



Health Sciences IRB Compliance Statement & IRB Composition

The Health Sciences Institutional Review Board (HS-IRB) serves as one of the IRBs for human subjects research conducted at the University of Wisconsin-Madison. The HS-IRB reviews and approves research in accordance with the law of the United States of America and the State of Wisconsin. The HS-IRB complies with the applicable requirements of the Department of Health and Human Services (DHHS) regulations, 45 CFR Part 46; the Food and Drug Administration (FDA) regulations, 21 CFR Parts 50, 56, 312, and 812; Veteran's Administration (VA) Regulations pertaining to the protection of human subjects, 38 CFR Part 16; the privacy requirements of the Health Insurance Portability and Accountability Act of 1996 implemented by 45 CFR Parts 160 and 164 (Privacy Rule); and the Guideline for Good Clinical Practice of the International Conference on Harmonization (ICH/GCP), section 3, on institutional review boards, as published in 62 Federal Register 25692 on Friday, May 9, 1997.

The University of Wisconsin-Madison holds a Federalwide Assurance (FWA) from the Office for Human Research Protection (OHRP) at the United States Department of Health and Human Services, #FWA00005399, which was approved on August 20, 2003 and expires August 20, 2006. The FWA replaces the University of Wisconsin-Madison's Multiple Project Assurance (MPA) M-1285 that expired on October 31, 2003.

The HS-IRB consists of more than 5 members and membership includes scientists and non-scientists, as well as non-affiliated members. HS-IRB members do not participate in the discussion or vote on research protocols in which they may have a conflict of interest. The HS-IRB is composed of individuals, both female and male, with the following expertise and perspectives:

Administration/Research Administration	Medicine/Women's Health
Biostatistics	Neurology
Clergy	Nursing
Human Oncology	Pediatrics/Genetics
Law	Pharmacology/Investigational Drugs
Medical Ethics	Psychiatry
Medicine/Asthma-Allergy	Public Defender/Prisoner Representative
Medicine/Cardiology	Radiology
Medicine/ Family Practice	Surgery/Transplant
Medicine/Gastroenterology	Veteran's Administration Representative
Medicine/Oncology	

The HS-IRB considers the scientific or medical review of other University of Wisconsin-Madison committees and involves consultants with particular expertise as needed.

Nichelle Cobb 3/28/2005
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Health Sciences Institutional Review Boards Office

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