INFORMATION FOR IRB APPLICATION WHEN CREATING A NEW BIOSPECIMEN BANK

Justification must be provided when proposing creation of a new biospecimen bank, including verification that specimens are not available from an existing established bank or commercial vendor. Creating duplicate repositories may diminish efficiencies and be confusing for donor subjects.

When submitting a proposal to create a biospecimen bank (biobank) to the Institutional Review Board (IRB), researchers should provide comprehensive information to ensure ethical standards and regulatory compliance. Incorporate the information below in the applicable sections of the IRB application and attach as supporting documentation. Full IRB review is suggested for initial review of new bank proposals.

Institutional Review Board (IRB) Submission Checklist for Biospecimen Bank Protocols

Subject Demographics:

Donor Demographics: [Specify donor groups, e.g., minors, adults, healthy participants, patients.]

Consent Process:

If specimens are obtained through interaction with human subjects, describe consent process.

E-IRB and the ORI Consent Development webpage includes a sample Repository/Bank/Registry Template if needed.

Consent for Research Collections: [Confirm all information detailed in the application is provided in the consent form in a format understandable to the donor.]

Waiver of Consent: [Submit a waiver of consent if bank will receive only commercially obtained specimens or de-identified leftovers from clinical care].

Tracking Participant Choices: [Explain methods for recording and honoring participant preferences where options are provided within the consent.]

If minors enrolled, re-consent plan: [Explain procedures for re-consenting donors who reach the age of majority.]

Research Description:

Background:

Scientific Justification: [Explain the need for establishing this biobank and why existing established banks are insufficient.]

Relevant References or Supporting Documents: [Reference or attach any pertinent documents.]

Objectives:

Purpose of the Biobank: [Provide a clear statement of the biobank's purpose.]

Study Design:

Indicate if this protocol is solely designed to collect, store, and share material and/or information for future secondary research.

Bank Personnel Use: [Indicate if any bank personnel will use specimens for research.]

Research Procedures:

Potential Research: [Indicate if secondary research will be broad and unspecified or specific based on condition or another attribute.]

Genetic or Genomic Research: [Indicate if genetic or genomic studies are planned.]

Creation of Cell Lines or Animal Models: [Specify if applicable.]

Commercial Use and Sale of Biospecimens: [Clarify if specimens will be sold and under what conditions.]

Data Collection & Research Materials:

Types of Biospecimens to be Collected: [Specify the types of specimens, e.g., blood, tissue, saliva, etc.]

Source of Biospecimens: [Indicate whether specimens are left over from clinical procedures, research-specific collections, or both.]

Associated Data: [List any accompanying information or protected health information (PHI) to be stored with the specimens.]

Storage Facilities and Security Measures: [Describe where and how specimens and data will be stored and secured.]

Duration of Storage: [Specify how long specimens will be stored, e.g., indefinitely, until depleted.]

Resources:

Describe adequacy of personnel, infrastructure, and facilities to manage bank.

Potential Risks & Benefits:

Risk Assessment of Confidentiality Breach: [Assess potential risks associated with breaches, including impacts on privacy, insurability, and stigmatization.]

Records, Privacy, & Confidentiality:

Access Controls: [Explain who will have access and how access will be managed.]

Measures to Protect Privacy: [Describe measures to protect participant privacy and data confidentiality such as coding or encrypting.]

Re-contact Plans: [Describe procedures for re-contacting participants, if necessary, for re-consent or incidental findings.]

Withdrawal Procedures: [Describe how participants can withdraw and how their specimens/data will be handled.]

Future Use & Sharing of Material:

Sharing of Biospecimens: [Identify potential recipients, e.g., internal researchers, external collaborators, commercial entities.]

De-identification and Coding Procedures: [Describe methods for de-identifying specimens and prior to sharing.]

Honest Broker System: [Identify individuals or systems managing de-identification. Indicate honest broker training completed.]

Verification of need for IRB review: [Indicate if bank will require either a Not Human Research determination or IRB approval.

Data-Use Agreements: [Provide details of any agreements in place such as agreement for secondary user to use responsibly and not attempt to re-identify donors.]

HIPAA:

HIPAA applies if accessing or contributing Protected Health Information in medical records.

Research Attributes:

Check applicable attributes such as:

- ☐ Biological Specimen Bank Creation (for sharing)
- ☐ Collection of Biological Specimens for banking and use
- ☐ Genetic Research
- ☐ NIH Genomic Data Sharing (GDS) (databases such as GWAS, dbGaP, GenBank)
- ☐ Registry or data repository creation
- ☐ Stem Cell Research

Funding/Support

Funding Sources: [List funding sources supporting the biobank.]

Contact ORI, request a consult, or attend office hours for assistance.