

# Guidance for Investigators regarding External IRB Reliance

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## What is an external reliance?

An external reliance is when ETSU chooses to accept the review and approval of an IRB from an external organization.

## When is this possible?

Here are the factors to consider:

- a. The external organization must have an accredited human subject protection program. In very rare circumstances, in the absence of accreditation, ETSU may rely on an external IRB that meets ETSU human research protection standards.
- b. The external IRB must have a current FWA and be registered with OHRP (and FDA if applicable).
- c. 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. In studies where these may be an issue, and at the discretion of the HRPP Director and Vice Provost for Research (VPR), review by one of the ETSU IRBs may be required.
- d. VA studies require ETSU/VA IRB review and may not use an external reliance unless the external IRB is listed on the VA FWA.

## How do I submit a request to rely on an external IRB?

You must be an active user of ETSU's electronic system, IRBManager. Contact the IRB at 423-439-6053 if you need to be authorized to use this system. If you are not the PI, the PI will need to be an approved user of this system as well.

In IRBManager, submit a "Request to Rely on External IRB" xform. This form has two steps for the investigator. You will first be asked to provide some basic

information, which will then be reviewed by the HRPP Director and VPR. The PI will receive an email about whether reliance is appropriate.

If the study is eligible to be reviewed by an external IRB, then you will be asked to attach all the required documents in your xform. One of those documents is an agreement called an Institutional Authorization Agreement, or IAA, that must be signed by the appropriate signatory at both institutions. Other required documents include a copy of the external IRB approval letter, as well as documents reviewed and approved by the external IRB.

Once you submit the Request to Rely on External IRB xform with the required attachments, the VPR will evaluate the request. If the request is accepted, the PI will receive a “Registration” letter from ETSU. The research study may NOT be started until you receive this Registration letter from ETSU, as well as any other applicable institutional approvals.

### **What are the PI’s responsibilities?**

The PI is responsible for safeguarding participants’ rights and welfare, complying with all applicable policies and regulations, and ensuring that the research is conducted in accordance with the reviewing IRB’s determinations. ETSU expects that ETSU investigators and study will be familiar with and comply with all ETSU IRB Policies and Procedures, including reliance requests. The PI must:

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. 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 applicable), 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.
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.

**How do I submit the reports required in the section above?**

All reports are submitted electronically in IRBManager and must be signed by the PI. To submit the results of a continuing review from the external IRB, submit an “External Continuing Registration” xform. To submit any other report, including amendments, protocol deviations/violations, UPIRTSOs, monitoring reports, submit an “External Events” xform. The HRPP Director and VPR evaluate the post-approval reports and confirm that reliance continue to be appropriate.

**What if I have other questions about this process?**

There are additional guidance documents and educational resources available on the ETSU IRB website. The HRPP Director is the primary contact for all reliance-related questions and can be reached at 423-439-6054.