

III.K. HUMAN RESEARCH PROTECTION PROGRAM

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The University of Pennsylvania is committed to maintaining a comprehensive program to protect human subjects engaged in research conducted or supported by the University and the University of Pennsylvania Health System.

The institution adheres to the ethical principles and guidelines for the protection of human subjects in research enumerated in the Belmont Report, produced by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (April 1979). The University has provided the Department of Health and Human Services' Office for Human Research Protections (OHRP) a Federal-wide Assurance of compliance with the ethical principles and regulations governing research with human subjects. This Federal-wide Assurance is written documentation of Penn's commitment to comply with local and federal laws and regulations governing human research.

The Vice Provost for Research is empowered by the Board of Trustees through the Provost to coordinate the overall human research protection program and has direct authority over the key components of that program. The responsibilities of the Vice Provost for Research include:

- Ensuring protection of human research subjects.
- Ensuring compliance with local, state and federal laws and regulations.
- Ensuring the independence of the Institutional Review Boards (IRBs).
- Ensuring the number of IRBs is appropriate for the volume and types of human research reviewed, and that reviews are accomplished in a thorough and timely manner.
- Responding to allegations of scientific misconduct.

The Vice Provost for Research has the authority to:

- Create and approve policies and procedures governing the human research protection program.
- Create an annual budget for the human research protection program.
- Allocate resources within the program.
- Suspend or terminate research.
- Place administrative sanctions on investigators for noncompliance, such as suspension or termination of research privileges; requiring investigators or research staff to undergo additional training as a condition of continuing research; and mandating independent monitors for ongoing research.

The Vice Provost for Research may not approve a study that has been disapproved by one of the IRBs.

The Vice Provost for Research has established an oversight committee known as the Human Research Advisory Committee (HRAC). The HRAC represents all the offices of the University with interest in the conduct of human research including the Office of Regulatory Affairs; the Office of Research Services; the Office of General Counsel; the Office of Audit, Compliance and Privacy; representatives of the schools conducting research as well as faculty members. This committee advises the Vice Provost for Research on the need for and implementation of

policies and procedures governing human subject research. Upon the recommendation of the HRAC, the University shall conduct periodic reviews of the human research protection program and budget support for the various components of the program, either through independent mechanisms or as part of a scheduled accreditation process.

Prior to initiating any research on human subjects, investigators at the University of Pennsylvania must first obtain the approval of one of the University IRBs through their established policies and procedures. The University supports eight IRBs through the Office of Regulatory Affairs (ORA). IRB is composed of scientists, nonscientists and members who are unaffiliated with the University of Pennsylvania. The Director of the ORA reports directly to the Vice Provost and informs the Vice Provost for Research of the IRB actions to approve, withhold approval, disapprove, terminate or suspend human subject research.

All personnel—faculty, research fellows, students and staff—engaging in human research must have documented education regarding human subject protection, in accordance with certification standards defined by the Vice Provost for Research. Training for investigators engaged in biomedical research is available through a webbased program developed by the Perelman School of Medicine's Office for Human Research. Researchers engaged in social and behavioral research are offered web-based training through the Office of the Vice Provost, in cooperation with the IRB.

In addition, the Perelman School of Medicine Office for Human Research (OHR) maintains high level support for medical researchers conducting trials including those where the faculty member has a role as sponsor-investigator. The OHR also provides monitoring of investigator compliance for the University.

Any individual with questions concerning human research or noncompliance with regulations may contact the Office of Regulatory Affairs at (215) 898-2614. Allegations of noncompliance may also be reported to the Office of Audit, Compliance and Privacy using 1-888-BEN-TIPS. All allegations are investigated with appropriate protections of the rights of the complainant.

This notice shall be published periodically as a reminder to the University community or when the various components of the human research program are materially changed.