CHAPTER 3 – Investigator Responsibilities

PRINCIPAL INVESTIGATOR (PI)
1. Agrees to maintain current contact information, education, compliance related education/certification and applicable experience.

2. Accurately identifies research site and team members.

3. Assures all Investigators and study personnel complete initial and continuing education in human research protections annually to remain up-to-date on Federal regulations, ETSU policies and procedures, and compliance expectations.

4. Adheres to Federal regulations, state and local laws, Institutional policies, IRB policies and procedures regarding the safety and protection of human participants and Good Clinical Practice (GCP) guidelines (if applicable to the type of research).

5. Adheres to all Federal and ETSU policies regarding the responsible conduct of research as presented at http://www.etsu.edu/research/researchethics.htm.

6. Ensure that the ETSU IRB and ETSU/VA IRB (registered and holding OHRP approved Federalwide Assurances (FWA) in compliance with the requirements of 45 CFR 46, 38 CFR 17, and 21 CFR Part 56) will be responsible for the initial and continuing review and approval of the research.

7. Reports adverse events and unanticipated problems involving risk to participants and others to the IRB according to IRB policies and procedures, sponsors and appropriate Federal agencies as required.

8. Assures continuing review applications are submitted in a timely manner so that their review occurs prior to their expiration date. The Investigator acknowledges that the Federal regulations do not allow a grace period. The Investigator is responsible for being aware of the current literature in his/her field of study to assure participants are no longer placed at risk if additional risks have been identified or no benefit has been proven. The Investigator should build off previously conducted research to decrease the potential for participants to be needlessly placed at risk.


10. Supervises the research process, ensuring that research is conducted in a manner which will minimize risks to subjects. Responsibility for assuring key study personnel are properly trained, qualified and have appropriate facilities and resources to conduct the research. To ensure that all students, faculty, associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments. Assures adherence to the study protocol. Monitors the informed consent process regularly and effectively with their research staff. Responsible for protection of the safety and welfare of research participants.

11. Oversees external performance sites, assuring adequate staff, resources, pharmacy practices and Federal assurances with appropriate IRB approvals.

12. Assures the IRB protocol is reflected in the grant proposal for extramural or intramural support, informs the IRB of any updates or modifications to the protocol prior to their implementation and in compliance with Federal and institutional regulations.

13. Assures proper performance of the informed consent process. Retains a copy of the signed and dated informed consent document in the study file and provides a copy to the research participant.

14. Promotes compliance and maintains documents in accordance with Federal and state regulations, and sponsor and institutional policies and procedures regarding the safety and welfare of human participants. Agrees to make those records available for inspection in accordance with 21 CFR 312.68.

15. Agrees to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, to not make any changes in the research without written IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

16. Reviews and approves IRB applications, amendments and adverse events prior to their submission to the IRB, as documented by their signature on the IRB application. Submits applicable reports in a timely manner or according to published deadlines;

17. If applicable, read and understand the information in the investigator’s brochure, including the potential risks and side effects of the drug.

18. Assures participant privacy (relates to person) and confidentiality (relates to data) according to HIPAA guidelines, Institutional and IRB policies and procedures.

19. Agrees to conduct the study in accordance with the relevant, current protocol and to only make changes in a protocol after obtaining IRB approval, and if funded, notifying the sponsor, except when necessary to protect the immediate safety of subjects.

20. Agrees to inform the OPHRS, VA R&D, the ETSU or ETSU/VA IRB (as appropriate) at the time of research site or records audits conducted by study sponsor, monitor or other internal, external or regulatory entity, whether announced or unannounced, for-cause or not for-cause. The initial notification (auditors on site) will be followed by a copy of the written audit findings forwarded by the auditing body to the PI, within 30-days of the PI receiving the report. The audit report must bear a stamped date indicating the receipt of the report at the local site. As available, a copy of the PI response, along with any corrective actions plans must additionally be forwarded.

21. Agrees to inform and identify to any subject, or any persons used as controls, those procedures or other interventions being used for research purposes and ensure that the requirements related to obtaining informed consent and IRB review and approval found in 45 CFR 46 are met.
22. Be responsive to IRB request for information

23. Notify IRB in writing of completed study (xform 107)

24. For non-VA studies, the PI is responsible for obtaining a disclosure of conflict of interest from all study staff members who are involved in designing, conducting, or reporting the research presented in the protocol (anyone with direct contact with participants or direct contact with data collection, reporting or analysis of data, i.e., anyone who could influence outcome of the data). The PI is responsible for obtaining this disclosure from study staff by having each person complete the “Potential Conflict of Interest for Study Staff Form.” The PI is responsible for keeping these completed forms with their study records. Audits of these forms may be conducted by the IRB.

25. The PI is responsible for providing an attestation on new protocol submissions and modifications adding study staff that written disclosures have been obtained and reviewed for any conflict of interest. This attestation is documented on the new protocol submission xform completed by the PI for new protocol submissions and the modification request xform for modifications.

26. For VA investigators, investigators are required to prepare and maintain adequate and accurate case histories. A case history is a record of all observations and other data pertinent to the investigation on each research subject. Case histories include the case report forms and supporting data including signed and dated consent forms, any medical records including, but are not limited to: progress notes of the physician, the individual's hospital chart(s), and nurses' notes. The case history for each individual must document that informed consent was obtained prior to participation in the study.

27. For VA studies, if the PI will not personally obtain consent, the researcher must formally and prospectively designate to another research team member the responsibility of obtaining consent.

28. For VA studies, the principal investigator, local site investigator, and investigator must uphold professional and ethical standards and practices and adhere to all applicable VA and other Federal requirements, including the local VA facility's standard operating procedures, regarding the conduct of research and the protection of human subjects. The responsibilities of the investigator may be defined in the protocol or IRB application.

29. Promotes compliance and maintains documents in accordance with Federal and state regulations, and sponsor and institutional policies and procedures regarding the safety and welfare of human participants. Agrees to make those records available for inspection in accordance with 21 CFR 312.68.

30. For VA studies, students and trainees (including residents and fellows), including VA employees, from schools with an academic affiliation agreement consistent with current VHA policy, may serve as researchers within a VA facility, or use data, or human biological specimens, that have been collected within VA for clinical, administrative or research purposes. A researcher sufficiently experienced in the area of the trainee’s research interest must serve as PI or co-PI and is responsible for oversight of the research and the trainee.
31. For Dept. of Education-funded studies: All instructional material—including teachers’ manuals, films, tapes, or other supplementary instructional material—which will be used in connection with any research or experimentation program or project must be available for inspection by the parents or guardians of the children engaged in such research. Research or experimentation program or project means any program or project in any research that is designed to explore or develop new or unproven teaching methods or techniques. Children are persons enrolled in research not above the elementary or secondary education level, who have not reached the age or majority as determined under state law.

32. For researchers conducting FDA studies: A Researcher may ask a participant who is withdrawing whether the participant wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study. Under this circumstance, the discussion with the participant distinguishes between study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through non-invasive chart review, and address the maintenance of privacy and confidentiality of the participant's information. The Researcher must obtain the participant's consent for this limited participation in the study (assuming such a situation was not described in the original consent document). The IRB or EC must approve the consent document. If a participant withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the Researcher must not access for purposes related to the study the participant's medical record or other confidential records requiring the participant's consent. However, a Researcher may review study data related to the participant collected prior to the participant's withdrawal from the study, and may consult public records, such as those establishing survival status.

Additionally, for studies with investigational drugs or devices,

1. Agrees to inform any subject, patients, or any persons used as controls, that the drugs are being used for investigational purposes and ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21CFR Part 56 are met. Agree to protect the rights, safety and welfare of the participants under their care.

2. Administer the drug or device only to participants under their personal supervision or the supervision of a sub-investigator

3. Supply investigational drug or devices only to persons authorized to receive it under 21 CFR 312.61; 21 CFR 812.110

4. Maintain adequate records of the disposition of the drug, including dates, quantity and use by participants. Device records must include records of receipt, use or disposition of a device including the type and quantity of a device, the receipt date, the batch number or code mark, names of all persons who received, used, or disposed of each device, records of returns, repairs or disposals.
5. Return unused supplies of the drug to the sponsor or otherwise provide for disposal of the unused drug according to regulations at 21 CFR 312.59; 21 CFR 312.62; 21 CFR 812.110

6. Maintain adequate and accurate records recording all pertinent data including the obtaining of informed consent prior to study participation. Allow authorized persons to have access to, and copy and verify records or reports (21 CFR 312.62 and 21 CFR 812.145)

7. Maintain records to meet the standards of all applicable regulations, including federal guidance, institutional standards and sponsor requirements. FDA requires record retention for drug studies to be maintained for a period of 2 years following the date a marketing application is approved for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation if discontinued and FDA is notified (21 CFR 312.62). FDA requires record retention for device studies to be maintained for 2 years after the latter of the following two dates: termination of completion or when records are no longer required (21 CFR 812.140). ETSU policy requires retention of records for six years from the end of the calendar year in which the study has been closed. Sponsor requirements may vary.

8. Furnish reports to the sponsor of the drug, including report shortly after completion of their participation

9. Promptly report to the sponsor any adverse effect that may reasonably be regarded as caused by, or probably caused by, the drug.

10. Provide sponsor with accurate disclosure statements as required at 21 CFR 312.64; 21 CFR 812.110; 21 CFR 54.4(b)

11. Assure that an IRB meeting the requirements of part 56 is responsible for initial and continuing approvals

12. For investigational drug subject to the Controlled Substances Act, take all required security precautions

13. Prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. The case history for each individual shall document that informed consent was obtained prior to participation in the study.
Unaffiliated Investigators

Investigators and physicians in private practice settings who are not acting as employees or agents of the institutions under the approved Federalwide Assurances noted in this policy are subject to all of the usual human protection requirements and responsibilities. Such investigators must sign an Unaffiliated Investigator Agreement (UIA), agreeing to comply with all educational requirements and to be bound by the human protection policies of the institution and its designated IRB. A copy of the fully executed document will be returned to the investigator to be added to the research records. The original copy will be maintained in the IRB Administrative records, along with the curriculum vitae for the investigator.

Study Coordinator and Research Staff

1. All study personnel must complete initial and continuing education in human research protections to remain up-to-date on Federal regulations, ETSU (and VA if applicable) policies and procedures, and compliance expectations.

2. Adheres to Federal regulations, state and local laws, Institutional policies, IRB policies and procedures regarding the safety and protection of human participants and Good Clinical Practice (GCP) guidelines (if applicable to the type of research).

3. Reports adverse events and unanticipated problems involving risks to the participants and others to the IRB according to IRB policies and procedures, sponsors and appropriate Federal agencies as required.

4. Acts as a liaison between the IRB, the Investigator and the sponsor.

5. Promotes compliance and maintains documents in accordance with Federal and state regulations, and sponsor and institutional policies and procedures.

6. Assures participant privacy and confidentiality according to HIPAA guidelines, Institutional and IRB policies and procedures.

7. Disclose any personal conflict of interest as well as any conflict of an immediate family member according to Policy 17a.

Department Chair, Dean or VA Service Chief (ETSU/VA applications) or Vice Provost for Research (MSHA investigators not employed by ETSU or VA)

1. Promotes compliance with Federal and state regulations, and sponsor and institutional policies and procedures regarding the safety and welfare of human participants involved in research studies initiated from their department.

2. Reviews and approves IRB applications prior to submission, as documented by their signature on the IRB application to assure the soundness of the research design, scientific and scholarly merit in relation to the departmental capacities, and adequate staff and resources to conduct the study.
Thesis/Dissertation Chair/ Non-Thesis Faculty Advisor Responsibilities

1. Agrees to meet with the student investigator on a regular basis to monitor study progress;

2. Agrees to be available, personally, to supervise the student investigator in solving problems, should problems arise during the course of the study;

3. Advises the investigator that he/she and all study personnel must complete the ETSU human subjects training program;

4. Advises the student investigator that the project must be performed only by approved personnel according to the approved IRB application;

5. Advises the student investigator not to implement any changes to the approved IRB application before receiving IRB approval for the change(s); (see exception in Policy 10);

6. Advises the student investigator to only obtain legally effective informed consent form human participants or their legally responsible representative, (if IRB approved). Furthermore, advises the student investigator to only use the currently approved date stamped informed consent document for human participants; and that a copy of the informed consent is provided to the participant unless a Waiver or Alteration of Requirement to Obtain Informed Consent has been granted;

7. Advises the study investigator to promptly report any unanticipated problems involving risks to participants or others to the IRB in accordance with ETSU IRB Policies and Procedures;

8. Advises the student investigator that he/she must assume the responsibility for the accurate documentation, investigation, and follow-up of all possible study-related unanticipated;

9. Advises the student investigator to promptly provide the IRB with any information requested relative to the project including a continuing review application;

10. Advises the student that regulations require that a change in study status, including study completion, be communicated to the IRB (xForm 107). Additional guidance must be obtained from the IRB, if a completed xForm 107 closing the study is not submitted prior to graduation.

11. Ensures that the student investigator obtains continuing review approval prior to the expiration of the study unless the study has been determined to be exempt. Further, understands that if the student investigator fails to apply for continuing review, approval for the study will automatically expire; and advises the student that all study activity must cease until IRB approval is obtained.

12. Advises the student investigator that failure to comply with an IRB request of continuation review is non-compliance and that this is true even after graduation. Advises the student that failure to respond to IRB requests may constitute serious.

and/or continuing non-compliance which is reportable to the Office for Human Research Protection (OHRP) and other appropriate authorities, as applicable.

**ALL members of the organization**

1. Be aware of definitions of human subject research and consult the IRB when an uncertainty exists about whether a proposed activity is human subjects research

2. Not conduct human subject research or allow human subject research to be conducted without institutional IRB approval

3. Report allegations of non-compliance to the IRB

**Conflict of Interest**

**Pertinent Definitions**

*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.

*Financial Interest Related to the Research:* means financial interest in the sponsor, product or service being tested.

*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.

*Significant Financial Interest* includes, but is not limited to, any economic or monetary interest of the types listed in "(a)" through "(f)" below, that is held by a covered individual (or by his/her immediate family member), and that to an independent observer would reasonably appear to affect or be affected by research in which the individual is involved, or that is held by any entity in which a covered individual (or his/her immediate family member) has a financial or fiduciary interest the financial interests of which entity would reasonably appear to an independent observer to affect or be affected by the
research (e.g. stock values, etc.). (Such an entity may be a financially interested entity):

A. "Compensation interest," meaning salary, consulting fees, wages, retainers, honoraria (including honoraria from a third party, if the original source is a financially interested company), gifts or other emoluments, "in kind" compensation from a financially interested company (or entitlement to the same), or any other thing of economic or monetary value whether for consulting, lecturing, travel, service on an advisory board, or for any other purpose not directly related to the reasonable costs of conducting the research (as specified in the research agreement), that in the aggregate have in the past 12 (twelve) months exceeded $5,000, or are expected to exceed that amount in the next twelve months;

B. "Equity interest," meaning

1. any equity interest (or entitlement to the same), in a publicly-traded financially interested entity that exceeds $5,000 in value or represents more than 5% ownership interest in any single entity (see exclusions below), or
2. equity interests, including stock options, warrants, or other convertible securities, of any amount in a non-publicly-traded financially interested entity (or entitlement to the same) whether or not financial value can be determined through reference to public prices;

C. "Intellectual property interest" meaning

1. royalty income or the right to receive future royalties under a patent license or copyright, where the research is directly related to the licensed technology or work; or
2. any other direct or indirect interest in a patent, trademark, copyright, trade secret, know-how or other intellectual property right where the research is directly related to the interest;

D. "Extraneous research payments," meaning any non-royalty payments or entitlements to payments in connection with the research that are not directly related to the reasonable costs of the research (as specified in the research agreement between the sponsor and the institution), including any bonus or milestone payments to the investigators in excess of reasonable costs incurred, whether such payments are received from a financially interested entity or from the institution;

E. "Fiduciary relationship," meaning service as an officer, director, or in any other fiduciary role for a financially interested entity, whether or not remuneration is received for such service.

F. “Compensation affected by the outcome of the research” meaning compensation of any amount that could be higher for a favorable outcome than for an unfavorable outcome, such as compensation that is explicitly greater for a favorable result or compensation to the investigator in the form of an equity interest
in the sponsor of a covered study or in the form of compensation tied to sales of the product, such as a royalty interest.

Exclusions: Significant financial interest excludes, and therefore is not meant to refer to, the following types or categories of economic or monetary interest:

"Mutual fund interests," meaning interests of any amount in publicly traded, diversified mutual funds;

"De minimis equity interests," meaning stock or stock options in a publicly traded company that, when aggregated for the covered individual (and/or his or her immediate family members) meets both the following tests: it does not exceed $5,000 in value (as measured in reference to public prices or other reasonable measure of fair market value) and does not represent more than a 5% ownership interest in any single entity;

"Outside payments," meaning salary, royalties, and other payments from entities other than the University, or via the University to the individual, that when aggregated for the covered individual (and/or his or her immediate family members), over the next 12 months, are not expected to exceed $5,000;

"Regular research payments," meaning payments to the University, or via the University to the individual, that are directly related to reasonable costs incurred in the conduct of research as specified in the research agreement between the sponsor and the University;

"University compensation," meaning salary, royalties, and other remuneration for services from the University;

"Public or non-profit income," meaning income for service on advisory committees or review panels for public or non-profit entities, or from seminars, lectures, or teaching engagements sponsored by public or non-profit entities.

The policy of both the East Tennessee State University Campus Institutional Review Board (ETSU IRB) and the East Tennessee State University/Veterans Affairs Institutional Review Board (ETSU/VA IRB) is to establish procedures for reporting and managing conflict of interest as it pertains to research conducted at ETSU and James H. Quillen VAMC that involves use of human research subjects. They are based on policies set forth in VHA Handbook 1200.13 and the ETSU Faculty Senate Handbook 1.17. These policies are not intended to eliminate any situation of conflict of interest, but to give an understanding of what is conflict of interest and how to report and manage it. It is the policy of the ETSU IRB and the ETSU/VA IRB that all significant financial interest, as well as other conflict of interests, be reported to the IRB for review to assure protection of the rights and welfare of participants in human subject research.

Study Staff 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. For non-VA studies, the PI is required to submit this information in the IRB potential conflict of interest section of the new protocol submission xForm.
For non-VA studies, the PI is responsible for obtaining this disclosure from all study staff members who are involved in designing, conducting, or reporting the research presented in the protocol (anyone with direct contact with participants or direct contact with data collection, reporting or analysis of data, i.e., anyone who could influence outcome of the data). Study staff members must disclose any personal conflict of interest as well as any conflict of an immediate family member. The PI is responsible for obtaining this disclosure from study staff by having each person complete the “Potential Conflict of Interest for Study Staff Form.” The PI is responsible for keeping these completed forms with their study records. Audits of these forms may be conducted by the IRB.

The PI is responsible for providing an attestation on new protocol submissions and modifications adding study staff that written disclosures have been obtained and reviewed for any conflict of interest. This attestation is documented on the Potential Conflict of Interest for Investigators Form completed by the PI for new protocol submissions and the modification request form for modifications.

For VA studies, all research personnel are required to have a VA Conflict of Interest Form on file with the VA R&D Office. The VA Administrative Officer for Research is responsible for attesting to the IRB that those forms have been reviewed and any reported conflict disclosed to the IRB. This is applicable to both new protocol submissions and modifications adding study staff.

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, then 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. Like all VA employees, VHA employees conducting VA research approved by the Research and Development Committee, must comply with the Federal criminal code and the Standards of Ethical Conduct for Executive Branch Employees.

⇒ For researchers affiliated with both institutions, both forms must be completed and submitted as noted above (two parallel pathways).

The proposal will be held by the IRB Coordinator until a management plan as detailed below is received in the IRB Office. 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. The IRB Director will inform either the Vice Provost for Research or the ACOS/R of the disclosed financial interest.

If the Vice Provost for Research or the ACOS/R has already reviewed the financial interest, the Vice Provost for Research or the ACOS/R will inform the IRB in writing of all actions taken
according to the relevant policies. Otherwise the Vice Provost for Research or the ACOS/R 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/R has completed the review. All IRB members will be provided with a copy of the report of Vice Provost for Research or the ACOS/R.

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.

**Managing Conflicts of Interest**

In addition to actions taken by the Vice Provost for Research or the ACOS/R, 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 cannot 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. The researcher will be required to attend a mandatory educational session with the VPR. 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)

**Human Research Protections Training**

The IRB has contracted with a group of collaborating professionals through the University of Miami to manage and provide the necessary educational materials for Investigators engaged in research involving humans. The **Collaborative Investigator Training Initiative** (CITI) is a required course for those Investigators and study personnel who have not previously completed ETSU initial or continuing human research training requirements. IRB applications will not be accepted from Investigators who have not successfully completed the training. In addition, all study personnel listed on the application will have to complete CITI. IRB approval will not be granted for initial or continuing review of research of protocols in which study staff do not have current human research protections training.

Modules from each pathway will take approximately 10 to 30 minutes. The course does not have to be completed in one sitting and the modules can be completed in any order. A combined score of 80% or better is required for passing. To complete the CITI training, Investigators and all key study personnel should review the following instructions:

**Study Personnel** - anyone who is responsible for the design or conduct of the study. This list may include, but not limited to, sub-investigator (Co-investigators), research assistants, research coordinators, research nurses, etc.

**First Time Users of CITI Training Program**

1. Go to [www.citiprogram.org](http://www.citiprogram.org) and click on “Register for the CITI Program”, then submit
2. Under ALL OTHERS, Choose “East Tennessee State University” and submit
3. Select your Username and Password, then press submit. This is what you are going to use to go in and out of the program

4. Fill out Registration Page, then submit information

5. Select your group below and submit:
   ⇒ Group 1- Biomedical not affiliated with VA
   ⇒ Group 2- Biomedical affiliated with VA
   ⇒ Group 3- Social and Behavioral not affiliated with VA
   ⇒ 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.

9. 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.

The IRB might require that you complete additional requirements from the “Optional Modules” section. However, you do not have to complete these modules until notified to do so.

**Ongoing Training Requirement**

The IRB requires that all Investigators and study personnel have ongoing training in the area of human research protections. As studies are submitted for continuing review to the IRB, the staff will check to see that this requirement is met.

The IRB Office will provide a reminder when recertification is required. Failure to meet this requirement will delay the continuing review process, which may result in expiration of study approval.

Additionally, faculty members are invited to contact the IRB Office to schedule a topic specific seminar, if further training is necessary. In-depth instruction on specific topics is also available, and will be scheduled by IRB staff in response to departmental request.

In addition, basic training materials, including the *Belmont Report*, and links to the pertinent Federal regulations and other resources, are available on the IRB website [http://www.etsu.edu/irb](http://www.etsu.edu/irb). All IRB forms and related information are also posted on the website.
In addition, the Policies and Procedures Manual is also available on-line, as is specific guidance directed to graduate students, residents, etc.

The IRB Staff create a quarterly newsletter containing information about new developments in policies, procedures and regulations as well as a spotlight on a topic. This newsletter is posted on the IRB website.