

## 7.2 Use of Human Biological Material in Research

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### 1.0 Purpose

The purpose of this policy and procedure is to describe the Organizations requirements for the use of human biological material (HBM) in research.

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### 2.0 Policy

It is the policy of the Organization that HBM be used in research in accordance to HHS regulations at 45 CFR 46; FDA regulations at 21 CFR 50, 56; HIPAA Privacy Rule, applicable HRPP policies, and Organizational requirements.

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### 3.0 Definitions

- **3.1. Human Biological Materials:** HBM 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. 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.
    - **3.2.1.** At a minimum, HBM is identifiable when it is associated with any of the 18 HIPAA identifiers.  
*Note: Following the effective date for the Revised Rule, 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*
  - **3.3. Coded HBM** refers to HBM which is associated with a code which can be used to indirectly identify the donor of the HBM.
    - **3.3.1.** Coded HBM is considered identifiable for the purposes of this and other HRPP policies unless:
      - **3.3.1.1.** Specimens were not collected specifically for the research AND
      - **3.3.1.2.** The investigators cannot readily ascertain the identity of the individuals
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### 4.0 IRB Review and Consent Requirements

- **4.1.** The use of identifiable HBM previously stored in an HBM bank or pathology archive constitutes human subject research, and will be reviewed in accordance with all applicable federal regulations and HRPP policies.
- **4.2.** The use of identifiable HBM previously stored in an HBM bank or pathology archive requires informed consent of the donor, unless:
  - **4.2.1.** Consent can be waived under 45 CFR 46.116(d) (or rev 45 CFR 46.116(f)).
  - **4.2.2.** Consent obtained at the time the HBM was obtained and banked was sufficiently detailed with regard to the future use of the HBM that a reasonable person would expect that the consent would permit the types of research conducted.
- **4.3.** The use of non-identifiable HBM previously stored in an HBM bank does not constitute human subject research subject to 45 CFR 46; therefore, no IRB review is required and no informed consent is needed.
  - **4.3.1.** Under FDA regulations, clinical investigations using human specimens (even those that are non-identifiable) conducted in support of premarket submissions to FDA are considered human subject investigations, and therefore subject to the informed consent requirements of 21 CFR 50.20. However, FDA intends to exercise enforcement discretion as to the informed consent requirements for clinical investigators, sponsors, and IRBs if an in vitro diagnostic device investigation is performed and the requirements in section 4 of FDA Guidance “Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable” (April 25, 2006) are met.
- **4.4.** The use of coded HBM previously stored in an HBM bank or pathology archive constitutes human subject research, and requires IRB review, unless (1) the HBM was not collected specifically for the proposed research AND (2) the investigator cannot readily ascertain the identity of the donors of the HBM. If both these conditions are met, the HBM is considered non-identifiable, and no IRB review is required.
- **4.5.** If the coded HBM is identifiable (as above), informed consent is required unless:
  - **4.5.1.** Consent can be waived under 45 CFR 46.116(d) (or rev 45 CFR 46.116(f)).
  - **4.5.2.** Consent obtained at the time the HBM was obtained and banked was sufficiently detailed with regard to the future use of the HBM that a reasonable person would expect that the consent would permit the types of research conducted.

- **4.6.** The use of HBM previously stored in an HBM bank may qualify for expedited review (under category 5), as per [HRPP policy 2.3](#) (Expedited Review).
- **4.7.** The use of HBM previously stored in an HBM bank may be exempt under 45 CFR 46.101(b)(4) (prior to the effective date of the Revised Rule), or rev 45 CFR 46.104(d)(4) (following the effective date of the Revised Rule). The Organization does not utilize the exemption under rev 45 CFR 46.104(d)(8).

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