be made available to the Physician Adjudicator who is adjudicating the possible WHI Extension Study outcomes. This is to maintain continued objectivity and uniformity in the adjudication process and ensure unbiased adjudication of events.

## 8.1 Overview of Outcomes Process

The types of events collected in the WHI main program have been streamlined in the WHI Extension Study and outcomes ascertained through self-report alone has been expanded. Major outcomes of interest require full ascertainment and documentation supporting the event or procedure. See the list of outcomes requiring adjudication in *Table 8.1 – WHI Extension Study Outcomes*. Note that outcomes collected for HT (PE, DVT, and hysterectomy) will only be collected through 2007. Those outcomes identified by self-report alone (i.e., do **not** require investigation, documentation, or adjudication) are also included in the table under "Self-reported outcomes requiring adjudication for a hospitalization of 2 nights or more."

The entire process of ascertainment of an outcome plus the adjudication of a final diagnosis by the Physician Adjudicator should be completed within 3 months of initial identification of a possible outcome. The three-month interval begins with the completion of *Form 33 – Medical History Update* and ends with the adjudication of the event by completion of the appropriate outcomes form. See *Figure 8.1 – Outcomes Ascertainment and Adjudication Process* for a flow diagram of the entire process. Given the delays often inherent in obtaining records, it may at times not be possible to meet this 3-month deadline. However, all efforts should be made to obtain and process all documents as quickly as possible.

These sections of the WHI Extension Study Manual contain instructions and resources for FC physicians and staff to follow for each step of the outcomes and adjudication process.

- *Section 8.2– Identification of Outcomes, Section 8.3 – Investigation of Outcomes,* and *Section 8.4 – Documentation of Outcomes* describe how to process the initial identification of an outcome, investigate and obtain the required documents for each outcome, assemble the documentation into an adjudication case packet, and forward the case packet with appropriate outcomes forms to the CCC for central adjudication. Note that other outcomes ascertained only by self-report are identified in *Table 8.1 – WHI Extension Study Outcomes*.
- *Section 8.5 – Fatal Events – Special Considerations* describes additional procedures and guidelines for follow-up of participant deaths, including contacts with participant families.
- *Section 8.6 – Physician Adjudication* describes the procedures Physician Adjudicators must follow in reviewing documents related to a possible WHI Extension Study outcome and assigning a WHI Extension Study-defined diagnosis.

- *Sections 8.6 to 8.11 – Fatal Events, Cardiovascular, Other, Fracture, and Cancer Adjudication* describe in detail how to complete the specific outcomes forms which assign specific diagnoses.
- *Appendix A – Field Center and Participant Forms:* Includes *Forms 33, 33D, 120, 125, and 134* as well as other forms completed by participants and FC staff.
- *Appendix B – Coding Reference, ICD 9-CM and ICD-10*
- *Appendix C – Explanation of Medical Terms*: medical terms used in outcomes documents.
- *Appendix D – Medications Used for Treatment of Cardiovascular Disease*
- *Appendix E – Model HIPAA Medical Release of Information*

### 8.1.1 Definitions Used for WHI Extension Study Outcomes

Definitions specific to WHI Extension Study outcomes and outcomes investigations are included below.

**Adjudication**: The assignment of the final decision/diagnosis by a Physician Adjudicator or Clinical Coordinating Center (CCC) Cancer Coder after reviewing the outcome documents contained in an adjudication case packet and recording the decision/diagnosis and details supporting the diagnosis on the outcomes forms.

**Adjudication case packet:** Materials relevant to a specific outcome case. Each case packet includes an *Investigation Documentation Summary* (*WHIX0988*), *Members Outcomes Status Report* (*WHIX1215*), relevant outcomes forms, and required medical record documents pertaining to the type of outcome(s) being adjudicated.

**Ascertainment**: The initial identification of a possible WHI Extension Study outcome, investigation of sources of supporting medical records, and documentation for an adjudication case.

**Closed outcome case**: A WHIX database function in which further ascertainment and/or adjudication procedures are stopped or concluded, either because a final diagnosis has been assigned or it has been determined that no WHI Extension Study outcome occurred. A closed outcome is recorded in the database via assignment of a "close date" in the WHIX Outcomes Management Subsystem.

**Discovery**: Review of medical records indicates a possible WHI Extension Study outcome or provider visit not self-reported by the participant on her *Form 33 – Medical History Update* or *Form 33D – Medical History Update (Detail).* Investigation of the unreported outcome or provider visit is appropriate as they were located in medical records the Outcomes Coordinator (OC) is authorized to review. Also includes identification of a death through the Social Security Death Index or National Death Index (SSDI or NDI) and obituaries.

**Documentation**: The assembly of required supporting medical records (obtained through investigation of a possible outcome) into an adjudication case packet. Documentation also includes tracking these documents and packets through the WHIX database and/or manual tracking systems until the adjudication case is closed.

**Emergency Room (ER) or Emergency Department (ED) visit**: Visit or admission to a hospital ER/ED. This may or may not lead to a hospital admission. Several events (i.e., newly diagnosed hip fractures, cancers, PTCAs, strokes, and HT deep vein thrombosis [DVT], pulmonary embolism [PE]or hysterectomy) occurring or diagnosed solely at an ER visit (without subsequent hospitalization) will be investigated, documented, and adjudicated as possible outcomes. Also includes ER/ED documentation in all adjudication case packets when the ER visit results in a WHI ES defined outcome.

**Five major cancers:** The five primary WHI cancer outcomes sites: breast, colon, rectum, endometrium, and ovary.

**Hospitalization**: An overnight stay in an acute care hospital, for any reason. In the WHI Extension Study, there is no minimum length of stay required for specified outcomes of interest. Other selected outcomes are investigated only if the hospitalization is for 2 nights or more. (See *Table 8.1 – WHI Extension Study Outcomes* for the complete list of outcomes to investigate based on the hospitalization length of stay.) Short stays, observation stays, and day surgeries may be referred to in medical records as outpatient visits, but for the WHI ES these stays are considered hospitalizations if they result in overnight stays at an acute-care facility due to a complication or need for close observation. (Note that an overnight stay in a rehabilitation facility is **not** considered an overnight hospitalization.) Psychiatric admissions are also not investigated or

adjudicated in the WHI ES. Transfers from one hospital to another, on the same day, are considered one "case" for WHI ES purposes, and medical records are obtained from both facilities.

**Identification**: The routine procedures through which the FC learns of a possible outcome, which is typically through participant completion of an annual *Form 33 – Medical History Update* and subsequent *Form 33D – Medical History Update (Detail)* or in the event of a participant's death, through some other interim report to FC staff by the participant's proxy (family, friend or health care provider). The initial notification of a participant's death may also come from other sources (e.g., CCC returned mail, newspaper obituaries, National Death Index reports).

**Investigation**: The process of locating provider (e.g., hospitals, clinics, physicians) information about a possible outcome, requesting medical records that may support its diagnosis, and filing such documents in a participant's outcomes file.

**Medical History Update Forms**: *Form 33 – Medical History Update* is a self-administered form (routinely mailed by the CCC to the participant) annually. *Form 33* collects information on those outcomes that do not require further ascertainment procedures, as well as screens for those participants who have had a major clinical event. *Form 33D – Medical History Update (Detail)* is required from those participants who indicate on *Form 33* that they have had a major clinical event that may require adjudication. *Form 33D*, collected by FC staff by phone or mail, is used to obtain more detailed information to assist the OC with outcomes ascertainment.

**Outcomes file:** A participant's file of outcomes-related documents. This file may include medical records documents that are not currently required for a pending adjudication case packet, as well as copies of pending and closed adjudication case packets. There is no required organization for the WHI ES chart. Instead the CCC recommends the following be included in the charts: *Form 33 – Medical History Update*, *Form 33D – Medical History Update (Detail)*, *Form 85 – Mammogram* with accompanying documentation attached, Personal Information Updates (PIU), Consents, and Release of Information (ROI). The Personal Information Updates (PIUs) from the WHI chart may be included in the outcomes chart. It may also be helpful to keep the *Form 85*s and chart/progress notes from WHI with the chart. The original WHI outcomes charts need to be accessible during the WHI Extension Study, but it is not necessary for immediate or frequent retrieval.

**Outcomes forms:** *Forms 120-132*, are completed by the FC Outcome Coordinator (OC), Physician Adjudicator, or CCC resource. Forms completed by FC staff and participants are located in *Appendix A* and outcomes forms are located in *Sections 8.6 – 8.11*.

**Outpatient visits:** Any short stay, observation stay, clinic visit, or day surgery that does not involve an overnight stay. Only certain events (e.g., newly diagnosed stroke, hip fractures, cancers, cardiac revascularization procedures, and in the HT, DVT and hysterectomy) occurring at an outpatient visit alone without hospitalization will be investigated, documented, and adjudicated as possible outcomes. If the selected outpatient visit results in an overnight hospital stay, collect and include the outpatient documentation in the adjudication case packet. See *Table 8.1 – WHI Extension Study Outcomes* for a complete list of outpatient visits requiring investigation.

**WHIX:** The WHI Extension Study database that assists with the collection and tracking of outcome cases through the ascertainment and adjudication process. The review of the participant's outcomes chart should not be replaced by the sole use of the WHIX tracking system.

## Table 8.1
## WHI Extension Study Outcomes

As identified on *Form 33*, *Form 33D*, and *Form 120*

### Outcomes Requiring Adjudication

- **Coronary heart disease & other cardiovascular disease*** *Form 121*
  Hospitalized one or more nights:
  Acute myocardial infarction (MI)
  Coronary artery bypass graft (CABG)
  Peripheral arterial disease, symptomatic and/or requiring a procedure
  Carotid artery disease requiring a procedure or surgery
  Hospitalization not required:
  Coronary death
  Coronary revascularization (PTCA, coronary stent, laser)
- **Stroke*** (hospitalization not required) *Form 132*
- **Venous thromboembolic disease*** – *Form 126* (HT only)
  Hospitalized one or more nights:
  Pulmonary embolism (PE)
  Hospitalization not required:
  Deep venous thrombosis (DVT)
- **Five major cancers*** – *Form 130*
  Hospitalization not required:
  Breast, Colon, Endometrium, Rectal, Ovary

  **Other Cancers* (excludes non-melanoma skin cancer)**
- **Hip and Upper Leg Fractures*** – *Form 123*
  Hospitalization not required
- **All deaths*** – *Form 120, 124*
  Out of hospital death: Adjudicate death with last relevant hospitalization (if available).
- **Hysterectomy*** – *Form 131* (HT only)
  Hospitalization not required:
- **Any hospital stay of 2 nights or more except those solely for certain procedures** – *Form 125*

**Self-reported outcomes requiring adjudication for a hospitalization of 2 nights or more.** *Form 125*

- **Self-report events on *Form 33***
  Diabetes mellitus requiring therapy
  Other age-related outcomes:
  inflammatory arthritis
  macular degeneration
  moderate or severe memory problems (dementia, Alzheimer's)
  Benign breast disease
  Colorectal polyps
  Venous thromboembolic disease (non HT)
  Congestive heart failure
  Angina pectoris (chest pain)
  TIA
  Parkinson's disease
  Systemic lupus erythematosus (lupus)

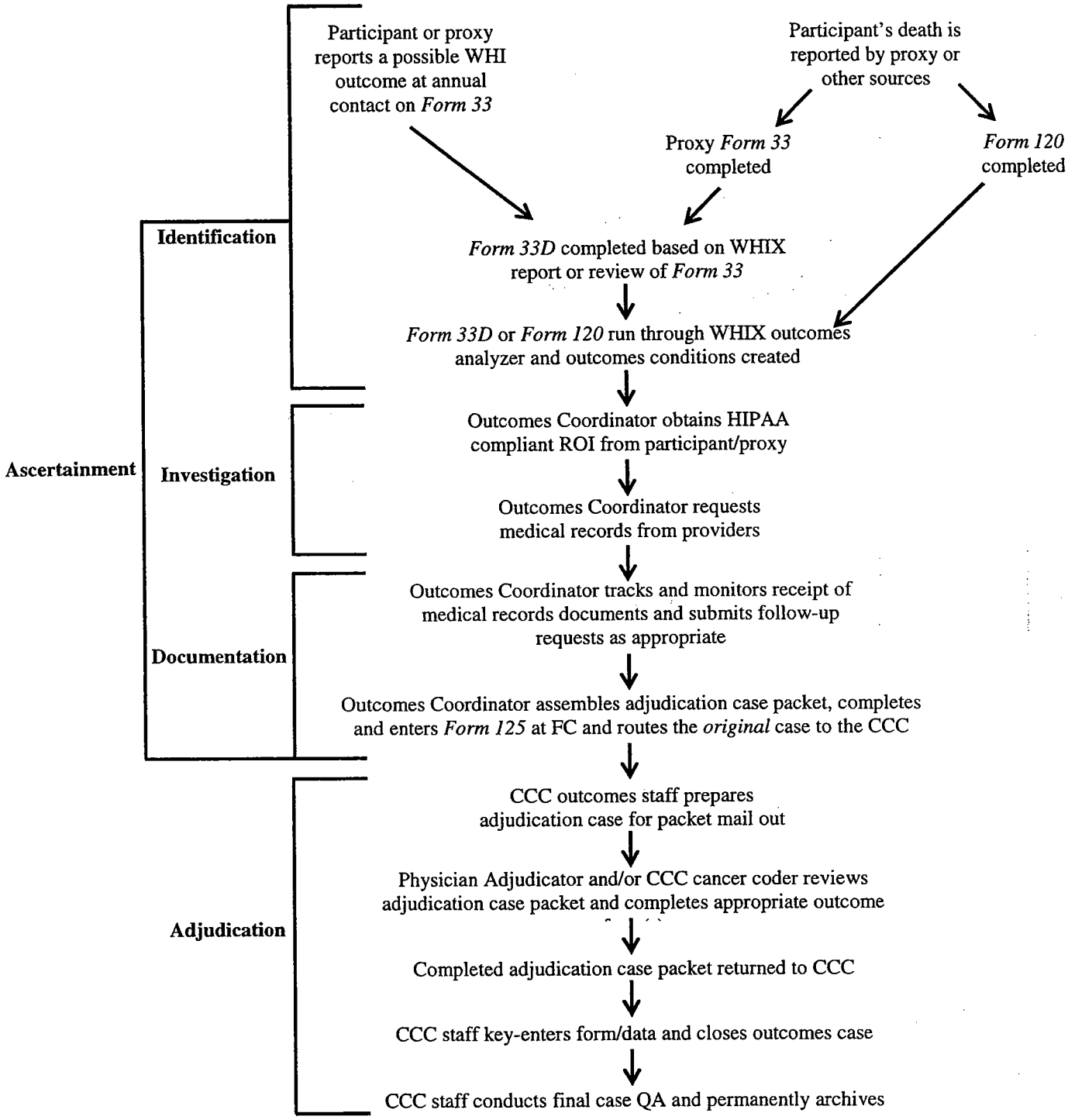
* Complete *Form 125* if hospitalized one or more nights.

### Investigation and Adjudication NOT Required

- **Selected hospitalized procedures requiring no follow-up** (no required outcomes forms):
  Appendectomy
  Bunionectomy
  Carpal tunnel repair/release
  Cholecystectomy
  Club foot release
  COPD exacerbation
  Corneal transplant
  Cosmetic/plastic surgery, **other than breast**
  Extracapsular cataract extraction (EEC)
  Fractures, other than hip and upper leg
  Glaucoma
  Hemorrhoidectomy
  Inguinal herniorrhaphy
  Knee arthroscopy
  Laceration repair
  Laminectomy (see spinal disorders below)
  Ligation and stripping, vascular (varicose vein strip)
  Out of country overnight hospitalization for gastrointestinal (GI) symptoms related to travel. (Requires PI signature.)
  Overnight hospitalization < 2 **nights (excludes extension outcomes of interest)**
  Overnight hospitalization for:
  - Any research study (that does not involve a WHI outcome)
  - Sleep studies (not related to a research study)

  Pelvic floor surgeries (for stress urinary incontinence, vaginal, uterine or rectal prolapse)
  Psychiatric admission
  Rhinoplasty / septoplasty / septorhinoplasty
  Rehabilitation facility admissions
  Rotator cuff repair
  Scleral buckle
  Skin disorders and procedures (includes non-melanoma **and excludes melanoma**)
  Spinal disorders/procedures: For example, spinal stenosis, spondylolisthesis, degenerative disc disease, spinal fusion, facectomy
  Stapedectomy
  Synovectomy of wrist
  Tonsillectomy & adenoidectomy (T & A)
  Total joint replacement (knee, hip or shoulder)
  Turbinectomy
  Tympanostomy tube
  Upper gastrointestinal (GI) endoscopy
  Vitrectomy
- **Recurrence of selected outcomes** (associated hospitalizations **must** still be adjudicated; see *Table 8.3 – Subsequent Conditions*)

**Figure 8.1**
**Outcomes Ascertainment and Adjudication Process**



### 8.1.2 Field Center Outcomes Staff

Each FC will identify an Outcomes Coordinator. This person is responsible for overseeing the activities of the outcomes team and the process of outcomes ascertainment, including:

- Identifying medical events and having working knowledge of outcomes procedures.
- Collecting *Form 33D* from participant.
- Requesting medical records documentation from providers.
- Ongoing tracking of documents.
- Final assembling into adjudication case packets.
- Forwarding the case packets to the CCC.

The Outcomes Coordinator (OC) is the key FC person involved in outcomes ascertainment, but other WHI Extension Study staff may assist in this effort. The OC contacts participants by phone or mail to obtain detailed self-report information about potential WHI Extension Study outcomes and thereby initiates the ascertainment process with the identification of potential outcomes. Investigation commences when the OC requests medical records documentation from the healthcare provider and prepares the documentation for the Physician Adjudicator. The OC is responsible for performing data entry, generating reports, conducting interviews to elaborate self-report data, requesting documents, and preparing and tracking case packets for adjudication.

To ensure unbiased ascertainment of outcomes, it is **recommended** that FC staff involved in outcomes ascertainment **not** be exposed to information through participant contacts or reports that is effectively or definitively unblinding (i.e., information that, respectively, allows "educated guesses" or provides "proof" of treatment arm.). However, each FC will determine, based on local resources and operations, the extent to which these recommendations can be followed.

### 8.1.3 Physician Adjudicator

The Physician Adjudicator is responsible for review of assembled adjudication case packets and assigning the appropriate outcome diagnosis based on WHI Extension Study defined criteria. It is **strongly recommended** that WHI Extension Study Physician Adjudicators **not** be exposed to information through participant contacts or reports that is effectively or definitively unblinding (i.e., information that, respectively, allows educated guesses or provides "proof" of treatment arm). Thus, Physician Adjudicators should not have contact with participants or participant files (except appropriate adjudication case packets) to ensure unbiased adjudication. See *Section 8.6 – Physician Adjudication* for more information on the Physician Adjudicator's roles and responsibilities.

An outcome case is assigned to committees based on outcome type following a single-adjudicator review model. The four adjudication Committees include:

- Cardiovascular Disease (CVD)/Death: The CVD Committee is responsible for adjudicating myocardial infarction, CABG, coronary revascularization, peripheral arterial disease, carotid artery disease, and venous thromboembolic disease (HT only through 2007). The Committee will also adjudicate all deaths, selected hospitalization stays of two nights or more, and hysterectomies (HT only through 2007). They complete *Form 121 – Report of Cardiovascular Outcome*, *Form 124 –Final Report of Death*, and *Form 126 – Report of Hysterectomy (HT)* as needed, and review *Form 125 – Summary of Hospitalization Diagnosis* as requested by CCC outcomes staff. See *Sections 8.7 – 8.9* for details of completing the forms.
- Stroke: A group of neurologists who adjudicate all strokes, completing *Form 132 – Report of Stroke Outcome* (see *Section 8.8 – Cardiovascular Outcomes*).
- Fracture: Staff at University of California, San Francisco (UCSF), adjudicate all hip fractures, completing *Form 123 – Report of Fracture Outcome* (see *Section 8.10 – Fracture Outcomes*).
- Cancer: The CCC cancer coders adjudicate the five primary sites (breast, ovary, endometrium, colon, and rectum), completing *Form 130 – Report of Cancer Outcome* (see *Section 8.11 – Cancer Outcomes*) using SEER (Surveillance, Epidemiology, and End Results) guidelines. Cancer cases for which the CCC

staff cannot assign a final diagnosis will be forwarded to the CCC consulting pathologist for coding and adjudication. The CCC cancer coders also adjudicate all "other cancers" by completing a subset of the questions of *Form 130*.

Adjudication case packets are typically distributed to one of four central adjudication committees based on the participant's self-report. In the event that a case has more than one outcome included (or discovered) in the documentation, the case may be routed to more than one committee.

Physician Adjudicators will primarily adjudicate by mail, with cases being routed from and returned to the CCC. The exception is cancer coding, which is conducted at the CCC.

### 8.1.4 Outcomes Adjudication Committee (OAC)

The Outcomes Adjudication Committee (OAC), formerly called the Morbidity and Mortality Committee (M&M) in WHI, is an Advisory Committee whose role is to review protocol, policy, and procedures as they relate to outcomes and adjudication, and make recommendation to the Extension Study Executive Committee (ESEC). The OAC is comprised of Physician Adjudicators from FCs, other WHI Extension Study investigators, an OC FC representative, and appropriate CCC staff. Adjudicators and staff are assigned to central adjudication subcommittees based on their professional expertise.

## 8.2 Identification of Outcomes

Field Centers (FCs) may become aware of potential outcomes through different mechanisms:

- Routine annual *Form 33 – Medical History Update* and/or *Form 33D – Medical History Update (Detail).*
- Death reported by proxy (e.g., family, friend, health care provider) or other source (e.g., newspaper obituary, returned mail to the CCC, National Death Index report).

Note that even if a participant reports a primary outcome, she will continue to be followed for the duration of the study for other WHI Extension Study outcomes.

### 8.2.1 Outcomes to be Identified

#### 8.2.1.1 Outcomes Requiring Full Adjudication

Outcomes to be identified and forwarded for adjudication are listed in *Table 8.1 – WHI Extension Study Outcomes*, under "Outcomes Requiring Adjudication". In general, only the first occurrence of a particular outcome is adjudicated. There are however some outcomes that require ongoing investigation and adjudication. See *Section 8.3.2 – First vs. Recurrent Events* for more detailed information.

#### 8.2.1.2 Outcomes Identified Only by Self-Report on *Form 33/33D - Medical History Update* (Detail)

Specific outcomes are identified by the participant's self-report alone on *Form 33 – Medical History Update* or *Form 33D – Medical History Update (Detail).* See the list of outcomes under the heading "Self-Reported outcomes requiring adjudication for a hospitalization of 2 nights or more" in *Table 8.1 – WHI Extension Study Outcomes*. These self-reported outcomes do not require investigation, documentation, or adjudication unless the outcome is associated with a hospital stay of 2 nights or more.

#### 8.2.1.3 Hospitalizations Due Solely to Selected Conditions or Elective Procedures

Selected outcome diagnoses and elective procedures do not require investigation, documentation, or adjudication. See the list in *Table 8.1 – WHI Extension Study Outcomes* in the column labeled "Investigation and Adjudication NOT Required." Do not complete *Form 125 – Summary of Hospitalization Diagnosis* if the participant reports these events or procedures as the only reason/event during the hospitalization, even if the hospital stay is 2 nights or more. In the WHIX outcomes subsystem adjudication screen, enter Closure Code 10 – *Extension case, not adjudicated, not forwarded to the Clinical Coordinating Center (CCC).* (See *Section 8.4.3 – WHIX Outcomes Closure Codes* for more details.

### 8.2.2 Routine Administration of *Form 33 – Medical History Update*

Potential outcomes will primarily be identified through the routine administration of *Form 33 – Medical History Update* and, if needed, *Form 33D – Medical History Update (Detail). Form 33* collects information on those outcomes that do not require further ascertainment procedures (outcomes by self-report alone), as well as screens for those participants who have had a medical problem, event, or procedure that may require adjudication.

**CCC mailing of Form 33**: Participants typically complete *Form 33* as a self-administered form, although FCs may choose to administer it as an interview if the participant is unable or unwilling to complete and mail in the form, or if the participant has difficulty understanding or completing forms. At each annual contact date, the CCC will mail a *Form 33* to the participant to be completed and returned to the CCC for scanning. The CCC is responsible for mailing the *Form 33*s to all WHI Extension Study participants as part of their annual contact (see *Section 7 – Follow-Up Contacts*).

**CCC repeat mailings**: Following the CCC mailing, if the *Form 33* is not returned within three months of the first mailing, the CCC will send it again. If the form is not returned within two months of the second mailing, the CCC will send it a third time. If the form is still not returned, the FC becomes responsible for collecting the missing *Form 33.*

**FC Follow-up**: The FC is also responsible for collecting any additional information from the participant to resolve questions or missing data identified when the CCC scans the returned *Form 33* (see *Section 8.2.8 - Forms Processing Reports* for more details). For incapacitated or deceased participants, a participant's proxy (e.g., family, friend, or health care provider) may complete a *Form 33* (see *Section 8.5 – Fatal Events – Special Considerations*).

### 8.2.3 Routine Administration of *Form 33D - Medical History Update (Detail)*

When a participant reports an outcome of interest or a hospital stay of 2 nights or more on *Form 33*, FCs follow-up by asking her to complete *Form 33D*, which collects more specific information about the potential outcomes. *Form 33D* asks participants to provide names and addresses of hospitals, outpatient clinics, and physician offices where possible outcomes were diagnosed or treated. *Form 33D* also asks participants to provide more detailed information regarding cardiovascular and stroke diagnoses, incident cancer, causes of hip fractures, venous thromboembolic disease (PE, DVT) and hysterectomy operations (HT only through 2007), and revascularization procedures.

**Identify participants needing a *Form 33D***: Following the scanning of *Form 33 – Medical History Update*, the FC can run *WHIX0622 – Members with Potential Outcomes Report* to identify those participants who need to complete *Form 33D – Medical History Update (Detail)*. Based on WHI experience, an estimated 10% of the completed *Form 33s* will need a *Form 33D*. As the study population ages, the number of participants needing a *Form 33D* will likely increase. Refer to the *Form 33* form instructions (in *Appendix A*) for the algorithm that indicates, based on the participant's form responses, who needs to complete a *Form 33D*.

**Administer *Form 33D***: FCs will probably find that administration of *Form 33D* by interview gathers more complete data for proceeding with a timely outcomes investigation. However, depending on the FC staffing levels it may be more time efficient to mail *Form 33Ds* to participants and follow up with information errors as they arise. FCs are advised to obtain new, signed medical release forms when *Form 33D* is collected.

**Additional hospitalizations**: If the participant indicates more hospitalizations/provider visits than are allotted on the *Form 33D*, the participant is instructed to write the details for the additional hospitalizations on the last page of the form. The OC then manually creates and links the additional visits indicated on the form and investigates the possible outcomes as appropriate (see *Section 10 – Data Management* documentation for instructions on manually creating and linking conditions).

# Statistical Power/Data Analysis

## A3.2 Observational Study

There are a number of factors to be considered in describing the power of the OS to elucidate relationships between baseline measurements and subsequent disease risk, as well as relationships between changes in measurements from baseline and three years and subsequent disease risk. These include:

(i) **Incidence rates for diseases of interest** - as described in *Section 1* of the Protocol and in the earlier part of this Appendix, incidence rates are quite variable for the diseases of interest in the Women's Health Initiative (WHI). For example, the annual incidence rates for some key outcome categories, assuming that 10%, 20%, 45% and 25% of OS enrollees are in the age categories 50-54, 55-59, 60-69 and 70-79, respectively, are approximately 5.0 for CHD, 3.0 for breast cancer, 1.8 for colorectal cancer, and 4.0 for hip fractures, per 1,000 enrollees. Naturally, it will be desirable to use the OS for studies of less common outcomes, including specific cancers (e.g., endometrial, ovarian), selected vascular diseases (e.g., hemorrhagic stroke, deep vein thrombosis), and fractures at specific, less common sites. The annual incidence rates for such diseases may be less than 1.0, or even less than 0.5 per thousand. Hence, generic power calculations have been conducted for annual incidence rates of 0.1, 0.5, 1.0, 2.0 and 5.0 per thousand.

(ii) **Follow-up durations** - it is particularly important that the OS begin to generate research reports as early as possible during the course of the WHI program. Hence, power calculations have been performed for average cohort follow-up durations of 3, 6 and 9 years. The three-year power calculations, for example, can be applied to studies of baseline characteristics when the average follow-up time for the OS (or a subset thereof) is three years, or to the study of changes in characteristics between baseline and three years when the average follow-up time is six years, since outcomes prior to a participants three-year visit do not contribute to these latter analyses.

(iii) **Sample size and subset analyses** - power calculations based on the entire intended OS sample size of 100,000 are perhaps of most interest, but there is also considerable interest in analyses based on various OS subsets. For example, separate analyses for each decade of baseline age would require power calculations for cohorts in the range of 25,000 to 45,000 subjects in view of the anticipated OS age distribution mentioned above. Similarly, the anticipated OS enrollment by racial/ethnic subgroup is as follows: non-Hispanic, white - 80,000; African American - 10,000; Hispanic - 6,000; Native American - 2,000; Asian Pacific Islander - 2,000. Other analyses may be restricted to OS women for whom a certain measurement falls within selected percentiles relative to the overall OS distribution. For example, an important goal of the OS pertains to further elucidation of the relationship between a low-blood cholesterol or a recent reduction in blood cholesterol and subsequent mortality. Analyses restricted to the approximately 40,000 women with baseline blood cholesterol in the lowest two quintiles may provide particular insights. For example, one will be able to compare the mortality rates of women with blood cholesterol measurements in the lowest quintile at both baseline and three years, to those whose cholesterol has dropped from the second lowest to the lowest quintile between baseline and their three-year visit.

Power calculations were conducted for sample sizes of 100,000; 80,000; 40,000; 20,000; 10,000; 6,000 and 2,000 in order to explore the relationship between power and subset sample size.

(iv) **Distribution of exposures or characteristics** - the characteristics or exposures to be related to disease risk may involve a variety of types of measurements, including binary, categorical and continuous variates, and mixtures thereof. However, most analyses, especially exploratory analyses, will involve the comparison of disease risks between two groups of OS members distinguished by their values of one or more characteristics. For example, one may compare current ERT users to non-users; or may compare women in the highest quintile of baseline blood cholesterol, or baseline dietary fat intake, to corresponding women in the lowest quintile. Hence, power calculations were conducted as a function of the frequency of a binary characteristic or exposure, with 'exposure' frequencies taking values of 0.5%, 1%, 10%, 30% and 50%. For example, to obtain the power of a comparison of the highest quintile to lowest quintile of blood cholesterol in the entire OS cohort one can examine the following tables for a sample size of 40,000 (the highest and lowest quintiles combined) with an exposure frequency of 50% (one-half of the 40,000 women will be in the highest quintile).

(v) Odds ratio - there are a range of odds ratio values that may be pertinent to associations of interest in the OS. Odds ratios of 2.0 or above may have particular public health importance, particularly if the characteristic under study is fairly common. Note that odds ratios and relative risks are virtually identical for the range of

*Table 1-A3.1.* provides power calculations for analyses based on the entire cohort of size 100,000. For example, from the lower section of *Table 1-A3.1.* one can see that the power for detecting a relative risk of 1.5 associated with a characteristic present in 50% of the cohort is 72% after an average three years of follow-up, and 95% after an average of six years of follow-up, even for a disease with annual disease incidence of .05% per year, which is close to that for cancers of the endometrium and ovary, for example. An odds ratio of about 1.5 for above versus below the median fat intake can be projected from international correlation analyses for endometrial and ovarian cancer, after accounting for regression dilution. Similarly, an odds ratio of 2.0 associated with a characteristic arising in only 1% of the cohort can be detected with adequate power for diseases as common as breast cancer or hip fractures, and can be detected with power 83% after an average of only three years of follow-up for a disease such as CHD having an annual incidence of about .5% per year or greater.

*Table 1-A3.2.* presents corresponding analyses for a subsample of the OS of size 80,000. As such, it gives projected power for OS analyses restricted to non-Hispanic white women or for analyses on the entire 100,000 women based on a case-control analysis with four controls per case. Note that the power reductions in moving from *Table 1-A3.1.* to *Table 1-A3.2.* tend to be fairly modest. Consider two specific associations which could be examined in the OS: About 5-10% of postmenopausal women have serum ferritin concentrations about 200 µg/liter. A study in Finnish men indicates that such elevated concentrations may convey an odds ratio of about 2.2 for CHD. *Table 1-A3.2.* indicates that a 1:4 matched case-control study in the OS cohort would have power in the vicinity of 90% for detecting an elevated serum ferritin and CHD association, even if the odds ratio is as small as 1.25. As a second example, suppose that a particular occupational group, such as a lab technician or hair dresser, constitutes only .5% of the OS cohort. *Table 1-A3.2.* indicates that a 1:4 matched case-control study based on the OS would have power of at least 76% by an average six years of follow-up, or 94% by an average of nine years of follow-up, for detecting an odds ratio of 3.0 for a disease such as breast cancer with an annual incidence rate of two per 1,000 or greater. In fact, a British Columbia study suggests a breast cancer odds ratio of about four for these occupational groups.

*Table 1-A3.3.* shows corresponding power calculations for a subsample of size 40,000, as corresponds, for example, to studies restricted to extreme quintiles of a measured characteristic. A relative risk as small as 1.50 between extreme quintiles of a nutrient intake variable, for example, will be able to be detected with power 90% or greater by an average of three years of follow-up for diseases such as breast cancer, hip fractures or CHD having an annual incidence of at least .2%. Such an odds ratio can be detected with a power of 80% for a much rarer disease with incidence of .05% per year, by an average of nine years of follow-up. *Table 1-A3.4.* gives corresponding power calculations for a subsample of size 20,000. These entries are pertinent to full-cohort analyses restricted to the subset of women in the age range 70-79 at baseline, and to subsamples of size 40,000 under 1:1 matched case-control sampling.

*Table 1-A3.5.* gives power calculations for a subsample of size 10,000 - the anticipated number of African Americans in the OS. Note that there will be adequate power to detect an odds ratio of 1.50 or larger for diseases of annual incidence of .2% or larger, provided the characteristics or exposure arises in about half of the women in the subsample. *Table 1-A3.6.* gives power calculations for a subsample of size 6,000 - the anticipated number of Hispanic American women in the OS. There is adequate power to detect an odds ratio of 1.75 or larger for diseases of annual incidence of .2% per year or larger, again provided the characteristic arises in about 50% of the subsample. Finally, *Table 1-A3.7.* gives power calculations for a subsample of size 2,000 - the anticipated number of Native American, and of Asian and Pacific Islander American women in the OS. Odds ratios of 3.0 will be able to be detected for diseases having annual incidence of about .2% per year or greater, provided the characteristic under study arises in about 50% of the subsample.

In considering the range of odds ratios pertinent to the OS, it is important to consider the regression attenuation that arises from random measurement error in the assessment of characteristics of interest. For example, the slope of the regression line that relates the log-disease incidence (e.g., log-CHD incidence) to a single blood cholesterol measurement are attenuated by a factor of about 2/3 on the basis of such random measurement error, so that an odds ratio of 2 is reduced to exp[(2/3)log 2]=1.59 by (non-differential) measurement error. The corresponding attenuation factor for estimates of nutrient intakes based on a food frequency instrument may be in the vicinity of 1/3 depending upon the nutrient and assessment instrument, so that an odds ratio of 2 is attenuated to about 1.26 based on random measurement error for such exposures. Hence, to explore the power of the OS under various configurations of association strength and regression dilution, power calculations have been conducted for odds ratios of 1.25, 1.50, 1.75, 2.0 and 3.0.

(vi) **Sampling procedures, and confounding factor control** - the power calculations that follow assume the characteristic or exposure under study to be available on all pertinent study subjects, and uses the asymptotic distribution of a simple odds ratio statistic. However, many of the OS analyses will use time-matched case-control, or stratified case-cohort, sampling to reduce the number of women for whom expensive analysis of stored specimens or complicated questionnaires must be carried out. The efficiency of a time-matched case-control analysis as compared to a full cohort analysis is approximately $k(k+1)^{-1}$, where $k$ is the number of controls matched to each case. Hence, a one-to-$k$ matched case-control study based on a cohort of size $n$ has power approximately equal to a full-cohort analyses based on a sample of size $nk(k+1)^{-1}$.

The following array can be used to approximately convert full-cohort sample size to corresponding 1:$k$ matched case-control effective sample size for $k$= 1,2,3,5.

Effective Cohort Sizes for 1:$k$ Matched Case-Control Analysis

| Controls (k) per case | Full Cohort Sample Sizes 100,000 | 80,000 | 40,000 | 20,000 | 10,000 | 6,000 | 2,000 |
|---|---|---|---|---|---|---|---|
| 1 | 50,000 | 40,000 | 20,000 | 10,000 | 5,000 | 3,000 | 1,000 |
| 2 | 66,667 | 53,333 | 26,667 | 13,333 | 6,667 | 4,000 | 1,333 |
| 3 | 75,000 | 60,000 | 30,000 | 15,000 | 7,500 | 4,500 | 1,500 |
| 4 | 80,000 | 64,000 | 32,000 | 16,000 | 8,000 | 4,800 | 1,600 |
| 5 | 83,333 | 66,667 | 33,333 | 16,667 | 8,333 | 5,000 | 1,667 |

Most OS analyses will also make provision, via stratification, matching or regression modeling, for factors that have potential to confound the association under study. Such control is essential to accurate odds ratio, or relative risk estimation, and corresponding more complex tests will tend to have reduced power, relative to the corresponding test in which confounding control is unnecessary. However, the power reduction is likely to be quite minor in most OS analyses so that no provision for confounding control is included in the OS power calculations.

The following tables present the power calculations for the configurations listed above, with the exception that combinations of factors for which the power is less than 50% are omitted for brevity.

**Table 1-A3.1**
**OS Power Calculations for Cohort Size of 100,000**

| | | Annual Disease Incidence Per 1,000 Women | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 0.1 | | | 0.5 | | | 1.0 | | | 2.0 | | | 5.0 | | |
| Average Years of Follow-up | | 3 | 6 | 9 | 3 | 6 | 9 | 3 | 6 | 9 | 3 | 6 | 9 | 3 | 6 | 9 |
| Exposure Frequency | Odds Ratio | | | | | | | | | | | | | | | |
| 0.50% | 1.75 | | | | | | | | | | | | | | | 0.79 |
| | 2.00 | | | | | | | | | | | | 0.55 | | 0.82 | 0.95 |
| | 3.00 | | | | | | | | | 0.73 | | 0.88 | 0.98 | 0.96 | 1.00 | 1.00 |
| 1.00% | 1.50 | | | | | | | | | | | | | | 0.60 | 0.79 |
| | 1.75 | | | | | | | | | | | | 0.69 | 0.59 | 0.91 | 0.98 |
| | 2.00 | | | | | | | | | 0.55 | | 0.72 | 0.90 | 0.83 | 0.99 | 1.00 |
| | 3.00 | | | | | | 0.72 | | 0.89 | 0.99 | 0.89 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| 10% | 1.25 | | | | | | | | | 0.52 | | 0.65 | 0.83 | 0.75 | 0.96 | 1.00 |
| | 1.50 | | | | | 0.57 | 0.77 | 0.57 | 0.89 | 0.98 | 0.89 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| | 1.75 | | | | 0.55 | 0.89 | 0.98 | 0.89 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| | 2.00 | | | 0.51 | 0.78 | 0.97 | 1.00 | 0.97 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| | 3.00 | | 0.83 | 0.97 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| 30% | 1.25 | | | | | | 0.59 | | 0.72 | 0.88 | 0.72 | 0.95 | 0.99 | 0.98 | 1.00 | 1.00 |
| | 1.50 | | | | 0.64 | 0.92 | 0.99 | 0.92 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| | 1.75 | | 0.51 | 0.71 | 0.92 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| | 2.00 | | 0.73 | 0.90 | 0.99 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| | 3.00 | 0.86 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| 50% | 1.25 | | | | | | 0.66 | | 0.8 | 0.93 | 0.80 | 0.98 | 1.00 | 0.99 | 1.00 | 1.00 |
| | 1.50 | | | | 0.72 | 0.95 | 0.99 | 0.95 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| | 1.75 | | 0.59 | 0.78 | 0.95 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| | 2.00 | | 0.80 | 0.94 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| | 3.00 | 0.90 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |

**Table 1-A3.2**
**OS Power Calculations for a Subsample Size of 80,000**

| | | Annual Disease Incidence Per 1,000 Women | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 0.1 | | | 0.5 | | | 1.0 | | | 2.0 | | | 5.0 | | |
| Average Years of Follow-up | | 3 | 6 | 9 | 3 | 6 | 9 | 3 | 6 | 9 | 3 | 6 | 9 | 3 | 6 | 9 |
| Exposure Frequency | Odds Ratio | | | | | | | | | | | | | | | |
| 0.50% | 1.75 | | | | | | | | | | | | | | | 0.67 |
| | 2.00 | | | | | | | | | | | | | | 0.71 | 0.89 |
| | 3.00 | | | | | | | | | 0.57 | | 0.76 | 0.94 | 0.88 | 1.00 | 1.00 |
| 1.00% | 1.50 | | | | | | | | | | | | | | | 0.69 |
| | 1.75 | | | | | | | | | | | | 0.57 | | 0.83 | 0.95 |
| | 2.00 | | | | | | | | | | | 0.59 | 0.81 | 0.72 | 0.97 | 1.00 |
| | 3.00 | | | | | | 0.57 | | 0.77 | 0.95 | 0.77 | 0.99 | 1.00 | 1.00 | 1.00 | 1.00 |
| 10% | 1.25 | | | | | | | | | | | 0.54 | 0.73 | 0.64 | 0.92 | 0.98 |
| | 1.50 | | | | | | 0.66 | | 0.80 | 0.94 | 0.80 | 0.98 | 1.00 | 1.00 | 1.00 | 1.00 |
| | 1.75 | | | | | 0.79 | 0.94 | 0.79 | 0.98 | 1.00 | 0.98 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| | 2.00 | | | | 0.66 | 0.95 | 1.00 | 0.95 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| | 3.00 | | 0.69 | 0.91 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| 30% | 1.25 | | | | | | | | 0.62 | 0.80 | 0.62 | 0.90 | 0.98 | 0.95 | 1.00 | 1.00 |
| | 1.50 | | | | 0.53 | 0.85 | 0.96 | 0.85 | 0.99 | 1.00 | 0.99 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| | 1.75 | | | 0.60 | 0.84 | 0.99 | 1.00 | 0.99 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| | 2.00 | | 0.62 | 0.82 | 0.97 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| | 3.00 | 0.75 | 0.98 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| 50% | 1.25 | | | | | | 0.56 | | 0.69 | 0.86 | 0.69 | 0.94 | 0.99 | 0.98 | 1.00 | 1.00 |
| | 1.50 | | | | 0.61 | 0.90 | 0.98 | 0.90 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| | 1.75 | | | 0.68 | 0.89 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| | 2.00 | | 0.69 | 0.87 | 0.98 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| | 3.00 | 0.81 | 0.99 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |

**Table 1-A3.3**
**OS Power Calculations for a Subsample Size of 40,000**

| | | Annual Disease Incidence Per 1,000 Women | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 0.1 | | | 0.5 | | | 1.0 | | | 2.0 | | | 5.0 | | |
| Average Years of Follow-up | | 3 | 6 | 9 | 3 | 6 | 9 | 3 | 6 | 9 | 3 | 6 | 9 | 3 | 6 | 9 |
| Exposure Frequency | Odds Ratio | | | | | | | | | | | | | | | |
| 0.50% | 2.00 | | | | | | | | | | | | | | | 0.53 |
| | 3.00 | | | | | | | | | | | | 0.57 | | 0.87 | 0.98 |
| 1.00% | 1.75 | | | | | | | | | | | | | | | 0.67 |
| | 2.00 | | | | | | | | | | | | | | 0.70 | 0.89 |
| | 3.00 | | | | | | | | | 0.57 | | 0.76 | 0.94 | 0.88 | 1.00 | 1.00 |
| 10% | 1.25 | | | | | | | | | | | | | | 0.64 | 0.81 |
| | 1.50 | | | | | | | | | 0.66 | | 0.79 | 0.93 | 0.88 | 1.00 | 1.00 |
| | 1.75 | | | | | | 0.64 | | 0.79 | 0.94 | 0.79 | 0.98 | 1.00 | 1.00 | 1.00 | 1.00 |
| | 2.00 | | | | | 0.66 | 0.86 | 0.66 | 0.95 | 1.00 | 0.95 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| | 3.00 | | | 0.51 | 0.82 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| 30% | 1.25 | | | | | | | | | | | 0.61 | 0.79 | 0.71 | 0.95 | 0.99 |
| | 1.50 | | | | | 0.53 | 0.73 | 0.53 | 0.85 | 0.96 | 0.85 | 0.99 | 1.00 | 1.00 | 1.00 | 1.00 |
| | 1.75 | | | | 0.51 | 0.84 | 0.96 | 0.84 | 0.99 | 1.00 | 0.99 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| | 2.00 | | | | 0.73 | 0.97 | 1.00 | 0.97 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| | 3.00 | | 0.76 | 0.93 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| 50% | 1.25 | | | | | | | | | 0.56 | | 0.69 | 0.86 | 0.79 | 0.97 | 1.00 |
| | 1.50 | | | | | 0.61 | 0.80 | 0.61 | 0.90 | 0.98 | 0.90 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| | 1.75 | | | | 0.59 | 0.89 | 0.98 | 0.89 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| | 2.00 | | | 0.55 | 0.80 | 0.98 | 1.00 | 0.98 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| | 3.00 | | 0.81 | 0.95 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |

**Table 1-A3.4**
**OS Power Calculations for a Subsample Size of 20,000**

| | | Annual Disease Incidence Per 1,000 Women | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 0.1 | | | 0.5 | | | 1.0 | | | 2.0 | | | 5.0 | | |
| Average Years of Follow-up | | 3 | 6 | 9 | 3 | 6 | 9 | 3 | 6 | 9 | 3 | 6 | 9 | 3 | 6 | 9 |
| Exposure Frequency | Odds Ratio | | | | | | | | | | | | | | | |
| 0.50% | 3.00 | | | | | | | | | | | | | | | 0.69 |
| 1.00% | 2.00 | | | | | | | | | | | | | | | 0.53 |
| | 3.00 | | | | | | | | | | | | 0.56 | | 0.86 | 0.98 |
| 10% | 1.25 | | | | | | | | | | | | | | | 0.50 |
| | 1.50 | | | | | | | | | | | | 0.65 | 0.56 | 0.87 | 0.97 |
| | 1.75 | | | | | | | | | 0.64 | | 0.79 | 0.93 | 0.88 | 1.00 | 1.00 |
| | 2.00 | | | | | | 0.50 | | 0.66 | 0.86 | 0.66 | 0.95 | 1.00 | 0.98 | 1.00 | 1.00 |
| | 3.00 | | | | | 0.82 | 0.97 | 0.82 | 0.99 | 1.00 | 0.99 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| 30% | 1.25 | | | | | | | | | | | | | | 0.71 | 0.87 |
| | 1.50 | | | | | | | | 0.53 | 0.72 | 0.53 | 0.85 | 0.96 | 0.92 | 1.00 | 1.00 |
| | 1.75 | | | | | 0.51 | 0.81 | 0.51 | 0.84 | 0.96 | 0.84 | 0.99 | 1.00 | 1.00 | 1.00 | 1.00 |
| | 2.00 | | | | | 0.73 | 0.90 | 0.73 | 0.97 | 1.00 | 0.97 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| | 3.00 | | | 0.59 | 0.86 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| 50% | 1.25 | | | | | | | | | | | | 0.56 | | 0.78 | 0.92 |
| | 1.50 | | | | | | | | 0.61 | 0.79 | 0.61 | 0.90 | 0.98 | 0.95 | 1.00 | 1.00 |
| | 1.75 | | | | | 0.59 | 0.78 | 0.59 | 0.89 | 0.98 | 0.89 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| | 2.00 | | | | | 0.80 | 0.94 | 0.80 | 0.98 | 1.00 | 0.98 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| | 3.00 | | | 0.67 | 0.90 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |

**Table 1-A3.5**
**OS Power Calculations for a Subsample Size of 10,000**

| | | Annual Disease Incidence Per 1,000 Women | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 0.5 | | | 1.0 | | | 2.0 | | | 5.0 | | |
| Average Years of Follow-up | | 3 | 6 | 9 | 3 | 6 | 9 | 3 | 6 | 9 | 3 | 6 | 9 |
| Exposure Frequency | Odds Ratio | | | | | | | | | | | | |
| 1.00% | 3.00 | | | | | | | | | | | | 0.69 |
| 10% | 1.50 | | | | | | | | | | | | 0.75 |
| | 1.75 | | | | | | | | | 0.63 | 0.54 | 0.87 | 0.97 |
| | 2.00 | | | | | | 0.50 | | 0.66 | 0.86 | 0.77 | 0.98 | 1.00 |
| | 3.00 | | | 0.65 | | 0.82 | 0.96 | 0.82 | 0.99 | 1.00 | 1.00 | 1.00 | 1.00 |
| 30% | 1.25 | | | | | | | | | | | | 0.57 |
| | 1.50 | | | | | | | | 0.53 | 0.72 | 0.63 | 0.91 | 0.98 |
| | 1.75 | | | | | 0.51 | 0.71 | 0.51 | 0.84 | 0.96 | 0.91 | 1.00 | 1.00 |
| | 2.00 | | | 0.58 | | 0.73 | 0.90 | 0.73 | 0.97 | 1.00 | 0.99 | 1.00 | 1.00 |
| | 3.00 | | 0.86 | 0.97 | 0.86 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| 50% | 1.25 | | | | | | | | | | | | 0.64 |
| | 1.50 | | | | | | | | 0.61 | 0.79 | 0.71 | 0.95 | 0.99 |
| | 1.75 | | | | | 0.59 | 0.78 | 0.59 | 0.89 | 0.98 | 0.95 | 1.00 | 1.00 |
| | 2.00 | | | 0.66 | | 0.80 | 0.93 | 0.80 | 0.98 | 1.00 | 1.00 | 1.00 | 1.00 |
| | 3.00 | 0.58 | 0.90 | 0.98 | 0.90 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |

Data Analysis

Observational Study

The ability to estimate relative risks for the outcomes of interest reliably in the OS as a function of baseline characteristics (exposures, behaviors or biologic measurements), or as a function of changes in such characteristics between baseline and three years is dependent on the accurate measurement of the characteristics (and outcomes) under study, and the accurate ascertainment and proper accommodation of all pertinent confounding factors. Even measurement error that is nondifferential in the sense that it is unrelated to disease risk given the 'true' characteristic values, can severely attenuate or otherwise distort relative risk estimates. Since many of the characteristics to be ascertained in the OS (e.g., nutrient intakes, blood cholesterol) are subject to noteworthy measurement error, a stratified 1% random subsample of the OS women will have repeat baseline information and specimens obtained at between one and three months following their OS enrollment, and again at between one and three months following their three year clinic visit. This reliability subsample will provide information of the reproducibility of the measurements taken, and can be used, under classical measurement error assumptions, to correct relative risk estimates for non-differential error in predictor and confounding variables. The 1% reliability sample will be stratified on age, racial/ethnic group, and socioeconomic group. The size of the OS cohort, and the comprehensive set of measurements to be obtained will allow a particularly thorough accommodation of confounding, by means of individual matching, stratification or regression modeling.

Relative risk regression methods (e.g., Cox, 1972) will also provide the primary data analytic tool for the OS. These methods, which can be thought of as an extension of classical person-year methods that avoids the assumption of constant disease risk for a study subject across the follow-up period, allow flexible modeling of the risks associated with the characteristics under study, as well as flexible accommodation of potential confounding factors, by means of stratification, matching, or regression modeling. Though less well developed they can also accommodate the types of reliability sample alluded to above (e.g., Pepe et al., 1989, Espeland et al, 1989; Lin et al, 1992), in order to produce 'deattenuated' relative risk estimates. Finally, relative risk regression methods are also readily adapted to accommodate nested case-control (Liddell et al., 1977; Prentice and Breslow, 1978) and case-cohort (Prentice, 1986) sampling schemes.

Nested case-control sampling proceeds by selecting for each 'case' of a study outcome one or more 'control' women who have not developed the disease in question by the follow-up time at which the corresponding case was ascertained. Additional matching criteria in the OS will typically include baseline age, clinic, and date of enrollment, and depending on the analysis may also include racial/ethnic or socioeconomic group, or other factors. Nested case-control sampling provides the only practical approach to reducing the number of OS women whose blood specimens need be analyzed and processed, if the measurements of interest cannot be assumed to be stable over time. For example, certain of the antioxidant concentrations to be measured in blood specimens are known to substantially degrade over the course of a few months or years of storage, in which case the follow-up-time-matched aspect of the nested case-control approach is essential to valid relative risk estimation. For measurements that are stable over time, however, case-cohort sampling could provide an alternative that has some decided advantages. Case-cohort sampling involves the selection of a random, or a stratified random, sample of the cohort to serve as a comparison (control) group for the cases of all the outcomes under study.

Analyses that relate change in risk factors to disease risk have particular potential for gaining insight into disease mechanisms. For example, the OS will provide a valuable forum for addressing the issue of whether or not the association between low blood cholesterol (e.g., <160 mg/dl) and excess non-cardiovascular mortality derives primarily from persons who have experienced major reductions in blood cholesterol over the preceding three years. In fact the OS is large enough that such analysis could be restricted to women with relatively low baseline blood cholesterol (e.g., lowest two quintiles) in order to avoid a complicated interpretation if the effect of interest happened to 'interact' with baseline cholesterol

measurement. Furthermore the OS, by virtue of ascertaining a range on non-specific markers of debility or disease (e.g., serum albumin, hemoglobin; cancer biomarkers; baseline and follow-up disease prevalence by questionnaire and physical exam) may be able to examine whether the excess mortality associated with reduced blood cholesterol can be explained by the presence of recognized or latent disease. The careful accommodation of measurement error in predictor and confounding variables is particularly important in such risk-factor-change analyses.

## Clinical Trial and Observational Study

Separate analyses in both the CT and OS will be conducted according to self-reported baseline prevalence of the clinical outcome being analyzed. In fact, whenever applicable, relative risk analyses based on randomized CT comparisons will be accompanied by corresponding OS relative risk analyses. The comparability of these analyses is enhanced by the common aspects of baseline data collection procedures and outcome determination procedures in the CT and OS. Estimated relative risk functions from the two sources will take suitable account of prior "exposure" histories and of measurement error in exposure assessment. As indicated earlier (3.2.) under circumstances in which careful analyses of this type lead to substantial agreement between CT and OS results, it may often be reasonable to extrapolate the relative risk results beyond those examined in the CT, using the OS.

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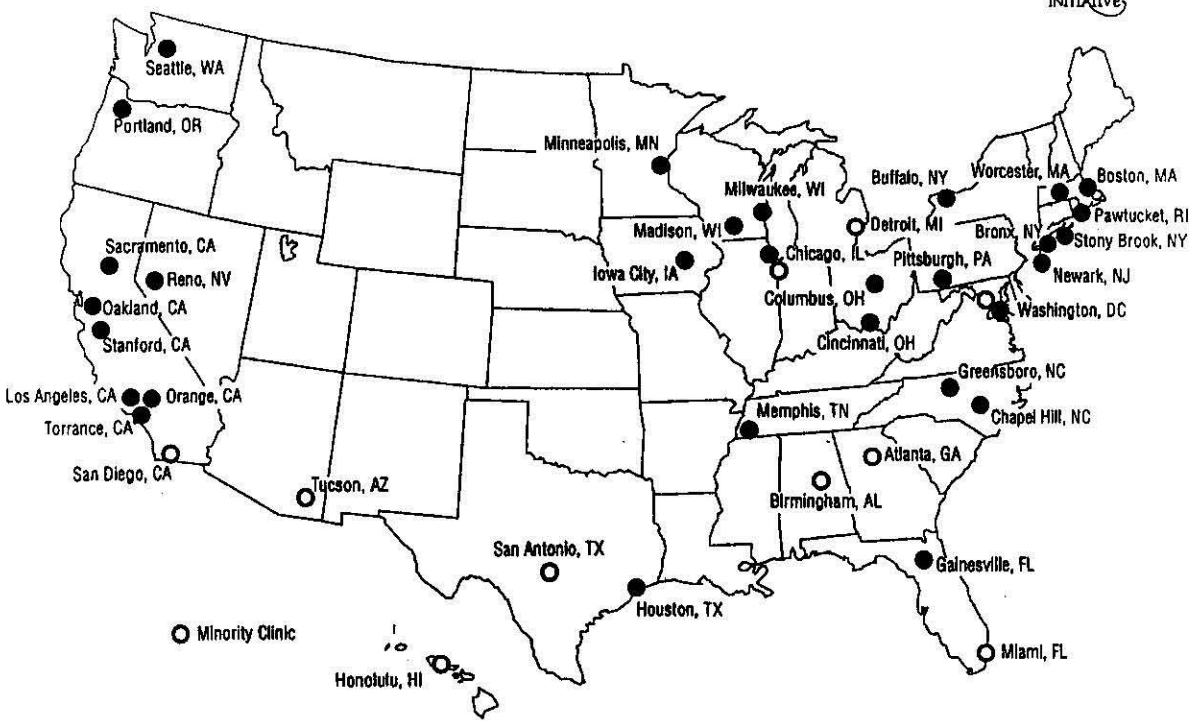
WOMEN'S HEALTH INITIATIVE

# Women's Health Initiative Clinical Centers

National Institutes of Health



# Published papers

The list below includes all 429 published WHI papers, updated 11/9/09. Primary papers and Important Study Papers (ISP) are listed in bold text. Unpublished papers still in progress are not listed. Note that the citations provided below may not conform to requirements for all journals.

Most browsers will let you search this page by pressing CTRL+F. You may also use the filter below to generate a list of the papers in each focus area.

## Paper focus: all

Change paper focus: Select one

| ID | Citation | PubMed | PDF |
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| 846 | Prentice RL, Huang Y, Hinds DA, Peters U, Pettinger M, Cox DR, Beilharz E, Chlebowski RT, Rossouw JE, Caan B, Ballinger DG. Variation in the FGFR2 gene and the effects of postmenopausal hormone therapy on invasive breast cancer. Cancer Epidemiol Biomarkers Prev. 2009 Oct 27. [Epub ahead of print] | abstract | full |
| 598 | Resnick SM, Espeland MA, An Y, Maki PM, Coker LH, Jackson R, Stefanick ML, Wallace R, Rapp SR; for the Women's Health Initiative Study of Cognitive Aging Investigators. Effects of conjugated equine estrogens on cognition and affect in postmenopausal women with prior hysterectomy. J Clin Endocrinol Metab. 2009 Oct 22. [Epub ahead of print] | abstract | full |
| 567 | Crandall CJ, Aragaki AK, Chlebowski RT, McTiernan A, Anderson G, Hendrix SL, Cochrane BB, Kuller LH, Cauley JA. New-onset breast tenderness after initiation of estrogen plus progestin therapy and breast cancer risk. Arch Intern Med. 2009 Oct 12;169(18):1684-91 | abstract | full |
| 718 | Carbone LD, Johnson KC, Robbins J, Larson JC, Curb JD, Watson K, Gass M, Lacroix AZ. Antiepileptic Drug Use, Falls, Fractures and BMD in Postmenopausal Women: Findings from the Women's Health Initiative (WHI). J Bone Miner Res. 2009 Oct 19. [Epub ahead of print] | abstract | |
| 510 | Rajpathak SN, Freiberg MS, Wang C, Wylie-Rosett J, Wildman RP, Rohan TE, Robinson JG, Liu S, Wassertheil-Smoller S. Alcohol consumption and the risk of coronary heart disease in postmenopausal women with diabetes: Women's Health Initiative Observational Study. Eur J Nutr. 2009 Oct 13. [Epub ahead of print] | abstract | full |
| 375 | De Roos AJ, Ulrich CM, Ray RM, Mossavar-Rahmani Y, Rosenberg CA, Caan BJ, Thomson CA, McTiernan A, Lacroix AZ. Intentional weight loss and risk of lymphohematopoietic cancers. Cancer Causes Control. 2009 Oct 23. [Epub ahead of print] | abstract | full |
| 575 | Michael YL, Gold R, Manson JE, Keast EM, Cochrane BB, Woods NF, Brzyski RG, McNeeley SG, Wallace RB. Hormone therapy and physical function change among older women in the Women's Health Initiative: a randomized controlled trial. Menopause. 2009 Oct 23. [Epub ahead of print] | abstract | full |
| 794 | Espeland MA, Tindle HA, Bushnell CA, Jaramillo SA, Kuller LH, Margolis KL, Mysiw WJ, Maldjian JA, Melhem ER, Resnick SM; for the Women's Health Initiative Memory Study. Brain volumes, cognitive impairment, and conjugated equine estrogens. J Gerontol A Biol Sci Med Sci. 2009 Sep 3. [Epub ahead of print] | abstract | full |
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| 392 | Li R, O'Sullivan MJ, Robinson J, Safford MM, Curb D, Johnson KC. Family history of myocardial infarction predicts incident coronary heart disease in postmenopausal women with diabetes: the Women's Health Initiative Observational Study. Diabetes Metab Res Rev. 2009 Sep 24. [Epub ahead of print] | abstract | full |
| **848** | **Chlebowski RT, Schwartz AG, Wakelee H, Anderson GL, Stefanick ML, Manson JE, Rodabough RJ, Chien JW, Wactawski-Wende J, Gass M, Kotchen JM, Johnson KC, O'Sullivan MJ, Ockene JK, Chen C, Hubbell FA; for the Women's Health Initiative Investigators. Oestrogen plus progestin and lung cancer in postmenopausal women (Women's Health Initiative trial): a post-hoc analysis of a randomised controlled trial. Lancet. 2009 Sep 18. [Epub ahead of print].** | **abstract** | **full** |
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| 882 | Kabat GC, Kim M, Chlebowski RT, Khandekar J, Ko MG, McTiernan A, Neuhouser ML, Parker DR, Shikany JM, Stefanick ML, Thomson CA, Rohan TE. A Longitudinal Study of the Metabolic Syndrome and Risk of Postmenopausal Breast Cancer. Cancer Epidemiol Biomarkers Prev. 2009 Jul;18(7):2046-53. Epub 2009 Jun 30. | abstract | full |
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| 301 | Gray SL, LaCroix AZ, Aragaki AK, McDermott M, Cochrane BB, Kooperberg CL, Murray AM, Rodriguez B, Black H, Woods NF; Women's Health Initiative Observational Study. Angiotensin-converting enzyme inhibitor use and incident frailty in women aged 65 and older: prospective findings from the Women's Health Initiative Observational Study. J Am Geriatr Soc. 2009 Feb;57(2):297-303. | abstract | full |
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| 560 | Carbone LD, Johnson KC, Bush AJ, Robbins J, Larson JC, Thomas A, LaCroix AZ. Loop diuretic use and fracture in postmenopausal women: Findings from the Women's Health Initiative. Arch Intern Med. 2009 Jan 26;169(2):132-40. | abstract | full |
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