



Conducting Research with Human Subjects



WHAT EVERY GRADUATE STUDENT AND FACULTY ADVISOR SHOULD KNOW ABOUT THESIS AND DISSERTATION RESEARCH INVOLVING HUMAN SUBJECTS

Office for the Protection of Human Research Subjects (OPHR)
East Tennessee State University
James H. Quillen Veterans Affairs Medical Center
Institutional Review Boards

The federal regulations governing research that involves human subjects probably affect the work of more faculty, staff, and students at ETSU and the VA than any other research compliance requirement. At the same time, the provisions of those regulations and the system of review that they mandate are complex. The ways in which we can interact with human beings in the course of research are so varied that to standardize procedures for every possible encounter would be at best difficult, if not impossible.

To the researcher meeting the system of review for the first time, the regulations and procedures, and the language they use, may seem foreign and complicated. Therefore, the Office for the Protection of Human Research Subjects, the East Tennessee State University Institutional Review Board (ETSU IRB - Non-Medical) and the East Tennessee State University / James H. Quillen Veterans Affairs Institutional Review Board (ETSU/VA IRB - Medical) have produced this booklet in the hope of addressing some of the most frequently asked, broad questions on the subject of conducting human subject research. After reviewing the material, please contact the Office for the Protection of Human Research Subjects should you require further assistance. As gatekeepers for the protection of potential research participants and partners in research, it is our desire to provide the researcher maximum assistance within the framework of the review system provided by institutional policies, state and local laws, federal mandates, and best practices in applied research ethics and human subject research.

This is just an overview. For more details, consult the IRB Policies & Procedures and/or the Investigator's Handbook.

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WHAT SHOULD GRADUATE STUDENTS AND THEIR ADVISORS KNOW ABOUT THESIS AND DISSERTATION RESEARCH INVOLVING HUMAN SUBJECTS?

To receive a graduate degree from East Tennessee State University (ETSU), the completion of all requirements for that degree are required. In addition to the prescribed academic program demands, these requirements include fulfillment of all institutional obligations and compliance with all applicable regulations imposed upon the University. If the research that contributes to the thesis or dissertation involves human subjects, however slightly, the graduate student acquires an obligation to comply with certain federal regulations and the University's system of review that implements them. Technically, degree requirements are not complete unless the student fulfills this compliance obligation.

Two boards, the East Tennessee State University Institutional Review Board (ETSU IRB) and the East Tennessee State University/James H. Quillen Veterans Affairs Institutional Review Board (ETSU/VA IRB), serve as the institution's IRBs to review non-medical and medical research involving human subjects, in accordance with the Title 45 Code of Federal Regulation Part 46 (45 CFR 46) from the Department of Health and Human Services (DHHS). The ETSU IRB and ETSU/VA IRB are also University standing committees. In addition to federal regulations, every researcher commits him or herself, in submitting a proposal for review, to *The Belmont Report (Ethical Principles and Guidelines for the Protection of Human Subjects of Research)*, as well as to the University assurance of compliance. To further assist investigators in designing projects that meet current regulations, in understanding the review system, and in preparing materials for Committee review, researchers are also invited to visit the IRB online at www.etsu.edu/irb.

In this booklet, the basic elements of graduate student responsibility, with respect to thesis and dissertation research involving human subjects, will be explored. This quick journey through the human subjects review system will provide a handy checklist for both graduate students and their Dissertation/Thesis Committee Chair.

This booklet will leave many questions unanswered. It is therefore presented as a supplement to the required compliance education session. The researcher and any study personnel must complete a training session entitled **Collaborative IRB Training Initiative- CITI**. For instructions on how to complete the training, see page 5.

Please note that completion of this or a similar compliance course in the ethical conduct of human subject research is required prior to proposal submission.

The following are instructions on how to complete the CITI training:

First Time Users of CITI Training Program

1. Go to www.citiprogram.org and click on “ Register Here ”, then submit
2. Under Participating Institutions, Choose “East Tennessee State University” and submit
3. Select your Username and Password, then submit. This is what you are going to use to go in and out of the program. DO NOT FORGET IT!!!!
4. Fill out Registration Page, then submit information

Select your group and submit :

Group 1- Biomedical not affiliated with VA

Group 2- Biomedical affiliated with VA (ETSU/VA members)

Group 3- Social and behavioral not affiliated with VA (ETSU
Campus Members)

Group 4- Social and behavioral affiliated with VA

6. On the Learners Menu, click on “Basic Course (required; Status Incomplete)”
7. Complete the Required modules (top of page).
8. To get access to the optional modules (not part of required training unless requested), click on “View the Grade Book” after completing the test on the last module. Scroll down. This will give you all the score of the modules you have completed and give you access to the optional modules.

It is important that you print the certificate by clicking on “Print a certificate of completion” after finishing the test on the last module. This will trigger an email to the IRB, letting us know you completed the training.

If you have already registered at CITI, just enter your username and password. This will take you to where you left off.

Note: you do not have to complete the CITI Training until the old training has expired.

An Overview of the Review System

Following the Nuremberg Trials after World War II, the United States developed a national concern for the health, safety, and rights of human research subjects. By 1966, The National Institutes of Health (NIH) had established a requirement for review of research submitted for funding. Shortly thereafter (1974), ETSU and the VA established its first committee dedicated to the protection of human research subjects. Growing interest in these matters resulted in the National Research Act of 1974, which required institutions conducting research involving human subjects to establish IRBs for the purpose of reviewing such research prior to its implementation. DHHS (the Department of Health and Human Services) established regulations (the first version of 45 CFR 46) to set guidelines for the composition of IRBs and the standards of review. Revised in 1981, the regulations require that the Institutions review all research involving human subjects regardless of the source of funding (or not), the slightness of the contact with human subjects, and the harmlessness of the research.

As required by law and institutional policies, the membership of the ETSU IRB and ETSU/VA IRB includes faculty, as well as community members, non-scientists, and representation of minorities. This diverse membership allows for a wide variety of project review expertise in research methodologies, as well as legal, ethical, community, and professional standards of practice. In reviewing a proposed research project, the IRBs examine:

- ⇒ the risks imposed upon subjects;
- ⇒ the means taken to minimize those risks, and to protect the subjects;
- ⇒ the reasonableness of those risks relative to the benefits of the research either for the subjects or for the state of knowledge;
- ⇒ the equitability of subject selection;
- ⇒ the propriety of methods to be used in obtaining informed consent from the subjects;
- ⇒ any requirements to protect the subjects' safety and rights, confidentiality and privacy; and
- ⇒ the acceptability of the project in terms of institutional commitments, applicable law, standards of professional conduct, community standards, and any special vulnerabilities of the subjects (e.g., minors, women, minority groups)

Additional safeguards are provided in reviewing activities to which the Code of Federal Regulation Subpart B (Fetuses, Pregnant Women, and Human In Vitro Fertilization), Subpart C (Prisoners) or Subpart D (Children) apply to assure that they conform to appropriate ethical standards and relate to important societal needs. (45 CFR 46.202)

Performance Sites

Engagement

Definitions:

Engaged: An institution becomes "engaged" in human subjects research when its employees or agents¹ (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes [\[45 CFR 46.102\(d\),\(f\)\]](#).

An institution is automatically considered to be "engaged" in human subjects research whenever it receives a direct HHS award to support such research. In such cases, the awardee institution bears ultimate responsibility for protecting human subjects under the award.

Performance Site Category	Description	FWA required?	Required approval
Category 1	engaged in research with federal research support or direct award for study	Yes	Submit copy of site IRB approval or request that ETSU IRB be IRB of Record.
Category 2	engaged in research with no federal research support or direct award for study	No	Submit copy of site IRB approval or request that ETSU IRB be IRB of Record.
Category 3	Performance site not engaged in research with established IRB	No	Submit copy of site IRB approval or request that ETSU IRB be IRB of Record.
Category 4	Performance site not engaged in research without established IRB	No	Submit letter of permission from the appropriate institutional official stating that the research may be conducted at site.

Level of Research and Application Process

Thesis/Dissertation Committee Approval

Before submitting a project for human subjects' review, be sure to obtain the approval of your thesis or dissertation committee. Advisors and advisory committees often recommend changes in proposed research, and these could force you to redo your human subject submission unless you obtain full approval first from those guiding you toward your degree. For thesis and dissertation research, **you must sign the Form 103 and both you and your Dissertation/Thesis Committee Chair must sign the Faculty Assurance Statement.** Completion of CITI training is also required. (see page 5 for instructions). **All IRB Forms mentioned in this section are available at www.etsu.edu/irb.**

Current regulations distinguish three categories of human subjects research. These categories (or levels) are: exempt, expedited and full. Each category is determined based on the risk imposed by the research.

Thesis/Dissertation Committee Chairs: Please be advised that when you sign the Faculty Assurance Statement you certify that the proposal has been reviewed for scientific merit and is approved for submission to the IRB. You will also ensure the student will notify the IRB immediately when the study is completed by submitting a **completed** Form 107 to the IRB Office. See Faculty Assurance Statement for complete list of responsibilities.

A. **Exempt:**

First of all, **exemption does not mean “do nothing.”** In each instance, the investigator will make the initial request for exempt status and the IRB Chair will make the final determination. If the research is submitted by the IRB Chair, either the Vice Chair or the Vice Provost for Research at East Tennessee State University will review this determination.

Neither the Chair nor the Vice Chair may review for approval research studies submitted for exempt or expedited review from their respective departments or divisions (for larger departments). In the absence of the Chair or Vice Chair, the Vice Provost for Research, or the Associate Chief of Staff for Research will review the determination. If upon this review the determination of exemption is not upheld, the investigator will be informed and provided with the reasons for denial of exemption. The protocol will then be submitted for either expedited or full review, as appropriate to the level of risk, by the IRB.

The institution retains the option under the assurance to not claim the options provided for exempt status, but instead choose to require IRB review. If the Chair identifies ethical concerns in the research submitted for exemption, the study will not be exempted. Documentation for all exemptions will include citation of the specific category justifying the exemption and include enough information in the records to justify the exemption.

If you are submitting your proposal for **exemption**, the IRB Coordinator will review your submission and, if appropriate, present it to the appropriate Chair for their review.

The appropriate Chair will review the proposal for approval and certify it as exempt from Board review, if it meets the appropriate criteria. Approval, in most instances, will take two weeks. If it is determined that the project does not meet exemption requirements, it will be forwarded through the expedited or full review process.

Categories

Only studies that meet one or more of the six specific categories of exempt activities as delineated by HHS Regulations 45 CFR 46 (101) (b) are eligible to be given exempt status.

NOTE: These categories do not apply to prisoners and categories 1-5 do not apply to FDA regulated research. For a list of the categories that qualify for exempt approval, go to the IRB website.

Ethical Standards:

Studies submitted requesting exempt status will be reviewed by the Chair or Vice Chair to determine whether the research fulfills the organization's ethical standards. The standards are as follows:

1. The research holds out no more than minimal risk to the participants.
2. The selection of participants is equitable.
3. If the study includes recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data.
4. If the study includes interactions with participants, there is a consent process that discloses such information as:
 - a. that the activity involves research
 - b. a description of the procedures
 - c. that participation is voluntary
 - d. the name and contact information for the investigator
5. The research has adequate provisions to maintain the privacy interests of participants.

If the Chair or Vice Chair identifies ethical concerns in the research submitted for exemption, the study will not be exempted.

Modifications

Any proposed changes to an exempt study must be submitted to the IRB for review and approval prior to implementation. Some modifications to the research may change the review status and require the investigator to submit an application for expedited or full review. (refer to IRB Policies and Procedures)

To submit an exempt study, complete a **Form 103**, a Faculty Assurance Statement and a **Narrative**. After obtaining the Thesis/Dissertation Committee Chair signature on the Faculty Assurance Statement, **the original copy** with appropriate signatures as well as a **completed Narrative** and any **associated material (see list on page 2 of Form 103)** must be sent to the IRB Office.

The Thesis/Dissertation Committee Chair must be listed as a Co-Investigator and their contact information provided on question #4 on the Form 103.

B. Expedited:

These studies fall into the minimal risk categories. **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. Those proposals that qualify for this category are reviewed for approval by the IRB Chair and/or by two or more IRB members who have been selected based on their expertise and experience. If a study qualifies for this level of review, an approval can take up to 4-6 weeks of review time.

If you are submitting your project for **expedited** review, the IRB Coordinator will review your submission and, if appropriate, present your proposal to the Chair and/or the selected IRB members. The Chair or selected IRB members may approve the proposal, alternately request modifications in the proposal to meet current regulations, or they may determine that the project requires review by the full committee. You will receive written notice documenting the Board's decision.

Expedited review **MAY NOT** be used if:

- X** research is minimal risk but does not appear in one of the listed categories
- X** research involves greater than minimal risk.
- X** research where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are not greater than minimal.
- X** research is classified and involves human subjects.

Only those research activities that present no more than minimal risk to human subjects **AND** involve only categories listed may be reviewed by the IRB through the expedited review procedure authorized by [45 CFR 46.110](#) and 21 CFR 56.110. For categories that qualify for expedited approval, go to the IRB website.

To submit an expedited study, complete a **Form 103 and Faculty Assurance Statement**. After obtaining the Thesis/Dissertation Committee Chair signature on the Faculty Assurance Statement, **the original copy** with appropriate signatures, as well as a **completed Narrative**, an **Informed Consent Document (ICD)** with version date on footer and copies of any **associated material (see list on page 2 of Form 103)** in addition to **three copies** of the same (total of four complete sets) must be sent to the IRB Office.

The Thesis/Dissertation Committee Chair must be listed as a Co-Investigator and their contact information provided on question #4 on the Form 103.

C. Full:

Any study that does not meet the requirements for exemption or for expedited review will require review by the full board.

The ETSU and ETSU/VA IRBs meet monthly to review submitted projects. The deadline for submission is at least two weeks prior to the date of the meeting in order to permit time for distribution of materials to members and for detailed study of the proposal. The deadline and meeting dates are posted on the IRB website.

The Principal Investigator or a qualified knowledgeable study representative will be invited and required to attend the IRB meeting to offer a brief synopsis of the study and answer questions about the information submitted for board review and about the project in general. Particular attention is given to the issues of benefit vs. risk and to subject safety, welfare and rights.

Student presenters MUST be accompanied by their Thesis/Dissertation Committee Chair or their Faculty Advisor.

If you are submitting your project for a full review, the IRB Coordinator will submit copies to both the Primary Reviewers and to all board members for review. The Board may approve the proposal, alternately request modifications in the proposal to meet current regulations, or they may decide not to approve the project. In either case, you will receive written notice documenting the Board's decision. In the event that a proposal is disapproved, the investigator (student) and student's faculty advisor or Thesis/Dissertation Committee Chair will be notified in writing of the Board's disposition along with an invitation to respond either in person or in writing. The appeal process will additionally be made available. (More on this process, go to page 32). The student may alternately choose to represent the protocol rather than appeal the Committee's decision.

To submit a Full study, complete a **Form 103 and Faculty Assurance Statement**. After obtaining the Thesis/Dissertation Committee Chair signature on the Faculty Assurance Statement, **the original copy** with appropriate signatures, as well as a **completed Narrative**, an **Informed Consent Document (ICD)** with version date on footer, and copies of any **associated material (see list on page 2 of Form 103)** in addition to **thirty (30) copies** (total of 31 complete sets) must be sent to the IRB Office. Only one copy of the Protocol and Investigator's Brochure will also need to be submitted.

The Thesis/Dissertation Committee Chair must be listed as a Co-Investigator and their contact information provided on question #4 on the Form 103.

It is strongly recommended that investigators submit one copy of the packet to the IRB Office on the Thursday before the posted submission deadline for administrative review. This will help ensure that your submission to the IRB is complete before you make the 30 copies.

Continuing Review

Full Continuing Review

Studies initially reviewed by the full, convened IRB undergo continuing review by the full convened IRB with recorded vote on each study, unless the study has been modified such that it meets the federal guidelines to be eligible for reclassification for expedited continuing review. For full continuing review, the IRB reviews proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in the nonscientific areas (45 CFR 46.108(b)).

In conducting full continuing review, a Primary Reviewer System is utilized. Consideration for the selection of Primary Reviewers to serve on the is based on area(s) of expertise in compliment to the research under review, term of IRB membership, dedication to continuing education and availability to accept new and continuing research proposals. The Chair and/or Vice Chair review each continuing review submission to determine which members have the relevant expertise to conduct an in-depth evaluation of the protocol. Primary Reviewers are responsible for analyzing the protocol and the complete IRB application in detail and are authorized to discuss any unanswered questions with the investigators, associated researchers or consultants prior to or during the convened meeting.

For continuing review of research that does not qualify for expedited review, all IRB members receive for review a copy of the proposal. Upon request, any IRB member has access to the complete IRB protocol file and relevant IRB minutes prior to or during the convened IRB meeting. In addition, any IRB member has access to additional information provided to individual reviewers.

The full IRB Committee is informed of the Primary Reviewer's findings at a convened meeting. Particular attention will be paid to the Risk/Benefit ratio of the investigations and the adequacy of the Consent Forms in conveying the procedures, implications and full intent of each study. Problems identified by the Primary Reviewers or by other IRB members will be discussed and suggestions for any necessary changes will be agreed upon by the IRB.

After discussion, including an explanation of the important issues that were evaluated, the full, convened board makes its determination with a recorded vote. Any controverted issues will be recorded in the minutes. This process allows the IRB to conduct a more substantive review and discussion at convened meetings.

Expedited Continuing Review

Expedited continuing review may be conducted if the study was initially eligible for, and approved by, an expedited mechanism, with the following exception: if an amendment or continuing review indicates changes in the study so that it is now ineligible for expedited continuing review as noted with submission of modification/continuing review.

The IRB is only permitted to use expedited review for the continuing review of research that involves solely one or more of the activities published at 63 FR 60364-60367. If the study is modified such that it fails to meet expedited criteria for review, the study will undergo full continuing review.

In limited circumstances described by expedited review categories (8) and (9) at 63 FR 60364-60367 addition, studies that were initially reviewed by the full convened board may undergo expedited continuing review if certain criteria are met.

Exempt Studies

Studies that have been determined to meet exempt status do not undergo continuing review unless a change in the study renders it ineligible for exempt status per federal guidelines. Investigators are informed in the exempt status letter to inform the IRB of any change in the project prior to its implementation, and reclassification under expedited or full review would be determined at that time by the IRB Chair.

Approval Criteria

Approval, both initial and continuing, must meet DHHS regulations at 45 CFR 46.111, including determinations by the IRB regarding risks, potential benefits, informed consent and participant safeguards. Criteria for both initial and continuing review approval are the same and therefore, IRB continuing review must include a determination by the IRB that

- ⇒ Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- ⇒ Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
- ⇒ Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
- ⇒ Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by [§46.116](#).
- ⇒ Informed consent will be appropriately documented, in accordance with, and to the extent required by [§46.117](#).

- ⇒ When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- ⇒ When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

If interim changes in IRB policy have occurred such that the proposal submitted for continuing review would not be approved if the same study were an initial submission, the IRB does not approve the continuing review of that protocol.

Changes/New Information

The IRB is also responsible for ensuring that changes in approved research are promptly reported to, and approved by, the IRB [21 CFR 56.108(a)(3-4)]. Continuing review will include an IRB determination of whether new information or unanticipated risks have been discovered since the previous IRB review. Based on new information or unanticipated risk, the IRB has the authority to reconsider its approval, require modifications to the study, and/or revise the continuing review timetable. Any significant new findings which may relate to the subject's willingness to continue participation should be provided to the subjects in accordance with 21 CFR 50.25.

Informed Consent

IRB continuing review will also include evaluation of the informed consent document currently in use. The currently approved informed consent, as well as any proposed informed consent document, will be reviewed to determine if the information provided continues to be accurate and complete, and to determine if any new information needs to be added. The informed consent document will also be reviewed to ensure that any significant new findings that may relate to the subject's willingness to continue participation are provided to the subject in accordance with DHHS regulations at 45 CFR 46.116(b)(5). Review of the informed consent document will take place not only at continuing review, but at other times when new information becomes available that needs to be communicated to participants.

Source Verification

When conducting continuing review, the IRB is responsible for determining which studies need verification from sources other than the investigator that no material changes in the research have occurred since the previous IRB review [21 CFR 56.108(a)(2)]. The need for additional verification will be determined by the IRB on a case-by-case basis according to the following criteria. Source verification will be required when:

- ⇒ Investigator is providing inconsistent information that can not be resolved
- ⇒ The IRB doubts the investigator's veracity
- ⇒ IRB doubts that the investigator has sufficient relevant knowledge
- ⇒ IRB perceives that investigator is intentionally not providing necessary information

If a reviewer determines the need for source verification for an expedited study, the continuation review must be referred to the full board. If the IRB determines that a need for source verification exists, the IRB may request an independent assessment. This scope and extent of this assessment will be determined by the IRB on a case-by-case basis.

Sources for information could include site visits conducted by authorized personnel, literature searches, or a directed audit. The IRB has the authority to observe or have a third party observe the consent process and the research [45CFR46.109(e)].

No Grace Period

Per regulations, there is **no** grace period that allows the conduct of research beyond the expiration date of IRB approval. Therefore, continuing review and re-approval of research must occur on or before the date when IRB approval expires. If any activity occurs or continues after the expiration date, the investigator is deemed to be out of compliance with both federal regulations and ETSU/VA policies.

If the study is approved pending changes, the IRB approval is not given until the requested changes are received and approved. **The approval period is not extended.**

The IRB may restrict, require modifications, or terminate a research project based on continuing review by the IRB Committee. All studies in which the IRB requests changes to current documents are assigned a pending status.

If continuing review and re-approval fails to occur by the continuing date specified by the IRB, all research activities must stop, unless the IRB finds that it is in the best interests of individual subjects to continue participating in the research interventions or interactions.

If the IRB does not re-approve the research by the expiration date, the IRB approval expires. The PI, upon receipt of an expiration letter, must immediately submit to the Chair a list of participants that could be harmfully affected by the expiration of the research. The IRB Chair, with appropriate consultation with (for VA) either the Chief of Staff (COS), or in his/her absence, the ACOS/R, or (for ETSU), the Vice Provost for Research (VPR), will determine if the subject(s) may continue in the research. If the ACOS/R or VPR is not a physician, they will designate a physician as a consultant. If the study is an FDA regulated study, the COS, ACOS/R or VPR and the IRB Chair will follow FDA requirements in 21 CFR 56.108(b)(2) and (3) in making their decision. The sponsoring agency or private sponsor will additionally be informed. In addition, the IRB Coordinator faxes a copy of expiration letter pertaining to VA Studies to the VA Administrative Officer (AO) on the date the letter is mailed/faxed to the PI.

Informed Consent Document (ICD)

Informed Consent is a process. The investigator must obtain informed consent from every research subject to participate in the research unless a waiver is granted (see description below). Federal regulations (45 CFR 45.116 (a)) require that certain elements be present in the consent document. Additional elements may be required. The normal mode of obtaining informed consent is through a signed written statement. The subject must be given a copy of the fully executed (signed) consent form. For more specific information about Informed Consent Document or process, refer to the IRB Policy #13.

However, there are certain circumstances in which the ETSU/VA IRB or ETSU IRB can entertain **waivers of the consent**.

The Federal regulations allow for two types of waivers of Informed Consent:

- ⇒ **Waiver or Alteration of Requirement to Obtain Informed Consent OR**
- ⇒ **Waiver of Requirement for Written Documentation of Informed Consent.**

Waiver or Alteration of Requirement to Obtain Informed Consent

DHHS provides for waiving or altering elements of informed consent under certain conditions [§.116(c)-(f)]. FDA has no such provisions because the types of studies that would qualify for waiver or alteration are either not regulated by FDA or are covered by the Emergency Treatment provision of FDA Regulation 21 CFR 50.23.

Waiver of informed consent can not be given when research is subject to FDA regulation.

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent under 45 CFR 46.116(c) **OR** 45 CFR 46.116(d).

A waiver of parental permission (or student consent if the student is an adult) may not be granted if the study involves funding from the Department of Education and the study involves a survey, analysis, or evaluation that reveals information concerning the following categories:

- (1) political affiliations or beliefs of the student or the student's parent;
- (2) mental or psychological problems of the student or the student's family;
- (3) sex behavior or attitudes;
- (4) illegal, anti-social, self-incriminating, or demeaning behavior;
- (5) critical appraisals of other individuals with whom respondents have close family relationships;
- (6) legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers;
- (7) religious practices, affiliations, or beliefs of the student or student's parent; or
- (8) income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program),

In addition, all instructional materials, including teacher's manuals, films, tapes, or other supplementary material which will be used in connection with any survey, analysis, or evaluation as part of any applicable program shall be available for inspection by the parents or guardians of the children.

Waiver of Requirement for Written Documentation of Informed Consent

Under certain conditions, the IRB can waive the requirement that the participant sign the consent form. However, waiver of documentation of informed consent does not constitute waiver of informed consent. The IRB reviews the written description of the information that will be provided to participants. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all participants under (46 CFR 117(c)(1) OR (46 CFR 117(c)(2) . However, when the IRB waives the requirement for the investigator to obtain a signed consent form from the participant under 46 CFR 117 (c)(1), the participant must be asked whether he or she wants documentation linking them to the research. This means that an approved stamped ICD must be made available for the participant to sign.

In cases where the documentation requirement for informed consent is waived, the IRB requires the investigator to provide participants with a written statement regarding the research.

Confidentiality of Identifiable Data

HIPAA: The Health Insurance Portability and Accountability Act (HIPAA), also referred to as, "The Privacy Rule," at 45 CFR parts 160 and 164, establishes a category of health information, defined as protected health information (PHI), which a covered entity may only use or disclose to others in certain circumstances and under certain conditions.

In general, the Privacy Rule requires an individual to provide his/her signed permission, known as an *Authorization* under section 164.508 of the Privacy Rule, before a covered entity can use or disclose the individual's PHI for research purposes.

Under certain circumstances, however, the Privacy Rule permits a covered entity to use or disclose PHI for research without an individual's Authorization. One way a covered entity can use or disclose PHI for research without an Authorization is by obtaining proper documentation of a waiver of the Authorization requirement by the IRB, or another type of review body, known as a Privacy Board. The ETSU/VA IRB shall serve as the Privacy Board.

Pre-screening activities, without the use of an Authorization, are permitted under HIPAA [45 CFR 164.512(i)(1)(ii)]. Pre-screening activities involving prospective subjects, conducted to prepare a research protocol, or to enroll (or exclude) subjects from participation must be documented in the study file whether or not the subject meets the inclusion criteria.

Documentation of screening (pre-enrollment) activity only form, (available online) or a similar instrument may be used for this purpose.

Note: VHA policy is more restrictive regarding Activities Preparatory to Research. Accessing patient records for recruitment into research requires prior IRB approval, waiver of authorization, even for a VA researcher's own patients.

The IRB has the authority to approve a waiver or an alteration of the Privacy Rule's Authorization requirement in addition to the traditional IRB authorities to protect research participants from risks under 45 CFR part 46 (Department of Health and Human Services (HHS) Regulations for the Protection of Human Subjects) 38 CFR 16, and 21 CFR parts 50 and 56 (Food and Drug Administration (FDA) Regulations on Protection of Human Subjects). Other Federal and State laws and regulations may impose other or additional restrictions and limitations on the use of health information for research that may not be waived or altered by an IRB (or Privacy Board) under the authority granted to it by the Privacy Rule. The IRB and the OPHRS shall enforce the mandates of the Privacy Rule pursuant to the requirements necessary for the protection of the subject and/or their protected health information as applicable to the research.

Confidentiality of Identifiable Data

Staff of the HRPP and IRB Members consult with the University Privacy Officer, who serves as an Ex-Officio ETSU/VA IRB Committee member, on matters concerning the management of personal health information (PHI) as it relates to the enforcement of the Privacy Rule.

Training on the requirements imposed by the Privacy Act and other information regarding HIPAA, including guidance, forms and continuing education, will be made available to researchers online.

Conflict of Interest

- ⇒ **Conflict of interest** refers to instances when there is a convergence between an individual's personal financial, relational, or other interests and his/her professional obligations to East Tennessee State University (ETSU) or the James H. Quillen Veterans Affairs Medical Center (VAMC) such that an independent observer might reasonably determine that the individual's professional actions or decisions are adversely affected, distorted or otherwise compromised by the individual's personal interest. The term conflict of interest is broader and encompasses more professional activities than the term financial conflict of interest in research and for the purposes of this policy includes conflicts that may arise in review and approval of protocols submitted to the IRB when an IRB member is part of the team designing, conducting, or reporting the research presented in the protocol, or has an immediate family members involved in the design, conducting or reporting the research presented in the protocol.
- ⇒ **Covered individual** includes any faculty or staff member (whether fully-, partially-, or non-salaried), student, fellow, trainee, administrator or other employee who is involved in research for which the ETSU or the VAMC is responsible, or who, pursuant to the review and approval of the ETSU/VA or ETSU Institutional Review Board (IRB), conducts or engages in research involving human subjects, or is otherwise identified as involved in research by a principal investigator, chair or unit head, or other University administrative officer responsible for research activities.
- ⇒ **Immediate Family Members** includes spouse, domestic partner, and dependent children.

For more definitions on Conflict of interest, see IRB Policy # 17a

Investigator Conflict of Interest

When an investigator submits a protocol, a disclosure of significant financial interest to the IRB is required for all Covered Individuals and consultants serving as study personnel involved in designing, conducting, or reporting the research presented in the protocol.

The investigator may submit this information on the IRB Potential Conflict of Interest for Investigators Form. If a potential conflict of interest is present for the investigator or any Covered Individuals or consultants serving as study personnel involved in designing, conducting, or reporting the research presented in the protocol (question number 2 is answered "yes"), then in addition, additional forms must be submitted as follows:

- For ETSU researchers, an ETSU Conflict of Interest Form must be completed and submitted to Vice Provost for Research
- For VA Researchers, a VA conflict of interest form must be completed and submitted to the VA R&D Office.
- For researchers affiliated with both institutions, both forms must be completed and submitted as noted above (two parallel pathways).

The IRB Coordinator holds the proposal until a management plan as detailed below is received in the IRB Office. The IRB Coordinator forwards a copy of the Potential Conflict of Interest Form to the IRB Director. The IRB Director forwards copies of any disclosures of conflict of interest to the VPR and/or ACOS/Research.

Once the management plan is received, the IRB Coordinator forwards the proposal with the management plan to the convened board.

- ⇒ If the Conflict of Interest is such as to require either a VAMC or ETSU conflict management plan the approved plan must be submitted to the IRB prior to review of the protocol.
- ⇒ In addition, the investigator must submit a revised Conflict of Interest Form within ten days of any change from previous disclosures, and annually disclose any changes on the continuation review Form 107.
- ⇒ When presenting a proposal or modification to the convened IRB, the investigator and any accompanying study staff leave the room prior to the deliberation and vote.
- ⇒ The investigator must comply with all recommendations of the IRB Office to minimize conflict of interest.
- ⇒ The IRB Director will inform either the Vice Provost for Research or the AcoSR of the disclosed financial interest.
- ⇒ If the Vice Provost for Research or the ACOS/Research has already reviewed the financial interest, the Vice Provost for Research or the ACOS/Research will inform the IRB in writing of all actions taken according to the relevant policies. Otherwise the Vice Provost for Research or the ACOS/Research will review the financial interest and inform the IRB in writing of all actions taken according to the relevant policies.
- ⇒ In all cases, IRB review will be held until the Vice Provost for Research or the ACOS/Research has completed the review.
- ⇒ All IRB members will be provided with a copy of the report of Vice Provost for Research or the ACOS/Research.
- ⇒ When presenting a proposal or modification to the convened IRB, the investigator and any accompanying study staff leave the room prior to the deliberation and vote.

Managing Conflicts of Interest

- ⇒ In addition to actions taken by the Vice Provost for Research or the ACOS/Research, the IRB reviews the management (resolution) plan. The IRB may accept the plan, request modifications, or disapprove the research. The IRB makes the final determination and may take the following actions to manage, reduce, or eliminate conflict of interest.
 - Public disclosure of significant financial interests
 - Monitoring research through oversight/audit
 - Modify research plans and/or ICD
 - Disqualification from participating in research
 - Divestiture of significant conflict of interest or
 - Severance of relationship that create actual or potential conflicts
 - More frequent continuing review
 - Disapproval of research

- ⇒ If a conflict of interest is identified after a study has been approved or initiated, the Chair or VPR will consult with the IRB and, if appropriate, the R&D Committee to identify the impact of the conflict on the protocol and the research subjects to ensure actions are taken to decrease the impact. Corrective actions may include:
 - Modifying the protocol and ICD
 - Re-consenting subjects
 - Removing the investigator from the subject selection process
 - Supervision of the protocol by independent reviewers and/or
 - Requiring disclosure in all publications/presentations resulting from the research
- ⇒ The conflict must be managed so that it does not affect the rights and welfare of participants. Disclosure alone can not be used to manage a conflict of interest that might affect participant rights and welfare.
- ⇒ An inability to resolve these issues will be reported to the ETSU President, and if applicable, the VA Medical Center Director, through the appropriate committees.

Failure to Comply with Conflict of Interest Policy

If an investigator fails to comply with this policy or with the corrective actions relating to it, the Chair will report this to the VPR, and if applicable, the Medical Center Director. Failure to comply may also result in additional conditions or restrictions including:

- A. Termination of the protocol
- B. Removal of the investigator from the research team
- C. Revocation of the privilege to conduct research at ETSU or within the VA
- D. Sanctioning by PHS, FDA (or other applicable entities)

Reporting Changes

It is the policy of both the ETSU IRB and the ETSU/VA IRB to review all requests for modifications to any previously approved research study (including exempt studies) to determine if the change will alter the risk/benefit ratio of the study. A complete description of the modification must be received prior to review. Modifications may include, but are not limited to, protocol amendments, changes in the number of subjects, changes in the informed consent, etc. All requested changes in the conduct of a study and/or changes to study documents must be approved by the IRB prior to implementation of that modification. The only exception is a change necessary to eliminate apparent immediate hazards to the research subjects [21 CFR 56.108(a)(4)]. In such a case, the IRB will be promptly informed of the change following its implementation (within 10 working days) and will review the change to determine that it is consistent with ensuring the subject's continued welfare. IRB members with a conflict of interest may provide information requested by the IRB, but may not participate in the deliberation or vote of the IRB on the involved modification.

Reconsenting/Notification of Participants

If the modification warrants changes to the informed consent document, the investigator must address whether the information needs to be communicated to currently or previously enrolled participants, and if so, how it will be communicated. This may be accomplished by using an addendum to the initial ICD or by re-consenting the subject using the modified ICD. While the investigator is responsible for making the initial decision regarding any necessary document changes, the IRB will make the final determination of whether the The IRB makes the final determination. The IRB will also make the final determination of the necessity of re-consenting of currently enrolled participants or notification of participants who have completed research interventions.

Minor Modifications

The initial request as to whether a modification alters risks to the participants is made by the Principal Investigator. The modification is received by the Coordinator and presented to the Chair for his/her review. The Chair is responsible for evaluating the change in procedures and risks, and determining whether full IRB review of the modification is necessary.

Proposed changes for previously approved research that are classified as minor modifications may be reviewed and approved in an expedited manner by the IRB Chair or, in the case of the Chair's absence or conflict of interest, his/her Designee. The designee should be one or more experienced reviewers designated by the chairperson from among the IRB membership. Examples of minor modifications may include, but are not limited to, the following:

1. Administrative changes, such as correction of typographical error(s)
2. Revision of phone number(s)

Non-Minor Modifications

When a modification is determined to be non-minor, the Chair or his/her designee serves as a primary reviewer. The IRB Committee receives a synopsis of the primary reviewer's findings at the convened meeting. The IRB must review and approve changes at a convened meeting* before changes can be implemented (*meeting at which a majority of the members are present, including at least one member whose primary concerns are non-scientific).

At the Chair's discretion, the Principal Investigator may be required to present the non-minor modification to the convened board.

Examples of non-minor modifications may include, but are not limited to, the following:

- ⇒ Change in protocol procedures, such as increasing the number of times a test is performed or adding additional procedures
- ⇒ Deletion or decrease in tests performed as part of safety evaluations
- ⇒ The addition of serious unexpected adverse events or other significant risks to the ICD
- ⇒ Changes, which, in the opinion of the IRB Chair or his/her Designee, do not meet the definition of a minor modification
- ⇒ Any change that increases the risk of the study

Exempt Research

Any changes in an exempt study must be submitted to the IRB for approval prior to initiation of the change. The IRB Chair will determine if the modification renders the study ineligible for continuing exempt status; and if so, the modification will not be approved. The investigator will be notified in writing that he may withdraw the modification request and continue the study as previously determined to qualify under exemption guidelines or submit the study for appropriate review and approval through an expedited or full board review.

VA Studies

Modifications must also be submitted to the VA R&D Office, if the study involves VA patients, VA staff, VA resources, time or equipment. Any change in authorized prescribers of the investigational drug requires the submission of a revised 10-9012.

Changes in Study Sites or Investigators

Changes in study sites, investigators or revisions in study staff must also be reported to the IRB. These may require a cover letter, a revised Form 103, or, as applicable, a revised protocol. In the case of a change in the principal investigator, if at all possible, the letter should be signed by the investigator who holds the approval. The newly assigned investigator of a full review study however, must show proof of having obtained required education, submit a current CV for the purpose of assessment of qualifications. If the PI is unknown to the IRB, the PI must also attend a convened IRB meeting. The change will be noted in the minutes.

Reporting Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO)

Pertinent Definitions:

- ⇒ **Unanticipated Problem:** Unanticipated problems /events are those that are NOT already described as potential risks in the consent form, NOT listed in the Investigator Brochure, or NOT part of an underlying disease.
- ⇒ **Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO):** Includes those events that (1) are not expected given the nature of the research procedures and the subject population being studied (2) suggest that the research places subjects or others at a greater risk of harm or discomfort related to the research than was previously known or recognized.

Summary Policy

Federal regulations require the organization to ensure promptly reporting of “any unanticipated problems involving risk to subjects or others” to the IRB, regulatory agencies, and institutional officials. The ETSU/VA and ETSU IRB require investigators to promptly submit any problem or event that meets the following criteria to the IRB within 10 working days using the Form 109 (unanticipated problem report) signed by the PI. Note: VA reporting requirements require immediate reporting of the loss or theft of VA research data/information or portable media such as laptops, or personal computers (see “VA Reporting of Loss or theft of VA research data/information section on page 24”)

Events to be reported include:

- a. any serious event, including on-site and off-site adverse events, injuries, side effects, deaths, or other problems, which in the opinion of the local PI, was unanticipated, involved risk to participants or others, and was possibly, probably or definitely related to the research.
- b. Any serious accidental or unintentional change to the IRB-approved protocol that involves risks or has the potential to recur
- c. Any deviation from the protocol taken without IRB approval to eliminate apparent immediate hazard to a research participant
- d. Any publication in the literature, safety monitoring report,(including Data and Safety Monitoring Reports), interim result, or other finding that indicates an unexpected change to the risk/benefit ratio of the research.
- e. Any breach in confidentiality that may involve risk to the participant or others
- f. Any complaint of a participant that indicates an unanticipated risk or that cannot be resolved by the research staff
- g. any local death, whether anticipated or not
- h. incarceration of a participant
- i. Any other serious and possibly related event which in the opinion of the investigator constitutes an unanticipated risk.

Reports of off-site events occurring in studies that are completed and closed at the local site should be reported if the event meets the IRB definition as detailed above AND the local PI judges that this event may affect risk to participants who have completed the study.

All problems/events that do not meet these criteria should be reported to the IRB in summary form (table or spreadsheet) at the time of continuing review.

Follow-up reports of an off-site event may be submitted on a tracking log without an accompanying Form 109 if the following are true:

- ⇒ the initial report of the event was submitted as a UPIRTSO on a Form 109
- ⇒ the local PI has determined that the follow-up information does not contribute meaningful new information

All problems/events that do not meet these criteria should be reported to the IRB in summary form (table or spreadsheet) at the time of continuing review.

***VA Reporting of Loss or Theft of VA research data/ information**

The loss or theft of VA research data/information or portable media such as laptops or personal computers must be immediately reported (as soon as it is discovered that there has been a loss) as follows:

1. Report the loss to security/ police officers IMMEDIATELY. If within a VA health care facility, notify the VA police. If the loss or theft occurs while on travel or at another institution, notify the security police officers at the institution (such as hotel security, university security, etc.) as well as the police in the jurisdiction where the event occurred.
2. Obtain the case number and the name and badge number of the investigating officer. If possible, a copy of the case report should be obtained.
3. Report the incident IMMEDIATELY to your immediate supervisor*
VA Privacy Officer at your facility *
VA Information Security Officer at your facility*
ACOS at your facility*
4. Report the incident to the IRB using a Form 109 (Unanticipated Problem Involving Risks to Subjects or Others).

* The name and contact information should always be readily available. Wallet cards that list the contact name and number of the James H. Quillen VA ACOS, the VAMC Privacy Officer and the VAMC Information Security Officer are available through the VA R&D office and the IRB Office.

IRB Responsibilities

The IRB Coordinator will present the written report of the unanticipated event received from the investigator to the IRB Chair within 5 days. (SEE EXCEPTION ABOVE FOR VA STUDIES) The Chair will perform an initial review, and determine whether the event is an unanticipated problem involving risks to participants or others. The Chair determines the action required based on his/her decision; if no, no further action; if yes, consider suspension and go to IRB. If the Chair determines that there is the potential of immediate harm to participants, the Chair may immediately suspend the study pending the IRB's receipt and review of the unanticipated problem and determination of any required actions.

If Chair says UPIRTSO, the report, with any attached documents, and the current approved informed consent, will be forwarded to the IRB Primary Unanticipated Problem (UP) Reviewer for initial review. The UP Reviewer, appointed by the IRB, will review all UPIRTSOs submitted and report findings and any recommendations for local ICD revisions to the IRB. In addition, all IRB members receive a copy of the Unanticipated Event Form (Form 109). If additional information is required in order to make a final determination concerning the event, the investigator will receive such a request in writing from the Chair/ Board. The report will be added to the next agenda for the convened board. The IRB may reconsider study approval, require modifications to the study, revise the continuing review timetable, require notification of past participants, or require modification of the consent process or documents. The IRB may deem it necessary to directly audit the research site and medical records pertaining to the event, monitor the consent process, interview participants or witnesses, or suspend/withdraw IRB approval until such time that the safety of the participants can be assured. If information that may relate to subject's willingness to continue to take part in the research is noted, the IRB will require notification of current participants. The IRB may require that current participants be re-consented. The IRB may terminate the research.

Correspondence will be forwarded to the Principal Investigator as per the decision of the IRB following the completion of the review process.

The ETSU/VA IRB Chair is responsible for reviewing any report of a local death to determine if the death is unanticipated. For VA studies, if the Chair determines that the death is unanticipated, the ETSU/VA IRB Coordinator immediately forwards the Chair's written assessment to the VA AO. The VA AO is responsible for submitting the report to ORO within 24 hours of the Chair's determination that the death was unanticipated. If the local site submits a tracking log for non-reportable events to satisfy sponsor requirements, the events/problems listed on the tracking log will be acknowledged by the IRB Chair, as indicated by his/her initials and date in the final column of the tracking log. A copy of the log will be filed with the study file, and the original returned to the investigator.

***FOR VA STUDIES**

If the IRB receives a report of a reported loss or theft of VA research data/information or portable media, the report will be immediately forwarded to the HRPP Director. The HRPP Director will immediately follow the reporting pathway outlined in the "VA Reporting of Loss or theft of VA research data/information section on page 24".

Recruitment

It is the policy of both the ETSU IRB and the ETSU/VA IRB that non-coercive methods must be used by investigators to recruit subjects. Procedures for enrolling subjects and compensation for subjects must minimize the possibility of coercion or undue influence. Direct advertising for research participants is considered to be the start of the informed consent and participant selection process.

For VA Studies: Non-veterans may be entered into VA approved research studies only when there are insufficient veterans available to complete the study. All regulations pertaining to the participation of veterans as research subjects pertain to non-veterans subjects enrolled in VA-approved research.

In VA studies, during the recruitment process, researchers must make initial contacts with veterans in person and/or by letter prior to any telephone contact and provide a telephone number or other means that veterans can use to verify the validity of the study (One source of information about clinical trials is <http://www.clinicaltrials.gov>). After recruitment and during the follow-up phase, VA researchers should begin phone calls by referring to previous contacts and the information provided on the informed consent document .

In addition, for VA studies, researchers must restrict their telephone and other contacts with veterans to only those procedures and data elements outlined in IRB-approved protocols. **In these contacts, researchers must not request social security numbers.**

Recruitment of Healthy Volunteers

Methods for subject recruitment must be addressed in the research narrative. When recruiting healthy volunteers, one of the following methods are recommended:

- ⇒ Use of public advertisement, (i.e., bulletin boards) including telephone number that a potential research subject may call to volunteer for the study.
- ⇒ Use of a letter briefly explaining the study and including a telephone number that a potential research subject may call to volunteer for the study.
- ⇒ Any alternative method (i.e., public advertisement, flyers, web site announcements) of contacting volunteers for research.

Items 1-3 above require IRB approval prior to use.

Research Advertising Materials Guidelines

All advertisements, questionnaires, surveys, testing forms and/or introduction letters associated with the study and intended for subject use or view must be submitted to the IRB for approval.

Advertisements may include item such as name, address of the Investigator, purpose of the research, criteria to be used to determine eligibility in a summary form, location of the research (e.g., ETSU), a brief description of the study activities, when appropriate; and time or other commitment required, brief list of potential benefits, if any; and name and phone number of the person to contact for further information.

Recruitment

Advertisements may not include:

- ⇒ The ad cannot state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.
- ⇒ The ad cannot make claims, either explicitly or implicitly, that the drug, biologic, or device is safe or effective for the purposes under investigation.
- ⇒ The ad cannot make claims, either explicitly or implicitly, that the test article is known to be equivalent or superior to any other drug, biologic, or device.
- ⇒ The ad cannot use terms such as “new treatment,” “new medication,” or “new drug” without explaining that the test article is investigational.
- ⇒ The ad cannot promise free medical treatment when the intent is only to say participants will not be charged for taking part in the investigation.
- ⇒ The ad cannot include any exculpatory language.

For more information on recruitment, see IRB Policy # 16.

Vulnerable Populations

The ETSU and ETSU/VA IRB will consider certain groups of human subjects to be particularly vulnerable to coercion or undue influence in a research setting, to include children (also indirectly an infant, if mother nursing the infant is a subject of research), fetuses, pregnant women, mentally disabled (cognitively impaired) persons, prisoners, and economically or educationally disadvantaged persons. In reviewing research projects, the IRB will scrutinize those involving these vulnerable groups, to ascertain that their use is adequately justified, and additional safeguards are implemented to minimize risks unique to each group.

Any proposal engaging subjects of vulnerable categories, such as children, prisoners, pregnant women, mentally disabled persons, will additionally be reviewed by one or more individuals who are knowledgeable about and experienced in working with these subjects.

In reviewing research projects, the IRB will scrutinize those involving these vulnerable groups, to ascertain that their use is adequately justified, and additional safeguards are implemented to minimize risks unique to each group and to protect the rights and welfare of individuals who may be vulnerable to coercion or undue influence. Additional supplemental form, for the specific population, is required at the time of submission to the IRB.

Vulnerable population may include, but is not limited to, children, prisoners, pregnant women, fetuses, neonates, minorities, physically impaired, etc. VA studies may not involve children.

For further information on Vulnerable populations, see IRB Policy #15.

Research at the VA

NOTE: Investigators seeking to conduct research at the James H. Quillen Veterans Affairs Medical Center (VAMC) *must additionally seek approval from the VA R&D prior to initiating research activity. VA R&D approval is, however, contingent upon IRB approval. Please contact the ETSU IRB and the VA R&D Administration. (Contact Information on page 34)

Appeals Process

If an investigator feels that his/her research proposal was denied or restricted unnecessarily, he/she may initiate the following procedure:

1. Submit a written request to the Chair of the IRB, within ten (10) working days from the date of the letter that an appeal of the decision be initiated.
2. The Chair will then have five (5) working days to request the Vice Provost for Research (VPR) at ETSU, or the Associate Chief of Staff for Research ACOS/R) at the VAMC to appoint an Ad Hoc Committee composed of IRB and non-IRB members to review the project in question. The VPR or ACOS/R will have five (5) working days to appoint and charge this committee.
3. The Ad Hoc Committee members will review the project and send a written report to the IRB with their recommendations. This review will normally take no more than ten (10) working days.
4. The IRB will again review the project and deliver its decision, considering the report of the Ad Hoc Committee, but is in no way to be bound by its recommendation. If the IRB Chair chooses to act in opposition to the report of the Ad Hoc Committee, it should offer a compelling reason for such a decision. A called meeting of the IRB may be necessary for this review, if the next scheduled meeting is not within 14 days of receipt of the report.

When planning your research project, be sure to allow sufficient time for review and approval at all applicable levels. Tight deadlines for starting and finishing research are the investigator's responsibility, not the reviewer's. Therefore, one important key to good thesis and dissertation research is extensive advance planning.

Before submitting your Form 103, check it carefully to be certain that you have addressed all the questions fully and relevantly. For thesis and dissertation research, list not only your name, address and phone number, but the name, campus address, and campus phone number of your Thesis/Dissertation Committee Chair as well. This information permits the Coordinator to communicate effectively about your project with minimum delay. Also, before transmitting the form to the IRB Office, be sure that you have all original signatures on one copy of the Form 103. These signatures include your own, and your thesis/dissertation committee chair.

When your study has been completed, you must notify the IRB Office of the completion immediately by submitting a completed Form 107 (Available on our website). No emails or memos will be accepted. If the office is not notified in a timely fashion, then your study will expire. Serious and/or continuing non-compliance will be reported to the appropriate officials and may prevent you from being able to do future research.

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