

Title: <b>IRB Review of Research Involving Biospecimen Banking</b>	*Applicable to: <b>Beaumont Health</b>	Effective Date: <b>01/12/2018</b>
		Last Periodic Review Date: <b>01/12/2018</b>
Policy Owner: <b>Administrative Director</b>	Document Type: <b>Policy</b>	Functional Area: <b>IRB and Clinical Research, Research Institute</b>

**\*For This Document, Beaumont Health Includes:**  
 Beaumont Corporate Shared Services  
 Beaumont Hospital, Dearborn  
 Beaumont Hospital, Farmington Hills  
 Beaumont Hospital, Grosse Pointe  
 Beaumont Hospital, Royal Oak  
 Beaumont Hospital, Taylor  
 Beaumont Hospital, Trenton  
 Beaumont Hospital, Troy  
 Beaumont Hospital, Wayne  
 Beaumont Medical Group  
 Beaumont Pharmacy Solutions  
 Post Acute Care

**I. PURPOSE:**

The purpose of this policy is to provide guidelines for the collection and archiving of human specimens for future study at Beaumont Health (BH).

**II. SCOPE:**

This policy applies to investigators, research staff, key research personnel, BioBank staff, Pathology staff, Institutional Review Board (IRB) members and staff.

**III. GENERAL:**

Researching human disease may involve the study of tissue or other biologic materials. Stored or archived specimens are often used for this purpose. These specimens may come from a clinical repository or may have been stored from a prior study. In accordance with federal regulations, informed consent and authorization from participants or a waiver of consent granted by the IRB must be obtained prior to specimen collection.

**IV. BACKGROUND:**

Biospecimen banks and repositories are established to store specimens for a variety of reasons, including the use of samples collected for research purposes, clinical evaluation and diagnosis, or specimens intended to be discarded, as having no clinical utility. Samples from these biospecimen banks and repositories are also increasingly used for genetic research, which leads to new ethical

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and regulatory considerations regarding the use and distribution of these materials. Among these considerations is the real or perceived risk of loss of confidentiality to the participant and his/her family.

**V. DEFINITIONS:**

- A. **Biological Specimens** - The term biological specimen or biospecimen is widely used and encompasses a full range of human specimen types including but not limited to:
1. Cells or tissues from any part of the human body
  2. Blood and blood fractions; plasma, serum, buffy coat, red blood cells
  3. Sub-cellular components such as Deoxyribonucleic Acid (DNA) and Ribonucleic Acid (RNA)
  4. Bodily products such as urine, cerebral spinal fluid, cystic fluid, teeth, hair, nail clippings, feces
  5. Saliva and buccal cells.
- Collection of gametes and fetal tissues raise special issues which are outside the scope of this policy.
- B. **Genetic Research** - Genetic research is research using human DNA samples, genetic testing or genetic information. Genetic research may involve:
1. The analysis of DNA for the purpose of deriving information concerning an individual about the presence, absence or mutation of genes, DNA markers or inherited characteristics; **or**
  2. Other studies with the intent of collecting and evaluating information about inheritable diseases and/or characteristics within a family.
- C. **Prospective Biospecimen Collection Study** - A prospective biospecimen collection study is a study in which the collection of biospecimen has not yet occurred i.e., the biological specimen is not in existence at the time of the IRB review. Once approved by the IRB, these specimens may be:
1. Obtained during a standard of care procedure in which the patient has consented to allow tissue be collected for research purposes;
  2. Obtained specifically for research purposes which requires the participant to undergo a procedure to obtain a specimen for research purposes; **or**
  3. Collected from discarded clinical samples.

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- D. Retrospective Biospecimen Collection Study** A retrospective biospecimen collection study is a study utilizing existing biospecimen i.e., biospecimen already collected at the time of the IRB request for approval. This may include:
1. Specimens collected for clinical purposes and then stored e.g., pathology specimens, left over serum, tissue; or
  2. A secondary use of specimens previously collected for a different research use e.g., material in a tissue bank.
- E. De-identified Samples** - Biological specimens without any identifying information and without a link to the individual participant source are de-identified specimens and may not include any identifiers defined in the HIPAA regulations. A minimal amount of de-identified information may be linked to the specimen such as:
1. **Year** of collection
  2. **Year** of surgery
  3. A description that represents a point in time (i.e., within 2 hours of surgery or at diagnosis)
  4. Type of specimen
  5. Diagnosis (unless rare diagnosis which could identify the patient)
  6. Stage of disease
  7. Gender
  8. Age ( $\leq$  89 years)
  9. Treatment status
  10. Outcome
  11. Race or ethnic group.
- F. Coded/Linked Samples** - Biological specimens coded to allow identification through the use of a code or a master list.
- G. Identifiable Samples** - Biological specimens with attached identifiers, such as name, medical record number, date of service (if collected during a clinical visit) or date of birth.

**VI. POLICY:**

The level of IRB review required for research involving the use of biospecimens is primarily dependent upon the tissue specimen source, the timing of collection, and ability to link the specimen to the source participant. All projects require IRB review and approval prior to any data collection.

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- A. **Working with the BioBank** - Investigators who wish to work with the BioBank must submit a *BioBank Contract*, describing the project and services being requested, for review and approval by the BioBank Scientific Review Committee. For prospective collection studies, specimen collection begins following IRB approval and BioBank Scientific Review Committee approval. The BioBank has an existing broad IRB approval for specimen collection, however project specific IRB approval will be required when a protocol includes more than just biospecimen collection and/or requires a separate consent associated with the collection. The project specific IRB approval letter, and the IRB application, must be submitted to the BioBank prior to collection utilizing a project-specific consent or specimen analysis.
- B. **Procedure for Requesting Biospecimen Samples** - An IRB approved protocol detailing the extent and purpose of human biological specimen use must be in place prior to requesting specimens from the BioBank. Request for biological specimens and or data to be used for research must be submitted to the Biobank via the *Beaumont BioBank Material Request Form*. A copy of the IRB approved protocol and IRB approval letter must accompany submission of the *Beaumont BioBank Material Request Form*.
- C. **Specimen Sent to Another Facility** - A *Material Transfer Agreement (MTA)* must be executed prior to any specimen being sent from the Biobank to another facility. An MTA template is available from the BioBank. Projects involving non-Beaumont collaborators who will have access to specimen **and** limited data sets also require a fully executed *Limited Data Use Agreement (LDUA)* prior to sharing the specimen(s) and/or data. When elements of protected health information (PHI) beyond those allowed in a limited data set are shared outside of Beaumont, a more comprehensive agreement between the parties is required. When the transfer of specimens is part of a project covered by such an agreement, MTA language should be incorporated into that agreement. Proper specimen handling must be followed in accordance with hospital policy
- D. **Agreements of Usage/Liability** - The Principal Investigator (PI) must agree to use the BioBank-supplied biological specimens and data solely for the purpose cited in the IRB approved research application. In addition, no attempt may be made to obtain additional identifying information unless IRB approval specifically permits, and no specimen will be sold or shared with a third party without prior written permission of the BioBank and Research Administration. All specimens will be treated as potentially infectious, and there is no implied warranty on the specimens. Any publications resulting from the use of the BioBank specimen(s) will acknowledge the BioBank and BH.

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- E. **Retrospective Studies - Retrospective studies of stored biospecimens** requires IRB review and approval prior to any data collection. The level of review and specific requirements for informed consent for retrospective studies of stored tissue specimens may depend upon the following:
1. Research using de-identified samples (without linkage to participant identifiers) may be submitted to the IRB as an Exemption request.
  2. Research using samples which can be linked to the source participant, by the PI or a third party, requires Expedited review or Full Board review. Based on the federal regulatory requirements, the IRB will review the new use to determine whether informed consent and HIPAA authorization from the participants will be required, or if a waiver of consent is appropriate.
- F. **Prospective Studies - Prospectively collected specimens obtained for research purposes** described in a current protocol must have IRB approval before they are collected and used. If the PI plans to store specimens for future research use, the use must be specified, justified, and included in the informed consent and authorization document.
- If the future use cannot be specified, or is significantly different from the original plan, then prospective IRB approval will be required for the specimens use in future protocols. The IRB may require the PI to re-consent each of the participants prior to using their specimens in this or any subsequent study.
- G. **Prospectively collected specimens obtained for clinical or diagnostic purposes**, and subsequently used for research purposes, require IRB approval for this subsequent research use. Left-over specimens and biological waste are included in this category. These type of studies will require Full Board or Expedited review. Based on the requirements in the federal regulations, the IRB will review the new use to determine whether informed consent and HIPAA authorization from the participants is required, or if a waiver of informed consent and HIPAA authorization is appropriate.
- H. **Informed Consent and Authorization** - Research protocols involving the use of biologic specimens requiring informed consent and authorization (as deemed necessary by the IRB) are subject to the regulations governing the consent process for research in human participants, as described in IRB Policy [\*Informed Consent and Authorization in Research\*](#). In addition to these requirements, the informed consent and authorization document must contain the following information (as appropriate to the individual protocol):
1. Procedures used to protect the confidentiality and privacy of personal identifiers associated with the source of a biospecimen or cell line.
  2. Procedures regarding maintaining the security of the biospecimens.

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3. Information about the control and ownership of the biospecimens during storage.
4. The participant’s right to withdraw consent at any time when biospecimen is stored with identifiers either by requesting the biospecimen be destroyed, or all personal identifiers be removed.
5. Information about the length of storage.
6. Whether the participant can obtain future access to the stored samples for information that may be of clinical relevance to him/her. Participants must be told if such information will or will not be available in the future (based on whether personal identifiers are maintained with the sample).
7. How the investigator will handle future third-party access.
8. Disclosure of the type of research the biospecimen will be used for, and who will be allowed to access the samples and conduct the research (if not known, this must be indicated).
9. Information about possible secondary use of the stored biospecimen, or the possible creation of an immortalized cell line based on the specimen.

The PI and the IRB must consider whether the results of proposed genetic research could possibly harm the participant or his/her family members in the future. These risks include psychological, social and economic harm. An example of harm may include an employer or insurance company learning of a genetic predisposition for a certain disease and refusing employment or coverage. Therefore, the issue of confidentiality becomes paramount, and the investigator must include details in the IRB application of the steps which will be taken to prevent misuse of the participants’ records.

**VII. APPLICABLE REGULATIONS AND GUIDELINES:**

- 21 CFR 56.108 - IRB Functions and Operations
- 45 CFR 46.108 - IRB Functions and Operations
- 45 CFR 46.116-117- Requirements of Informed Consent
- OHRP Guidance: Issues to Consider in the Research Use of Stored Data or Tissues Dated 8/7/97
- OHRP Guidance: Guidance on Research Involving Coded Private Information or Biological Specimens Dated 08/10/04
- The Genetic Information Nondiscrimination Act of 2008

**VIII. REFERENCES TO OTHER POLICIES:**

IRB Policy [Guidelines for Blood Collection in Research](#)

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IRB Policy [IRB Initial Review of Research Protocols](#)  
 IRB Policy [Informed Consent and Authorization in Research](#)  
 RI Policy 119 *Specimen Collection and Storage in the Beaumont Biobank*  
 Beaumont Health System Laboratory Compliance Plan

**CORPORATE AUTHORITY:**

Beaumont Health (“BH”) as the corporate parent to William Beaumont Hospital, Botsford General Hospital, and Oakwood Healthcare Inc., (“Subsidiary Hospitals”) establishes the standards for all policies related to the clinical, administrative and financial operations of the Subsidiary Hospitals. The Subsidiary Hospitals, which hold all health facility and agency licenses according to Michigan law, are the covered entities and the providers of health care services under the corporate direction of BH. The Subsidiary Hospitals’ workforces are collectively designated as BH workforce throughout BH policies.