# RES-007 Human Research Protection Program

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**Policy Type** University

**Contact Office**
Vice President for Research (Office of the)

**Oversight Executive**
Vice President for Research

**Applies To**
Academic Division The Medical Center

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## Reason for Policy

The University of Virginia is committed to the highest standards of excellence in human subjects research. This policy establishes a Human Research Protection Program to carry out this mission.

## Definition of Terms

### Human Subject

An individual, including that individual's data and biospecimens, who meets the definition of "human subject" in 45_CFR_46 and/or 21_CFR_56 and/or "subject" in 21_CFR_812.

### Institutional Official

The Vice President for Research or his/her designee.

### Research

A systematic investigation designed to develop or contribute to generalizable knowledge. The term encompasses both basic and applied research and includes all research meeting the definition of "research" in the Code of Federal Regulations, Section 45_CFR_46 and/or "clinical investigation" in the Code of Federal Regulations,

Section 21_CFR_56. The term includes but is not limited to any such activity for which research funding is available from a Public Health Service (PHS) Awarding Component through a grant or cooperative agreement, whether authorized under the Public Health Services Act (42 U.S.C 6A) or other statutory authority, including but not limited to a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

**Policy Statement**

The University of Virginia fosters a research environment that promotes the respect for the rights and welfare of individuals recruited for, or participating in, research conducted by or under the auspices of the University of Virginia. In the review and conduct of research, actions by the University of Virginia will be guided by the principles (i.e., respect for persons, beneficence, and justice) set forth in the ***Ethical Principles and Guidelines for the Protection of Human Subjects of Research*** (often referred to as The Belmont Report). The actions of the University of Virginia will also conform to all applicable federal, state, and local laws and regulations.

In order to fulfill this mission, the University of Virginia has established a Human Research Protections Program (HRPP). The mission of the HRPP is to:

- Safeguard and promote the health and welfare of human research subjects by ensuring that their rights, safety and well-being are protected.
- Provide guidance and support to the research community in the conduct of research with human subjects.
- Assist the research community in ensuring compliance with relevant regulations.
- Provide timely and high quality education, review and monitoring of human research projects.
- Facilitate excellence in human subjects research.

1. **Institutional Official:**
   The University of Virginia will designate an Institutional Official (IO) who has overall responsibility for the University of Virginia's HRPP. The duties of the Institutional Official are as follows:

   - Fostering, supporting, and maintaining an organizational culture that supports the ethical conduct of all research involving human subjects and the adherence to regulations and organizational policies.

   - Ensuring that the Institutional Review Boards (IRBs) function independently by, among other mechanisms, being directly accessible to the IRB Chairs and members if they experience undue influence or if they have concerns about the function of the IRBs.

   - Having oversight of the Institutional Review Boards for Health Sciences Research (IRB-HSR) and the Institutional Review Board for the Social and Behavioral Sciences (IRB-SBS).

   - Having oversight over the conduct of human subjects research conducted by all University of Virginia investigators.

   - Ensuring the IRB members are appropriately knowledgeable to review research in accordance with ethical standards and applicable regulations.

- Ensuring that all investigators are appropriately knowledgeable to conduct research in accordance with ethical standards and applicable regulations.

- Having oversight of the development and implementation of an educational plan for IRB members, staff, and investigators;

- Ensuring compliance with institutional policies and all applicable regulations for the protection of human subjects.

- Verifying compliance with the terms of the Federal-wide Assurance to the Office of Human Research Protections.

- Providing support to the human research protections program, by ensuring that the HRPP has sufficient staff and resources to fulfill its mission and obligations.

In the performance of these duties, the Institutional Official has the authority to delegate such activities as may be necessary in order to fulfill these duties.

2. **Institutional Review Boards:**
   To conduct its responsibility effectively, the University of Virginia maintains three Institutional Review Boards (two IRBs-HSR and one IRB-SBS, referred to herein collectively as “the IRB”) to review research protocols involving human subjects. Each IRB is an autonomous administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the University of Virginia. The IRB has the following duties and authority:

   - Developing and implementing an educational plan for IRB members, staff, and investigators.

   - Approving, requiring modifications to secure approval, or disapproving all human subjects research activities overseen and conducted under the auspices of the University of Virginia, regardless of location of the research activities.

   - Requiring that informed consent be obtained and documented in accordance with regulatory requirements (as specified in 45_CFR_46 and 21_CFR_56) unless the criteria for the waiver or alteration of such requirements has been satisfied and approved by the IRB. The IRB may require that information, in addition to that specifically mentioned in the regulations, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

- Conducting continuing review of research at intervals appropriate to the degree of risk of the research, but not less than once per year.

- Suspending or terminating approval of research not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.

- Observing, or having a third party observe, the consent process.

- Observing, or having a third party observe, the conduct of the research.

- Determining whether data or information gathered without IRB approval or in association with serious noncompliance may be published or used for research purposes.

- Acting on behalf of those components of the University that are HIPAA-covered components, as the privacy board for the making of determinations required by and in compliance with the HIPAA Privacy Rule (45 CFR Part 160 and Subparts A and E of Part 164) regarding the use and disclosure of protected health information of human subjects.

The IRB may delegate one or more of its duties and authority regarding a particular protocol to a non-University of Virginia Institutional Review Board under a reliance agreement that complies with applicable regulations for the protection of human subjects.

All IRB-approved research studies are subject to ongoing review, which must be conducted at least once annually by the IRB. If approval by the IRB lapses, all research activity must stop unless it is determined to be in the best interest of already enrolled subjects to continue participating in the research. The investigator can petition the IRB to continue an individual subject's research intervention/interaction during a period of lapsed IRB approval if the investigator believes there is a safety concern or ethical issue such that it is in the best interests of the individual participant to do so.

The IRB has jurisdiction over all human subject research conducted under the auspices of the University of Virginia, regardless of funding source or performance site. Research under the auspices of the institution includes research:

- Being conducted at this organization.

- Being conducted by or under the direction of any employee or agent of this organization (including students) in connection with his or her organization responsibilities.

- Being conducted by or under the direction of any employee or agent (including students) of this organization using any property or facility of this organization.

- Involving the use of this organization's non-public information to identify, contact, or study human subjects.

No research involving human subjects may be conducted without IRB approval or exempt research review and no research may commence until all required Institutional approvals (including IRB) are obtained. Exempt research is subject to review for determination of exemption status. At the University of Virginia, exemptions are reviewed and granted by IRB staff trained in exempt review determinations.

3. **Review of Human Subjects Research Protocol:**
   The University of Virginia may review any human subjects research protocol and has the right to disapprove or terminate approval of a research protocol that has been approved by the IRB. However, no one at the University of Virginia shall approve the implementation of human subjects research requiring an IRB approval that has been rejected by the IRB.

4. **Performance Sites:**
   All institutional and non-institutional performance sites for the University of Virginia, domestic or foreign, will be obligated by this policy to conform to ethical principles which are at least equivalent to those of this institution or as may be determined by the Department of Health and Human Services (DHHS) Secretary.

5. **Research Data Security:**
   Per IRM-003: Data Protection of University Information, unpublished research data (inputs or results) are "sensitive data" or "highly sensitive data" and must be safeguarded in accordance with the applicable data protection standard and procedures. When a discrepancy exists between a University data protection standard and an applicable external data protection standard the more stringent will apply and must be implemented to safeguard the data. See the Research Data Security content on the Vice President for Research's website for information on sponsor requirements/expectations and links to UVA resources available to support research.

6. **Adoption of Operating Procedures:**
   The Institutional Official and the IRB shall adopt operating procedures to implement this policy. These procedures shall serve as the governing procedures for the conduct and review of all human research conducted under the auspices of the University of Virginia.

7. **Compliance with Policy:**
   Failure to comply with the requirements of this policy may result in (1) administrative actions including removal from a human subjects research protocol or removal as PI from a research grant or contract; and (2) disciplinary action up to and including termination and expulsion in accordance with relevant University policies.

   Questions about this policy should be directed to the Office of the Vice President for Research.

**Procedures**

HRPP - Standard Operating Procedures (SOP)

**Related Information**

VPR- Human Research Protection Program
Code of Federal Regulations, Title 45, Part 46 – Protection of Human Subjects (45 CFR 46)
The Belmont Report

**Major Category** Research Administration

**Next Scheduled Review** Friday, February 23, 2024

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**Applies To Text**

Academic Division and Medical Center.

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**Approved By** Executive Vice President and Chief Operating Officer

**Approved Date** February 9, 2018 - 12:00pm