IRB Policy 21a: External IRB Procedure
Version January 7, 2020

I. Summary

The IRB policy is to make guidelines and procedure for investigators, IRB staff, and IRB members understandable and available to all involved in the process, including this information about procedures for submitting research where an external IRB or institution is involved.

ETSU may choose to accept the review and approval of human subject research studies as granted by an external IRB organization. ETSU has procedures in place to determine whether relying on an external IRB is appropriate on a study-by-study basis. If reliance is deemed appropriate by HRPP Administration, the procedures in this document should be followed.

Research which includes veteran populations or is otherwise supported by VA resources is subject to 38 CFR 16 and must be reviewed for approval by the ETSU/VA IRB as well as the VA Research & Development Committee. VA may only rely on an external IRB that is listed on the VA FWA. For multisite studies, an IRB of a non-affiliated institution can serve as the IRB of Record for a VA facility if that IRB has been specifically designated by ORD as an IRB that may serve as a multi- site IRB for VA facilities. However, the use of a commercial IRB is prohibited for VA research.

II. Responsibilities

ETSU retains ultimate responsibility for safeguarding the rights and welfare of human research participants involved at its performance site. The ETSU Human Research Protection Program is responsible for ensuring the ethical review and regulatory oversight of human subjects research in which ETSU or its employees or agents are engaged.

A. Responsibilities of ETSU as Relying Institution:

1. Maintain approved federal-wide assurances (FWAs), including ensuring that the arrangement with the reviewing IRB is documented by a written Institutional Authorization Agreement.
2. Maintain policies and procedures for the conduct of human subjects research as appropriate for ETSU.
3. Maintain program for education of investigators and research staff and training in human subjects research.
4. Maintain and confirm appropriate institution-specific required credentialing of staff.

5. Implement oversight to ensure compliance with the determinations of the reviewing IRB.
6. Prior to IRB review, evaluate the local context in which the research will be conducted, including consideration of any specific requirements of state or local laws, regulations, policies, or standards, and provide the IRB with any local context issues relevant to the research protocol.
7. Communicate with institution and reviewing IRB as appropriate to ensure oversight and compliance of human subjects research.
8. Conduct monitoring in addition to, and in cooperation with, the reviewing IRB, as appropriate to the degree of risk for each protocol.
9. Notify the reviewing IRB when local policies or laws change such that IRB review and oversight may be affected.
10. In coordination with the reviewing IRB, review and coordinate the investigation of potential serious or continuing noncompliance, unanticipated problems, or research misconduct.

B. Responsibilities of PI:

1. Provide ETSU with the required documents from the reviewing IRB, which include the approval letter from the external IRB, the approved protocol, the approved informed consent, the grant (if applicable), relevant Investigator's Brochure (if applicable), participant documents (i.e., advertisements, surveys, questionnaires, phone scripts), documentation of approved waiver, documentation regarding HIPAA, and any other documentation reviewed by the external IRB in the approval determination.
2. Disclose financial conflicts of interest according to the agreed upon process and complying with any conflict management plans that may result.
3. Ensure that other ancillary reviews (e.g., Biosafety) required by ETSU are obtained and provided to the reviewing IRB in accordance with their policies.
4. Ensure that no individuals will be enrolled in research prior to review and approval by the IRB and receipt of the registration documents from ETSU and receipt of any other required institutional approvals, including institutional approval for MSHA studies.
5. Cooperate with the reviewing IRB's responsibility for initial and continuing review, recordkeeping, and reporting. Submit all information requested by the reviewing IRB in a timely manner. When responsible for enrolling participants, obtain, document, and maintain documentation of informed consent for each participant, or each participant's legally authorized representative, using the process approved by the reviewing IRB.
6. Submit copies of results of the external IRB review of amendments or other approvals to ETSU within 10 days of receipt. Required documents for modifications are: the proposed amendment, the IRB approval letter, IRB-approved protocol, informed consent document, and any other relevant documents.

7. Report non-compliance, participant complaints, protocol deviations or other events, including UPIRTSOs, according to the requirements specified in the reliance agreement. Submit any UPIRTSOs that involve ETSU research participants or personnel to ETSU within 10 days. In addition, the results of the external IRB's review must be submitted to ETSU within 10 days of receipt.
8. Submit copies of monitoring reports to ETSU within 10 days of receipt.
9. Submit the reviewing IRB continuing review approval letter, the final approved protocol and informed consent, the progress report, and any other documents reviewed by the external IRB and any monitoring reports not previously submitted to ETSU in a timely manner.
10. At study closure, submit a copy of the final report provided to the external IRB and the closure approval letter from the external IRB to ETSU. If MSHA study, notify MSHA Research Department.
11. Maintain research study documentation in accordance with ETSU Policy and retain the records for a period of six years after the calendar year in which the study is closed.

C. Responsibilities of the HRPP Director and Vice Provost for Research:

1. Administratively review initial reliance requests to determine whether reliance is appropriate and acceptable on a study-by-study basis.
2. Communicate with external IRBs as needed to facilitate IRB review and provide local context information.
3. Confirm or establish any necessary reliance agreements.
4. Ensure roles and responsibilities are satisfactorily defined in the terms of the reliance agreement.
5. Confirm compliance with local laws, standards, and institutional requirements as appropriate on a study-by-study basis.
6. Ensure all appropriate local ancillary reviews are completed.
7. Administratively review all external registration events.

D. Responsibilities of IRB Staff:

1. Conduct a pre-review to ensure the reliance requests and subsequent events are complete by verifying applicable fields in the xform.
2. Confirm investigator and study staff training and qualifications in accordance with ETSU IRB Policy.
3. Prepare the request for administrative review.
4. Prepare letters using the appropriate templates.
5. Assure all appropriate database entries are completed in IRBManager.
6. Assure the PI and reviewing IRB receive the Registration Letter.
7. If MSHA study, ensure MSHA Research Department is notified of new submission.
8. Facilitate the education of investigators and study in regards to their responsibilities, requirements, and the review process.

III. Requirements

The ETSU Principal Investigator must prepare an electronic submission in IRBManager and submit the Request to Rely on an External IRB xform. The xform will route through the IRB Coordinator, IRB Chair, HRPP Director, and VPR for administrative review. If the study involves MSHA, the xform will route through the MSHA Research Office prior to ETSU review.

The following documentation must be submitted for consideration:

1. Request to Rely on External IRB xform
2. Documents from the reviewing IRB, which include the initial approval letter from the external IRB, the approved protocol, the approved informed consent, the grant (if applicable), relevant Investigator's Brochure (if applicable), participant documents (i.e., advertisements, surveys, questionnaires, phone script), documentation of approved waiver, documentation regarding HIPAA, and any other documentation reviewed by the external IRB in the approval determination.
3. For local investigators and key personnel, copies of letters or other documents (e.g., course syllabus, certificate, CEU or CME awarded, etc.) assuring compliance education in the ethical conduct of human subject research in order to establish and maintain a culture of compliance with Federal regulations and institutional policies relevant to the protection of human subjects
4. Reliance Agreement signed by the Reviewing IRB's Signatory Official
5. If deemed necessary by ETSU HRPP Director, copies of relevant minutes indicating initial review and approval, any controverted issues, continuing review and/or requested revisions to the research

Correspondence from the reviewing IRB must include the IRB project number issued by IRB of Record along with the study approval and expiration dates. The informed consent document must include ETSU IRB or MSHA (if MSHA study) language in research-related injury, confidentiality, and HIPAA sections as applicable.

IV. Registration

Upon completion of all requirements, the IRB coordinator will issue an "External Reliance Registration" letter to the local PI. The registration period will be for the same period as the IRB approval period. The local PI is responsible for sharing this documentation with the lead site. Reminders regarding the ETSU registration expiration will be sent to the ETSU investigator by the IRBManager system.

If the request to rely is not accepted, notification will be forwarded to the PI indicating the reasons for the decision and offering the PI an opportunity to respond in writing. The PI may choose to submit the proposed protocol for review by the local IRB.

V. Continuing Review

Continuing review of approved research will be initiated by the IRB of Record, who shall remain responsible for determining the frequency and extent of continuing review for each study as adequate to ensure the continued protection of the rights and welfare of research subjects. The period of continuing review shall not exceed twelve months from the date of IRB approval. The ETSU investigator must submit documentation of this substantive review and outcome, as conducted by the IRB of record. ETSU will administratively review the submission, and if accepted, issue an External Continuing Registration letter with the same expiration date as IRB approval.

The ETSU investigator will submit the following documentation in IRBManager:

- External Continuing Registration xform
- The continuing review approval letter from the externa IRB
- The most recent approved protocol and informed consent
- The progress report
- Any other documents considered by the external IRB in making its determination to approve the continuing review

VI. Modifications or Amendments

During the conduct of the study, the ETSU investigator remains responsible for reporting all substantive study modifications to ETSU within 10 days of the external IRB's approval. Study modifications that do not affect the conduct of the study locally do not have to be reported to ETSU; for example, adding study staff at any study site. ETSU will administratively review the modification, and if accepted, issue an External Events Acknowledgement letter.

The ETSU investigator will submit the following documentation in IRBManager:

- External Events Report xform, select results of an external IRB review of an amendment and describe the changes
- The amendment approval letter from the external IRB
- The amendment form or document describing the changes
- The approved, revised protocol and/or consent document
- Any other documents considered by the external IRB in making its approval determination

VII. Other reportable events

During the conduct of the study, the ETSU investigator is responsible for reporting to ETSU any safety events, including monitoring reports, serious adverse events, protocol deviations, or unanticipated problems (UPIRTSOs) that involve ETSU or MSHA personnel or research participants within 10 days of the event. If the reviewing IRB makes a determination of serious or continuing non-compliance, or suspension or termination of the

study, that determination must be reported to ETSU promptly. The ETSU investigator must notify ETSU immediately if there is an allegation of noncompliance that may rise to the level of serious or continuing noncompliance. ETSU will notify MSHA Research Department if applicable.

As soon as documentation is available, the external IRB's resolution of the event must be provided to ETSU including any applicable corrective action plans.

The ETSU investigator will submit the following documentation in IRBManager:

- External Events Report xform, select appropriate reportable event and describe the event
- The event report and any other documentation considered by the reviewing IRB during its assessment of the event
- The external IRB's letter documenting review of the event, including corrective action plans as applicable

ETSU will administratively review all external event reports including the external IRB's resolution of the event. As appropriate, ETSU may determine that additional corrective actions are required by the ETSU investigator. An External Event Acknowledgment letter, and supplemental documentation as applicable, will be provided to the ETSU investigator once ETSU is satisfied with the resolution of the event.

In coordination with the reviewing IRB, the Vice Provost for Research will be responsible for reviewing and coordinating the investigation of potential serious or continuing noncompliance, UPIRTSOs, or research misconduct involving ETSU or MSHA personnel or research participants. The VPR has the ultimate authority in determining whether or not reliance continues to be appropriate for a particular study with consideration for any compliance issues that arise during the conduct of the research.

VII. Credentialing of Staff

ETSU relies on the credentialing process of Mountain States Health Alliance for MSHA studies. If the study is not submitted by a MSHA investigator, then required licenses will be verified by the Vice Provost for Research at ETSU.

References:

ETSU IRB Policy 21: IRB Reliance
VHA Directive 1200.5
Considerations Document: CITI Use of Central IRBs in Multicenter Clinical Trials
FDA Information Sheet, Non-Local IRB Review (1998)
OHRP Guidance, IRB Knowledge of Local Research Context, August 27, 1998 (updated July 21, 2000)