Decision Tree for **Human Biospecimen Research Approvals** at UC Davis

Are use of human biospecimens a component of your study?

YES → NO → No biospecimen related approvals needed

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**

HASTOC Approval? — YES / NO (Resubmit)

NO ↓

Project involves human subjects as defined by DHHS or FDA

NO → **Not Human Subjects Research (NHSR)** *(use of existing anonymous, de-identified or coded samples with no access to PHI or contact with subjects)*

Do you want an NHSR determination from IRB? — NO / YES

YES ↓

Does the study use PATH resources involving either clinical or research-specific samples? (testing, space, staff)

NO →

Yes ↓

Submit **CQR-001 Form** to Hs-pathresearch and follow PATH guidelines

Pathology Approval? — 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**

IRB Approval? — NO (Revise and resubmit) / YES → **Proceed with Study**

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