Are use of human biospecimens a component of your study?

**YES**
- No biospecimen related approvals needed

**NO**
- Grossly Identifiable Anatomical Materials? (e.g., human cadaver, human cephalus) 
  - (does not include blood, urine, semen, microscopic tissue samples, paraffin blocks)
  - Submit to HASTOC
  - YES
  - HASTOC Approval?
  - YES
  - Proceed with Study
  - NO
  - NO
  - NO
  - NO

- Project involves human subjects as defined by DHHS or FDA
  - YES
  - Does the study use PATH resources involving either clinical or research-specific samples? (testing, space, staff)
    - YES
    - Submit CQR-001 Form to Hs-pathresearch and follow PATH guidelines
    - NO
      - Pathology Approval?
        - NO
          - (Revise and resubmit)
        - YES
          - Proceed with Study
  - NO
  - Not Human Subjects Research (NHSR) (use of existing anonymous, de-identified or coded samples with no access to PHI or contact with subjects)
    - NO
    - NO
    - NO
    - YES
      - Do you want an NHSR determination from IRB?
        - NO
          - Proceed with Study
        - YES
          - Develop “Comprehensive” Biospecimen & Data Management Plan
            - Consent of Pts (staff & responsibilities)
            - Collection Custodians(s)
            - Sample Processing
            - Storage Location/Distribution
            - Data Collection/Analyses/Storage
            - CTSC Data Consult/Service Request
              - Concierge Service available to assist with management planning
            - Submit “Final” Study to IRB for review via IRBNet
              - NO
                - (Revise and resubmit)
              - YES
                - Proceed with Study