Virginia Tech Human Subjects Research Policy

No. 13040

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Policy Owner:
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Affected Parties:
Undergraduate
Graduate
Faculty
Staff
Other

1.0 Purpose

This policy establishes the requirement for ethical conduct of research involving human subjects. These requirements have been established to protect the rights, well-being, safety, and personal privacy of individuals participating in research and apply to all faculty, staff, and students who conduct research involving human subjects.

2.0 Policy

Virginia Tech is committed to the ethical conduct of research involving human subjects and creating an environment that fosters the development and conduct of high quality, ethical research. Part of this commitment involves providing support and resources for researchers and protecting the interest of participants in Virginia Tech research.

Virginia Tech's commitment is guided by the ethical principles described in the *Belmont Report* and in applicable federal regulations. To comply with federal requirements, Virginia Tech has established Institutional Review Boards (IRBs) that are supported by the Human Research Protection Program (HRPP). The IRBs are responsible for protecting the rights and welfare of individuals who participate in research. The HRPP is staffed with individuals who have knowledge and expertise in the human subjects regulations and serves as a resource for the entire research community at Virginia Tech.

2.1 Applicability of Policy

This policy, its amendments and additions, applies to all human subjects research as defined by the U.S. Department of Health and Human Services (HHS) and clinical investigations as defined by the Food and Drug Administration (FDA), regardless of the funding sources involved. All the university's human research activities, regardless of whether the research is subject to federal regulations, will be guided by the ethical principles of *The Belmont Report*.

3.0 Oversight

3.1 Senior Vice President and Chief Research and Innovation Officer – Institutional Official

The Senior Vice President and Chief Research and Innovation Officer serves as the Institutional Official (IO) for the university and is responsible for ensuring both institutional and individual researcher compliance with federal and state laws, regulations, policies, and guidelines for the protection of human subjects.

The IO will specify any additional responsibilities necessary for the function and operation of the program to ensure the protection of research subjects, and delegate these responsibilities to the appropriate individuals.

The Senior Vice President and Chief Research and Innovation Officer will appoint members to the IRBs.

3.2 Division of Scholarly Integrity and Research Compliance

The division of Scholarly Integrity and Research Compliance (SIRC) is an administrative unit directed by the Associate Vice President (AVP) for Research and Innovation. SIRC has executive responsibility for the implementation of all Virginia Tech policies and procedures for research involving human subjects.

3.3 Human Research Protection Program

The Human Research Protection Program (HRPP) is an administrative unit within SIRC and is responsible for administrative support to the IRBs and serves as a resource for Virginia Tech researchers and investigators. The HRPP is charged with supporting the IRBs in fulfilling their responsibility for ensuring individual research compliance with federal and state laws and regulations, as well as university policies and guidelines for the protection of human subjects and for creating the foundation for the ethical conduct of research involving human subjects.

The HRPP consists of the HRPP Director, HRPP Protocol Coordinators, the Quality Assurance/Quality Improvement Coordinator, and the HRPP Administrative Specialist. These individuals have knowledge and expertise in applying the federal human subjects regulations and have frequent and varied contacts inside and outside of the organization as required to establish policies and procedures for the program's success. They have general oversight responsibility for this policy and shall consider policy changes that are required to comply with federal regulations, to ensure fairness to investigators, or to protect more adequately the rights and welfare of human subjects in research. When appropriate, such policy changes are recommended by the HRPP Director to the AVP and Director of SIRC.

The HRPP Director attends convened IRB meetings and acts as a liaison for the IRB, with support from the AVP and the IO. The HRPP Protocol Coordinators review all protocols that are submitted to HRPP to ensure that the submissions are complete, and the information provided by the researchers is consistent with the HRPP and IRB requirements. They are responsible for making research and nonresearch determinations and have the authority to review exempt research. They are also responsible for guiding researchers through the IRB process, assisting researchers with federal and university requirements. The HRPP Administrative Specialists provides support to the HRPP staff and IRB, including but not limited to coordinating IRB meetings, assisting with the database, filing, and correspondence management, communicating and interfacing individuals within and outside the university, and assisting with scheduling meetings and activities associated with the HRPP.

IRB's role is to partner with researchers to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of Virginia Tech.

3.4 Institutional Review Boards (IRBs)

On behalf of Virginia Tech, the IRBs are responsible for the following:

- Protecting the rights and welfare of research participants in all research under their purview. The IRBs' actions must comply with ethical norms and legal and policy related requirements including federal regulations and university policies.
- Promoting open communication between IRB members and university researchers.

IRB Chairs and Vice Chairs, with the assistance from HRPP staff, are responsible for leading and setting the tone for each IRB meeting striving for the appropriate degree of consistency across reviews.

The IRBs have the authority to approve, require modifications, disapprove, or halt research activities that fall within its jurisdiction as specified by federal regulations, state law, and university policy. The IRBs have the authority to require appropriate training of faculty and student researchers and to prohibit individuals who have not completed training from working under an approved protocol. The IRBs act as a surrogate for the federal government in ensuring regulatory compliance.

Deliberations and decisions of the IRBs and substantive information associated with specific projects or research activities acquired by the members in the course of IRB business shall be considered confidential, to the extent permitted by Commonwealth of Virginia law, except insofar as the dissemination of information regarding research projects or activities and IRB deliberations, decisions, and recommendations to appropriate university officials is required to effectuate or support the policies or interests of the university.

4.0 Responsibilities of Researchers

Researchers, and all staff and students participating as a member of the research team, are responsible for being familiar with human research regulations, this policy, and other related university policies. The principal investigator has the primary overall responsibility for the conduct of the research. Researchers are required to:

- Complete the required training in research ethics and human subjects regulations before serving as a member of a research team.
- Maintain competency in research ethics and human research regulations by completing the required refresher training every 3 years.
- Submit proposed research activities to the HRPP office for review prior to the initiation of any research activities. Ensure that the design of the proposed activities conforms to acceptable scientific, ethical, and legal requirements. Determine that sufficient resources are allocated to ensure the protection of research participants. Disclose any conflicts of interest.
- Obtain IRB approval or HRPP determination before initiating research activities and comply with the following:
    - Adhere to all the terms of the IRB approval or HRPP determination and implement the research as outlined in the protocol. Do not deviate from the approved research or determination except (1) when the IRB has approved, (2) when necessary to eliminate apparent immediate hazards to participants, or (3) research is exempt and does not meet the criteria for submitting an amendment.
    - Promptly report any unanticipated problems involving risks to subjects or others, deviations from approved activities or to eliminate apparent immediate hazards to participants, serious or continuing noncompliance, and substantive complaints from participants.
    - Ensure that informed consent is obtained and documented from each participant or their legally authorized representative, unless the IRB has approved waivers or alterations of the consent form and the process.
    - Ensure appropriate additional safeguards when subjects are likely to be vulnerable to coercion or undue influence. Such subjects include children, prisoners, pregnant women, persons with cognitive disabilities, economically or educationally disadvantaged persons, and Virginia Tech students.

- Obtain continuing IRB approval before the approval expires for research that requires continuing review. Cease all human subjects research activities when the IRB approval lapses.
- Submit a progress report, for research that requires a progress report, as often and in the manner prescribed by the HRPP or IRB.
- Close out the study and disposition of the research data in accordance with the protocol's data management plan upon completion of the research, including the primary analysis and publication of results.

- Create and maintain a research binder electronically or paper-based for all study related records (for specific requirements refer to HRPP's "Regulatory Binder Guidelines and Checklist."). These records must be retained for at least three (3) years after completion of the research or in accordance with the university policy, whichever is greatest. Such documents are deemed to be the property of the university, per Policy 13015 "Ownership and Control of Research Results."
- For clinical trials research, comply with all requirements related to registering and maintaining records with ClinicalTrials.gov.
- A principal investigator who leaves the university before completing an approved research protocol must, in conjunction with their department head or institute director, identify and name a new principal investigator for the project and complete the "Virginia Tech Faculty Departure Checklist" or the "Virginia Tech Graduate Student Departure Checklist.". If the research has been completed, the researcher must close out the protocol. A co-investigator who leaves the university must be removed from the protocol and identify a replacement if needed.

5.0 Definitions

Assurance of Compliance (Human Subjects) or Federalwide Assurance (FWA) – An assurance of compliance or FWA is a written commitment to protect human research subjects and comply with the federal requirements of the Common Rule (45 CFR part 46).

Human subject (HHS definition)—A human subject, as defined by HHS, is a living individual about whom an investigator (whether professional or student) conducting research:

- Obtains information about a person or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- Obtains, uses, studies, analyzes, or generates identifiable private information.

Human subject (FDA definition) – A human subject, as defined by FDA, is an individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject can be either a healthy human or a patient. A human subject includes an individual on whose specimen a medical device is used.

Institutional Official - Institutional official (IO) is the term used by HHS to refer to the individual who is legally authorized to act for the institution and, on behalf of the institution, obligates the institution to the terms of the assurance. The IO is responsible for ensuring that the HRPP functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects. The IO represents the institution named in the Federalwide Assurance (FWA).

IRB Approval – An IRB approval is the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

Research (HHS definition) – Research, as defined by HHS, refers to a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Research (FDA definition) – Research, as defined by FDA, refers to any experiment that involves a test article and one or more human subjects, and that meets any one of the following:

- Must meet the requirements for prior submission to the FDA under section 505(i) of the Federal Food, Drug, and Cosmetic Acting meaning any use of a drug other than the use of an approved drug in the course of medical practice;
- Must meet the requirements for prior submission to the FDA under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; or
- Any activity, the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

Serious Non-Compliance – Serious non-compliance refers to non-compliance such that the failure to comply could adversely affect the rights, safety, or welfare of a human subject; place a human subject at increased risk of harm; cause harm to a human subject; affect a human subject's willingness to participate in research; or damage or compromise the scientific integrity of research data

Unanticipated problem - Unanticipated problem involving risks to subjects or others (UPIRTSO) refers to any incident, experience, or outcome that meets the three following conditions:

- Is unexpected (in terms of nature, severity, or frequency) given the procedures described in the research protocol documents (e.g., the IRB-approved research protocol and informed consent document) and the characteristics of the human subject population being studied;
- Is related or possibly related to participation in the research. Possibly related means there is a reasonable possibility that the incident, experience, or outcome could have been caused by the procedures involved in the research); and
- Suggests that the research places human subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, even if no harm actually occurred.

6.0 References

Virginia Tech HRPP website
http://www.irb.vt.edu

US Code of Federal Regulations (CFR) at 45 CFR 46

FDA Policy for the Protection of Human Subjects

The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research

Policy 13015, "Ownership and Control of Research Results"

7.0 Approval and Revisions

Revised September 30, 2006

Revised August 8, 2014 (formatting only)

- Revision 1

  This policy was completely revised based on the changes to the human subjects regulations (45 CFR 46) which became effective January 21, 2019. Substantial changes were also made to align with the policy pyramid and focuses on what is mandated or required to comply with the human subjects regulations.

  Approved by the Commission on Research on November 9, 2023.
  Approved by the University Council on February 5, 2024.
  Approved by Cyril Clarke, Executive Vice President and Provost, on March 14, 2024.

Appendix A

Virginia Polytechnic Institute and State University
Research Compliance Office: Administrative Relationships