



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES  
OFFICE OF THE SECRETARY  
OFFICE OF PUBLIC HEALTH & SCIENCE  
OFFICE FOR HUMAN RESEARCH PROTECTIONS

## Office for Human Research Protections

The Office for Human Research Protections (OHRP) supports, strengthens and provides leadership to the nation's system for protecting volunteers in research that is conducted or supported by the U.S. Department of Health and Human Services (HHS).

OHRP provides clarification and guidance to research institutions, develops educational programs and materials, and promotes innovative approaches to enhancing human subject protections.

To carry out their research mission, nearly 10,000 universities, hospitals, and other research institutions in the U.S. and abroad have formal agreements ("assurances") with OHRP to comply with the regulations pertaining to human subject protections.

### Compliance

OHRP's Division of Compliance Oversight evaluates all written substantive indications of noncompliance with HHS regulations—Title 45, Part 46, Code of Federal Regulations (45 CFR part 46). OHRP asks the institution involved to investigate the allegations and to provide OHRP with a written report of its investigation. The Office then determines what, if any, regulatory action needs to be taken to protect human research subjects.

### Education

OHRP's Division of Education and Development provides guidance to individuals and institutions conducting HHS-supported human subject research; conducts national and regional conferences; participates in professional, academic, and association conferences; and develops and distributes resource materials in an effort to improve protections for human research subjects. OHRP also helps institutions assess and improve their human research protection programs through quality improvement consultations.

### Policy and Assurances

OHRP's Division of Policy and Assurances prepares policies and guidance documents and interpretations of requirements for human subject protections and disseminates this information to the research community. The Division also administers the assurances of compliance.

### Secretary's Advisory Committee

The Secretary's Advisory Committee on Human Research Protections (SACHRP) advises the HHS Secretary on issues of human subject protections. OHRP's director serves as the Executive Secretary for SACHRP, and the Office provides technical and logistical support to the Committee.

### International Activities

From the Office of the Director, OHRP provides training to institutions involved in international research, to help ensure that ethical protections are afforded to those who participate in research outside the United States. The Office also provides quality improvement consultations to international institutions.

*September 2005*