Pre-2018 Standard Operating Procedures

NOTE: The following are pre-2018 policies as of January 21, 2019 and are in effect only until new policies are posted (in progress).

Purpose & Applicability of Manual

Section 1 of Policies and Procedures Manual

The IRB documents its written procedures according to 45 CFR 46.115(a)(6), 45 CFR 46.103(b)(4) and 45 CFR 46.103(b)(5). Information contained within the VT IRB website is reflective of its approved policies, procedures and guidance, and will be updated frequently to reflect new standards, regulations, and VT policies.

The policies, procedures and guidance set forth in this manual are applicable to all VT faculty, staff, student, and employee research investigators and to those conducting human subject research in which VT is engaged.

About the Virginia Tech IRB

What is an IRB?

An Institutional Review Board (IRB) is a committee, or board, of volunteers including scientists, non-scientists, community members, and health care professionals that ensures research protocols involving human subjects are ethical and that the rights of participants are protected.

Specific areas for IRB review include:

1. Evaluation of the nature and purpose of the research;
2. Evaluation of proposed procedures involving human subjects;
3. Evaluation of the risks or harms to the subjects (including physical, psychological, sociological, economic, and legal;
4. Evaluation of the benefits;
5. Evaluation of the risk/benefit relationship;
6. Evaluation of subject population;
7. Evaluation of subject recruitment;
8. Evaluation of the process of obtaining informed consent;
9. Evaluation of research data processing and storage; and
10. Whether there is a need for additional IRB follow-up than on an annual basis.

The application of conscientious judgment by the members who serve on IRBs is pivotal to the entire system of protection of research subjects. Indeed, the system recognizes that there is no simple formula to apply to ethical decisions, and instead it vests the major responsibility of ethical decision making with the IRB. IRB actions are to be based on ethical principles (such as outlined in The Belmont Report). They should fully recognize that ethical decisions involve a balance among such principles (such as respect for persons, beneficence, and justice) along with the importance of the knowledge that may reasonably be

expected to result from proposed research (the requirement for which is itself grounded in the principle of beneficence).

Mission Statement (Policy No. 2.00)

Virginia Tech is committed to protecting the rights of and ensuring the safety of human subjects participating in research conducted by faculty, staff, and students of the University. This 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 Federalwide Assurance (FWA) on file with the Office for Human Research Protection (OHRP) within the U.S. Department of Health and Human Services (DHHS).

Virginia Tech Administration of Human Subject Research (Policy No. 2.01)

The Office of the Vice President for Research is responsible for the administration and oversight of research compliance at VT. It oversees the functioning of the IRB, which is within the Office of Research Compliance (ORC). The ORC is under the direction of Associate Vice President for Research Compliance, David M. Moore, DVM. Contact information for VT IRB personnel is available on the Contact Us webpage.

FWA and IRB Registration (numbers & signatory authority) (Policy No. 2.02)

Virginia Tech's Federalwide Assurance (FWA) is, in essence, a contract with the government, specifically, the Office for Human Research Protections (OHRP). The FWA contract documents VT commitment to adhere to the principles outlined in the Belmont Report and to the Terms of the Federalwide Assurance for its conduct and support of human subjects research activities.

- VT's Federalwide Assurance number is **FWA00000572**
- VT's IRB registration number is **IRB00000667**
- VT's IORG number is **0000389**

Note: the Vice President for Research holds the FWA signatory authority.

Purview of the VT IRB (Policy No. 2.03)

It is the researcher's responsibility to seek and obtain prior VT IRB approval as deemed appropriate using the Activities Requiring Virginia Tech IRB Approval flowchart. Projects requiring VT IRB review according to the flowchart require approval regardless of the location of the research activity (i.e., conducted on or off campus), source of funding (i.e., federally funded, privately funded or non-funded),

and whether the research is exempt under the Code of Federal Regulations for Protection of Human Subjects (45 CFR 46).

The VT IRB may cede authority to a collaborating institution's IRB, if both institutions agree to do so. VT does not conduct or provide oversight over human subjects research for which investigational devices or drugs are used. The VT IRB will typically not consider review requests from agencies and organizations outside the University for research that does not involve VT faculty or that is not sponsored by VT.

Review agreements exist between VT and Carilion Medical Center, and VT and Virginia College of Osteopathic Medicine (view details).

IRB Review (general policy information) (Policy No. 2.04)

VT has one IRB responsible for conducting initial and continuing reviews, and providing oversight for all human subjects research activities involving VT researchers or for which VT is engaged.

Review procedures will be conducted in accordance with Virginia Tech's Federalwide Assurance Terms.

Any time the IRB or staff determine they do not have the necessary scholarly or scientific expertise for sound review, they may request ad hoc consultants. Consultants are independent of the IRB and are selected according to scholarly and scientific expertise. Consultants may be called upon to judge the scientific soundness of a research protocol, make a fair and accurate determination of the risk-benefit ratio, review the cultural appropriateness of the informed consent process, and offer additional and unique expert advice. However, consultants cannot make any review determinations; they may only provide counsel. Individuals providing consultation to the IRB agree to and sign a confidentiality agreement prior to the receipt and review of submission documents, unless the principal investigator waives his/her right to confidentiality.

Confidentiality of the Review Process & Protocol Files (Policy No. 2.05)

Protocol materials provided to the IRB shall be considered privileged information, and are accessible to the IRB, Office of the Vice President for Research (OVPR), University Legal Counsel, VT Internal Audit, the Office for Human Research Protections, and others as deemed appropriate by the IRB.

The IRB may deny requests for copies of protocol materials as deemed appropriate or require the written permission of the protocol's principal investigator prior to the release of records.

Record Retention Requirements for the IRB (Policy No. 2.06)

The Office of Research Compliance maintains protocols files in a secure manner. Records required by 45 CFR 46 are retained according to 45 CFR 46.115(b).

Board Meetings (Policy No. 2.07)

Virginia Tech IRB meetings are held at least once monthly, typically occurring on the second Monday of each month, from noon until 1:30 p.m.

The deadline for submission of protocols requiring full IRB review and approval at official convened meetings is 10 business days (2 weeks) before the scheduled meeting. Materials submitted for review after that deadline will typically not be considered or reviewed by the IRB until the next scheduled meeting to be held the following month. Learn more about full review deadlines.

The IRB office typically mails all agenda items for review to IRB members 7-14 days prior to each scheduled meeting date. Supplemental materials may be provided to the IRB members any time prior to or on the day of the meeting, as deemed appropriate by the IRB office, if doing so does not hinder full consideration of a protocol. If a Board member advises he/she has insufficient time to fully review a protocol or supplemental material, the protocol may be (as determined by members in attendance) held for review and/or vote at a subsequent meeting or the member may abstain from voting on the particular protocol.

At the discretion of the Chair, and in consideration of the quantity and complexity of protocols to be reviewed by the full IRB, it may be necessary to convene an interim meeting at which those protocols would be discussed.

If no protocols are received prior to the monthly deadline, the Chairperson may cancel the regularly scheduled IRB meeting for that month.

With the permission of the IRB office or Board, investigators are welcome to attend the IRB meeting, or be available by telephone, to respond to any questions that may be raised during the Board's discussion of the study. Investigators are asked to leave the meeting during all votes.

IRB Meeting Minutes (Policy No. 2.08)

Minutes of each IRB meeting are recorded in writing in accordance with 45 CFR 46.115(a)(2). The IRB approves the previous month's minutes at the subsequent IRB meeting; however, a quorum is not required for such approval. If the Board requests revisions, changes are made after the meeting. The final version of the approved minutes is signed by the IRB Chair and filed (hardcopy) within the IRB office.

Minutes include:

1. Attendance (designating any advocates for vulnerable populations that are present and visitors)
2. A list of full board studies with the respective information:

    - Actions taken and decisions made by the Committee, including disapprovals;

- Vote on these actions (including the number of members voting for, against, and abstaining);
- Basis for requiring modifications to the research proposal or consent documents or for disapproving the research proposals;
- A summary of the discussion of controversial issues and their resolution;
- A summary of discussion of issues pertinent to the protocol;
- Minutes will also document determinations required by HHS regulations and in accordance with VT's FWA to include those for waiver or alteration of consent; waiver of consent documentation; and research involving pregnant women and fetuses, prisoners, and children.

3. A list of all initial and continuing review approvals that were taken administratively (i.e., Exempt and Expedited reviews) during the previous month (separate document from the minutes).

Minutes include separate deliberations, actions, and votes for each protocol undergoing initial, continuing, or amendment review by the convened IRB. The vote on all IRB actions include the number of persons voting for, against, and abstaining, in order to document the continued existence of a quorum. The minutes include the documentation of any potential conflict of interest that an IRB member may have with a particular protocol. The IRB Chair or designated person is responsible for monitoring quorum, vote counts, and recording IRB discussion points for the minutes.

IRB Members (Policy No. 2.09)

The IRB Chair is appointed by the Vice President for Research. Members of the IRB, and alternate members, are nominated by the Chairperson and appointed by the Vice President for Research. Members of the IRB typically serve for 3-year terms, which may be renewed at the discretion of the Vice President for Research. Upon recommendation of the Chair, the Vice President for Research may terminate the appointment of a member or alternate prior to the expiration of his/her term.

The VT IRB is comprised in accordance with 45 CFR 46.107. There are no quantified attendance requirements placed on IRB members; however, the Chair may recommend termination of membership for attendance reasons. The membership list is not made publicly available.

Undue Influence of IRB Members or Staff (Policy No. 2.10)

In cases in which an IRB member or staff person experiences either direct or indirect undue influence or coercion to make a ruling for a specific research study or investigator, the IRB member or staff person is asked to document the issues related to the case in writing to both the IRB Chair and Vice President for Research in order to open a formal report.

Board Functions, Activities & Responsibilities (Policy No. 2.11)

1. At the meetings, the IRB will conduct official business only if (a) a quorum [majority including members or alternates, and the Chair or designated chair] is present and (b) 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.
2. 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 to 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.
3. 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.
4. 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.
5. 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.
6. If a member of the IRB has an interest (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. The Chair polls all members in attendence for potential conflicts of interest prior to the discussion of each protocol agenda item.
7. 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 principal investigator waives his/her right of confidentiality.
8. 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.
9. 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.
10. Unless waived, the IRB will 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 to observe the consent process, or any other part of the research process involving human subjects.
11. The IRB will determine that there are adequate provisions in the research plan to protect the privacy of subjects and to maintain confidentiality of data, where appropriate.
12. 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.

IRB Chair & Office Functions, Responsibilities & Duties (Policy No. 2.12)

1. Serves as a resource person for investigators conducting research involving human subjects and investigators contemplating such research;
2. Keeps abreast of all changes in the regulations governing human subjects research and keeps the IRB and investigators informed;
3. Develops and maintains education and training programs for the IRB members, departmental reviewers, departmental Human Subjects Committees, and research investigators who use human subjects;
4. Determines whether all the required documents are in the applications. If parts are missing or incomplete, returns the application to the principal investigator for revision;
5. Chair, or designated reviewer, determines which applications qualify for "Exemption" and which exemption category applies. Notifies the principal investigator and departmental reviewer;
6. Chair, or designated reviewer, determines which applications qualify for "Expedited Review". If all parts of the application are complete and in order, gives "Expedited Approval" and notifies the principal investigator and departmental reviewer;
7. Determines which applications require full IRB review and approval.
8. The Chair may request assistance from any IRB member concerning any application;
9. Nominates IRB members and alternate members for appointment or re-appointment by the Vice President for Research;
10. Selects the time and place for IRB meetings;
11. Informs the IRB of "Exemptions" and "Expedited Approvals" given by the Chair since the last meeting of the Board;
12. Records complete minutes of each IRB meeting including discussion and requests for modifications of each application;
13. Records votes on each action taken by the IRB, including abstentions. The total number of votes must equal the number of members present;
14. Distributes the minutes of the last IRB meeting with the agenda materials for the next meeting;
15. Notifies principal investigators and departmental reviewers in writing of Board actions;
16. The Chair may appoint a member of the IRB as "designated Chair" for a meeting or part of a meeting;
17. Approves requests for Interim approval;
18. Serves as the official University contact for all matters regarding research involving human subjects.

Reporting Responsibilities of the IRB (Policy No. 2.13)

The IRB will report protocol non-compliance, unanticipated problems, suspension, and termination to the appropriate agencies and officials in accordance with the *Policy for Noncompliance Involving Subjects Research* and OHRP's Guidance on Reporting Incidents to OHRP.

In the event that the VT IRB is found to be noncompliant with its Federalwide Assurance or applicable federal regulations, the noncompliance is related to one or more federally funded, non-exempt research protocols, and the noncompliance is serious or continuing, then the incident will be reported to the OHRP. The report will include a detailed description of the noncompliance, and actions the University is taking or plans to take to address the noncompliance.

Mandated Background Requirements for IRB Members

The IRB must have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The following categories must be represented on the Board:

- At least one scientist;
- At least one non-scientist;
- At least one community member who (or his/her immediate family) has no employment or contractual relationships with the institution (Virginia Tech); and
- At least one health care professional.

Federal law requires that the IRB be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB must be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB must therefore include persons knowledgeable in those areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration must be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with those subjects.

Applications Reviewed by Chair vs. Board

All activities involving human subjects in research, regardless of funding source, must be reviewed by the Virginia Tech IRB before recruiting, enrolling, or involving subjects in that research.

Virginia Tech, in following established federal regulations, utilizes three classes of review of human subjects research:

- Exempt review
- Expedited review
- Full Board review

The IRB Chair may review and approve studies that qualify for exempt and expedited review.

General Research Policies

Collaborative Research (Policy No. 3.00)

Collaborative research is defined as research conducted in cooperation with an institution or facility that is not affiliated with Virginia Tech or that does not fall under Virginia Tech's authority.

Collaborative research is subject to special procedures for coordination of research review and may involve more than one IRB responsible for research oversight. In coordinating collaborative research reviews, the IRB takes into consideration the source of funding for the research activity.

It is the Principal Investigator's (PI) responsibility to obtain IRB approval from all collaborating institutions and institutions at which research will be conducted, as appropriate based on those institutions' requirements.

Engagement in Research Determinations

For federally-funded collaborative research projects, the PI makes the determination whether the off-site* facility is "engaged" in research according to the guidance outlined in the Office for Human Research Protections (OHRP) Engagement Memo by considering the involvement of the off-site personnel in implementing research procedures and/or collecting data at the site. The IRB assists the PI in making this determination, as appropriate.

The VT IRB ensures all engaged institutions a) have or apply for a Federalwide Assurance (or similar assurance), and b) will have their own designated IRB review the protocol, if ALL of the following criteria are met:

- The project is funded by any federal department or agency that has adopted the Common Rule [view list of applicable departments/agencies (click on "The Common Rule" link)];
- The IRB application is deemed non-exempt by the IRB; and
- VT is the primary awardee or coordinating center of the project.

Contract Requirements for Special Review Arrangements

If VT agrees to allow the collaborating institution to rely on the VT IRB's review of a non-exempt protocol funded by any federal department or agency that has adopted the Common Rule [view list of applicable departments/agencies (click on "The Common Rule" link)], then VT and the collaborating institution must enter into a formal agreement.

The collaborating institution must have or apply for a Federalwide Assurance (or similar assurance) to enter into such a review arrangement (called an Authorization Agreement), unless the criteria are met to qualify for an Individual Investigator Agreement.

VT may enter into agreements to rely on other institutions for research review or to cooperate in review. An Authorization Agreement or Memorandum of Agreement is required for such review arrangements if the project is non-exempt and supported by any federal agency or department that has adopted the Common Rule [view list of applicable departments/agencies (click on "The Common Rule" link)].

All review arrangements in which one institution is relying on the review of another are subject to the approval of both institutions, and are only considered under limited circumstances.

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*The term *Off-Site Research* designates research conducted at sites not owned or operated by Virginia Tech, or at sites that do not fall under the VT IRB's authority.

Sponsored / Funded Research (Policy No. 3.01)

The Release of OSP Funds

The Office of Sponsored Programs (OSP) may not release funds for proposals involving human subjects until an IRB approval letter for such human subjects activities has been received. It is the principal investigator's (PI) responsibility to provide OSP with the IRB approval letter that matches the grant proposal / application.

Interim Approval

Interim approval allows for the release of OSP funds prior to the completion of an IRB application and receipt of an IRB approval letter (learn more).

Informing the IRB of OSP Proposal and Grant Numbers

It is the principal investigator's (PI) responsibility to apprise the IRB of the IRB application's related OSP proposal and grant numbers. The IRB application requests such numbers, and if unknown at the time of submitting the IRB application, the PI must email the numbers to the IRB, once available (irb@vt.edu), or enter the numbers using the IRB Protocol Management system.

Federally Funded Proposals

The Office of Sponsored Programs may not release funds for federally funded **non-exempt** studies until the IRB has the opportunity to compare the OSP proposal to the IRB application. In order to compare the two, the IRB must be informed of the OSP proposal number and/or be provided with the grant application / proposal. It is the responsibility of the principal investigator to supply the IRB with such information.

Prior to granting IRB approval, the IRB will compare the two documents for consistency and if found to be satisfactory, will release an approval letter indicating that the comparison has been completed; therefore, OSP may release study funds for study procedures related to human subjects.

If the PI is not informed of the OSP proposal number prior to IRB submission, the IRB may still approve the study and provide the PI with an IRB approval letter. The approval letter may indicate that the study's OSP proposal and IRB application have not been compared for consistency, unless the PI supplies the IRB with a copy of the related grant proposal. Once the OSP proposal number has been generated, OSP will contact the PI to inform him/her of the OSP proposal number. It is then the responsibility of the

PI to apprise the IRB of this number. The IRB will, as applicable, consequently review the IRB application and OSP application for consistency and if found to be consistent, will provide the PI with a second IRB approval letter indicating that the comparison is complete and that OSP may release funds for study procedures related to human subjects.

Allowing IRB Approval to Expire

Investigators who do not receive IRB re-approval or close the study prior to the study's IRB expiration date will receive correspondence from the IRB (departmental heads and OSP may also receive this letter) indicating that the study has expired and that all data collection and analysis must cease. In addition, OSP may receive a formal request from the IRB Chair to freeze funds until the issue is resolved.

Student Researchers (Policy No. 3.02)

A faculty member must be listed as the principal investigator on student's IRB applications. Principal investigators / faculty members are ultimately responsible for the conduct of the research and compliance with IRB determinations, federal and state regulatory requirements, and human participant protection standards.

Faculty members should take an active role in ensuring that projects are conducted in accordance with the IRB's requirements. Meeting periodically with students to review their progress is one way to meet this responsibility.

The Virginia Tech IRB no longer requires that class research projects be approved by the IRB unless there is intention of publishing or disseminating study results. This includes independent class projects, class assignments, and undergraduate research. This does NOT include senior theses and doctoral dissertation research. Research for senior thesis and doctoral dissertation still require IRB approval.

Conflict of Interest (Policy No. 3.03)

As it relates to human subjects research, a conflict of interest is defined as a set of conditions in which an investigator's judgment concerning a primary interest (e.g., subject's welfare, integrity of research) may be biased by a secondary interest (e.g., personal gain).

Researchers are required to report potential conflicts of interest within the appropriate IRB application(s).

A research investigator or IRB member is said to have a conflict interest whenever that investigator or IRB member, his or her spouse, or dependent child falls under any of the following conditions and/or meets the above definition:

1. Is an investigator on the protocol (only applicable to IRB members)

2. Has entered into a financial arrangement with the sponsor or agent of the sponsor, whereby the outcome of the study could influence the value of the economic interest
3. Acts as an officer, director, or agent of the sponsor
4. Has any equity interest in the sponsor exceeding $5,000 or 3% of the equity of the sponsor
5. Has received any payments or other incentives from any sponsor that total in excess of $5,000
6. Has identified him or herself for any other reason as having a conflicting interest

The IRB utilizes the DHHS's latest guidance document for direction on handling reported conflicts of interest.

Note: The VT University Legal Counsel provides information on filing a conflict of interest claim at http://www.ulc.vt.edu/ulc_faq.html#ConflictofInterest.

Scientific Merit (Policy No. 3.04)

In general, it is not the charge of the IRB to comment upon the scientific merit of proposals submitted for review. It is the responsibility of the faculty member listed as principal investigator and department reviewer, if available, to evaluate the research for merit appropriate to the research discipline. The exception, however, is where the scientific merit of the research, or lack thereof, increases either the risks to the subject (directly or indirectly) or the research burden to be borne by the subject. In such cases, the investigator may be referred to his/her advisor (in the case of a student) or to institutional experts for further guidance.

Applicable State of Virginia Laws (Policy No. 3.05)

Child Abuse / Neglect Reporting Requirements:

Section 63.2-1509 of the *Code of Virginia* provides that persons who, in their professional or official capacity, have reason to suspect that a child is an abused or neglected child, shall report that matter immediately to the local department of the county or city wherein the child resides or wherein the abuse or neglect is believed to have occurred or to the Department's toll-free child abuse and neglect hotline.

Section 32.1-162.16 defines the following:

1. "Legally authorized representative" as, in the following specified order of priority,
    - (i) the parent or parents having custody of a prospective subject who is a minor,
    - (ii) the agent appointed under an advance directive, as defined in § 54.1-2982, executed by the prospective subject, provided the advance directive authorizes the agent to make decisions regarding the prospective subject's participation in human research,
    - (iii) the legal guardian of a prospective subject,
    - (iv) the spouse of the prospective subject, except where a suit for divorce has been filed and the divorce decree is not yet final,
    - (v) an adult child of the prospective subject,

(vi) a parent of the prospective subject when the subject is an adult,
(vii) an adult brother or sister of the prospective subject or
(viii) any person or judicial or other body authorized by law or regulation to consent on behalf of a prospective subject to such subject's participation in the particular human research. For the purposes of this chapter, any person authorized by law or regulation to consent on behalf of a prospective subject to such subject's participation in the particular human research shall include an attorney in fact appointed under a durable power of attorney, to the extent the power grants the authority to make such a decision. The attorney in fact shall not be employed by the person, institution, or agency conducting the human research. No official or employee of the institution or agency conducting or authorizing the research shall be qualified to act as a legally authorized representative.

"Human research" means any systematic investigation, including research development, testing and evaluation, utilizing human subjects, that is designed to develop or contribute to generalized knowledge. Human research shall not be deemed to include research exempt from federal research regulation pursuant to 45 C.F.R. § 46.101(b).

"Informed consent" means the knowing and voluntary agreement, without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion, of a person who is capable of exercising free power of choice. For the purposes of human research, the basic elements of information necessary to such consent shall include:

1. A reasonable and comprehensible explanation to the person of the proposed procedures or protocols to be followed, their purposes, including descriptions of any attendant discomforts, and risks and benefits reasonably to be expected;
2. A disclosure of any appropriate alternative procedures or therapies that might be advantageous for the person;
3. An instruction that the person may withdraw his consent and discontinue participation in the human research at any time without prejudice to him;
4. An explanation of any costs or compensation which may accrue to the person and, if applicable, the availability of third party reimbursement for the proposed procedures or protocols; and
5. An offer to answer and answers to any inquiries by the person concerning the procedures and protocols.

"Minimal risk" means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

"Nontherapeutic research" means human research in which there is no reasonable expectation of direct benefit to the physical or mental condition of the human subject.

Online Research Data Collection Activities Involving Human Subjects (Policy No. 3.06)

Approval and Effective Date: July 12, 2010 (Version 3)

VT IRB Policy No. 3.06
VIRGINIA TECH INSTITUTIONAL REVIEW BOARD
Policy for Online Research Data Collection Activities Involving Human Subjects

PURPOSE
The purpose of this policy is to establish requirements for use of secure online data collection systems for human subject research activities (Subpart A below), and the secure transmission (Subpart B below) of data (including personally identifying information) on Virginia Tech (VT) owned or maintained computers, and computers not owned or maintained by VT.

SUBPART A: USE OF SECURE ONLINE DATA COLLECTION SYSTEMS
Human subject research activities conducted by VT researchers involving online* solicitation of participants' personal information (e.g., name, student ID) or anonymous data must utilize one of the following approved online services:

1. www.survey.vt.edu
2. VT Blackboard
3. Other approved service included on the list found at: http://www.irb.vt.edu/pages/validated.htm
4. Other VT service (including self developed software) on a VT machine as reviewed and found secure by VT IT Security (submit a request at http://www.security.vt.edu/)
5. External services only if SSL (https://) or similar encryption is enabled on the login AND all other data collection pages. For basic guidance as to whether SSL is properly enabled on an active online survey, please visit our webpage at: http://www.irb.vt.edu/pages/online.htm. Collaborative research projects in which VT is engaged, however with minor involvement** may use other services as approved by the lead institution's IRB. Collaborative research projects in which the principal investigator is affiliated with VT must comply with the above policy.

SUBPART B: SECURE TRANSMISSION OF DATA
Online research activities (under the purview of the VT IRB) involving the collection of sensitive data from human subjects may not collect identifying information within the same online form. Identifying information must be transmitted and stored (under encryption) separately from data. Online research activities (under the purview of the VT IRB) involving the collection of non-sensitive data from human subjects may collect identifying information within the same online form. Identifying information may be transmitted and temporarily *** stored (under encryption) with data. Online human subject activities include but are not limited to the following: recruitment, enrollment, screening for eligibility, surveys, and experimental procedures.
**Minor involvement encompasses one or more of the following research activities/circumstances: data analysis, consulting investigator, and recruitment. The following activities/circumstances do not constitute minor involvement (list not exhaustive): data collection, research for which a VT individual is the principal investigator.
*** Temporarily means a reasonable amount of time until data can be coded and stored separately.

Retention, Storage and Transfer of Human Subje|cts Research Records (Policy No. 3.07)

Approval and Effective Date: July 12, 2010 (Version 2)

VT IRB Policy No. 3.07
VIRGINIA TECH INSTITUTIONAL REVIEW BOARD
Policy for the Retention, Storage and Transfer of Human Subjects Research Records

PURPOSE
The purpose of this policy is to establish requirements for the retention (Subpart A below), storage (Subpart B below) and transfer (Subpart C below) of human subjects research records (hardcopy and electronic) related to non-exempt IRB protocols.

SUBPART A: REQUIREMENTS FOR THE RETENTION OF HUMAN SUBJECTS RESEARCH RECORDS
In accordance with 45 CFR 46.115(b), records related to research shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives at reasonable times and in a reasonable manner. It is the principal investigator's responsibility to ensure compliance with 45 CFR 46.115(b). Following the minimum 3-year retention of data, direct or indirect identifiable subject information (including the study code key and demographic information that could reasonably identify a subject) must be destroyed in accordance with the IRB-approved protocol. De-identified data may be retained indefinitely. Human subject research records of open VT IRB protocols containing direct or indirect identifiable subject information, including the study code key and demographic information that could reasonably identify a subject, must remain at VT or at the institution/facility specified on the approved IRB research protocol. Requests to move the data must be approved by the VT IRB via a formal amendment. Human subject research records of closed VT IRB protocols, including identifiable subject information may be removed from the VT premises without VT IRB approval; however, must be retained in a manner that will preserve the level of confidentiality promised to subjects.

SUBPART B: REQUIREMENTS FOR THE STORAGE OF HUMAN SUBJECTS RESEARCH RECORDS
During the retention period (see Subpart A above), data, signed consent forms, and other documentation related to human subjects must be stored in accordance with the project's IRB-approved protocol. Access to data, signed consent forms, and other documentation related to human subjects must be limited to those identified on the IRB-approved protocol as having access to study data. All direct identifiable subject information must be encrypted while stored on a computer or electronic external device. In addition, the computer on which direct identifiable subject information is stored must be password protected. When use of study codes is specified within a project's IRB-approved protocol, the following procedures must be adopted to enhance the level of confidentiality provided to subjects:

i. Stored coded data may not include information that could be used to directly identify a subject.
ii. Signed consent forms must be stored separately (i.e., separate computer, separate locked filing cabinet) from coded data.
iii. Signed consent forms and the study code key must be stored in a secure manner; examples include storing on a password-protected computer, in an encrypted manner, or within a locked filing cabinet.
iv. The study code key must be stored separately from coded data. At a minimum, the following standards related to the use of study codes must be implemented, as applicable:

a. Records related to research include but are not limited to consent forms, questionnaires, audiotapes/videotapes, photographs, and health records – regardless of whether the data are de-identified.
b. Authorized representatives include individuals within the applicable department or agency (as defined by 45 CFR 46.102), and the VT IRB.
c. Study code key is defined by the VT IRB as any documentation linking each subject to his/her specific and unique study code.
d. Open includes any protocol wherein data analysis at VT and/or data collection at VT or any involved institution is ongoing.
    1. When storing the study code key and coded data electronically, the study code key and coded data must not be stored on the same computer.
    2. When storing the study code key and coded data as hardcopy documentation, the study code key and coded data must not be stored in the same locked filing cabinet.

SUBPART C: TRANSFER OF HUMAN SUBJECTS RESEARCH RECORDS
If a VT IRB-approved research project (whether open or closed with the VT IRB) is to be fully transferred to another institution or facility, the principal investigator is responsible for (
1. 1 complying with the new institution's policies and procedures;
2. 2 complying with the researcher's VT departmental requirements;
3. 3 retaining research records consistent with human subjects protection regulations; and
4. 4 properly closing the research protocol with the VT IRB.

Collection of Subjects' Date-of-Birth (Policy No. 3.08)

In accordance with Virginia state law, codes 2.2-3801 and 2.2-3803 (listed below), in most cases, subjects' date-of-birth must not be collected for research purposes. However, if the researcher can provide scientific justification as to why that Personally Identifiable Information (PII) is required/necessary to complete the research aims, and the explanation is satisfactory to the IRB, approval may be granted by the IRB to collect that information. **2.2-3801**, Code of Virginia, states, Personal information means all information that

i. describes, locates or indexes anything about an individual including, but not limited to, his social security number, driver's license number, agency-issued identification number, student identification number, real or personal property holdings derived from tax returns, and his education, financial transactions, medical history, ancestry, religion, political ideology, criminal or employment record, or
ii. affords a basis for inferring personal characteristics, such as finger and voice prints, photographs, or things done by or to such individual; and the record of his presence, registration, or membership in an organization or activity, or admission to an institution. **2.2-3803**, Code of Virginia, states, Collect, maintain, use, and disseminate only that personal information permitted or required by law to be so collected, maintained, used, or disseminated, or necessary to accomplish a proper purpose of the agency.

- Paying / Compensating Subjects (Policy No. 3.09)

Introduction

Paying individuals to participate in research has been a controversial issue within the IRB community for many years; however, there are few regulatory guidelines to address this issue.

The Virginia Tech IRB's position is that compensation **may be provided to appropriately compensate subjects for their time, travel, and/or efforts, and may not be used to unduly influence potential human subjects to participate in research activities.**

General Items to Note:

- Compensation **must not be** large enough to be construed as **undue influence**. See below "Compensation Amounts" section for further information.
- Researchers and the IRB must consider the subject pool's **socioeconomics** while reviewing protocols involving payment for research participation.
- If possible, **prorate** compensation based on participation. See below "Prorating Compensation" section for further information.
- Compensation **must not be contingent upon completion of study procedures**. Even if the subject decides to withdraw from the study, he/she must be compensated, at least partially, based on the study procedures he/she has completed.

Informing Subjects of Compensation

In almost all cases, subjects must be fully informed of the amounts, methods, and timing of compensation, including details regarding prorated amounts and the maximum amount that may be received. Such information should be included within any relevant consent forms provided to subjects so they may consider the information before agreeing to participate.

Researchers may also elect to mention compensation within recruitment materials (e.g., flyers, ads). When doing so, refer to acceptable and unacceptable ways to describe compensation within recruitment materials (PDF).

Compensation Amounts

As noted above, compensation **must not be** large enough to be construed as **undue influence**. Unfortunately, there are no set standards for what amount is considered "undue influence."

The IRB often determines* whether a proposed payment amount is reasonable by thinking of the value in terms of an hourly payment. For example, $10 - $20 per hour is typically considered reasonable. Considerations are also made for the extent of participation. For example, subjects may be paid a greater amount for providing a muscle biopsy than for participation in a low-risk interview.

**Decisions regarding payment amounts are made on a case-by-case basis.*

Prorating Compensation

The VT IRB typically requires that compensation provided to human subjects be prorated based on the extent of participation. For example, subjects may receive a pre-determined dollar amount for each study session s/he attends. Another example is providing subjects a pre-determined dollar amount per hour of involvement.

However, at times, prorating compensation is unreasonable. For example, imagine the scenario of paying subjects $5 for the completion of a 20-minute online survey. In this given scenario, it is not reasonable to prorate a $5 amount. In contrast, conducting a three-hour interview session with subjects for a total payment of $30 should be prorated, perhaps at an hourly rate (i.e., $10/hour).

When prorating compensation, if the recruitment materials provided to or viewed/heard by subjects will mention compensation, the range of compensation or "amount per session" must be provided instead of simply listing the maximum amount that could be earned (i.e., if a subject were to complete all of the study activities). For example, if a research project involves three sessions and subjects are paid $50 per session, the recruitment materials should state: "Compensation ranges from $50 to $150" or "You will be compensated $50 per session for a total of $150 possible."

If providing subjects an hourly rate for participation, it is recommended that a cap or upper-limit be applied and that subjects be informed in advance (e.g., within the consent form) of the hourly rate and cap. Use of an upper-limit protects both subjects and researchers as it ensures the compensation amounts are agreed upon by all in advance and it is understood that only a certain amount may be received.

Finally, as noted above, compensation must not be contingent upon completion of study procedures. Even if the subject decides to withdraw from the study, he/she must be compensated, at least partially, based on the study procedures he/she has completed.

Performance-Based Compensation

The IRB carefully considers the ethical implications of research that proposes to provide a subject payment (monetary or other) based on the subject's performance on research tasks (in other words, subjects receive more money if they perform better than other subjects or to a given standard). When sufficient justification is provided for such a payment technique and the IRB approves the process, the IRB recommends and may require that the recruitment and consent materials clearly note that some or all of the payment is performance based.

The following are acceptable and unacceptable methods to describe performance-based compensation within **recruitment materials**:

- **Acceptable:** Include the performance-based dollar amount within the advertisement; however, list it separately from time-based compensation. For example, "You will be compensated $50 for your time and travel, and will have the opportunity to receive up to an additional $20 based on your performance on the research tasks."
- **Acceptable:** Include only the time-based compensation within the advertisement. For example, "You will be compensated $50 for your time and travel." (Note: subjects would be provided details of compensation, including performance-based compensation details, within the consent form.)
- **Unacceptable:** Include the performance-based dollar amount within the total compensation advertised. For example, "Earn up to $120."

Study Completion Bonuses

"Study completion bonuses" are payments assured to subjects should they complete all of the study activities. For example, a study asking subjects to participate in ten in-lab sessions may want to reward subjects a bonus payment if and when the subject completes all ten sessions. This technique is popular for longitudinal studies and, if properly justified and done correctly, may be acceptable to the IRB.

The IRB makes decisions regarding study completion bonuses on a case-by-case basis and is generally accepting of the practice as long as the bonus amount is reasonable and, in most cases, is a small proportion of the study's total payment. See the above "Prorating Compensation" section for more information.

Lotteries

If using a lottery method, the following information should be distributed to research participants (i.e., within consent document, invitation letter or script):

- The potential odds and amount for winning;
- Individual responsible for drawing the winner; and
- Individual responsible for observing the drawing, to ensure that the results are not biased.

Payment for Referrals

As of February 2014, the IRB decided to generally disallow the practice of paying subjects for referring others to the research program. In other words, the practice of paying a subject should they refer a friend, family member, colleague, etc. for participation in a research study is generally not permissible. Note: the IRB's decision does not disallow the practice of referrals altogether, it instead focuses on the ethical concerns of paying subjects for the referrals.

Virginia Tech Policies & Procedures

VT has specific policies and procedures for selecting and paying human subjects participants. Visit the following websites for a description of these policies and procedures:

- Controller's Office: Policy #23715c, Human Subject Selection & Payment
- Bursar's Office: Petty Cash Fund and Disbursement Fund Procedures

Research Involving Pregnant Women, Fetuses, & Neonates (Policy No. 3.10)

Overview

Research involving women who are or may become pregnant during research interventions requires special attention from IRBs because of women's additional health considerations during pregnancy and because of the need to avoid unnecessary risk to the fetus. The Virginia Tech IRB supports a policy of providing pregnant women the same opportunities as non-pregnant women to participate in research unless the exclusion of pregnant women is appropriately justified.

During its review of proposed research, the IRB must judge whether participation as a research subject would pose any potential or suspected risks to pregnant female volunteers and/or their fetuses and, if so, whether the involvement of pregnant women would yield any direct or indirect benefit that would outweigh such risks. In some instances there may be potential or suspected risk sufficient to justify that pregnant women either be specifically excluded from the research or advised to seek consultation from their primary care physician or other qualified health-care provider.

If it is determined that pregnant women should be excluded, the IRB must also assess whether the research team may rely on each female's self-report, or whether validation through a negative pregnancy test is required before female subjects of childbearing potential are involved in study-related activities.

If it is determined that pregnant women will be included, the IRB must assess whether female subjects who are or suspect they are pregnant should be advised to seek their primary care physician's consultation when considering whether or not to participate, and whether the research team should make pregnancy test strips available for female subjects who elect to complete a pregnancy test prior to participation.

To assist the IRB with these determinations and to ensure female subjects are provided sufficient information, the IRB protocol and information provided to subjects (within consent documents and recruitment/screening materials, as appropriate) should include the following:

1. Identified potential or suspected risks the research may present to pregnant women or fetuses,
2. Indication of whether, based on the research team's assessment of risks, pregnant women should be excluded,
3. Indication of whether pregnancy tests will be required of or offered to female subjects of childbearing potential, and

4. If pregnant women are to be included, discussion of whether it will be recommended to women who are or suspect they might be pregnant that they seek consultation from their primary care physician or other qualified health-care provider to discuss participation.

The below sections provide further discussion and example consent form language.

Applicability of Federal Regulations

Per VT's agreement with the Department of Health and Human Services (DHHS), VT is required to comply with 45 CFR 46 Subpart B, "Additional Protections for Pregnant Women, Fetuses and Neonates Involved in Research," for non-Exempt research conducted or supported by the DHHS. For research not conducted or supported by the DHHS, or for Exempt DHHS-supported research, the IRB has flexibility in its decision-making with regard to the inclusion of pregnant women in research.

Research Conducted or Supported by the DHHS

The IRB will approve non-Exempt DHHS funded research involving pregnant women, fetuses and/or neonates if, in addition to meeting all other requirements and review considerations, the research satisfies the conditions of 45 CFR 46 Subpart B.

Including Pregnant Women in Research

As discussed above, pregnant women shall be included in research unless exclusion is sufficiently justified.

When including pregnant women, depending on the nature of the research activities, it may be appropriate to advise women who are or suspect they might be pregnant that they seek guidance from their physician prior to participation. It may also be helpful to provide women with the opportunity to take a pregnancy test prior to participation. The following is sample language to insert into the Risks section of the consent document:

Additional information for women who may be pregnant:

If you know that you are pregnant, or suspect that you may be pregnant, it is recommended that you consult with your personal physician to determine whether you should or should not participate in this study.

If there is a chance that you could be pregnant at the time of your scheduled study participation, but you have not previously confirmed that you are pregnant, it is recommended that you consider using a home pregnancy test (available at pharmacies and other stores as an over-the-counter product) to assess whether you are or are not pregnant. Alternatively, you can request that the research team provide you with a pregnancy test stick, and you can check your urine in a private rest room at the research facility. Regardless of the outcome, you have the right to decide whether you want to participate. You do not need to tell the research team what the outcome is. If you are pregnant and

you choose not to participate, you can simply tell the research team that you have decided that you do not want to participate. No further explanation is needed.

Note that the research team may elect to and/or the IRB may, based on the nature of the research activities, require that the research team have pregnancy test strips and a private location for females to complete the test available for convenience purposes.

Excluding Pregnant Women in Research

The IRB is tasked with the anticipation and evaluation of a wide assortment of risks as they pertain to individuals, groups, and, for purposes of the involvement of pregnant women, fetuses. As part of risk assessment, the IRB regularly evaluates health-related exclusionary criteria, which includes a research protocol's potential to negatively impact the welfare of pregnant women and fetuses. As such, the IRB has the authority to approve protocols wherein pregnancy is listed as an exclusionary criterion and the exclusion is properly justified.

If pregnancy is established as an exclusionary criterion, then the following list of items should be incorporated into the Research Protocol and consent form.

Research Protocol

- Specification that pregnancy is an exclusionary criterion
- Sufficient justification for the exclusion, such as a description of potential or suspected risks to pregnant women and/or fetuses
- The screening process, as described within the protocol, must ensure females are properly informed of the exclusionary conditions and must include pregnancy as an exclusionary factor
- Discussion whether all females of childbearing potential must have a negative pregnancy test before undergoing any study-related activities*

Consent Form (sample language provided below):

- Reminder that pregnancy is an exclusionary criterion
- Explanation of any potential or suspected risks to the pregnant women and fetuses
- If pregnancy testing is required before the study, a description of the requirement and process, and how privacy will be provided
- If pregnancy testing is not required but pregnant test strips will be made available, language explaining the option to take a pregnancy test
- Any other pregnancy-related considerations

*Note that the IRB, following evaluation of the protocol, may require that the research team provide pregnancy tests to all females of childbearing potential to confirm negative results before involvement in study-related activities. If relying on self-report, the research team may elect to and/or the IRB may, based on the nature of the research activities, require that the research team have pregnancy test strips and a private location for females to complete the test available for convenience purposes.

Sample language for the Risks section of the consent form:

Additional information for women who may be pregnant:

Federal regulations governing the protection of human subjects, specifically in a section outlining the limitations in use of pregnant women, state that if a research study provides no direct benefit to the woman, and poses a greater than minimal risk to the developing fetus, then pregnant women must not be included in that research study. The IRB, to ensure compliance with those federal regulations, has determined that pregnant women should not participate in this study.

If there is a chance that you could be pregnant at the time of your scheduled study participation, but you have not previously confirmed that you are pregnant, the IRB recommends that you consider using a home pregnancy test (available at pharmacies and other stores as an over-the counter product) to assess whether you are or are not pregnant. Alternatively, you can request that the research team provide you with a pregnancy test stick, and you can check your urine in a private rest room at the research facility. In either case, you do not have to tell anyone on the research team what the outcome is. If the test indicates that you are pregnant, you can simply tell the research team that you have decided that you do not want to participate. No further explanation is needed.

If you are pregnant, due to the risks identified above, you are ineligible to participate in this particular study.

Definition of Childbearing Potential

Female subjects are considered of "childbearing potential" if they (a) are anatomically and physiologically capable of becoming pregnant and (b) they will be, or could possibly be, engaging in sexual activity with males while study interventions that pose the possibility of harm to a fetus are occurring.

Females who are postmenopausal or who have undergone a hysterectomy or bilateral oophorectomy are not considered of childbearing potential.

Typical Requirements Based on Study Activity

Although the IRB makes pregnancy-related decisions on a protocol-by-protocol basis, the following table represents what the IRB typically requires with regard to exclusion of pregnant women and pregnancy testing requirements based on study activities.

Research Activity	Involvement Criteria	Pregnancy Testing Requirement
Non-physically invasive research (e.g., surveys, interviews, focus groups)	Women shall be included unless scientific justification is provided.	None

MRI/fMRI	Pregnant women may be included but advised to consult physician (view webpage for suggested language)	None
X-ray (DEXA, CT scans)	Pregnant women excluded	Required for females of childbearing potential
Alcohol administration	Pregnant women excluded	Pregnancy testing required by NIAAA
Driving research	View VTTI's guidance document.	
Sensory evaluation (e.g., food tasting)	Pregnant women may be included. It may be appropriate to advise pregnant women to consult physician prior to participation.	None
Slip/fall research	Pregnant women may be included but advised to consult physician.	Pregnancy test strips made available.
Exclusion for scientific reasons only	N/A	Not required

HIPAA PHI Use (Policy No. 3.11)

Research Data Security:
HIPAA Privacy Rule Implementation at Virginia Tech

Receipt, Storage, and Use of Protected Health Information (PHI)

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), and two of its specific rules, the Privacy Rule and the Security Rule, regulates the use and disclosure of Protected Health Information (PHI) held by "covered entities" (generally, health care clearinghouses, employer sponsored health plans, health insurers, and medical service providers that engage in certain transactions).

HIPAA and Research

Virginia Tech researchers, in medical and other health-related disciplines, may rely on access to many sources of health information, ranging from patient medical records and epidemiological databases, to disease registries, hospital discharge records, and government compilations of vital and health statistics (e.g., the Centers for Medicare & Medicaid Services). For this reason, the HIPAA Privacy Rule may impact various areas of research, including clinical research, repositories and databases, and health services research. For example, health services researchers study the organization, financing, and delivery of

health care services, often by analyzing large databases of health care information maintained by providers, institutions, payers, and government agencies.

The responsibility to not knowingly or accidently disclose confidential and/or protected information about research subjects rests on the principal investigator (PI) who designs, leads, or otherwise has responsibility of the investigator-led research. This website provides an overview of the duties and responsibilities of Virginia Tech PIs and their research staff when acquiring, handling, storing and using research subject PHI data.

General Definitions

PHI - The HIPAA Privacy Rule defines protected health information (PHI) as individually identifiable health information that is transmitted or maintained in any form or medium (electronic, oral, or paper) by a covered entity or its business associates, relating to the past, present, or future physical or mental health or condition of an individual. Any data (e.g., demographic data) a healthcare provider stores or transmits is deemed PHI if it identifies a patient even if it doesn't give any insight into their medical history. Specific examples of PHI identifiers are provided below.

Covered Entities - Under HIPAA regulations hospitals, academic medical centers, primary care physicians and specialists, and other health care providers who electronically transmit claims transaction information directly or through an intermediary to a health plan are covered entities. Covered entities can be institutions, organizations, or persons. Researchers are covered entities if they are also health care providers who electronically transmit health information.

Business Associate - A person or entity (e.g., a Virginia Tech researcher or Center/Institute) who, on behalf of a Covered Entity, performs or assists in performance of a function or activity involving the use or disclosure of individually identifiable health information, such as data analysis and quality assurance reviews. For a Virginia Tech PI to gain access to PHI data under HIPAA, that individual must enter into a formal, signed Business Associate Agreement with the Covered Entity.

Business Associate Agreement - A contractual agreement that describes the expectations for and obligations of a Business Associate with respect to protecting the privacy and security of protected health information entrusted to them by the Covered Entity.

Anonymized Data - Anonymization is a process in which PHI elements are eliminated or manipulated with the purpose of hindering the possibility of going back to the original data set. This involves removing all identifying data to create unlinkable data, such that no one, not even the researcher, can connect the information back to the individual who provided it.

De-identified Data - De-identification of data covered by HIPAA is accomplished by stripping the data of common identifiers by one of the following methods: (1) removing the 18 specific identifiers [see the section on *Specific Examples of PHI Identifiers* on this webpage]; or, (2) seeking the expertise of an experienced statistical expert to validate and document that the statistical risk of re-identification is very small. De-identified data may be coded, with a link to the original, fully identified data set kept by an honest broker. Links exist in coded de-identified data making the data considered indirectly identifiable and not anonymized. In order to protect against accidental disclosure, the subject's name or other identifiers should be stored separately from their research data, and replaced with a unique code to create a new identity for the subject.

Limited Data Set- A limited data set excludes most of the 18 PHI identifiers, but may include the following identifiers: city; state; ZIP Code; elements of date; and other numbers, characteristics, or codes not listed as direct identifiers. Since some identifiable information is included, Limited Data Sets are still considered as PHI. A covered entity may use and disclose a limited data set for research activities conducted by itself, another covered entity, or by a researcher who is not a covered entity if the disclosing covered entity and the limited data set recipient enter into a data use agreement.

Data Use Agreement - A data use agreement is a written, signed document, and serves as the means by which covered entities obtain satisfactory assurances that the recipient of the limited data set will use or disclose the PHI in the data set only for specified purposes. Data Use Agreements must be routed through the OSP Contracts team for review and signature on behalf of Virginia Tech. If the covered entity providing the limited data set knows of a pattern of activity or practice by the recipient (e.g., the researcher) that constitutes a material breach or violation of the data use agreement, the covered entity must take reasonable steps to correct the inappropriate activity or practice. If the steps are not successful, the covered entity must discontinue disclosure of PHI to the recipient and notify HHS. Examples of sanctions/penalties associated with noncompliance are provided in a following section.

Specific Examples of PHI Identifiers

The HIPAA Privacy Rule specifies 18 PHI identifiers:

- *Name*
- *Geographic Indicators* street address, city, precinct, zip code, latitude and longitude (GPS) coordinates, etc. the first three digits of the zip code are usually considered ok for use except in the case of certain zip codes which cover a small population (less than 20,000)
- *All elements of dates except year* pertaining to significant events in an individual's life - birth, death, marriage, admission, discharge, etc. Just the year is generally considered fine for use except in the case of the very elderly (>89 years of age)
- *Telephone number*
- *Fax number*

- *Email address*
- *URL address*
- *IP address*
- *Social Security number*
- *Account numbers*
- *License numbers*
- *Medical Record number*
- *Health plan beneficiary number*
- *Device identifiers and their serial numbers*
- *Vehicle identifiers and serial number*
- *Biometric identifiers (finger and voice prints)*
- *Full face photos and other comparable images*
  o e.g. diagnostic images of the head [x-rays/radiographs, CT scans, MRI scans]
- *Any other unique identifying number, code, or characteristic*

Appropriate Transmittal, Receipt, Storage and Use of PHI under HIPAA

Transmittal and Receipt of PHI

- **Via Mail** (USPS, FedEx, UPS, DHL and other physical mailing entities) - The file should be wrapped or sealed in an envelope or pouch in such a manner that the PHI cannot be identified during the transportation process. The outside of the container should contain clear information regarding the addressee, which includes the name, address and telephone number where he/she can be reached. Covered entities should ensure that transported PHI be delivered only to the appropriate individuals who are authorized to receive the information. This can be accomplished by implementing a tracking method by which the sender and the recipient can sign and verify delivery and receipt of the information.
- **Via email**: the text in emails should not include PHI. Files containing PHI should be encrypted before being attached to and sent by email.
- **Via fax**: unless the fax machine is a personal, stand alone device in the Business Associate's own secure office, PHI should not be transmitted by fax.
- **Via internet / file drops**: ensure that files are encrypted prior to transmission.
- **Via social media** - Social Media accounts and social media messaging tools must not be used for exchanging PHI.
- **Receipt of Unsolicited or Improperly Transmitted PHI**: the PI should not open or retain improperly transmitted PHI, and should delete or properly dispose of the materials.

Storage of PHI

- Ensure that devices are password-protected with strong passwords
- Do not share authorized individuals' login name, credentials, or passwords with other individuals
- Avoid storing PHI on portable devices (laptops, tablets, smartphones)
- Encrypted thumb drives and external hard drives are also not recommended and strongly discouraged for storing or transferring PHI or any confidential files.

- Do not store PHI on removable media (e.g., CD or DVD) unless it has been verified that files on such media are fully encrypted

PHI Breach Determination and Notification

Notify the Virginia Tech IRB Administrator IMMEDIATELY of all events that may be potential breaches. Call (540) 231-4358 if you believe ePHI/PHI might have been lost, stolen, compromised, misdirected, etc., to determine what steps to take, and if further notifications are required.

What is a Breach? A breach is defined as the compromise, unauthorized disclosure, unauthorized acquisition, unauthorized access, or loss of control, where persons other than authorized users, or for an other than authorized purpose, have access or potential access to PHI, whether physical or electronic. Issues that should be reported include: lost, stolen, or misplaced records containing PHI; unauthorized personnel seeing or possessing PHI; lost, stolen, or misplaced electronic devices (e.g., tablets or laptops) that contain PHI. Most notifications must be provided without unreasonable delay and no later than 60 days following the discovery of a breach.

What Additional Notifications May Be Required? Under regulations related to HITECH provisions of HIPAA, organizations may be required to notify individuals whose PHI was compromised, the Department of Health and Human Services (DHHS), and in some cases, the media, if the Covered Entity or a Business Associate (e.g., a Virginia Tech researcher or Center/Institute) discovers a breach of unsecured PHI. Notification to organizations outside of Virginia Tech is required if there is a breach and PHI is "unsecured"; notification is not required if there is a breach and PHI is "secured".

Federal Agency Responsible for Enforcement

The federal Department of Health and Human Services (DHHS) Office for Civil Rights enforces the HIPAA Privacy, Security, and Breach Notification Rules. Violations may result in civil monetary penalties. In some cases, criminal penalties enforced by the U.S. Department of Justice may apply.

Common noncompliance issues include:

- Impermissible PHI uses and disclosures
- Lack of PHI safeguards
- Use or disclosure of more than the minimum necessary PHI
- Lack of administrative ePHI safeguards

Examples of Sanctions/Penalties Associated with Noncompliance

The federal Office for Civil Rights (OCR) has made it clear to Covered Entities that Business Associate Agreements (BAAs) must be in place prior to release of PHI, or the entity would face HIPAA penalties.

In March 2016, North Memorial Health Care of Minnesota agreed to pay $1.55 million to settle OCR charges that it violated HIPAA by disclosing PHI to its business associate, Accretive Health, without first executing a BAA. The issue surfaced following the theft of an Accretive employee's unencrypted, password-protected laptop containing PHI of approximately 9,500 individuals. It was the business associate's laptop that was lost, not the covered entity's; nevertheless, the OCR extracted the settlement from the covered entity. The OCR also cited North Memorial's failure to conduct an appropriate risk analysis. In addition to the $1,550,000 payment, North Memorial was required to develop an organization-wide risk analysis and risk management plan, as required under the Security Rule. North Memorial also had to train appropriate workforce members on all policies and procedures newly developed or revised pursuant to this corrective action plan. [HHS Press Office, 3-16-2016; Holland & Hart, 5-12-16]

In April 2016, Raleigh Orthopedic Clinic agreed to pay $750,000 to settle OCR allegations that it violated HIPAA by turning over thousands of x-rays and related protected health information to a vendor without a BAA. The vendor had promised to transfer the x-rays to electronic media in exchange for salvaging silver from the x-ray films. [Holland & Hart. 5/12/16]

Additional recent examples of noncompliance with HIPAA privacy and security rules can be found at:

- CardioNet - $2.5M settlement (2017)
- Memorial Healthcare System (MHS) - $5.5M settlement (2017)
- Children's Medical Center of Dallas - $3.2M settlement (2017)
- St. Joseph Health (SJH) - $2.14M settlement (2016)

Other Applicable Virginia Tech Policies

Policy 7000: Acceptable Use and Administration of Computer and Communication Systems
Policy 7010: Policy for Securing Technology Resources and Services

Virginia Tech HIPAA Training Requirements for Researchers, Staff, and Students

Contact the IRB administrative office to obtain guidance on training requirements for use of HIPAA PHI: irb@vt.edu

Virginia Tech Contact Information for Additional Assistance/Guidance on HIPAA Compliance

For additional information and guidance on research compliance with HIPAA rules, and safeguard control implementation, contact:

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HIPAA PHI Data Security Plan (Policy No. 3.11)

Complying with the HIPAA [PHI Data] Security Rule

The HIPAA Security Rule (45 CFR 164 Sections 302-318) requires organizations (Covered Entities and Business Associates) to identify and implement the most effective and appropriate **Administrative**, **Physical**, and **Technical** safeguards to secure electronic protected health information (e-PHI). All e-PHI created, received, maintained or transmitted by an organization is subject to the Security Rule. In contrast, the HIPAA Privacy Rule sets the standards for who may have access to PHI, and applies to all forms of patients' protected health information, whether electronic, written, or oral.

Virginia Tech researchers proposing to use PHI, to ensure compliance with the Security Rule, should do the following prior to receiving PHI from Covered Entities: assess current information security, risks, and gaps; develop an implementation plan to address PHI data security, including reading the Security Rule, reviewing the addressable implementation specifications, implement solutions, and determining security measures; implement solutions; document the analysis, decisions and the rationale for the decisions; and, reassess periodically.

This webpage provides an overview of the 3 primary safeguards that researchers must implement to ensure the security of PHI under the HIPAA Security Rule.

- Administrative Safeguards
- Physical Safeguards
- Technical Safeguards

Administrative Safeguards

Administrative Safeguards are a collection of policies and procedures that govern the conduct of the workforce, and the security measures put in place to protect ePHI. The administrative components are really important when implementing a HIPAA compliance program, you are required to assign a privacy officer, complete a risk assessment annually, implement employee training, review policies and procedures, and Business Associate Agreements (BAAs) must be in place for researchers who handle protected health information (PHI). The 9 standards associated with Administrative Safeguards are provided below, along with actions that must be implemented by the Business Associate/researcher.

A. Security Management Process

a. **Risk Analysis**: Perform and document a risk analysis to see where PHI is being used and stored in order to determine all the ways that HIPAA could be violated. .
b. **Risk Management**: Implement sufficient measures to reduce these risks to an appropriate level. .
c. **Sanction Policy**: Implement sanction policies for employees who fail to comply. .
d. **Information Systems Activity Reviews**: Regularly review system activity, logs, audit trails, etc.

B. Assigned Security Responsibility

a. **Officers**: Designate HIPAA Security and Privacy Officers.

C. Workforce Security

a. **Employee Oversight**: Implement procedures to authorize and supervise employees who work with PHI, and for granting and removing PHI access to employees. Ensure that an employee's access to PHI ends with termination of employment.

D. Information Access Management

a. **Multiple Organizations**: Ensure that PHI is not accessed by parent or partner/collaborating organizations or subcontractors that are not authorized for access.
b. **ePHI Access**: Implement procedures for granting access to ePHI that document access to ePHI or to services and systems that grant access to ePHI.

E. Security Awareness and Training

a. **Security Reminders**: Periodically send updates and reminders about security and privacy policies to employees.
b. **Protection Against Malware**: Have procedures for guarding against, detecting, and reporting malicious software.
c. **Login Monitoring**: Institute monitoring of logins to systems and reporting of discrepancies.
d. **Password Management**: Ensure that there are procedures for creating, changing, and protecting passwords.

F. Security Incident Procedures

a. **Response and Reporting**: Identify, document, and respond to security incidents.

G. Contingency Plan

a. **Contingency Plans**: Ensure that there are accessible backups of ePHI and that there are procedures for restore any lost data.
b. **Contingency Plans Updates and Analysis**: Have procedures for periodic testing and revision of contingency plans. Assess the relative criticality of specific applications and data in support of other contingency plan components.
c. **Emergency Mode**: Establish (and implement as needed) procedures to enable continuation of critical business processes for protection of the security of ePHI while operating in emergency mode.

H. Evaluations

a. Perform periodic evaluations to see if any changes in your business or the law require changes to your HIPAA compliance procedures.

I. Business Associate Contracts and Other Arrangements

a. Have special contracts with research partners/collaborators who will have access to your PHI in order to ensure that they will be compliant. Choose partners that have similar agreements with any of their partners to which they are also extending access.

Additional information on Administrative Safeguards can be found here.

Additional information on Organizational, Policies and Procedures and Documentation Requirements can be found here.

Additional information on Risk Analysis and Risk Management can be found here and here.

Physical Safeguards

Physical Safeguards are a set of rules and guidelines that focus on the physical access to PHI. In contrast, Administrative Safeguards focus on policy and procedures, while Technical Safeguards focus on data protection. The 4 standards associated with Physical Safeguards are provided below, along with actions that must be implemented by the Business Associate/researcher.

A. Facility Access Controls

a. **Contingency Operations**: Establish (and implement as needed) procedures that allow facility access in support of restoration of lost data under the disaster recovery plan and emergency mode operations plan in the event of an emergency (at Virginia Tech this is the *Continuity of Operations Plan* [COOP]).
b. **Facility Security Plan**:: Implement policies and procedures to safeguard the facility and the equipment therein from unauthorized physical access, tampering, and theft.
c. **Access Control and Validation Procedures**: Implement procedures to control and validate a person's access to facilities based on their role or function, including visitor control, and control of access to software programs for testing and revision.
d. **Maintenance Records**: Implement policies and procedures to document repairs and modifications to the physical components of a facility which are related to security (e.g. hardware, walls, doors, and locks).

B. Workstation Use

a. Implement policies and procedures that specify the proper functions to be performed, the manner in which those functions are to be performed, and the physical attributes of the surroundings of a specific workstation or class of workstation that can access ePHI.

C. Workstation Security

a. Implement physical safeguards for all workstations that access ePHI, to restrict access to authorized users.

D. Device and Media Controls

a. **Disposal**: Implement policies and procedures to address the final disposition of ePHI, and/or the hardware or electronic media on which it is stored.
b. **Media Re-Use**: Implement procedures for removal of ePHI from electronic media (e.g. hard drives, memory sticks) before the media are made available for re-use.
c. **Accountability**: Maintain a record of the movements of hardware and electronic media and any person responsible therefore.
d. **Data Backup and Storage**: Create a (secure) retrievable, exact copy of ePHI, when needed, before movement of equipment.

Additional information on Physical Safeguards can be found here.

Technical Safeguards

Technical Safeguards focus on the technology that protects PHI and controls access to it. The 5 standards associated with Physical Safeguards are provided below, along with actions that must be implemented by the Business Associate/researcher.

A. Access Control

a. **Unique User Identification**: Assign a unique name and/or number for identifying and tracking user identity.
b. **Emergency Access Procedure**: Establish (and implement as needed) procedures for obtaining necessary ePHI during an emergency.
c. **Automatic Logoff**: Implement electronic procedures that terminate an electronic session after a predetermined time of inactivity.
d. **Encryption and Decryption**: Implement a mechanism to encrypt and decrypt ePHI.

B. Audit Controls

a. Implement hardware, software, and/or procedural mechanisms that record and examine activity in information systems that contain or use ePHI.

C. Integrity

a. **Mechanism to Authenticate ePHI**: Implement electronic mechanisms to corroborate that ePHI has not been altered or destroyed in an unauthorized manner.

D. Authentication

a. Implement procedures to verify that a person or entity seeking access to ePHI is the one claimed.

E. Transmission Security

a. **Integrity Controls**: Implement security measures to ensure that electronically transmitted ePHI is not improperly modified without detection until disposed of.
b. **Encryption**: Implement a mechanism to encrypt ePHI whenever deemed appropriate.

Additional information on Technical Safeguards can be found here.

Virginia Tech Contact Information for Additional Assistance/Guidance on HIPAA Compliance

For additional information and guidance on research compliance with HIPAA rules, and safeguard control implementation, contact:

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Training in the Protection of Human Subjects - Policies

The training policy below has been replaced by HRP-010 Human Research Protections Training Requirements.

~~TRAINING OPTIONS (Accepted Training) (Policy No. 4.00)~~

~~To satisfy Virginia Tech IRB training requirements, investigators may choose one from the following list:~~

~~VT IRB Tutorial~~

~~The VT IRB Tutorial is entitled "VT Human Subjects Protection Tutorial", and is available online to everyone (not just VT individuals).~~

~~Individuals who successfully complete the tutorial (including 10 question quiz) will be presented with a certificate of completion.~~

~~Training from Outside Institutions~~

~~The Virginia Tech IRB accepts the training of any other institution as long as there is sufficient documentation of the completion of such training. Appropriate documentation (e.g., certificate, correspondence from IRB office or institution at which training was completed) must be submitted to the IRB office before a new application or amendment is submitted. NIH's online tutorial is an excellent option for human subject protections training.~~

Training Requirements (Policy No. 4.01)

Although the human subjects protections training mandate from the HHS applies only to NIH grants and contracts, the VT policy extends this mandate to include all human subjects research under the VT IRB's purview (see Policy No. 2.03: *Purview of the VT IRB*).

All investigators (including researchers from other institutions and independent researchers), originally listed on an approved IRB application or later added to the project through an amendment, must provide the IRB with documentation of the completion of human subjects protections training, unless the IRB has verification of prior training within its records.

It is the Principal Investigator's responsibility to ensure all members of the research team who interact with research subjects, or collect or handle human subjects data have completed human subjects protection training prior to interacting with subjects, or handling or collecting the data. This includes team members (graduate students, undergraduate students, etc) who code recordings (e.g., video or audio recordings), observe research activities, and/or enter data.

Training need not be renewed unless specifically required by the VT IRB or outside institution.

Training Verification (Policy No. 4.02)

Completion of appropriate training is verified automatically* by the IRB Protocol Management (PM) system for all investigators listed on new applications and amendments. Note: if the amendment is to a research protocol initially submitted before the implementation of the IRB PM, verification is completed manually by the IRB office using the IRB PM training database.

Investigators who do not complete human subjects protection training and/or submit documentation of their successful completion of appropriate training before an IRB application is submitted to the IRB office will not be an approved investigator on the project. To be added as an investigator after the application has been submitted to the IRB office, an amendment must be submitted only after the initial application receives approval from the VT IRB.

*Automatic verification is performed by cross-checking the IRB PM training database. The IRB PM training database contains a completion date and training type for all previous and current investigators/users. Such dates are pulled automatically for users who complete the online VT Human Subjects Protection Tutorial quiz. All other training data are manually entered into the IRB PM training database by the VT IRB office upon receipt of training documentation.

Retention of Training Documentation (Policy No. 4.03)

VT Human Subjects Protection Tutorial (hardocpy and online):

Online quiz version: The date of successful completion is automatically stored in the IRB Protocol Management training database. Quiz results are graded automatically and are not retained. Certificates sent to users are not saved by the IRB office, but can be regenerated upon request.

Manual quiz version: Completed quizzes are retained by the IRB office. Certificates sent to users are not saved by the IRB office, but can be regenerated upon request.

In-Class Training by IRB Chair:

Certificates sent to users are not saved by the IRB office, but can be regenerated upon request. The IRB office retains class rosters.

Training from Outside Institutions:

The IRB retains the documentation submitted by the investigator as verification of successful completion of the training.

Virginia Tech Human Subject Protections Tutorial (Policy No. 4.04)

As one of the options for human subject protections training, the VT IRB offers an online tutorial accessible to both VT and non-VT individuals: Virginia Tech Human Subject Protections Tutorial.

Successful completion (score of 70% or higher) of the tutorial's quiz is necessary to receive a certificate of completion. Tutorial grading and certificate generation is automated. Users will receive their certificate via email. Record of successful completion is retained in the IRB Protocol Management system's training database.

Training for IRB Members and IRB Staff (Policy No. 4.05)

IRB members and staff are provided with training that provides information and copies of, links to, or access to the following information:

1. VT IRB Policies, Procedures, & Guidance Manual
2. VT Human Subjects Protection Tutorial
3. Amdur, R. (2003 or 2007). *Institutional Review Board: Member Handbook*. Massachusetts: Jones and Bartlett Publishers.
4. Education items distributed with agenda items (not always on a monthly basis)

Attendance at regional and national meetings, such as PRIM&R and AAHRPP are encouraged and supported for staff members, as appropriate.

Initial IRB Review

Requirements for Initial Review (Policy No. 5.00)

Initial review application materials must be submitted using the IRB Protocol Management system, and include information in sufficient detail in order for the IRB to make the determinations required under HHS regulations at 45 CFR 46.111.

The application should include the below-listed items. The IRB retains final authority to require additional information (even for exempt protocols), or determine that sufficient information is included in the original submitted application that excludes one or more of the below-listed items.

Application Materials:

- Research Protocol or Existing Data Research Protocol
- Proposed informed consent document (unless consent is to be waived by the IRB or the project is deemed exempt)
- Additional study documents related to human subjects including data collection instruments and recruitment materials*
- Any relevant grant application(s) for federally-funded, non-exempt protocols
- Bio-sketch or CV for all investigators

Training requirements specified under Policy No. 4.01 must also be satisfied.

*Guidance is available on the VT IRB website related to the development of recruitment materials and methods for protecting confidentiality or anonymity.

Guidance is also available for conducting research on a variety of topics (e.g., research involving children, pregnant women, sensitive or illegal information) on our Researchers webpage.

Submission Deadlines (Policy No. 5.01)

Protocols requiring full review (i.e., review by the Board at a convened meeting) must adhere to deadlines as described under Policy 2.07. There are no deadlines for protocol qualifying for Exempt or Expedited review; however, it is the responsibility of the investigators to allow sufficient time for the IRB to review/approve a protocol before the commencement of human subject activities.

Research Determinations (Policy No. 5.02)

Principal investigators make the determination as to whether a project requires IRB review by using the Activities Requiring Approval flowchart.

Any questions about the applicability of the definition of human subjects research, jurisdiction of the VT IRB, or otherwise relating to necessity of review are directed to the administrator or Chair. The Chair and/or administrator will make the final determination based upon the definition of human subjects

research, as stated in 45 CFR 46. As necessary, the IRB may consult with OHRP for policy guidance or the OHRP decision charts for human subjects research.

The IRB formally notifies the PI in writing when a submitted protocol does not qualify as research as defined by 45 CFR 46.

Departmental Review (Policy No. 5.07)

The University allows each department and/or distinct research unit to create a departmental review system that best meets its needs. Some departments / research units at Virginia Tech do not utilize a departmental review system. It is the individual department decision to implement and require IRB submissions to be reviewed and approved by the departmental reviewer prior to submission to the IRB. The IRB office holds a list of departments requiring departmental review, which may be found A) (not publicly accessible) on IRB Protocol Management using a program administrator's account ("Manage Reviewers" link), or B) within the Frequently Asked Questions (note: must sign in before viewing) page while completing an online IRB application.

Typically, a departmental review system consists of one faculty member or department head responsible for the review, approval and overview of the project being conducted through the department. This individual is the departmental reviewer. The purpose of the departmental reviewer is to provide first tier review of human subjects research by investigators of similar training. Thus, scientific merit, and relevant research design are considered important questions to be asked by the departmental reviewer. While departmental reviewers are encouraged to provide direct review of the research protocol and informed consent process, departmental reviewers do not make final decisions about IRB-related determinations.

IRB Protocol Management directs new applications for which the principal investigator is affiliated with a department requiring departmental review to the appropriate departmental reviewer prior to submittal to the IRB. Once the departmental reviewer departmentally approves the new application, the new application is automatically submitted to the IRB.

Appeal of Decisions Made by the IRB (Policy No. 5.08)

Approvals, favorable actions, and recommendations made by the IRB are subject to review and further restriction by the institutional administration (VP for Research, President). For example, protocols could be approved by the IRB on a scientific and ethical basis, but be restricted or disapproved by institutional administration due to the potential for adverse public/community reaction. Protocol disapproval, restrictions or conditions imposed by the IRB upon any activity involving human subjects cannot be rescinded or removed except by subsequent action of the IRB.

Exempt Research Review (Policy No. 5.03)

The IRB reviews and approves research under three distinctive categories, specified by federal regulations: Exempt, Expedited, and Full IRB Research Review.

Exempt Research Review (Policy No. 5.03)

- Exempt human subject research projects may be reviewed by the IRB Chair or designee, and do not require full Board review.
- There are no deadlines for IRB applications qualifying for Exempt Review.
- Obtaining written, signed consent from research participants is not required by federal regulations; however, certain departments (e.g., psychology) or the IRB may require written consent even for exempt research.
- The IRB holds the authority to recommend or require modifications to submitted IRB materials in the interest of protecting human subjects.
- IRB approval does not expire; therefore, continuing review is not required.
- Modifications to the research protocol must be approved by the IRB prior to implementation (except where necessary to eliminate apparent immediate hazards to subjects) to ensure the research continues to meet Exempt status.
- It is the researchers' responsibility to report promptly to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.
- Once approved, involved researchers are notified of the Exempt status via an official Exempt approval letter sent via e-mail.

What Qualifies for Exempt Review?

To qualify for Exempt Review, the research must meet **all** of the following criteria:

- Must not involve pregnant women, prisoners or mentally impaired persons;
- Must not include survey research with minors unless involving standard educational activities (e.g., educational tests) within the particular education system;
- Must not include observation of a minor's public behavior unless there is no researcher interaction;
- Research must not involve video or audio recording of subjects; and
- **Must be in one or more of the following categories:**

Categories for Exempt Review

1. Research will be conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research will involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, **unless** the subjects can be identified directly or through identifiers linked to the subjects **and** disclosure of responses could reasonably place the subjects at risk or criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.

3. Research will involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under item (2) above, **if** (a) the subjects are elected or appointed public officials or candidates for public office; **or** (b) Federal statute(s) require(s) that the confidentiality or other personally identifiable information will be maintained throughout the research and thereafter.
4. Research will involve the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.
5. Research and demonstration projects which are conducted by or subject to the approval of federal agency sponsoring the research, and which are designed to study, evaluate or otherwise examine (a) public benefit or service programs, (b) procedures for obtaining benefits or services under those programs, (c) possible changes in or alternatives to those programs or procedures, or (d) possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies, if (a) wholesome foods without additives are consumed, or if (b) a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Expedited Research Review (Policy No. 5.04)

- An expedited review procedure consists of a review of research involving human subjects by the IRB Chairperson or by one or more experienced reviewers designated by the Chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.
- There are no deadlines for IRB applications qualifying for Expedited Review.
- IRB approval will be granted for a determined length of time not to exceed one year. The IRB approval expiration date will be specified in the approval letter. Continuing review is required for re-approval if the research is to continue beyond the expiration date.
- Unless waived by the IRB, signed consent must be obtained from all subjects prior to their involvement in the research.
- The IRB holds the authority to recommend or require modifications to submitted IRB materials at any time.
- Modifications to or additions/deletions of human subject research-related documents (including the research protocol) must be approved by the IRB prior to implementation (except where necessary to eliminate apparent immediate hazards to subjects).
- It is the researchers' responsibility to report promptly to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.
- Once approved, involved researchers are notified of the Expedited approval via an official Expedited approval letter sent via e-mail.

What Qualifies for Expedited Review?

To qualify for Expedited Review, the research must meet **all** of the following criteria:

- Be of minimal risk (see definitions, below) to the subjects;

- Must not involve pregnant women, prisoners or mentally impaired persons;
- **Involve only procedures listed in one or more of the following categories:**

Categories for Expedited Review

1. Clinical studies of (a) drugs for which an investigational new drug application is not required (Note: research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review), or (b) medical devices for which an investigational device exemption application is not required; or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds (Note: amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than two time per week) or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected (Note: amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an eight week period and collection may not occur more frequently than two times per week).
3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) Hair and nail clippings in a nondisfiguring manner; (b) Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) Permanent teeth if routine patient care indicates a need for extraction; (d) Excreta and external secretions (including sweat); and (e) Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) Placenta removal at delivery; (g) Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) Sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinoraphy, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight and health of the individual.
5. Research involving materials (data, documents, records or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language communication, cultural beliefs or

practices, social behavior), or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Full IRB Research Review (Policy No. 5.05)

- A project that involves greater than minimal risk (see definition, below) requires approval by an IRB panel, the Board, composed of members qualified to review research in that field. The Board typically meets once per month.
- There are deadlines for IRB applications requiring Full IRB Review. View deadlines.
- IRB approval will be granted for a determined length of time not to exceed one year. The IRB approval expiration date will be specified in the approval letter.
- Continuing review is required for re-approval if the research is to continue beyond the expiration date. The continuing review request must be reviewed by the Full IRB at its monthly meeting unless one of the following applies: 1) the research is permanently closed to the enrollment of new subjects; all subjects have completed all research related interventions; and the research remains active only for long-term follow-up of subjects; or 2) where no subjects have been enrolled and no additional risks have been identified; or 3) where the remaining research activities are limited to data analysis; or 4) continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories for expedited approval do not apply, but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.
- Unless waived by the IRB, signed consent must be obtained from all subjects prior to their involvement in the research.
- The IRB holds the authority to recommend or require modifications to submitted IRB materials at any time.
- Modifications to or additions/deletions of human subject research-related documents (including the research protocol) must be approved by the IRB prior to implementation (except where necessary to eliminate apparent immediate hazards to subjects).
- It is the researchers' responsibility to report promptly to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.
- The Board's decision to contingently approve, table, or disapprove a protocol will be communicated to the investigators via e-mail, which will specify the reasons for the decision and proposed actions/revisions, as applicable.
- Once approved, involved researchers are notified of the Full IRB approval via an official approval letter sent via e-mail.

What Types of Research Require Full IRB Review?

Research that requires full committee review may include one or more of the following:

- Prisoners
- Pregnant Women
- Fetuses
- Human in Vitro Fertilization
- Mentally Disabled Persons
- Microwaves or X-Rays

- General Anesthesia or Sedation
- Poses greater than minimal risks to subjects (unless qualifying for Exempt review)
- Vulnerable Populations (see definitions, below)

This list is not exhaustive. The final decision as to whether an application is reviewed by the Board at a convened meeting is that of the IRB Chair and/or Board.

Definitions

Minimal Risk

Minimal risk means that the probability and magnitude of the harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Vulnerable Populations

Individuals whose willingness to volunteer in a study or clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces (i.e., ROTC or Corps of Cadets), and persons kept in prison or detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

Failure to Submit an Acceptable Protocol or Implement Required Revisions (Policy No. 5.06)

About IRB Applications

What is Interim?

The Dilemma

When applying to the IRB, a researcher must have developed his or her study documents to allow thorough review by the IRB. Sometimes, researchers will seek sponsored funding from external organizations with the intent to: (1) develop the research plan using a portion of the funding, then (2) subsequently submit a developed protocol to the IRB for approval. Since an IRB approval letter is required to obtain funds, this presents a serious dilemma - the researcher cannot develop the human subjects research protocol without the funding; however, OSP has been told not to release funding without IRB approval.

The Solution

The IRB may grant interim approval for studies needing the release of funds for study procedures not involving human subjects (e.g., designing survey instruments, developing the study design, etc.).

Granting Interim approval is supported by 45 CFR 46.118.

Note regarding NSF grant proposals: It has been the IRB's experience that NSF rarely accepts Interim approval letters, and will typically only make the consideration if the grant proposal clearly indicates that the first year of the project will be required for the development of the protocol for human subjects. Contact your NSF Administrator for further information.

Amendments to Protocols (Policy No. 6.01)

Once the IRB has approved a **non-exempt** project, it must be carried out as planned/described in the original IRB submission package. Any changes to the IRB application must be approved by the IRB prior to implementation of changes, unless it is in the best interest of research participants. Examples of changes to the IRB application include changes in subject population, recruitment plans, research procedures, study instruments, consent form language, and wording within study instruments. Along with any additions to study procedures or study instruments, the IRB must approve the removal of study procedures or study instruments.

Proposed changes to the research protocol of **Exempt** protocols must be submitted to the IRB and approved prior to implementation.

Continuing Review Requests (Policy No. 6.00)

In accordance with federal regulations, the IRB may approve a non-Exempt protocol for no greater than one year. If the research is to continue beyond the assigned approval expiration date, the IRB must reevaluate the protocol based on any new information available, including the protocol's progress, and re-approve the protocol for another term. This re-approval process is called "continuing review," and the protocol's progress is reported to the IRB by the research team via a "continuing review request." Following receipt of a continuing review request, the IRB determines whether the research protocol may be re-approved for another term (typically another one-year period), and whether any changes to the protocol are necessary.

All Expedited and Full Review protocols must either receive continuing review approval or be reported as closed prior to the protocol's expiration date (see "When is Continuing Review Required?" to help you decide whether to close or continue your protocol). A protocol's expiration date is located on the IRB approval letter.

If continuing review is not approved by the IRB prior to the expiration date, activities involving human subjects must cease immediately. Human subjects activities may continue on an expired protocol only if

it is in the best interest of study participants; however, such occurrences (including justification) must be reported to the IRB immediately.

When is Continuing Review Required?

Continuing review is not applicable for Exempt research. Exempt research does not expire.

Continuing review is required **unless** data collection at all sites is complete AND data analysis at Virginia Tech is complete. If you are still analyzing or using data for any type of research write-up (e.g., dissertation paper, journal publication, etc.), the study must be re-approved by the IRB.

If data collection at all sites is complete and data analysis at Virginia Tech is complete, you may report the study as "closed" at any time using our online system, IRB Protocol Management.

If, after the study is closed, there is a desire to reanalyze the data, the protocol must be re-opened (see below "How Do I Re-Open a Closed or Expired Protocol?" for further information).

Allowing a Protocol to Expire

Failure to report your project as closed or have your study re-approved on or before the study's expiration date will result in the issuance of an expiration letter that will be sent to you, and possibly your Department Head, Dean, OSP, sponsoring agency, and the Office for Human Research Protections (OHRP).

The expiration letter will serve as notification that subject enrollment, and use of and collection of data from existing subjects must be halted. Researchers are encouraged to contact the IRB office (irb@vt.edu) immediately upon receipt of an expiration letter.

Federal regulations make no provision for any grace period extending the conduct of research beyond the expiration date of IRB approval. Data collected in the interim period prior to re-approval will typically not be approved for analysis or publication purposes.

Issuance of an expiration letter may result in a compliance audit of all research conducted under the principle investigator and/or further sanctions. For funded projects through OSP, issuance of an expiration letter may result in a halt of funds.

Incomplete re-approval submission packages will be sent back to the principal investigator. This may result in a late submission and expired protocol.

How Do I "Re-Open" a Closed or Expired Protocol?

If no longer than one year has passed since the protocol expired or was properly closed, submit a request for continuing review. With your application for continuing review inform the IRB office as to whether any human subjects activities have occurred under the protocol during the lapse of IRB approval.

If it has been longer than one year since the protocol expired or was properly closed, submit a new application. If the protocol is being "re-opened" for data analysis purposes only, the new protocol may simply cover the data analysis activities.

Reminder Emails Sent by the IRB Office

For Expedited and Full Review research, the IRB office will typically send 2 reminder emails (approximately one four weeks prior and the other two weeks prior to the study's Continuing Review Due Date). However, the responsibility to obtain re-approval (i.e., continuing review approval) prior to the study's expiration date is that of the research team.

Continuing Review for Expedited Protocols

If a protocol is approved under the Expedited category, and the level of risk to subjects has not increased, then the IRB Chair is authorized to provide re-approval of the project.

Continuing Review for Full Review Protocols

For protocols approved under Full Review (i.e., reviewed and approved by the Board members during a convened meeting), the continuing review request must be reviewed by the IRB at a convened meeting (held monthly) unless one of the following applies:

1. The research is permanently closed to the enrollment of new subjects, all subjects have completed all research related interventions, and the research remains active only for long-term follow-up of subjects.
2. Where no subjects have been enrolled and no additional risks have been identified.
3. Where the remaining research activities are limited to data analysis.
4. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories for expedited approval do not apply, but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Deadline = Two weeks before the monthly Board meeting at which the research must be reviewed and approved so as not to expire (the Board typically meets the second Monday of each month). See approval letter for the expiration date and continuing review due date.

The IRB has the authority to conduct any of the following actions on a continuing review request:

- Approve for continuation
- Contingently approve* (if explicit clarifications are required)
- Table (if general clarifications are required
- Disapprove continuation

*Consistent with OHRP guidance item G3, when the Board contingently approves a continuing review request, the protocol is authorized to continue for another term while the contingencies are pending unless otherwise noted by the Board. The researcher is, however, required to respond to the Board's

contingencies within a reasonable period of time. Failure to respond to the Board's contingencies may result in suspension of the research by the IRB Chair or full Board.

Why is Continuing Review Required?

The goals of continuing review are to ensure that the risk/benefit ratio is still acceptable, that the measures taken to safeguard subjects are adequate, that the approved protocol is being followed, and that the project reflects any changes that have been made in the regulations for human subjects research since the last approval.

IRB review of proposed research is an ongoing process, not a one-time step. Regular reevaluation ensures that research is conducted responsibly. Even in responsibly conducted studies, a one-time review is inadequate, since the risks can really be understood only after research has begun, and since the regulations for human subjects research are constantly being refined as the risks and benefits are better understood. Unexpected developments and new findings in a project can raise questions about the conduct of the research. Periodic review by researchers and the IRB helps in assessing risks and maintaining a favorable risk/benefit ratio.

The Department of Health and Human Services (DHHS) Regulations, Title 45 Code of Federal Regulations Part 46 (45 CFR 46), require at Section 46.109(e) that "an IRB shall conduct continuing review covered by this policy at intervals appropriate to the degree of risk, but not less than once per year... ." OHRP interprets "not less than once per year" review to mean review on or before the 1-year anniversary date of the previous IRB review required by 45 CFR 46, even though the research activity may not begin until some time after the IRB has given approval. OHRP guidance on Continuing Review.

Greater Than Annual Continuing Review

The IRB may determine that a protocol needs to be reviewed more frequently than annually. The approval timeframe determined by the IRB is reflected in each approved protocol's approval letter. The frequency of continuing review is to be determined by the IRB appropriate to the protocol under review. The IRB may require more than annual review because of any of the following:

1. Noncompliance history
2. Marginal risk / benefit ratio
3. As necessitated by protocol

Identification and Reporting of Unanticipated Problems / Adverse Events (Policy No. 6.02)

If a sponsor funds or supports the study, then the Principal Investigator is responsible for notifying the sponsor of any adverse events. If the study is a multi-site project, the PI is responsible for notifying the other sites, as appropriate. Similarly, if the study is a multi-site project, and the unanticipated problem occurs at a site other than the University, then the PI must notify the VT IRB.

Serious unanticipated problems will be reviewed and handled by the full IRB, whereas minor unanticipated problems will be reviewed and handled by the IRB Chair.

What Do I Need to Report to the IRB & When?

Unanticipated Problems

When a participant or researcher in a research study experiences an unanticipated problem, the Principal Investigator (PI) must report this incident to the IRB within **5 business days**. A summary of the unanticipated problem must be submitted to the IRB using the Adverse Event Report form (above).

The University defines an unanticipated problem as new findings or unexpected events whose nature, severity, and frequency are not described in the information provided to the IRB or to study participants.

The University defines an unanticipated problem as any of the following:

- An actual unforeseen harmful or unfavorable occurrence to participants or others that relates or possibly relates to the research protocol (injuries, psychological harm)
- An unforeseen development that potentially increases the likelihood of harm to participants or others in the future
- Breach of confidentiality or privacy
- A participant complaint about research procedures
- Unexpected risk that is not listed in the consent form

Serious Unanticipated or Anticipated Problems

Notify the VT IRB of any serious unanticipated or anticipated problems **via email within 24 hours** of becoming aware of the occurrence, and follow-up with a detailed summary of the problem using the Adverse Event Report form within **5 business days.**

Serious = Results in death, is life threatening, requires inpatient hospitalization or prolongs existing hospitalization, results in persistent or significant disability/incapacity, cancer, overdose or is congenital anomaly/birth defect; reportable event even if identified in current investigator brochure/protocol.

See below section for examples of serious problems.

Deviations from IRB Approved Procedures or Documents

Notify the VT IRB of any deviations from IRB approved study procedures or documents within 5 business days of becoming aware of the deviation by submitting an unanticipated problem report through protocol management system. This makes it easier for tracking for both the researchers and the office.

If you are unsure if you should submit a report or your deviation spans multiple protocols, please contact the Post Approval Monitoring Specialist, Andrea Nash, at anash@vt.edu.

Minor Anticipated Adverse Events

Minor anticipated adverse events (adverse events described in the risks section of the consent form) are to be reported during the continuing review process.

Potential Responses from the IRB to the Report

The IRB Chair will send a response to the principal investigator regarding possible actions, which could include:

- Acknowledge report, no further action required;
- Request additional information;
- Request a meeting with principal investigator and/or other parties;
- Monitor the study for additional adverse events;
- Recommend a change in the IRB Application/protocol and/or consent form(s);
- Determine if current subjects need to be informed of adverse event;
- Determine if actions taken by the investigator adequately addressed the adverse event or request further actions to be administered by the investigator;
- Temporarily suspend enrollment and/or study treatments pending the collection of additional information;
- Permanently suspend enrollment and/or study treatments.

Examples of Serious Problems

Physical Harm

Exercise Studies:

* Fainting;
* Joint injuries;
* Spinal injuries;
* Stress fractures;
* Heart attack;
* Stroke;
* Miscarriage of pregnancy;
* Any problems requiring intervention by a physician

Ergonomic Studies:

* Joint injuries;
* Stress fractures;
* Prolonged muscle pain (> 3-4 days);
* Injury to head, neck, spine, limbs, hands, or feet;

* Miscarriage of pregnancy;
* Any problems requiring intervention by a physician

DXA Scans:

* Female participants discover after the fact that they were pregnant at the time of the scan;
* Miscarriage of pregnancy;
* Birth of a child with congenital defects subsequent to participation in a study

Transportation / Driving Studies:

* Vehicle accidents resulting in injury to subjects and/or vehicle occupants and/or other individuals;
* Any vehicle accident regardless of initial determination of "no injuries"

Blood Collection:

* Fainting;
* Uncontrolled bleeding after venipuncture;
* Evidence of acute nerve injury/damage

Interpersonal Actions:

* Spousal/partner/child abuse following involvement in a study where these actions might be triggered;
* Peer bullying of children involved in or who decline participation in studies

Psychological Harm

Significant emotional responses/reactions including, but not limited to:

* Inconsolable crying;
* Extreme sadness; depression;
* Rage (directed toward researcher, self, or others);
* Indication of suicidal thoughts;
* Self-mutilation or self-abuse;
* Alteration in family relationships as a result of participating (or deciding to not participate) in studies;
* Inadvertent disclosure of non-paternity;
* Lowered self esteem or other psychological problems related to failure to be selected for a study (after screening);
* Aggravation of psychological condition when placed on a wait list where standard or experimental treatment is not readily provided

Social Harm

Subsequent to participation:

* Ostracism/expulsion from civic, social or religious groups;
* Stigmatization/persecution because personal information revealed or "deduced" (i.e., HIV positive, infection with sexually transmitted diseases [STDs], sexual preference, past crimes/offenses, mental illness);
* Student complaints about pressure to participate or of being penalized for deciding to not participate;
* Damage to the doctor/patient relationship;
* Minor "thrown out" of parent's house;
* Permanent expulsion of minor or adult students from school/educational institution

Economic Harm

Prior to participation: loss of income while being placed on a wait-list

Subsequent to participation:

* Loss of job;
* Loss of business/clientele;
* Loss of state or federal benefits;
* Loss of health benefits or significant increase in health insurance costs post-participation

Legal Harm

Subsequent to participation

* Arrest or incarceration because personal information revealed or "deduced";
* Civil suits directed toward subject because personal information, revealed or "deduced", is claimed to have harmed someone outside of the study (i.e., slander/defamation of character, "discovery" of repressed memories of physical or sexual abuse leading to civil or criminal actions, falsification of job applications alleged if past "history" revealed)

Reporting a Project Closed

You may report an Expedited or Full Review project as closed if data collection at all sites is complete AND data analysis at Virginia Tech is complete. If you are still analyzing or using data for any type of research write-up (e.g., dissertation paper, journal publication, etc.), the study should not be closed. Exempt projects do not need to be closed.

A project can be closed at any time using the IRB Protocol Management system (see link at end of this page). You will be prompted by the IRB office a month prior to the project's IRB approval expiration date to renew your IRB approval or report your project closed.

Once you report your project closed using the IRB Protocol Management system, you will not hear back from the IRB office (in other words, the closure does not need to be approved by the IRB).

To begin any of the above applications, go to IRB Protocol Management.