SOP: Researcher and Investigator Responsibilities				
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1 PURPOSE

1.1 The purpose of this standard operating procedure (SOP) is to define the roles and responsibilities of researchers and investigators when conducting human subjects research (HSR).

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 HSR must be conducted in accordance with federal regulations, state law, university policies, and the human research protection program (HRPP) SOPs and researchers and investigators are responsible for ensuring compliance.

3.2 HRPP provides administrative support to the Institutional Review Board (IRB) and serves as a resource for researchers and investigators.

3.3 The IRB protects the rights and welfare of research participants in all research under their purview.

3.4 A principal investigator (PI) may delegate tasks to members of their research team, but they retain the ultimate responsibility for oversight and the conduct of the study.

3.5 Researchers and investigators may have additional responsibilities and obligations imposed by the department, funding agency, or study sponsor that are not covered in this SOP.

4 RESPONSIBILITIES

4.1 All Investigators and Researchers

4.1.1 Investigators and researchers are responsible for protecting the rights, welfare, health, and safety of human research participants and complying with the applicable federal regulations, state laws, university policies, and HRPP SOPs.

4.1.2 Training requirements for conducting HSR must be completed prior to interacting with research participants or collecting or handling human participant data as outlined in HRP-010.0, Human Research Protections Training Requirements. The refresher course must be completed every three years.

4.1.3 The research must be conducted in an ethical manner adhering to the principles outlined in the *Belmont Report*: Respect for persons, beneficence, and justice.

4.1.4 All proposed activities involving human subjects, including obtaining identifiable data or specimens, must be submitted to HRPP for review. Upon review, HRPP will determine whether the activity meets the definition of human subjects research, is eligible for an exempt determination, or requires IRB review. Investigators and researchers must receive HRPP authorization or IRB approval prior to the initiation of any research activities that involve human participants or human participant data. Submissions should include the current approved templates, which can be downloaded from the Protocol Management System or the HRPP website.

4.1.5 The design of the proposed activities must conform to acceptable scientific, ethical, and legal requirements.

4.1.6 There must be adequate resources and facilities available to carry out the proposed research study.

4.1.7 Conflicts of interest must be declared and disclosed.

4.1.8 The research must be conducted and implemented according to the IRB-approved study protocol. Researchers and investigators:

4.1.8.1 Must respond to all requests for information or submission of materials by HRPP or the IRB.

4.1.8.2 Must not deviate from the approved research or determination except: when the IRB has approved; when necessary to eliminate apparent

immediate hazards to participants, or research is exempt and does not meet the criteria for submitting an amendment.

4.1.8.3 Must report adverse events, unanticipated problems involving risks to subjects or others, deviations to eliminate apparent immediate harms or hazards to participants, serious or continuing noncompliance, and substantive complaints from participants. Informal reports must be submitted within 48 hours of the event and formal detailed reports must be submitted within five (5) business days.

4.1.8.4 Must obtain and document voluntary and informed consent from participants or their legally authorized representative, unless the IRB has approved a waiver or alteration of the consent process or documentation of consent.

4.1.8.5 Must obtain IRB approval before implementing changes to the protocol and other IRB approved materials, except as noted in 4.1.8.2.

4.1.8.6 Must obtain continuing IRB approval before the study expires or submit a progress report on or before the due date. **Must cease all HSR activities if IRB approval lapses.**

4.1.8.7 Must close the research study when the study and the primary publication are complete or when the data have been deidentified or destroyed.

4.1.9 Create and maintain an electronic or paper research binder that contains all study-related records according to the "Regulatory Binder Guidelines and Checklist." These records must be retained for at least three years after completion of the research or in accordance with university policy, whichever is greatest. These records must be made available for review, upon request, by authorized HRPP staff and IRB members to ensure adherence to the protocol and compliance with federal regulations.

4.1.10 Retain records for research involving Food and Drug Administration (FDA) regulated test articles (drugs, devices, and biologics), in accordance with applicable FDA regulations.

4.1.11 Comply with the university's data ownership policy (Policy 13015, "Ownership and Control of Research Results") and university requirements to transfer or access data after separation from the university.

4.1.12 Researchers and investigators, including faculty, staff, and students, who are leaving the university must begin the transition process by completing the "Virginia Tech Faculty Departure Checklist" or the "Virginia Tech Graduate Student Departure Checklist". For ongoing research, replacement researchers and investigators should be identified and assigned to the protocol if needed. Only Virginia Tech current faculty and saff can serve as PI unless an exception has been granted.

4.2 Principal Investigators

4.2.1 Principal investigators must comply with the requirements outlined in section 4.1 in addition to the requirements in this section.

4.2.2 The PI accepts overall responsibility for the conduct of the research including the actions of all members of the research team.

4.2.3 It is the PI's responsibility to ensure all members of the research team who interact with human research participants, or who collect or handle human participant data, have completed the appropriate training requirements and are added to the project personnel section in the Protocol Management System.

4.2.4 The PI must ensure that all members of the research team are appropriately trained on the research study procedures, informed consent requirements, potential adverse events associated with study participation and the steps to be taken to reduce potential risks, reporting requirements, and data collection and record-keeping procedures.

4.2.5 The PI must provide guidance to and mentor students on scientific, ethical, legal, and policy related practices for conducting HSR. Responsibilities include but are not limited to:

4.2.5.1 Provide leadership and oversight for student-initiated research.

4.2.5.2 Assist students with navigating the research determination, review, and approval process.

4.2.5.3 Review and critique the protocol and supporting documents before it is submitted to the HRPP to ensure that the proposed research uses procedures consistent with sound research design sufficient to yield the expected knowledge.

4.2.5.4 Participate in consultations when students seek assistance from the HRPP staff.

4.2.5.5 Ensure the student is appropriately trained and qualified to conduct the research.

4.2.5.6 Ensure the protocol is closed when the study and the primary publication are complete, when the data have been deidentified, or when the student separates from the university.

4.2.6 For clinical trials research, comply with all the requirements related to registering and maintaining records with ClinicalTrials.gov

4.3 Student Researchers

4.3.1 Student researchers must comply with the requirements outlined in section 4.1 in addition to the requirements in this section.

4.3.2 Student initiated HSR, whether dissertation, thesis, or other research projects must be supervised by a faculty mentor or advisor who will serve as the PI of the project. Students must identify a PI for their research studies.

4.3.3 Students must work closely with their PI on the design and development of their research protocol. The protocol must be reviewed by the PI prior to submitting to HRPP for review.

4.3.4 Make sure it is feasible to conduct the research considering resources and time. HRPP authorizations and IRB approval times vary depending on workloads and the quality of the submission.

4.4 Deans of Research, Department Heads, and Department Chairs

4.4.1 Ensure that researchers and investigators have adequate provisions for conducting research involving human participants, including education, experience, and supervision in appropriate scientific, ethical, legal, and policy-related practices.

4.4.2 Notify the HRPP of any potential noncompliance with the requirements of the Policy 13040, “Virginia Tech Human Subjects Research Policy”, or federal laws, regulations, guidelines, or specific study requirements as established by the IRB that has not been reported by a researcher or investigator..

4.4.3 Participate in meetings to discuss and resolve issues of serious and continuing noncompliance upon request. Enforce remediation and other sanctions of researchers and investigators when applicable.

5 DEFINITIONS

5.1 Adverse Event (AE): An adverse event is any untoward or unfavorable physical or psychological harm that occurs in a human research subject that is temporally associated with the subject’s participation in the research, regardless if it is related to the research.

5.2 Conflicting Interest: An individual involved in research review is automatically considered to have a conflicting interest when the individual, their spouse, or their dependent children have any of the following relationships or interests in the sponsor or product/service being tested, or competitor of the sponsor held by the individual or the individual’s immediate family:

5.2.1 Involvement in the design, conduct, or reporting of the research

5.2.2 Stock, stock options, or other ownership interest of any value, including investment vehicles if you directly control the investment decisions made through these vehicles

5.2.3 Compensation of any amount in the past year or of any amount expected in the next year, excluding compensation for costs directly related to conducting research

5.2.4 Proprietary interest including, but not limited to, a patient, trademark, copyright, or licensing agreement

5.2.5 Board or executive relationship, regardless of compensation

5.2.6 Any other reason for which the individual believes that it is not possible to be independent and objective

5.3 Continuing Non-Compliance: Continuing non-compliance refers to a pattern of non-compliance that suggests the likelihood that, without intervention, instances of non-compliance will recur; a repeated unwillingness to comply, or a persistent lack of knowledge of how to comply.

5.4 Expiration Date: The expiration date refers to the first date after which the protocol is no longer approved. It is the date after the end date of the approval period.

5.5 Human Research: Human research refers to any activity that either:[1]

5.5.1 Meets the HHS definitions of research and human subjects; or

5.5.2 Meets the Food and Drug Administration (FDA) definitions of research and human subjects.

5.6 Human Subject:

5.6.1 As defined by HHS: A human subject, as defined by HHS, is a living individual about whom an investigator (whether professional or student) conducting research (1) obtains information about a person or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. For the purpose of this definition:

5.6.1.1 Intervention: Intervention refers to procedures by which information or biospecimens are gathered (for example, questionnaire or venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

5.6.1.2 Interaction: Interaction refers to communication or interpersonal contact between investigator and subject.

5.6.1.3 Private Information: Private information refers to information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record).

5.6.1.4 Identifiable Private Information: Identifiable private information refers to private information for which the identity of the subject is known, either through identifiers associated with the record or when the identity of the subject can be readily ascertained by the investigator.

5.6.1.5 Identifiable Biospecimen: Identifiable biospecimen refers to a biospecimen for which the identity of the subject is known, either through identifiers associated with the record or when the identity of the subject can be readily ascertained by the investigator

5.6.2 As Defined by FDA: 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.

[1] The terms of "Human Subjects Research," Research Involving Human Subjects", "Clinical Research", "Clinical Investigation", "Clinical Study", and similar phrases are considered to be synonyms for the term Human Research.

5.7 Investigator[2]

5.7.1 As Defined by HHS: The term investigator refers to an individual performing various tasks related to the conduct of human subjects research activities. Tasks could include:

5.7.1.1 Obtaining information about living individuals by interpreting or interacting with them for research purposes;

5.7.1.2 Obtaining identifiable private information about living individuals for research purposes; and

5.7.1.3 Studying, interpreting, or analyzing identifiable private information or data for research purposes.

5.7.2 As Defined by FDA: The term investigator refers to the individual who actually conducts a clinical investigation.

5.8 Legally Authorized Representative (LAR): Legally authorized representative (LAR) refers to an individual or organization authorized under applicable law to provide permission on behalf of a prospective subject to the subject's participation in the procedures(s) involved in the research.

5.8.1 If there is no applicable law addressing this issue, then the LAR is the person recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject.

5.8.2 See HRP-013.1 - SOP - LARs, Children, and Guardians for who may serve as a LAR at this institution.

5.9 Non-Compliance: Non-compliance refers to failure to follow the regulations, or the requirements or determinations of the IRB.

5.10 Principal Investigator: The principal investigator is the individual who is ultimately responsible for assuring compliance with federal regulations, applicable state laws, university policies, and standard operating procedures and oversight of the research study.

5.11 Research as Defined by HHS:

5.11.1 Research, as defined by HHS, refers to systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

5.11.2 The following activities are not considered research as defined by HHS:

5.11.2.1 Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information that focus directly on the specific individuals about whom the information is collected

5.11.2.2 Public health surveillance activities conducted by a public health authority, limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance. Public health surveillance includes:

5.11.2.2.1 The collection and testing of information or biospecimens that is conducted, supported, requested, ordered, required, or authorized by a public health authority

5.11.2.2.2 The collection of data related to trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products

5.11.2.2.3 The collection of data associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or human generated disasters)

[2] The terms "investigator" and "researcher" are considered to be synonyms and are used interchangeably.

5.11.2.3 Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes

5.11.2.4 Authorized operational activities (as determined by the relevant federal agency) in support of intelligence, homeland security, defense, or other national security missions

5.11.2.5 Secondary research involving non-identifiable newborn screening blood spots

5.11.3 Research as Defined by FDA: 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:

5.11.3.1 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;

5.11.3.2 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

5.11.3.3 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.

5.12 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.

5.13 Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO): Unanticipated problem involving risks to subjects or others (UPIRTSO) refers to any incident, experience, or outcome that meets the three following conditions:

5.13.1 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;

5.13.2 Is related or possibly related to participation in the research

5.13.2.1 "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

5.13.3 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 MATERIALS

6.1 Regulatory Binder Guidelines and Checklists

6.2 Virginia Tech Faculty Departure Checklist

6.3 Virginia Tech Graduate Student Departure Checklist

7 REFERENCES

7.1 HHS: Office of Human Research Protections (OHRP): Investigator Responsibilities FAQ

7.2 FDA: Guidance for Industry: Investigator Responsibilities – Protecting the Rights, Safety and Welfare of Study Subjects

7.3 SOP: Human Research Protections Training Requirements (HRP-010.0)

7.4 *The Belmont Report, Ethical Principles and Guidelines for the Protection of Human Subjects Research*

7.5 Policy 13015, “Ownership and Control of Research Results”

7.6 Policy 13040, “Virginia Tech Human Subjects Research Policy”