Virginia Tech Human Subjects Research Policy

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Other

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1.0 Purpose

In order to protect the rights, well-being, safety, and personal privacy of individuals participating in research conducted by faculty, staff and students of the University, to assure a favorable climate for the conduct of scientific inquiry, and to protect the interests of Virginia Tech, the policy and procedures described below have been established for the conduct of research involving human subjects. 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 federal law, this commitment is vested in the Institutional Review Board for Research Involving Human Subjects (the IRB) which operates under a Federal-wide Assurance (FWA) on file with the Office for Human Research Protection (OHRP) within the U.S. Department of Health and Human Services (DHHS).

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.

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 be obtained. The elements of informed consent are established by the Federal government and by the University.

f. 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.

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 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.

2.0 Oversight

2.1 Administration of the Regulatory Functions: Research Compliance Office

The functional administrative unit that is charged with the 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.

The Research Compliance Office is an administrative unit under the supervision of the Assistant Vice President for Research Compliance, who reports to the Senior Vice President for Research and Innovation, the designated Institutional Official for regulatory compliance. The Research Compliance Office has executive responsibility for the implementation of all Virginia Tech policies involving the protection of human subjects used in research.

2.2 Compliance Committee Review – The IRB

The Virginia Tech Institutional Review Board shall have general oversight responsibility for this University policy on the protection of human subjects and shall consider policy changes that may be 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 should be recommended by the IRB to the Senior Vice President for Research and Innovation.

2.2.1 The IRB's Role

The 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

The IRB has 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 policy. The IRB acts 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:

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.

c. 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 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 Institutional officials is required to effectuate or support the policies or interests of the Institution.

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.

c. 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 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, and all staff and students participating as a member of the research team, must:

- acknowledge and accept individual responsibility for protecting the rights, welfare, health and safety of human research subjects and for complying with the applicable regulations;
- accept and endorse the Virginia Tech commitment to the protection and safety of human subjects in research;
- acknowledge the authority and responsibility of the IRB and IRB Chair to make the final approval (or disapproval) of research involving human subjects, and be responsible for complying with all IRB decisions, conditions and requirements;
- participate in the education/training program to qualify to conduct research involving human subjects.

4.2 Submission of Application and Protocol

Research investigators (PIs) will:

- be responsible for ensuring, in connection with all research involving 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, 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 45 CFR 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 fully inform subjects of the risks, benefits, subjects' expectations, compensation and other aspects of the research in which they are being asked to participate.

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 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

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 Senior Vice President for Research and Innovation 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 Senior Vice President for Research and Innovation 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 Senior Vice President for Research and Innovation 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.

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 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.

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 subject -- a living individual about whom an investigator (whether professional or student) conducting research obtains

- data through intervention or interaction with the individual;
- identifiable private information;
- data from existing records or data file;

IRB Approval -- 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.

7.0 References

1. Virginia Tech IRB website: http://www.irb.vt.edu

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

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

8.0 Approval and Revisions

Revised September 30, 2006
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Appendix A

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