**RESEARCH APPROVAL PROCESS**

**Is the study a clinical trial?**

**YES**

- PI submits Clinical Trial Information to CTO Portal

  **Budget and Contract**
  - (UT Health CTO and OSP)
  - CDA, grants or contracts, coverage analysis (billing review), Participant payments
  - CTO clears for submission to IRB/OCR

  CTO coordinates budget negotiations with affiliates

**NO**

- PI submits Research Application to IRB/OCR

  **UT Health IRB Submission**
  - Submit locally to IRBmail@uthscsa.edu
  - Institutional Research Application and UT Health IRB Application
  - OCR institutional activation based on the UT Health IRB submission

- OR

  **External IRB Submission**
  - Submit locally to OCRmail@uthscsa.edu
  - Institutional Research Application
  - Submission to the external IRB occurs after OCR receives a local application and provides clearance for IRB submission

**OR**

- IRB Approval
  - (UT Health or External IRB)
  - Human subjects protection following appropriate Federal requirements

- OCR coordinates institutional research application review with affiliates

- Institutional Activation
  - (Affiliates: UHS, VA)
  - Institution-specific policy (e.g., credentials, security, etc.)

- OCR coordinates final institutional documents

- Subject enrollment may begin

**INSTITUTIONAL ACTIVATION**

- OCR institutional activation

- Institutional Research Application

- OCR coordinates institutional research application review with affiliates

- Documents qualifications and training with scope of practice, COIs, committee reviews (i.e. radiation safety). clinicaltrials.gov, drug and device storage outside institutional pharmacy, sponsor investigator studies, DUAs, HIPAA authorizations, final contract, and participant payment

Subject enrollment may begin