PROCEDURE FOR DETERMINING THE USE OF AN EXTERNAL IRB

Who does this apply to?

This applies primarily to TTUHSC Principal Investigators who receive federal funding to conduct multi-site research and TTUHSC Principal Investigators whose research targets prisoners.

What is the process to obtain External IRB approval?

1) **Primary Award** – If the TTUHSC PI is the PI for a federally funded multi-site research project:
   a) While developing your grant, contact the TTUHSC IRB Office to ask if TTUHSC will be the IRB of record or if an external IRB is necessary (requires a reliance agreement).
      i) Lubbock IRB 806-743-4753
      ii) Amarillo IRB 806-414-9935

      The TTUHSC IRB Office will identify existing contracts TTUHSC has with external IRBs that oversee multi-site research. The PI may also choose to investigate the use of other commercial IRBs (examples: Western IRB (WIRB), IntegReview IRB, New England IRB, etc).
   b) TTUHSC IRB Office personnel will assist to establish a reliance agreement which may include:
      i) Consent procedures/documents
      ii) Recruitment procedures/documents
      iii) HIPAA Privacy Rule requirements
      iv) Translational services/documents.
   c) The time necessary to complete this process is variable and may be anywhere from 1- 4 weeks.
   d) The Research Integrity Office Managing Director or Assistant Vice-President of Research must sign reliance agreements prior to submission to an external IRB.

2) **Sub-Award** – If the TTUHSC PI is beginning a collaborative role on an existing or federally funded research project, the single IRB of record has already been determined.
   a) The TTUHSC PI should request the name of the single IRB (Reviewing IRB) of record (for example: National Cancer Institute Central IRB (CIRB), Western IRB (WIRB), etc. from the Study Sponsor (recipient of the primary federal funding).
   b) Contact the TTUHSC IRB Office to verify if an agreement with the external IRB is already in existence.
      i) Lubbock IRB 806-743-4753
      ii) Amarillo IRB 806-414-9935
   c) If no agreement is in existence, TTUHSC IRB Office personnel will assist with establishing a reliance agreement which may include:
      i) Consent procedures/documents
      ii) Recruitment procedures/documents
      iii) HIPAA Privacy Rule requirements
      iv) Translational services/documents.
   d) The time necessary is variable and may take anywhere from 1- 4 weeks.
   e) The Research Integrity Office Managing Director or Assistant Vice-President of Research must sign reliance agreements prior to submission to an external IRB.

What does the TTUHSC IRB require when I use an External IRB?
The use of an external IRB does not exempt TTUHSC from human research activity oversight. TTUHSC remains accountable for the conduct of human research by TTUHSC personnel. The PI and study personnel are required to comply with **BOTH** TTUHSC research policies **AND** the external IRB policies.

Therefore, the following is required:

- Completion of TTUHSC IRB Education and Training for all study personnel https://www.ttuhsc.edu/research/divisions/integrity-office/education/irb-training-requirements.aspx
- iRIS accounts for all study personnel https://www.ttuhsc.edu/research/divisions/integrity-office/education/iris-accounts.aspx
- Initial Submission
    - IRB application submitted via iRIS with the following attached:
        - External IRB Approval Letter
        - Protocol
        - Investigator Brochure (if applicable)
        - Consent Document(s)
        - Recruitment materials to be used at local site
- During the conduct of the Research
    - Continuing Review Form (frequency as required by the External IRB)
        - External IRB Continuing Review Approval Letter
    - Unanticipated Event Reports as required by TTUHSC for local subjects
    - Amendments
        - External IRB amendment approval letter
        - Any revised documents

TTUHSC written IRB acknowledgement is required prior to initiating research activities at the local site(s) and prior to initiating amendment changes at the local site.