Collection, Storage and Use of Human Biological Material (HBM) in Research (HRPP 7.2)

Description:

This policy describes UNMC's requirements for the use and/or banking of HBM in research.

Definitions:

Human Biological Materials (HBM): samples taken from a human that can include:

- Tiny structures like DNA
- Cells or tissues *(e.g. blood, muscle, skin, bone, teeth)*
- Organs *(e.g. liver, kidney, heart, etc.)*
- Reproductive cells *(e.g. sperm, eggs)*
- Bodily waste *(e.g. hair, nail clippings, urine, saliva, sweat)*

Excess HBM: HBM leftover after research or clinically indicated tests are conducted and would not be needed for purpose of their care

Extra (additional) HBM: HBM collected for the purposes of the research and would not otherwise have been collected had the subject not participated, including HBM collected solely for banking

Identifiable HBM: HBM to which identifiers (including codes linked to any identifier) are attached, or for which the identify of the subject may readily be ascertained by the investigator or is associated with the biospecimen.

Coded HBM: HBM for which identifying information has been replaced with a code, and a key to decipher the code exists, enabling linkage of the identifying information to the biospecimens.

HBM Bank (biobank or biorepository): collection of HBM intended for use in future, unspecified research. May consist of:

- Samples obtained from specific IRB-approved research (involving only that group of subjects participating in the associated research) and to be used for another unspecified research project; or
- Samples collected as part of an IRB-approved banking protocol to be used for another unspecific research project, whether those samples are used immediately or stored for future use

Requirements for Use of HBM:

- The **use of identifiable HBM** obtained from an HBM bank **is human subject research** and requires review
- The **use of coded HBM** obtained from an HBM bank **is human subject research** and requires review, *unless* the investigator cannot readily identify the private information or biospecimens. Examples include, but are not limited to:
    - The investigator and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased; or
    - There are IRB-approved written policies and procedures for an HBM bank that prohibit release of the key to the investigators under any circumstances, until the individuals are deceased; or
    - There are other legal requirements prohibiting the release of the key to the investigators until the individuals are deceased
- The **use of de-identified HBM** obtained from an HBM bank **is NOT human subject research**
    - "de-identified" means removing all 18 HIPAA identifiers, including dates

  NOTE: if the material was obtained specifically for banking, or the person obtaining the material is involved in the bank, the material is considered "*identifiable*"
- Excess HBM obtained from persons who refused to consent to the HBM banking may not be de-identified and used or banked

Informed Consent:

- **COLLECTION OF HBM:**
  - Collection of **identifiable HBM** (including **coded HBM**) requires informed consent of the person from whom the tissue is obtained, unless the IRB waives the requirement of consent
  - Collection of **de-identified HBM** does NOT require informed consent unless the donor of the HBM is known to the person obtaining the material and is reasonably accessible
- **USE OF HBM:**
  - Use of **identifiable** (including coded) **HBM** obtained from an HBM bank requires informed consent of the subject, unless:
    - The IRB waives consent; or
    - The IRB determines that consent obtained at the time the HBM was obtained and banked was sufficiently detailed regarding future use of the HBM
  - Use of **de-identified HBM** obtained from an HBM bank may not require informed consent

NOTE: if the material was obtained specifically for banking, or the person obtaining the material is involved in the bank, the material is considered "*identifiable*"

Mandatory Participation in HBM Collection and Banking:

- HBM may be collected as a component of another research protocol with or without the prospect of direct benefit to the subject
- Collection of HBM for future undefined use **cannot be a requirement** for participation in another study for which there is **potential of direct benefit**
- Collection of extra HBM for exploratory objectives **may or may not be a requirement** for participation in the study for which there is **potential of direct benefit** (see HRPP Policy 7.2)
- Collection of HBM **may be included as a requirement** for participation in a research protocol for which there is **no prospect of direct benefit**

NOTE: For studies conducted within the Organization where the UNMC IRB is the IRB of record, **consent for participation in HBM collection and banking** associated with a study with the prospect for direct benefit must be documented in a **separate consent form**