

ORGANIZATION AND MANAGEMENT

1. Overview

Osteoporotic Fractures in Men ("Mr.OS") is an observational study designed to assess risk factors for osteoporotic fractures and other age-related conditions in a cohort of approximately 5,700 men aged 65 and older.

Mr.OS is funded as a U01 grant jointly through the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) and the National Institute of Aging (NIA). Supplemental funds were also provided by the National Cancer Institute (NCI), to include collection of additional specimens and data pertaining to risk for prostate cancer. The funding for this study began in July, 1999 and extends through June, 2006. At present, two clinic visits are planned: a baseline visit beginning March 1, 2000 with anticipated completion in June, 2002; and a follow-up visit scheduled to begin approximately 4-1/2 years after baseline.

The organization of Mr.OS includes the following participating units: six clinical centers; a Coordinating Center, including quality assurance units for DXA, spine X-rays, CT and ultrasound; an administrative center; and the NIH funding institutions.

2. Participating Units

2.1 Clinical Centers

Six clinical centers are involved in this study:

University of Alabama, Birmingham, AL
Cora Lewis, MD, MSPH, Principal Investigator

University of Minnesota VA Medical Center, Minneapolis, MN
Kristine Ensrud, MD, MPH, Principal Investigator

University of Pittsburgh, Pittsburgh, PA
Jane Cauley, Dr.PH, Principal Investigator

Oregon Health Sciences University, Portland, OR
Eric Orwoll, MD, Principal Investigator

University of California, San Diego, CA
Elizabeth Barrett-Connor, MD, Principal Investigator

Stanford University, Palo Alto, CA
Robert Marcus, MD, Principal Investigator

The six clinical centers are responsible for: Recruiting, evaluating, and following a total of 5,700 participants (950 per center); timely transmission of the data to the Coordinating Center with the lowest error rate attainable; and participating in the scientific aspects of the study including design, analysis and publication. Each clinical center is also responsible for alerting the coordinating center and administrative center of problems that arise.

The Principal Investigator at each site is responsible for the conduct of the study at his/her site in accordance with the protocol, operations manual and all additional relevant study documentation.

2.2 UCSF Coordinating Center and CT Reading Center

Under the direction of Steven R. Cummings, M.D., FACP, Principal Investigator, the Coordinating Center at the University of California, San Francisco, serves as the mechanism for coordinating and assuring the excellence of aspects of the design and implementation of the study, and of the analysis and dissemination of findings. The Coordinating Center serves as the data and quality control center, and oversees the communication of the study.

Tom Lang, Ph.D. is the Principal Investigator for the CT Reading Center in the Dept. of Radiology and Osteoporosis and Arthritis Research Group at the University of California, San Francisco.

2.3 OHSU Administrative Center

Under the direction of Eric Orwoll, M.D., Principal Investigator, the Administrative Center at Oregon Health Sciences University provides scientific direction for the study. This includes oversight of design and implementation of the study, as well as analysis and dissemination of the findings. Dr. Orwoll will chair and oversee the activities of the Steering, Publications, and Ancillary Studies committees.

2.3 National Institutes of Health

The Coordinating Center is funded through NIA, while all clinical centers and the Administrative Center are funded through NIAMS. Primary contact information for NIH representation is as follows:

Joan McGowan, Ph.D.
Director, Musculoskeletal Diseases Branch
Musculoskeletal Diseases Branch
National Institutes of Arthritis and Musculoskeletal and Skin Diseases, NIH

Sherry Sherman, Ph.D.
Director, Clinical Endocrinology and Osteoporosis Research
The Geriatrics Program,
National Institute on Aging, NIH

Dr. McGowan is a voting member of the Mr.OS Steering Committee, whereas Dr. Sherman serves as a non-voting member.

3. Administration

3.1 Steering Committee

Appendix 1 describes the Mr.OS Steering Committee structure. All clinical centers, the Coordinating and Administrative centers, and the funding agencies are represented on the Steering Committee.

The Steering Committee is responsible for all decisions concerning the scientific and technical conduct of the study. Some of its specific responsibilities include:

- To achieve consensus on the design of the study
- To approve all substantive revisions or changes to the design / protocol
- To approve all scientific reports and publications resulting from data that are developed during the study.

The chairperson of the Steering Committee is the Principal Investigator of the Administrative Center, Dr. Eric Orwoll. The Steering Committee will meet monthly by conference call and in-person once a year unless otherwise needed.

APPENDIX 1
Mr.OS STEERING COMMITTEECLINICAL CENTERS

Cora Lewis, MD, MSPH
University of Alabama, Birmingham, AL

Kristine Ensrud, MD, MPH
University of Minnesota VA Medical Center, Minneapolis, MN

Jane Cauley, Dr.PH
University of Pittsburgh, Pittsburgh, PA

Eric Orwoll, MD
Oregon Health Sciences University, Portland, OR

Elizabeth Barrett-Connor, MD
University of California, San Diego, CA

Robert Marcus, MD
Stanford University, Palo Alto, CA

COORDINATING CENTER

Steven R. Cummings, MD, FACP
University of California, San Francisco, CA

ADMINISTRATIVE CENTER

Eric Orwoll, MD
Oregon Health Sciences University, Portland, OR

NIH

Joan McGowan, Ph.D.,

National Institute of Arthritis, Musculoskeletal and Skin Diseases

NON-VOTING MEMBERS:

Sherry Sherman, Ph.D, National Institute on Aging, NIH

Katie Stone, Ph.D., Project Director, UCSF Coordinating Center

Jan Blank, Project Director, Portland Administrative Center