DOES MY PROPOSED STUDY REQUIRE A SINGLE IRB?

STEP I: Is a Single IRB Required or Appropriate for the Proposed Study?

- Study is Deemed non-exempt human subjects research by ETSU IRB
  - YES
  - NO

  - More than one U.S. domestic site is involved in the study
    - NO
    - YES
      - Protocol is the same across U.S. domestic study sites
        - YES
        - NO
          - Federal funding is sought by PI at lead U.S. domestic site
            - NO
            - YES
              - sIRB Not Applicable; ETSU IRB has Oversight of Study

  - NO

  - sIRB Required by Common Rule

STEP II: ETSU Single IRB Review & Approval Process

- Submit study outline to Director, Protection of Human Research Subjects Office no later than 60 days prior to grant application deadline

- ETSU PI Plans to rely on ETSU IRB as sIRB
  - YES
    - ETSU Reviews and Approves sIRB Plan
      - ETSU PI exchanges letters with external entity attesting agreement to rely on its sIRB; Includes letter in grant application
  - NO
    - ETSU PI must seek alternative such as using a commercial IRB, the cost of which may be included in the proposal budget

- ETSU PI Plans to rely on external IRB as sIRB
  - YES
  - NO

1 Example: ETSU is lead institution and Prime awardee if study is funded

2 Example lead institution is external entity and ETSU will be Subawardee if study is funded

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