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)
    - **YES**
      - Submit to HASTOC
    - **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**
              - (Revise and resubmit)
              - Pathology Approval?
                - **YES**
                  - Proceed with Study
                - **NO**
                  - (Revise and resubmit)

        - **NO**
          - Not Human Subjects Research (NHSR) (use of existing anonymous, de-identified or coded samples with no access to PHI or contact with subjects)
            - **YES**
              - Do you want an NHSR determination from IRB?
                - **NO**
                  - (Revise and resubmit)
                - **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)
                      - IRB Approval?
                        - **YES**
                          - Proceed with Study
                        - **NO**
                          - (Revise and resubmit)