Examples of when IRB Reliance is appropriate

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. The following are examples of when reliance may be appropriate or required.

Contact the ETSU IRB Office to discuss your particular situation to determine if reliance is appropriate. The Vice Provost for Research has ultimate authority in determining whether or not to enter into any reliance agreement.

1. ETSU may be required to allow review by an external IRB if the institution wants to be a participating site in particular multisite research.

   Examples of when the use of a specific external IRB may be required:

   a. Research which includes veteran populations or is otherwise supported by VA resources may only rely on an external IRB that is listed on the VA FWA, or an IRB that been specifically designated by ORD.
   b. Multisite research as part of a consortium that is mandating use of a single IRB.
   c. Use of the Central IRB for the National Cancer Institute (NCI IRB).
   d. The funding entity requires use of an external IRB; an instance is the NIH Policy on the Use of a Single IRB for Multisite Research, which requires single IRB for all participating sites as named in the terms of the award (with few exceptions).
   e. Federal regulations, or other laws/policies, that require use of specific IRB, such as the 2018 Common Rule regulations requiring single IRB review for federally funded cooperative research initially approved after January 20, 2020.

Examples of when IRB Reliance is appropriate

2. ETSU may voluntarily decide to rely on an external IRB in a variety of situations.

   Examples of when ETSU may voluntarily decide to rely on an external IRB:

   a. When the ETSU IRBs lack the particular expertise for reviewing the proposed research
   b. When ETSU as an identified institutional conflict of interest preventing objective IRB review
   c. When ETSU has determined due to resource, legal, or other concerns that serving as the IRB for a single or multisite protocol is not feasible
   d. When reliance would facilitate collaborations among researchers and organizations
   e. Studies initiated by a PI at another institution and later transferred to ETSU
   f. Studies where research activities are predominantly conducted at another institution and supervised by a lead PI at another institution
   g. Studies where ETSU is a collaborator and the investigator's role does not include interaction with human subjects
   h. Studies where ETSU is engaged solely because it is a recipient of federal funds but the research activities take place elsewhere

The ETSU IRBs may conduct their own review and not accept the review of an external IRB if either the HRPP Director or VPR determine that there is uncertain satisfaction of drug control responsibilities or other FDA requirements. Similarly, external IRB may not be appropriate if other concerns such as culturally dissimilar patient populations or different geographical subdivisions with varied legal or regulatory constraints, or other concerns about the review/conduction of the study arise.