Washington University in St. Louis

Institutional Statement of Commitment
To the Protection of Human Participants in Research
At Washington University

Overview

The Washington University research community is guided by the ethical principles regarding research involving human participants as set forth in the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects [Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. 1979]. This fundamental commitment to the protection of human participants applies to all Washington University research involving human participants, regardless of whether the research is funded through government, non-profit or industry sponsors or through University funds and regardless of the location of the research. All research involving human participants must be reviewed and approved by Washington University's duly appointed Institutional Review Board. The organizational unit, which comprises the IRB and the administrative office that supports this committee is known as the Human Research Protection Office ("HRPO").

Organizational Roles

1. The Executive Vice Chancellor for Medical Affairs is charged by the Chancellor to provide administrative, programmatic and financial leadership and oversight of HRPO.

2. The Vice Chancellor for Research is charged by the Chancellor to serve as the Institutional Official on Washington University's Federalwide Assurance (FWA) with OHRP. As such, the Vice Chancellor assures compliance of the institution and all of its components and, in consultation with the appropriate Deans, has oversight responsibility for the University's Human Research Protection Program.

3. The WU IRB Executive Chair is appointed for an unlimited term by the Executive Vice Chancellor for Medical Affairs and has overall responsibility for ensuring that:

   (a) policies and procedures for protecting human research participants are in compliance with WU's FWA;

   (b IRB membership is of sufficient numbers and diversity of expertise to accomplish the review of the volume and types of human research to be undertaken and that reviews are accomplished in a timely manner;

   (c) expedited review is delegated to IRB members with appropriate expertise; and that

   (d) the Executive Vice Chancellor for Medical Affairs and Vice Chancellor for Research are kept apprised of issues concerning IRB activities and its responsibilities under the Assurance.

Institutional Authority

Washington University grants its IRB sole authority to:

(a) review, approve, require modifications in (to secure approval), or disapprove all human research activities overseen and conducted by Washington University;

(b) suspend or terminate approval of research not being conducted in accordance with its requirements, including WU policies, procedures, and guidance documents and research that has been associated with unexpected serious harm to participants;

(c) observe, or have a third party observe, the consent process; and

(d) observe, or have a third party observe, the conduct of the research.

Research reviewed by the WU IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by the WU IRB.

Institutional Autonomy

The WU IRB functions independently under the authority of the Chancellor, but in coordination with University officials and other committees. University officials, investigators, employees and sponsors of research are prohibited from attempting to unduly influence the IRB, any IRB members or any HRPO staff, or any member of the research team to obtain a particular result, decision or action. A decision by the WU IRB not to approve research is final and may not be overruled. "Undue influence" means attempting to interfere with the normal functioning and/or decision making outside of established processes or normal accepted methods.

Review of Research

Without exception, all instances where Washington University engages in research involving human participants must be reviewed and approved by the IRB prior to initiation.

Protection of Research Participants

Washington University, its' schools, departments and investigators conducting human research should allocate adequate resources to assure the protection of human research participants.