

**Commission on Research
Resolution to Revise Policy 13040
Virginia Tech Human Subjects Research
COR Resolution 2023-24A**

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First Reading by the Commission on Research	October 12, 2023
Approval by the Commission on Research	November 9, 2023
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First Reading, University Council	December 4, 2023
Approved, University Council	February 5, 2024
Approved, President	Date
Approved, Board of Visitors	Date
Effective Date	Upon Approval or Date

WHEREAS, Virginia Tech is required to protect the rights and welfare of individuals who volunteer to participate in research studies that are subject to the Federal Policy for the Protections of Human Subjects (the Common Rule, 45 CFR 46); and

WHEREAS, the U.S. Department of Health and Human Services issued final revisions to its regulations that govern sponsored research (the “Common Rule”); and

WHEREAS, Virginia Tech’s Human Subjects Research Policy (No. 13040) must be updated to comply with the revised Common Rule; and

WHEREAS, Policy 13040 has been updated to reflect the requirements that must be met to comply with the revised Common Rule; and

WHEREAS, Policy 13040 has been updated to reflect the new organizational structure, including the Human Research Protection Program (established in 2018); and

WHEREAS, Policy 13040 has been revised to remove internal processes, which are now documented separately in the Human Research Protection Program’s internal standard operating procedures; and

NOW, THEREFORE, BE IT RESOLVED that the attached revision of Policy 13040 be adopted effective immediately.

Overview of changes to the Virginia Tech Human Research Policy (13040): January 5, 2022

1. Changes to the Common Rule – The revisions to the human subjects regulations (45 CFR 46) became effective January 21, 2019. These revisions modernized, strengthened, and made the original federal policy more effective by enhancing the current system of oversight. The intent of the revised policy is to better protect human subjects while facilitating valuable research and reducing burden, delay, and ambiguity for researchers¹. The significant changes included:
 - a. Establishing new requirements for informed consent, including the use of broad consent;
 - b. Establishing new exempt categories for research based on their risk profile and including limited IRB review for certain categories to ensure there are adequate privacy safeguards for identifiable private information and biospecimens;
 - c. Mandating the use of a single IRB for U.S. based institutions involved in cooperative research; and,
 - d. Eliminating the requirement for conducting continuing review for research that undergoes expedited review and is analyzing study data or involves only observational follow up in conjunction with standard clinical care.
2. Alignment with the policy pyramid – The policy was revised substantially to adhere to the policy pyramid and focuses on what is mandated or required to comply with the federal policy. Elements that were in the previous version that were not required, were redundant (repeated what was in the federal policy), or subject to change, were removed and are part of standard operating procedures and guidelines.
3. What was removed and why – the table below and on the following pages provides a description of what was changed and why. In summary, the changes align with the changes to the Common Rule and the Policy Pyramid. In addition, the organizational structure has changed and a Human Research Protection Program was established in 2018. The procedural elements in the policy were removed so when procedures need to be changed in the future, the policy will not need to be updated. The Human Research Protection Program is still growing and making improvements and procedural changes are ongoing; whereas, the federal policy that governs the protection of human subjects is less likely to undergo frequent revisions.

Old Version	Summary of Changes	New Version
1.0 Purpose	Shortened to provide a concise description of the purpose of the policy. Some details were moved to the new policy section, 2.0	1.0 Purpose
1.1 Applicability of Policy	Modified to clarify that the policy only applies to human subjects research as	2.1 Applicability of Policy

¹ Excerpt from the [Summary](#) of the January 19, 2017 preamble to the revised Common Rule

	defined by the Department of Health and Human Services and clinical investigations as defined by the Food and Drug Administration. This is now section 2.1.	
2.0 Oversight		2.0 Policy
2.1 Administration of the Regulatory Functions: Research Compliance Office	<ul style="list-style-type: none"> • The information in this section was moved to the new section “3.0 Oversight.” • Revised to describe the oversight of the institutional official. This is now in section 3.1. • The information about the Research Compliance Office was updated to reflect the change in office name to the division of Scholarly Integrity and Research Compliance. This is in section 3.2. • A description of the Human Research Protection Program was added. This is in section 3.3. 	2.1 Applicability of Policy
2.2 Compliance Committee Review – The IRB	Revised to consolidate the role of the IRB, its authority, and the confidentiality of its deliberations and decisions. This is now section 3.4	
2.2.1 The IRB’s Role	Included in section 3.4.	
2.2.2 The IRB’s Authority	Included in section 3.4.	
2.2.3 Key Criteria for IRB Approval	Deleted from the policy because this is detailed in the human subjects regulations (45 CFR 46.111) and does not need to be reiterated in the policy.	
2.2.4 Confidentiality	Included in section 3.4.	
3.0 Functions, Activities, and Responsibilities of the IRB	In keeping with the aims of the Policy Pyramid, this section was deleted because it is a description of how the IRB does its work.	3.0 Oversight

	The information is now covered in standard operating procedures.	
		3.1 Senior Vice President and Chief Research and Innovation Officer – Institutional Official
		3.2 Division of Scholarly Integrity and Research Compliance
		3.3 Human Research Protection Program
		3.4 Institutional Review Boards (IRBs)
4.0 Responsibilities of Researchers	This section was consolidated to describe the responsibilities covered in the sub-sections, but removed the procedures associated with the responsibilities. These procedures are now described in standard operating procedures.	4.0 Responsibilities of Researchers
4.1 Basic Compliance	Moved to section 4.0	
4.2 Submissions of Application and Protocol	Revised into a concise statement. The detailed process is described in standard operating procedures.	
4.3 Submission of Amendments to an IRB-Approved Protocol	Deleted; described in standard operating procedures.	
4.4 Informed Consent Process – Obtaining Consent	Revised into a concise statement. The detailed process is described in standard operating procedures.	
4.5 Retention of Signed Consent Documents	Revised to include all research related documentation. Included in section 4.0.	
4.6 Submission of Progress Reports	Revised into a concise statement. The detailed process is described in standard operating procedures.	
4.7 Submission of Reports of Injury or Unanticipated Problems Involving Risks (Adverse Event Reporting)	Revised into a concise statement. The detailed process is described in standard operating procedures.	
4.8 Reporting Noncompliance	Section deleted; included a brief statement in new section 4.0; detailed in standard operating procedures.	

5.0 Policy Implementation	Most of the information in this section was moved to section 3.0	5.0 Definitions
5.1 University Administration	Moved to section 3.1	
5.2 The Institutional Review Board for the Protection of Human Subjects Used in Research (IRB)	Outdated information so this section was deleted.	
5.3 Research Compliance Office Personnel	Moved to sections 3.2 and 3.3	
5.4 Delegation of Responsibilities	Moved to section 3.1	
6.0 Definitions	Expanded and is now section 5.0	6.0 References
7.0 References	Updated to include FDA and is now section 6.0	7.0 Approval and Revisions
8.0 Approval and Revisions	Now section 7.0	
Appendix A: Virginia Polytechnic Institute and State University Research Compliance Office: Administrative Relationships	Outdated information so it was deleted.	



Virginia Tech Human Subjects Research Policy

No. 13040

Policy Effective Date:
9/30/2006

Last Revision Date:
8/8/2014

Policy Owner:
~~Theresa Mayer~~
Daniel Sui

Policy Author: (Contact Person)
Laurel Miner
Barbara DeCausey

Affected Parties:
Undergraduate
Graduate
Faculty
Staff
Other

1.0 Purpose

2.0 Policy

3.0 Oversight

~~3.0 Functions, Activities, and Responsibilities of the IRB~~

4.0 Responsibilities of Researches

5.0 Policy Implementation

~~6.0 Definitions~~

~~7.0 References~~

~~8.0 Approval and Revisions~~

1.0 Purpose

~~In order-~~ 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 conducted by and apply to all faculty, staff, and students of the University, to assure a favorable climate for the conduct of scientific inquiry, and to protect the interests of 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 policy and procedures described below have been established for the conduct of research involving human subjects. ~~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. ~~For operational purposes, as required by~~ To comply with federal law, this commitment is vested in the requirements, Virginia Tech has established Institutional Review Board for Research Involving Human Subjects (the IRB) which operates under a Federal wide Assurance (FWA) on file with the Office for 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 (OHRP) within 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 (DHHS)-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.

~~The following general principles apply equally to all research involving human beings, whether carried out solely with University resources or with the assistance of outside funds. The University assumes responsibility for communicating and explaining these principles to University personnel, and for providing procedural guidelines to affect their observance.~~



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a. Virginia Tech and the individual members of its faculty, staff and student body recognize their responsibility for protection of the rights, safety

and welfare of human subjects.

- b. Appropriate professional attention and facilities shall be provided to insure the safety and well-being of human subjects. No subject in a research activity shall be exposed to unreasonable risk to health or wellbeing.
- c. Research involving children (persons under 18 years of age), other legal incompetents, and persons unable to give informed consent may be approved if there is no risk or suffering for the individual subject. On the other hand, research involving a child, another legal incompetent, or a person unable to give informed consent should not be approved if there would be a significant risk or suffering without the possibility of benefit to the individual subject. Title 45, Code of Federal Regulations, Part 46, Subpart D, shall be followed for research involving children.
- d. The confidentiality of information received from subjects in experiments or respondents to questionnaires shall be fully protected, both during and after the conduct of a research activity, within the limits of the law.
- e. Before a subject participates in research involving risk or substantial stress or discomfort, this shall be carefully explained; the investigator shall be satisfied that the explanation has been understood by the subject, and the consent of the subject shall

formed consent are established by the Federal government and by the University.

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- e. A request by any subject for withdrawal from a research activity shall be honored promptly without penalty or without loss of benefits to which the subject is otherwise entitled, within the limits of the research.

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1.1 Applicability of Policy

This policy, its amendments and additions, applies to all situations which involve the use of human subjects at Virginia Tech in research conducted by faculty, staff, and students, regardless of the particular college or university division in which it uses human subjects in research, or the source of funding involved. Non-funded faculty and student research must also be reviewed and approved by the IRB.

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2.0 Oversight

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

2.1 Administration of the Regulatory Functions: Research Compliance Office

The functional administrative unit that is charged with the



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responsibility for ensuring both institutional and individual researcher compliance with federal and state laws, regulations, policies, and guidelines- for the protection of human subjects-~~used in research at Virginia Tech is the Research Compliance Office.~~



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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 Office

The division of Scholarly Integrity and Research Compliance (SIRC) is an administrative unit under the supervision of the Assistant Vice President for Research Compliance, who reports to the directed by the Associate Vice President (AVP) for Research, the designated Institutional Official for regulatory compliance. The Research Compliance Office and Innovation. SIRC has executive responsibility for the implementation of all Virginia Tech policies and procedures for research involving the protection of human subjects used in research.

2.2 Compliance Committee Review – The IRB

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 Institutional Review Board shall 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 University policy on the protection of human subjects and and shall consider policy changes that may be are required to comply with –Federal/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 should be are recommended by the IRB/HRPP Director to the Vice President for Research AVP and Director of SIRC.

2.2.1 The IRB's Role

The-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 they 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.

2.2.2 The IRB's Authority

3.4 The Institutional Review Boards (IRBs)



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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 ~~has~~ 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 ~~in~~, disapprove, or halt ~~all~~ research activities that fall within its jurisdiction as specified by federal regulations, state law, and ~~institutional~~ university policy. The ~~IRB acts~~ 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 ~~local~~ regulatory compliance.

2.2.3 Key Criteria for IRB Approval

The IRB shall determine that all of the following requirements are satisfied in order to approve the research application:



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- a. ~~Risks to the subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risks, and (ii) whenever appropriate, by using procedures already performed on the subjects for diagnostic or treatment purposes.~~
- b. ~~Risks to the subjects must be reasonable in relation to anticipated benefits, if any, to the subjects, and the importance of the knowledge that may reasonably be expected to result.~~
- e. ~~Selection of subjects must be "equitable".~~
- d. ~~Consent must be obtained from each prospective subject or a legally authorized representative, (except in specified limited circumstances where waivers may be granted).~~
- e. ~~Consent must be appropriately documented.~~
- f. ~~Where appropriate, there must be adequate provision to protect the privacy of subjects and to maintain the confidentiality of data.~~
- g. ~~Where subjects are likely to be vulnerable to coercion or undue influence, appropriate additional safeguards must be included to protect the rights and welfare of subjects. Such subjects include children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.~~

~~In addition, the IRB has an institutional responsibility to flag institutional administrative issues and to coordinate its review process with other necessary administrative or legal reviews, where institutional interests are involved.~~

2.2.4 Confidentiality

Deliberations and decisions of the ~~IRB~~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 ~~Institution~~university officials is required to effectuate or support the policies or interests of the ~~Institution~~university.

3.0 Functions, Activities and Responsibilities of the IRB

- a. ~~At its meetings, the IRB will conduct official business only if (i) a quorum [majority including members or alternates, and the Chair or designated chair] is present and (ii) a non-scientist member is present. If either condition fails during the meeting (someone must leave, etc.), the IRB may not take any official action from that point until the quorum conditions are restored. Only members or alternates and the Chair or designated chair may vote.~~
- b. ~~If necessary, IRB meetings may be conducted with one or more members or alternates via speaker phone provided that each person on the telephone has received all pertinent materials prior the meeting, and can actively and equally participate in the discussion of all protocols. The minutes of such meetings will document members or alternates who participated by telephone.~~
- e. ~~The IRB will review, and have authority to approve, require modification in, or disapprove all research activities involving human subjects, including proposed changes in previously approved human subject~~



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research. For approved research, the IRB will determine which activities require continuing review more frequently than every 12 months.

- d. IRB members will independently review and evaluate applications for approval prior to the IRB meeting, participate in appropriate discussions, and vote to approve, disapprove, require modifications, or table each submission during the IRB meeting. If a member feels that s/he cannot provide an unbiased evaluation of a particular application for any reason, s/he will inform the IRB Chair and not participate in the discussion and voting of that application.
- e. The IRB may invite the investigator(s) of a project to meet with the Board during discussion of that project. All visitors will be dismissed before the IRB begins deliberations and takes action.
- f. If a member of the IRB has an interest (is an investigator, has a student who is an investigator, etc.) in a request before the Board, that member may be present during the discussion phase to answer questions, etc., but will be excused before the Board begins deliberations and takes action.
- g. The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB. These individuals may be asked to sign a non-disclosure agreement if they are given a copy of the application, unless the investigator waives his/her right of confidentiality.
- h. The IRB will focus primarily on the risks and benefits to the participating human subjects and the measures proposed to reduce or eliminate the risks. However, the IRB may request modifications to the research design or methodology where, in the opinion of the IRB, such modifications will enhance the benefits, reduce the risks, or improve the quality of the research.
- i. The IRB will seek to insure that the selection of subjects is equitable, taking into consideration the purposes of the research and the setting in which the research will be conducted. The IRB (or Chair) will review and approve all advertisements for recruiting potential subjects.
- j. Unless waived, ensure that legally effective consent documents are obtained and documented from each subject or the subject's legally authorized representative. The IRB will have authority, or direct the Chair, to observe the consent process, or any other part of the research process involving human subjects.
- k. Determine that there are adequate provisions in the research plan to protect the privacy of subjects and to maintain confidentiality of data, where appropriate.
- l. Where appropriate, the IRB will determine when additional protections are required for children, pregnant women, prisoners, fetuses, persons with impaired mental abilities, non-English speaking subjects and other vulnerable subjects. For research involving prisoners as subjects, a prisoner or prisoner representative must be added to the IRB when that project is discussed and action taken. OHRP will be notified promptly when IRB membership is modified to satisfy the federal requirements.
- m. The Virginia Tech IRB has determined that they will not consider requests from agencies and organizations outside the University that do not involve Virginia Tech faculty or that is not sponsored by Virginia Tech.



4.0 Responsibilities of Researchers

4.1 ~~Basic Compliance~~

~~Researchers~~ Researcher, and all staff and students participating as a member of the research team, ~~must~~ acknowledge and accept individual 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 protecting the rights, welfare, health and safety of human ~~research subjects and for complying with the~~ applicable regulations; the conduct of the research. Researchers are required to:

- ~~accept and endorse~~ Complete the Virginia Tech commitment to the protection and safety of required training in research ethics and human subjects in research;
- ~~acknowledge the authority and responsibility of the IRB and IRB Chair to make the final approval (or disapproval) of regulations before serving as a member of a research involving human subjects, and be responsible for complying with all IRB decisions, conditions and requirements;~~ team.
- ~~participate~~ Maintain competency in the education/training program to qualify to conduct research involving 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.

4.2 ~~Submission of Application and Protocol~~



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Research investigators (PIs) will:

- be responsible for ensuring, in connection with all research involving 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 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 subjects, that an application and protocol are submitted to the IRB;
- prepare and submit to the IRB an appropriate application and a protocol giving a complete description of the proposed research. In the application and protocol, research investigators will make provisions for the adequate protection of the rights and welfare of prospective research subjects and ensure that pertinent laws and regulations are observed;
- use only the current IRB approved consent document(s) and study forms (as available at the time of submission on the IRB website <http://www.irb.vt.edu>).

4.3 Submission of Amendments to an IRB-Approved Protocol

A research protocol is, in essence, a contract between the researcher and the IRB (and by extension, comply with the federal government which allows the University to conduct research if it remains in compliance), and thus no changes may be made in the contract (protocol) without first seeking review of and approval by the IRB for any proposed changes. Any data collected as a result of study changes in the absence of IRB approval of the changes must be destroyed, as those data were collected in an unapproved/unauthorized manner. Proposed changes may be initiated without IRB review and approval when it is necessary to eliminate apparent immediate hazards/harm to the subjects.

4.4 Informed Consent Process – Obtaining Consent

Research investigators are responsible for obtaining informed consent (and assent of children, as applicable) in accordance with requirements of the Common Rule (45 CFR part 46, and for insuring that no human subject will be involved in the research prior to the obtaining of the consent Research investigators and research staff must



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~~fully inform subjects of the risks, benefits, subjects' expectations, compensation and other aspects of the research in which they are being asked to participate).~~



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Unless otherwise authorized by the IRB (e.g., by obtaining a specific waiver), research investigators are responsible for insuring that legally effective informed consent will:
be obtained from the

- **Human subject** or the subject's legally authorized representative;
- be stated in language understandable to the subject or the representative;
- be obtained under circumstances that offer the subject or the representative sufficient opportunity to consider whether the subject should or should not participate;
- be obtained in a non-coercive manner;
- not include exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the research investigator, the sponsor, the institution or its agents from liability for negligence; and,
- include providing each subject a copy (or duplicate original) of his/her signed Consent form.

The basic elements of the consent process and documents must include:

- A statement that the study involves research, an explanation of the purposes of the research and of the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
- A description of any reasonably foreseeable risks or discomforts to the subject.
- A description of any benefits to the subject or to others which may reasonable be expected from research.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
- For research involving more than minimal risk, an explanation as to whether any compensation and medical treatments will be available if injury occurs and, if so, what they consist of, and where further information may be obtained.
- An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subject; and
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

4.5 Retention of Signed Consent Documents

Research investigators are responsible for retaining the copies of consent documents including signatures of the human research subjects in a manner approved by the IRB for at least three (3) years after completion of the research project. Such documents are deemed to be the property of the Institution.

4.6 Submission of Progress Reports



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Research investigators are responsible for reporting the progress of the research to the IRB, as often as and in the manner prescribed by the IRB but no less than once each year. The IRB will review these progress reports as submitted administratively or by full committee review. In the event that no progress report is received by the IRB within 1 year of approval, the IRB shall notify investigators of the study's expiration in writing.

4.7 Submission of Reports of Injury or Unanticipated Problems Involving Risks (Adverse Events Reporting)

Research investigators are responsible for reporting promptly to their department heads and the IRB any injuries to human subjects, or any problems unanticipated in the application or protocol which involve increased risks—(including without limitation risks of physical, psychological, social or economic harm) to the human research subjects or others. Guidance on and forms for reporting adverse events to the IRB can be found at: <http://www.irb.vt.edu/pages/adverseevents.htm>.

4.8 Reporting Noncompliance

Research should be conducted by generally accepted ethical standards such that the rights and welfare of human subjects are not compromised, and that the greatest possible benefits accrue to the subjects and to society. Both research investigators and department heads are responsible for reporting promptly to the IRB any serious or continuing noncompliance with the requirements of this policy or federal laws, regulations, or guidelines, or the specific study requirements as established by the IRB.

5.0 Policy Implementation

The organizational structure for the implementation of these policies is centered in the Research Compliance Office, and includes the following administrative, advisory, and auxiliary relationships (See Appendix A).

5.1 University Administration

The Vice President for Research is the university official with final responsibility for ensuring that all research conducted at Virginia Tech involving human subjects is in compliance with all applicable laws, regulations, guidelines, and policies. The Vice President for Research assists the University President in maintaining continuing relationships with state and federal regulatory agencies which deal with human subjects protection.

5.2 The Institutional Review Board for the Protection of Human Subjects Used in Research (IRB)

The IRB considers matters involving university policies and procedures regarding the appropriate treatment/protection of human subjects used in research to ensure compliance with applicable federal and state regulations. The IRB also recommends policy to the Vice President for Research related to human subjects research compliance.

5.3 Research Compliance Office Personnel

Assistant Vice President for Research Compliance

The AVP for Research Compliance reports to the designated "Institutional Official", the Vice President for Research, and oversees the operation and management of the Research Compliance Office. The AVP for Research Compliance serves as the ex officio, voting Chairperson for the IRB.



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Research Compliance Officer

The Research Compliance Officer manages the staff of the office, and conducts ongoing assessments of the accuracy, timeliness, and completeness of records created and maintained by the Research Compliance Office staff. The Research Compliance Officer or designee will conduct post approval monitoring of studies to ensure that consent documents are signed and appropriately filed, and that the consent process is conducted as prescribed by the IRB.

IRB Administrator

The Institutional Review Board (IRB) Administrator applies her/his knowledge of human subjects research program compliance and related administrative processes to ensure institutional compliance with applicable federal laws, regulations, and policies [e.g., Title 45 Code Of Federal Regulations Part 46 Protection Of Human Subjects; the Belmont Report; the Common Rule; NIH Office of Human Research Protection (OHRP) regulations/policies]. This individual has frequent and varied contacts inside and outside of the organization as required to establish parameters/metrics for program success, e.g., developing policies and procedures, coordinating service delivery, promoting program(s) goals and objectives in addition to providing technical advice. External contracts include, but are not limited to, the following: the NIH Office of Human Research Protection (OHRP); applicable state agencies. Internal contacts include Deans, Associate Deans, and Department Heads of Colleges which use human subjects in research, faculty/staff/student "clients", occupational health and safety personnel from EHSS, Office of Sponsored Programs pre and post award specialists, University Relations administrators and staff, and University governance committees. The IRB Administrator must maintain proficiency in existing laws/regulations/policies, maintain contacts and resources to quickly identify changes in those laws/regulations/policies, be able to interpret those laws/regulations/policies and establish procedures and documentation practices to demonstrate University compliance, and to advise/educate administrators, compliance staff, and other applicable university personnel and students of their roles and responsibilities in ensuring compliance with those laws/regulations/policies. The IRB Administrator's responsibilities include: supporting long range program planning and development; monitoring program performance and service delivery; interpreting, developing, analyzing, and recommending policies and procedures; providing consultative services; monitoring and analyzing legislation; coordinating resources; and supervising program and administrative staff. The IRB Administrator ensures the quality control of programs by developing metrics and monitoring systems, and periodically assessing the performance of the personnel and program of compliance assurance for human subjects used in research at the University.

Administrative Assistant

The Administrative Assistant will apply her/his knowledge of human subjects research program compliance and related administrative processes to ensure institutional compliance with applicable federal laws, regulations, and policies [e.g., Title 45 Code Of Federal Regulations Part 46 Protection Of Human Subjects; the Belmont Report; the Common Rule; NIH Office of Human Research Protection (OHRP) regulations/policies]. The Administrative Assistant provides secretarial and database management support services to the Research Compliance Office, including but not limited to assisting in coordinating Institutional Review Board (IRB) compliance activities, database and file management, correspondence management, communicating and interfacing with individuals within and outside of the University, and assisting with scheduling meetings and activities associated with compliance committee functions/operations. The Administrative Assistant has direct accountability for service delivery, and may answer complex questions, referring unusual problems to higher levels (e.g., the IRB Administrator, the Research Compliance Officer, or the Assistant Vice President for Research Compliance). The



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~~Administrative Assistant will interpret and apply policies, procedures and guidelines, exercising independent judgment.~~

5.4 Delegation of Responsibilities

~~The Assistant Vice President for Research Compliance and the IRB will specify the additional responsibilities necessary for function and operation of the program to ensure human subject protection, and delegate these responsibilities to appropriate groups and individuals (HHS).~~

6.0 Definitions

~~**Research**—a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (e.g., intended to be published, disseminated, or presented in scientific publications, theses, dissertations, or at local, regional or national meetings). Activities which meet this definition constitute research, whether or not they are conducted or supported under a program which is considered research for other purposes.~~

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

- ~~• dataObtains 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;~~
- ~~• data from existing records or data file;~~

~~**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 health 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 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:~~



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- Must meet the requirements for prior submission to the FDA under section 505(i) of the Federal Food, Drug, and Cosmetic Act 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

1. Virginia Tech IRBHRPP website: <http://www.irb.vt.edu>
1. US Code of Federal Regulations (CFR) at 45 CFR 46
2. The Belmont Report: US Code of Federal Regulations (CFR) at 45 CFR 46
3. FDA Policy for the Protection of Human Subjects
- 2.4. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research
5. 8Policy 13015, “Ownership and Control of Research Results”

7.0 Approval and Revisions

Revised September 30, 2006
Revised August 8, 2014 (formatting only)
Revised xx/xx/xxxx



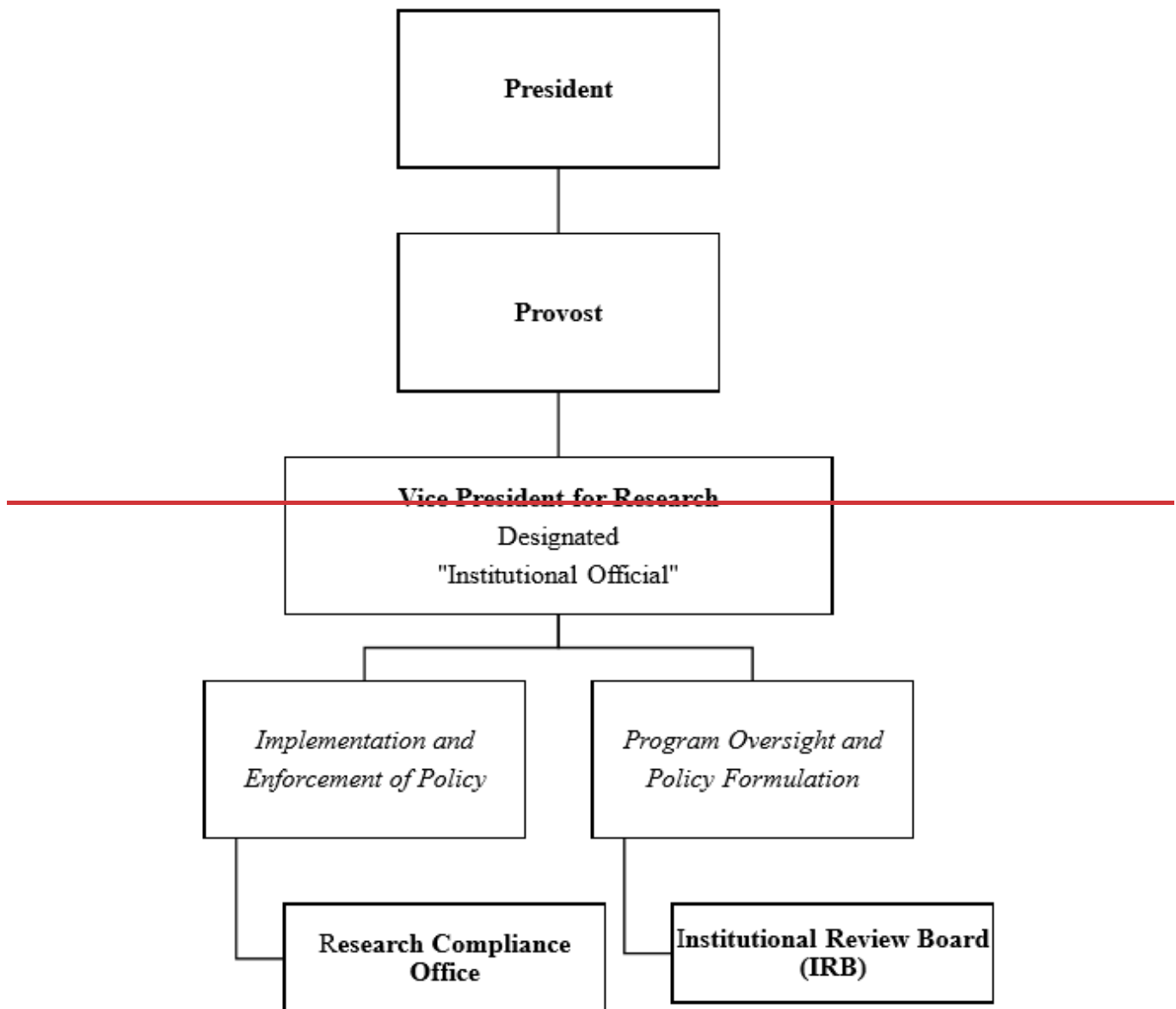
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This policy was completely revised based on the changes to the human subjects regulations (45 CFR 46) which became effective January 21, 2019. Substantial changes were also made to align with the policy pyramid and focuses on what is mandated or required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



Appendix A

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





Virginia Polytechnic Institute and State University



Virginia Tech Human Subjects Research Policy

No. 13040

Policy Effective Date:
9/30/2006

Last Revision Date:
8/8/2014

Policy Owner:
Daniel Sui

Policy Author: (Contact Person)
Barbara DeCausey

Affected Parties: Undergraduate Graduate Faculty
Staff Other

1.0 Purpose

2.0 Policy

3.0 Oversight

4.0 Responsibilities of Researchers

5.0 Definitions

6.0 References

7.0 Approval and Revisions

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



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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.



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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 Specialist 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.



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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

Researcher, 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.



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- 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 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.

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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 Act 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

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- 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

1. Virginia Tech HRPP website: <http://www.irb.vt.edu>
2. [US Code of Federal Regulations \(CFR\) at 45 CFR 46](#)
3. [FDA Policy for the Protection of Human Subjects](#)
4. [The Belmont Report](#): Ethical Principles and Guidelines for the Protection of Human Subjects of Research
5. [Policy 13015](#), "Ownership and Control of Research Results"



Virginia Polytechnic Institute and State University

7.0 Approval and Revisions

Revised September 30, 2006

Revised August 8, 2014 (formatting only)

Revised xx/xx/xxxx

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.



**2023-2024
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Vice President for Finance
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Secretary/Treasurer: Kari Evans
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Past President: Serena Young
University Ombuds
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ADHOC COMMITTEES

Staff Senate

<http://www.staffsenate.vt.edu/>

September 29, 2023

To: Vice President of Policy and Governance

The Staff Senate Committee on Policy and Issues has reviewed and approves COR Resolution 2023-24A.

There are a couple of apparent typos in the revised policy that we would like to note. First, on page 10 of the resolution pdf where "2.2.1 The IRB's Role" is struck through, at the end of the second line, "they" should be "the". Second, on page 20 of the resolution pdf, where the section is "Human subject (FDA definition)", at the end of the second line, "health" should be "healthy".

We have no further comment.

**Thank you,
Amber Robinson, Chair Staff Senate Policies and
Issues Committee**



Administrative and Professional Faculty Senate

<https://governance.vt.edu/ap-faculty-senate.php>

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Nikki Connors
Analytics and Institutional Research

September 29, 2023

To: Vice President of Policy and Governance

From: A/P Faculty Senate Polices and Issues Committee

The A/P Faculty Senate Polices and Issues Committee has reviewed and approves/endorsees the Commission on Research Resolution 2023-24A to Revise Policy 13040.

We have no further comment.