



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) provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U. S. Department of Health and Human Services (HHS). OHRP helps ensure this by providing clarification and guidance, developing educational programs and materials, maintaining regulatory oversight, and providing advice on ethical and regulatory issues in biomedical and behavioral research.

Compliance

OHRP's Division of Compliance Oversight (DCO) evaluates, at OHRP's discretion, 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. DCO also conducts a program of not-for-cause surveillance evaluations of institutions, and receives, reviews, and responds to incident reports from Assured institutions.

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 Federalwide Assurances of Compliance and the registration of institutional review boards.

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 assurance consultations to international institutions.

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