7.1 Banking Human Biological Material

Last Revised: 1/25/2018

1.0 Purpose

The purpose of this policy and procedure is to describe the Organization's requirements for banking human biological material (HBM) for future research. Subsequent use of stored HBM in research is addressed in HRPP policy 7.2 (Use of Human Biological Material in Research).

2.0 Policy

It is the policy of the Organization that excess or additional HBM may be collected for future unspecified research as part of an addendum study attached to another protocol, or as a free standing tissue banking protocol, in accordance to HHS regulations at 45 CFR 46, HIPAA Privacy Rule, other applicable HRPP policies and Organizational requirements.

3.0 Definitions

- **3.1.** ***Human Biological Materials:*** includes (but is not limited to) sub-cellular structures (e.g., DNA); cells; tissues (e.g., blood, bone, muscle, connective tissue, teeth, and skin); organs (e.g., liver, bladder, heart, kidney, and placenta); gametes (e.g., sperm and ova); and waste (e.g., hair, nail clippings, urine, feces, saliva, and sweat).
- **3.2.** ***Excess HBM*** refers to HBM that is leftover after research or clinically indicated tests are conducted, and would otherwise be discarded.
- **3.3.** ***Additional HBM*** refers to HBM that is collected for the purposes of the research, and would not otherwise have been collected had the subject not been participating; or HBM that is collected solely for banking .
- **3.4.** ***Identifiable HBM*** refers to HBM for which the identity of the subject is or may readily be ascertained by the investigator or associated with the HBM, as per 45 CFR 46.102(e)(6).

> Note: Per Federal regulations, what constitutes “identifiable” will be re-examined on regular occasions; therefore, HBM currently considered not identifiable may become identifiable in the future as technologies and techniques change.

- **3.5.** ***Human Biological Material (HBM) Bank*** (also referred to as ***biobank*** or ***biorepository***) is a collection of human biological materials that are stored for future use in research. Samples may be obtained from specific IRB-approved trials (involving only that group of subjects participating in the associated trial), or may be collected as part of an IRB approved banking protocol involving subjects with a particular disease or condition, or involving random groups of subjects without regard to disease or condition, or normal healthy persons. Biobanks may also be composed of already existing HBM collected during the course of routine clinical care (for example, leftover clinical material in a Pathology department).
  - **3.5.1.** HBM bank may be non-local, usually associated with a cooperative group, another academic or research institution, or a research sponsor or commercial entity. The IRB recognizes that the investigators at UNMC will not have control over what studies are performed utilizing HBM obtained through these banks.
  - **3.5.2.** HBM Bank may be located within the Organization or operated entirely, or in part, by an investigator affiliated with the Organization.

4.0 IRB Review and Consent Requirements

- **4.1.** The collection of identifiable HBM into an bank, whether as an addendum to another (clinical) protocol, or as a free standing HBM banking protocol, constitutes human subject research, and will be reviewed in accordance with all applicable federal regulations and HRPP policies.
- **4.2.** The collection of HBM into an HBM bank may qualify for expedited review (under categories 2, 3 or 5), as per HRPP policy 2.3 (Expedited Review).
- **4.3.** The collection of existing HBM into an HBM bank may be exempt as follows:
  - **4.3.1.** Prior to the effective date of the Revised Rule, the collection of HBM into an HBM bank may be exempt under 45 CFR 46.101(b)(4).
  - **4.3.2.** Following the effective date of the Revised Rule, the collection of HBM into an HBM bank may be exempt under rev 45 CFR 46.104(d)(4). The Organization does not utilize the exemption under 45 CFR 46.104(d)(7).
- **4.4.** The collection of identifiable HBM into a bank requires informed consent of the person from whom the tissue is obtained.
  - **4.4.1.** If the HBM to be banked will be collected as an addendum to another (clinical) protocol, separate informed consent must be obtained from the subject.
  - **4.4.2.** Collection of HBM for banking cannot be a requirement for participation in another study for which there is the potential of direct subject benefit.
  - **4.4.3.** Excess HBM obtained from persons who refuse to consent to HBM banking may not be de-identified and banked.
- **4.5.** If HBM is identifiable, the informed consent must include basic and additional elements of consent related to biospecimens as per 45 CFR 46.116.

- **4.6.** The banking of excess discarded de-identified HBM obtained solely for clinical purposes does not constitute human subject research subject to 45 CFR 46. However, where the donor of the HBM is known and reasonably accessible, consent of the donor is respectful.

5.0 Commercialization of Banked Human Biological Material

- **5.1.** It is reasonable to expect that the possibility exists that banked HBM may be used for commercial profit at some time in the future. Therefore, the consent form must include a statement that the subject's HBM (even if identifiers are removed) may be used for commercial profit and must state whether the subject will or will not share in this commercial profit. This statement must not contain any exculpatory language.
- **5.2.** If the bank will be housed within the Organization, the consent form must contain the standard statement indicating that the donated HBM is the property of the Organization.
- **5.3.** If the bank will be housed outside the Organization, the consent form must address the issue of who owns the HBM based on the agreement with the owner of the bank.
- **5.4.** The ICF is not meant to serve as a commercial contract where subject compensation is presented. Commercial compensation as negotiated by the researcher, representatives of the Organization, the subject, and their legal counsel is presented in a document separate from the ICF.

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