Appendix B
Abbreviations, Terms and Definitions

B.1 List of Abbreviations

BMD - bone mineral densitometry

BMI - body mass index

BSE - breast self-exam

CABG - coronary artery bypass grafting

CaD - Calcium and Vitamin D

CARET - Carotene and Retinol Efficacy Trial

CBE - clinical breast exam

CC - Clinical Center

CCC - Clinical Coordinating Center

CDP - Coronary Drug Project

CEE - conjugated equine estrogen

CES-D - Center for Epidemiologic Studies - Depression

CHD - coronary heart disease

CHF - congestive heart failure

CHRU - Cardiovascular Health Research Unit

CHS - Cardiovascular Health Study

CM - Clinic Manager

CSI - cholesterol saturated fat index

CT - Clinical Trial

CVD - Cardiovascular Disease

DA - Dietary Assessment

DC - Data Coordinator

DM - Dietary Modification

DMV - Department of Motor Vehicles

DSMB - Data and Safety Monitoring Board

ECG - electrocardiogram

ERT - estrogen replacement therapy

FDA - Food and Drug Administration

FFQ - Food Frequency Questionnaire

FHCRC - Fred Hutchinson Cancer Research Center

FIT - Fracture Intervention Trial

4DFR - Four-Day Food Record

FSMP - See WHT-FSMP

GPO - Government Printing Office

HCFA - Health Care Finance Administration

HDLC - high density lipoprotein cholesterol

HDL2 - high density lipoprotein subfraction 2 cholesterol

HDL3 - high density lipoprotein subfraction 3 cholesterol

HRQL - health-related quality of life

HRT - hormone replacement therapy

ICD-9 - International Classification of Diseases, Version 9

ICD-0 - International Classification of Diseases for Oncology

IND - Investigational New Drug

IOM - Institute of Medicine

IRB - Institutional Review Board

IRS - Inquiry Reporting System

LAN - local area network

LDH - lactic dehydrogenase

LDLC - low density lipoprotein cholesterol

Lp(a) - lipoprotein (a)

MAO - monoamine oxidase

MFA - monounsaturated fatty acids

MI - myocardial infarction

MPA - medroxyprogesterone

MRI - magnetic resonance imaging

MRL - Medical Research Laboratory

NCI - National Cancer Institute

NDI - National Death Index

NDS - (University of Minnesota) Nutrition Data System

NHLBI - National Heart, Lung, and Blood Institute

NIH - National Institutes of Health

NP - Nurse Practitioner

OMB - Office of Management and Budget

ORWH - Office for Research on Women's Health

OS - Observational Study

OSHA - Occupational Safety and Health Administration

P:S - polyunsaturated to saturated fat ratio

PA - Physician Assistant

PC - personal computer

PCP - primary care provider

PEPI - Postmenopausal Estrogen/Progestin Intervention Study

PERT - progestin/estrogen replacement therapy

PFA - polyunsaturated fatty acids

PI - Principal Investigator

PSA - Public Service Announcement

PTCA - percutaneous transluminal coronary angioplasty

QA - quality assurance

RBC - red blood cell

RC - recruitment coordinator

RDA - recommended daily allowance

S/C - sub-committee

SEER - Surveillance, Epidemiology, and End Result

SFA - saturated fatty acids

SOF - Study of Osteoporotic Fractures

SV0 - Screening Visit Zero

SV1 - Screening Visit 1, first screening visit

SV2 - Screening Visit 2, second screening visit

SV3 - Screening Visit 3, third screening visit

TC - total cholesterol

TG - triglyceride

TIA - transient ischemic attack

UM-NCC - University of Minnesota's Nutritional Coordinating Center

VCC - Vanguard Clinical Center

WAN - wide area network

WBC - white blood cell

W/G - working group

WHI - Women's Health Initiative

WHI PAC - Women's Health Initiative Program Advisory Committee

WHT-FSMP - Women's Health Trial - Feasibility Study in Minority Populations

B.2 List of Terms and Definitions

adherence - the degree to which a participant takes the prescribed study medications; one of three components of retention.

adverse effect - an undesirable physical or psychological change, occurring while a participant is receiving study intervention; it may or may not be attributable to that intervention.

alert - any physical finding, lying outside normal ranges or normal expectations, that requires follow-up; classified as requiring routine, urgent, or immediate referral.

ancillary study - an investigation based on information from the WHI Clinical Trial or Observational Study participants that is not described in the WHI protocol and involves data that are not collected as part of the routine WHI data set or biologic specimens for analysis or storage.

anthropomorphic measures - measurements dealing with size; weight or proportions; height and weight; waist and hip measurements.

arm - a treatment defined for a clinical trial component.

barcode - a set of parallel black lines used to represent a series of numbers or letters.

batch - a set of data or jobs to be processed in a single group.

bone densitometry centers - three CCs that perform bone densitometries on their participants, including those in the OS.

bulletin - official update to WHI Manuals from CCC.

CaD participant - a woman randomized to either arm of the CaD component of the WHI.

Calcium and Vitamin D component (CaD) - one of the three components of the WHI Clinical Trial comparing calcium and vitamin D to placebo for effects on disease incidence.

certification - documentation that a WHI staff member has demonstrated qualifications to perform a designated study task; a formal process of training and testing to assure the competency of study personnel.

Clinic Manager - designated, centrally trained CC staff person who is primarily responsible for the training/quality assurance of many of the clerical and support staff and interviewers.

Clinical Coordinating Center (CCC) - the WHI organization that has primary responsibility for overall coordination, quality assurance, data management, and analysis activities required for execution of the study as well as providing scientific advice and counsel for the design, conduct, and analysis of the CT and OS.

Clinical Center (CC) - a WHI organization responsible for the recruitment and management of WHI participants at a specific site.

clinical measurements - physical and performance assessment of WHI participants by CC staff; does not include measurements that require equipment such as ECG or bone densitometry.

Clinical Trial (CT) - the randomized WHI Clinical Trial consisting of three intervention components (DM, HRT, and CaD) to be tested singly and in combination with the others.

clinical trial - a research activity that involves administration of a test treatment to some experimental unit to evaluate the treatment.

cohort - a group of people defined by a common characteristic or set of characteristics.

comparison arm - the DM participants who are randomized to follow their usual diet.

component - one of the three clinical trials comprising the CT: DM, HRT, and CaD.

contact - any communication (written, telephone, or in-person) between a WHI participant or participant record and a CC.

control arm - CT participants randomized to the arm of a trial component that does not receive the dietary intervention (DM), or receives a placebo (HRT & CaD).

CT component - See trial component.

CT participant - a woman enrolled in any of the three components of CT.

current medication - any prescribed or over-the-counter drug or other supplement that a WHI participant is taking at the time of entry or at any other time in the study.

Data and Safety Monitoring Board (DSMB) - an independent board of scientists that regularly monitors WHI study progress, outcomes, and safety, and may make recommendations in regard to protocol changes.

Data Coordinator - centrally-trained CC staff person who is primarily responsible for maintaining the computer systems, data management and the training/quality assurance of CC data entry staff.

dietary change arm - the DM participants who are randomized to follow the intervention diet.

Dietary Modification component (DM) - one of the three CT components of the WHI designed to test the effect of a low-fat diet on incidence of disease.

DM group - a group of DM dietary change participants organized to meet together with a nutritionist at pre-determined times throughout the study cycle.

DM intervention participant - a DM participant who has been randomized to the intervention arm of the DM. (The DM component is the only one of the three WHI CT components that is unblinded).

DM participant - a woman randomized to either arm of the DM component of the WHI.

double blind clinical trial - a clinical trial in which the control and treatment arms are administered in identical fashion, and the actual treatment for a given participant is unknown by both the participant and the individual responsible for treatment.

eligibility criteria - conditions that a woman must meet to be eligible for a WHI study. Certain criteria (age, menopausal status, etc.) apply to all components, however, a trial component may also have its own criteria that a woman must meet to enter that study; encompasses both inclusion and exclusion criteria.

eligibility determination - a database function that evaluates all of a participant's data pertinent to a particular study component and summarizes her status.

encounter - an event in which an employee performs a task during a contact with a WHI participant.

endometrial aspiration - a clinical procedure in which a sample of the uterine lining is obtained; also known as an endometrial biopsy.

enrollment - the examination and data collection procedures associated with a participant's screening CC visits (pre-randomization visits). The participant is considered "enrolled" in a study component (OS, DM, HRT, CaD) at the time that her baseline and screening requirements (including randomization for CT components) have been met and documented the WHI database.

enrollment medications - single blind placebo pills taken by women interested in HRT to assess adherence prior to randomization.

Estrogen Replacement Therapy (ERT) - one of the three arms of the HRT component of the WHI.

exclusion criteria - existing conditions or factors that, for competing risk, safety, or adherence, make a woman ineligible for one or more of the WHI components. Ineligibility for one component does not necessitate ineligibility for all components. Also, certain criteria may be reevaluated at a later date, and, if they are no longer true, the woman may then be eligible.

exposure - the extent to which a person is subjected to a specific factor that may increase her or his risk of disease.

Fat Counter - a booklet containing a list of 1,100 foods and fat grams intervention women use to identify the grams of fat and calculate a fat score.

fat gram goal - the number of fat grams a participant aims to consume on a daily basis, based on self-monitoring, to reduce her fat consumption to 20% of total current calories. Each participant's goal is calculated using an algorithm based on height prior to randomization.

Fat Scan - a small booklet containing lists of food and corresponding grams of fat that DM intervention participants use as a quick self-monitoring method to monitor fat intake and calculate a fat score.

fat score - the average number of fat grams an individual consumes per day over a three-day period. This number can be calculated using a food diary with the Fat Counter or Fat Scan.

follow-up visit - a scheduled CC visit by a participant that takes place at a specified time post enrollment or randomization and is needed to collect follow-up data required by the protocol.

Food Diary - a booklet used by DM intervention participants to record the foods eaten during a designated number of days. The information recorded in the food diary is used to calculate the fat score using the Fat Counter. The Food Diary is similar to a 4DFR but the Food Diary is used as a self-monitoring tool during the first six weeks of DM intervention.

Food Frequency Questionnaire - self-administered assessment of participant's usual food intake over the previous three months (*Form 60*).

Food Record Inquiry - a request sent to a CC from the CCC for additional information on an incomplete or uninterpretable Four Day Food Record (*Form 68*).

form - any of a number of documents on which information regarding WHI participants is collected. This includes questionnaires on which a woman supplies information about herself and forms filled out by CC personnel.

Four-Day Food Record - a detailed documentation of food eaten over four days *(Form 62)*.

functional status - a woman's ability to perform activities of daily living based on her physical health; may be measured by physical performance measures or questionnaires.

guide edge - the side of a mark-sense form that aligns with the guide rail inside a scanner to ensure that rows of bubbles match exactly with the photocells in the scanner's read head. The timing track is always located along the guide edge.

Hormone Replacement Therapy (HRT) - one of the three trial components of the WHI designed to test the effect of ERT and PERT on disease incidence.

HRT Diary - a booklet that HRT participants fill out on a daily basis to record bleeding symptoms.

HRT participant - a woman randomized to any arm of the HRT component of the WHI.

inclusion criteria - existing conditions or factors that a woman must have to be eligible for the CT.

informed consent - the voluntary consent given by a participant in the study after being given information of the purpose, method of treatment, procedure for assignment to treatment, benefits and risks associated with participation, and required data collection procedures and schedules. Each of the three components of the CT and the OS have a separate informed consent form. An informed consent is a requirement in studies that are federally regulated or funded as well as by many state laws.

International Classification of Diseases, Version 9 (ICD-9) - a reference for abstracting and coding disease information.

intervention - an effort to prevent a disease or condition or to change the natural course of a disease or condition by attempting to alter the risk factors or precursors associated with the disease. In the WHI, intervention takes the form of hormone replacement, dietary modification, and calcium and vitamin D supplementation.

intervention arm - the dietary change intervention in the DM component.

Lead Clinic Practitioner - a centrally trained, licensed health care provider (physician, nurse practitioner, or physicians assistant) who is primarily responsible for training/quality assurance of clinical staff and whose scope of practice includes primary health care and women's health care in particular.

Lead Nutritionist - centrally-trained, CC staff person who is primarily responsible for the training/quality assurance of Dietary Assessment staff and/or Group Nutritionists.

leading edge - the end of a mark-sense form that enters the scanner first; where skunk marks are located.

litho-code - on mark-sense forms, an optional, binary-coded serial number unique to every form, usually accompanied by human-readable, decimal number equivalent.

local area network (LAN) - a configuration of computers whereby joint access to software and data are provided by a connection to a file server which stores all shared files.

medication - see study medication or current medication.

morbidity - an illness or some other health-related condition, except death.

mortality - death, usually verified through death certificates or some other reliable record of death.

National Cancer Institute (NCI) - a branch of the National Institutes of Health.

National Death Index (NDI) - a central registry of deaths, started in 1979 and operated by the National Center for Health Statistics of the United States Public Health Services.

National Heart, Lung, and Blood Institute (NHLBI) - a branch of the National Institutes of Health.

National Institutes of Health (NIH) - a group of institutes and related support structures located in Bethesda, Maryland, that is part of the United States Public Health Services. The NIH is responsible for funding basic and applied research in the health field; also initiates and carries out medical research on an intramural and extramural basis.

Nutrition Data System (NDS) - a microcomputer-based system for collection and analysis of dietary data. The NDS can be used to guide dietary recall interviews or to process written food records.

Observational Study (OS) - the component of the WHI in which women who are either ineligible for, or do not wish to participate in, the CT will be followed as a separate study to evaluate risk factors in women for the study outcomes.

OS participant - a woman enrolled in the OS of the WHI.

outcome - a health-related event of interest thought to be important in evaluating the effects of interventions of exposures; classified as primary or secondary depending on its relationship to the main study purpose.

participant - for the ease of writing and reading the WHI Manuals, any woman who meets basic study age and menopausal status requirements, and has agreed to at least one CC visit so screening can be performed, regardless of the outcome of the screening (i.e., women deemed ineligible for CT and OS who come to the SV1, randomized to any CT, or enrolled in the OS) are all participants. However, in preparing scientific papers and reports it is understood that a woman should be more definitively referred to as "potential participant" pre-randomization and a "CT participant" post-randomization, while a woman enrolled in the OS should be referred to as an "OS participant."

participant ID number - the unique 8-digit number assigned to a participant.

participation - the degree to which a participant performs the protocol defined tasks directed by the component to which she is enrolled or randomized; one of three components of retention.

performance - the degree to which a DM intervention arm maintains a low-fat diet; one of three components of retention.

placebo - a pharmacologically-inactive substance resembling a medication (in shape, texture, size, taste, etc.) given to participants randomized to the control arms of the HRT or CaD trial components; used to maintain the blinding of a participant and CC staff to the participant's treatment arm.

prescription - an order for hormones to be dispensed to a HRT participant in response to an adverse effect or nonsteroidal anti-inflammatory medications given to lessen discomfort of the endometrial aspiration.

primary care provider - a WHI participant's personal physician or other health care provider whom she sees regularly for routine health care.

Principal Investigator (PI) - term used by NIH to designate the individual responsible for the scientific content of a grant or contract-supported research project.

Progestin and Estrogen Replacement Therapy (PERT) - one of the three arms of the HRT component of WHI.

Project Officer - the NIH scientist responsible for oversight of scientific, administrative, and fiscal aspects of WHI and integration of participating NIH Institutes.

protocol - a narrative document that describes the general design and policies of a study.

quality assurance - procedures aimed at maintaining the protocol standards for WHI and evaluating WHI operations (at both CC and CCC) for deviation from the protocol.

questionnaire - a form that asks a number of questions on one or more topics and is generally filled out by a WHI participant and brought with her to a CC visit.

randomization - the process of assigning an individual to an arm (intervention/control) by a random method.

recruitment - the process of identifying and inviting a woman into the study for screening. Recruitment of a woman ends when either she attends the first screening visit or the CC determines it is not appropriate to invite her to schedule an SV1.

Recruitment Coordinator - centrally trained, CC staff person who is primarily responsible for the coordination of recruitment strategies, plans for informing and educating the medical and lay communities about WHI, and documenting monthly recruitment activities.

retention - the strategies and procedures CCs use to assure a participant's adherence, performance, and participation in the study.

satellite CC - a CC site that has operational ties but geographical distance from the main CC.

screening visits - visits by a participant to the CC which take place at or before randomization to CT or enrollment into OS and which are needed to collect eligibility or baseline data required by the study protocol.

session - a unit of instruction (self-contained educational material) that covers a single topic or a small section of a broad topic to aid in behavioral change. The material is designed to provide topic-specific information and recommendations to participants.

side effect - a physical or psychological change that is attributable to a study arm.

skunk marks - on a mark-sense form, a unique combination of black squares along the leading edge of the form that tells the scanner's computer which program to use in interpreting the forms.

study - a scientific endeavor designed to answer specific questions.

study medication - an drug, supplement, or placebo dispensed to a HRT or CaD participant.

study population - all women who are enrolled in either the CT or OS of the WHI.

symptom - a physical or psychological change reported by a participant.

target date - the specified date at which a contact (phone or CC visit) is required in accordance with procedures. The target date of routine follow-up contacts is based on the date of randomization.

timing mark - on a mark-sense form, a black rectangle that corresponds to a horizontal row of bubbles on a form.

timing track - on a mark-sense form, a series of timing marks that runs down the guide edge of a form and triggers the scanner's read head to read a row of bubbles.

transfer participant - a participant who was first seen at one CC and is later seen at another CC. This usually occurs because the participant moves to the new CC area.

trial component - any of the three intervention studies (DM, HRT, and CaD) that, along with the OS, comprise the WHI. Also CT component.

unblinding officer - an individual at each CC who is not involved in the ascertainment of outcomes. Should unblinding become necessary, the unblinding officer and the CC consulting gynecologist will be the only CC staff persons unblinded to the participant's treatment arm.

visit - a WHI participant's attendance at a CC for screening or follow-up purposes.

WHILMA - the WHI study database developed in the Oracle software system, and provided to each CC as well as the CCC.

WHI Manuals - the set of documents describing all key aspects of the conduct of this study.

Volume 1 Study Protocol and Policies
2 Procedures
3 Forms
4 Dietary Modification Intervention
5 Data System
6 DXA Quality Assurance
7 Quality Assurance

WHI participant - a woman who is enrolled in at least one component of the CT, or who is taking part in the OS.

WHI Staff - all persons employed by the WHI to perform the activities of the WHI studies. This includes CC, CCC, subcontractor, and NIH employees.

WHI Study - the CT (consisting of any of the three components: HRT, DM, & CaD), and the OS of the Women's Health Initiative.

wide area network (WAN) - a linkage of computers designed to allow joint access and transfer of files across long distances.

window - the time interval for performing a specified baseline or follow-up contact. The window for WHI follow-up visits is a 4-week period ($\pm$ 2 weeks) of the target date. For example, if a follow-up visit target date is 3-15-93, the visit window is 3-1-93 to 3-30-93.

Your New Eating Style booklet - a booklet given to randomized DM Intervention women who have been waiting at least one month for first group meeting.

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Contents **Page**