IRB Policy 21: External IRB Policy
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I. Summary Policy

ETSU may choose to accept the review and approval of human subject research proposals, protocols or studies as granted by an external IRB organization. However, the use of a commercial IRB is prohibited for VA research.

II. Criteria for External IRB

The external IRB, or *IRB of Record*, must

(a) have an accredited human research protection program or be determined by the ETSU VPR to meet ETSU standards
(b) be registered through the DHHS Office for Human Research Protection (OHRP).

The respective responsibilities of the IRB organization and the Assuring institution

(c) must be formalized in a written agreement
(d) approved and signed by the signatory official (Vice Provost for Research) at East Tennessee State University,
(e) approved and signed by the correlative officials of each of the other cooperating institutions, and
(f) retained by the Office for the Protection of Human Research Subjects at East Tennessee State University for at least three (3) years past completion of the related research project. Although the agreement does not have to be sent to OHRP for initial approval, it will be provided upon written request.

III. Responsibilities

ETSU retains ultimate responsibility for safeguarding the rights and welfare of human research participants involved at its performance site.
Responsibilities of ETSU:

1. Maintain program for education of investigators and research staff and training in human subjects research.

2. Maintain policies and procedures for the conduct of human subjects research as appropriate for ETSU.
3. Maintain appropriate institution-specific required credentialing of staff.
4. Maintain approved federal-wide assurances (FWAs), including ensuring that the arrangement with the central IRB is documented by a written Institutional Authorization Agreement.
5. Implement oversight to ensure compliance with the determinations of the reviewing IRB
6. Designate the IRB of record for the protocol.
7. Obtain IRB approval of research protocols involving human subjects.
8. For PHS-funded research, conduct a conflict of interest (COI) review pursuant to the Public Health Service regulations on Promoting Objectivity in Research, 42 CFR Part 50, Subpart F.
9. Notify the IRB promptly in writing of serious or continuing non-compliance or unanticipated problems involving risks to subjects or others.
10. 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.

Responsibilities of PI:

1. Provide to ETSU 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), advertisements, surveys, questionnaires, phone scripts and other participant documents, documentation of approved waiver, documentation regarding HIPAA, and any other documentation reviewed by the external IRB in the approval determination.

2. 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.

3. Submit any serious adverse events, protocol deviations/ violations, or UPIRTSOs promptly to ETSU (in addition to the reviewing IRB). Any UPIRTSOs that involve ETSU research participants or personnel must be reported 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.

4. Submit copies of monitoring reports to ETSU within 10 days of receipt.
5. 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.
6. 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.
7. Disclose financial conflicts of interest according to the agreed upon process and complying with any conflict management plans that may result.
8. 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 approval of MSHA Research Proposal Request Form for MSHA studies.
9. Allow ETSU, and MSHA if a MSHA study, to conduct post-approval monitoring in addition to, or in cooperation with, the reviewing IRB.
10. Cooperate with the reviewing IRB and provide information requested by the IRB in a timely manner.

Responsibilities of IRB Coordinator

1. Conduct a pre-review and determine whether the "Request to Rely on External IRB" is complete, verify applicable fields
2. Prepare the request for IRB Chair review
3. Prepare letters using the appropriate template.
4. Assure all appropriate database entries are completed in IRBManager
5. Assure that the PI and reviewing IRB receive the Registration Letter
6. If MSHA study, ensure MSHA Research Department is notified of new submission

Responsibilities of the HRPP Director and the IO

1. Review monitoring reports
2. Review report of UPIRTOs and non-compliance
3. Review any external IRB approvals
4. Review initial applications for external IRB registrations
5. Review external continuation registration form

IV. Determining Factors

Studies initiated by a Principal Investigator (PI) at another institution and later transferred to ETSU, and studies where the research activities are predominantly conducted at another institution with that site's IRB approval are potential instances where reliance upon another qualifying IRB may be appropriate.

Local laws, institutional policies and constraints, professional and community standards, and population differences are examples of pertinent local factors that can influence the setting of research [see 46.103(d)]. In these instances, and at the discretion of the appropriate IRB Chair, either the ETSU IRB or ETSU/VA IRB may elect to conduct their own review and not accept the review of the external IRB. For example, the considered opinion of an IRB of one institution may be blind to information that would alter its decision for another where:

- institutions draw from culturally dissimilar patient populations;
- institutions are located in different states or other geographical subdivisions with varied legal or regulatory constraints;
- Institutions are not accustomed to each other's operational policies, constraints , procedures, or commitments;
- there is uncertain satisfaction of drug control responsibilities, or other FDA requirements; or
- research populations are taken from certain vulnerable categories of human subjects.

In addition, 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 medical or dental school 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.

V. Requirements

Specifically, the following documentation must be submitted by the Principal Investigator (PI) or institution providing the FWA to the ETSU Office for the Protection of Human Research Subjects (OPHRS) for consideration:

- Request to Rely on External IRB xform
- 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), advertisements, surveys, questionnaires, phone scripts and other participant documents, documentation of approved waiver, documentation regarding HIPAA, and any other documentation reviewed by the external IRB in the approval determination. Correspondence must include the IRB project number issued by IRB of Record.
- ICD must include ETSU IRB and MSHA (if MSHA study) language in confidentiality and HIPAA sections
- 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
- Copies of relevant minutes indicating initial review and approval, any controverted issues, continuing review and/or requested revisions to the research
- Completed IRB Authorization Agreement, signed by the Signatory Official (Original Copy)
- Completed Unaffiliated Investigator Agreement (Original Copy)

VI. Registration

1. Upon completion of all the requirements, the IRB coordinator will issue an "External Reliance Registration" letter to the PI and the reviewing IRB. The registration period will be for the same period as the IRB approval period.

If the research 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 person or in writing [46.109(d)]. At the discretion of the IRB Chair, the PI may choose to submit it for formal review by the local IRB.

VII. 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 PI will be asked for documentation of this substantive review and outcome, as conducted by the IRB of record.

VIII. Non-Compliance

If the reviewing IRB makes a determination of serious or continuing non-compliance, or suspension or termination of the study, that determination will be reported to the ETSU or ETSU/VA IRB for informational purposes. ETSU will notify MSHA Research Department if a MSHA study.

IV. 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

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, 2998 (updated July 21, 2000)