

**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 standards outlined by the Office for Human Research Protection (OHRP), as codified by 45 CFR 46 and its Subparts A, B, C, and D and the FDA in 21 CFR 50; 21 CFR 56; the Belmont Report; the Declaration of Helsinki and the Nuremberg Code. 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 one of the Washington University's ten duly appointed Institutional Review Boards. The organizational unit, which comprises the IRBs and the administrative office that supports these committees 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 HRPO Executive Chair is appointed for an unlimited term by the Executive Vice Chancellor for Medical Affairs and has overall responsibility for ensuring that:
  - (a) HRPO policies and procedures for protecting human research participants are in compliance with WU's FWA;
  - (b) the institution has an appropriate number of IRBs for the volume and types of human research to be reviewed so that reviews are accomplished in a thorough and 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 HRPO and its responsibilities under the Assurance.

#### Institutional Authority

Washington University grants HRPO 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 HRPO 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 HRPO 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 HRPO.

#### Institutional Autonomy

HRPO 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 HRPO, any of its members or staff, or any member of the research team to obtain a particular result, decision or action. A decision by a HRPO Committee 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 research involving human participants (as defined by Federal regulations and described in the HRPO guidance document “What Needs HRPO Review” ([hrpo.wustl.edu](http://hrpo.wustl.edu)) conducted by Washington University investigators, staff, and students must receive prior approval from HRPO before the research begins.

#### Protection of Research Participants

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