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INTRODUCTION TO WOMEN'S HEALTH INITIATIVE: CLINICAL TRIALS AND OBSERVATIONAL STUDY

INTRODUCTION

The health of women has extraordinary medical, social, and economic importance, as well as the personal interest of women in making choices of healthy behaviors. However, too little research has focused on health issues unique to, or more common for, women. This is especially the case for studies of chronic diseases in mature women. These conditions, cardiovascular disease, cancer, and osteoporosis, are the leading causes of mortality, morbidity, and declining quality of life. Recognizing this, in 1991 the Director of the National Institutes of Health (NIH) announced the development of a research program to address these issues. These studies have been titled the Women's Health Initiative (WHI). Scientific staff from 10 Institutes of NIH joined together to plan this program that is coordinated by the Office of Disease Prevention and the Office of Research on Women's Health.

Purpose

The WHI is composed of three studies: a Clinical Trial (CT), an Observational Study (OS), and a community based study. For efficiency the CT and OS have been combined into one program. This manual describes the protocol for both of these studies and the study policies.

WHI Manuals

The design and implementation of the WHI, as captured in the study Protocol, policies, procedures, interventions, and data collection instruments are described in the WHI Manuals. The primary function of these manuals is to provide common training and reference materials across all participating WHI organizations as a way of assuring the quality of the study. Each operational unit is responsible for developing its own manual describing the policies and procedures specific to that unit.

The WHI Manuals are contained in several volumes. The allocation of topics to volumes was based on the WHI staff members who would most use the various sections.

Volume 1 - Study Protocol and Policies: This manual contains the Protocol for the CT and OS, the committee structure and the policies governing the scientific conduct of the study. As this is a document written for and by WHI Investigators, procedural aspects of the study that are performed by Investigators (e.g., outcomes classification) are included in this manual.

Volume 2 - Procedures: This manual describes all Clinical Center (CC) procedures and guidelines for operations other than Nutrition Intervention. As the primary CC training and reference source, this manual serves as the standard by which CC operations are assessed.

Volume 3 - Forms: All standardized study forms are displayed in the Forms Manual in numerical order. Accompanying each form is a detailed set of instructions describing who completes the form, when and how each data item should be coded, and what should happen to the form when completed.

Volume 4 - Dietary Modification Intervention: The Dietary Modification (DM) Intervention Manual consists of two parts: the Group Nutritionist Manual and the Participant Manual. The Group Nutritionist Manual describes the procedures for carrying out the intervention sessions for the DM component. The Participant Manual contains information pertinent to each intervention session.

Volume 5 - Data System: This is a user's manual for the WHI computing system. Information is provided on the general hardware and software used as well as the specific WHI database, WHILMA.

Volume 6 - DXA Quality Assurance Manual for Hologic QDR-2000 Bone Densitometer: This is a user's manual for the WHI Bone Density CCs. This manual is intended as a supplement to the Hologic User's Manual.

Volume 7 - Quality Assurance Manual: This manual provides procedures and checklists for CC QA Activities.

Volume 8 - Outcomes: This manual provides procedures and forms for outcome ascertainment and adjudication.