Title: **Using Databases, Repositories and Registries in Research**	*Applicable to: **Beaumont Health**	Effective Date: **01/11/2018**
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Policy Owner: **Administrative Director**	Document Type: **Policy**	Functional Area: **IRB and Clinical Research, Research Institute**

***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 Institutional Review Board (IRB) guidelines for the research use of databases, repositories, and registries at Beaumont Health.

II. SCOPE:

This policy applies to investigators, key research personnel, IRB members, IRB staff and anyone accessing Beaumont databases, registries or repositories for research purposes.

III. OVERVIEW:

Databases, registries, and repositories all involve the collection and storage of information and/or biological specimens over time. Some are created and maintained primarily for diagnostic or clinical purposes, while others are created specifically for research. These databases, registries (data banks), and repositories (tissue banks) constitute vast resources researchers can draw upon to address new questions extending beyond those envisioned when first created.

Research use of these resources is governed by federal regulations. Specific requirements depend upon how and why information or specimens are collected, stored, used, and shared. As a general rule, the research use or disclosure of individually identifiable protected health information (PHI) or individually identifiable human specimens by Beaumont employees or agents, or from Beaumont databases, repositories, data banks, tissue banks, or registries requires

the review, approval and oversight of the IRB. Investigators whose activities may be subject to human participant protection or privacy rule requirements must submit the appropriate materials to the IRB for an official determination prior to the start of any research activity.

When a database, registry or repository, containing identifiable PHI and/or identifiable human specimens, is established specifically for research purposes, it is always considered human participant research and requires oversight by the IRB.

IV. DEFINITIONS:

The terms **database, registry, data bank, repository, and tissue bank** are often used imprecisely, and sometimes interchangeably. The following definitions are provided solely to clarify usage in this policy.

A. **Database -** A **database** is a collection of information elements (i.e., data) arranged for ease and speed of search and retrieval. All databases at Beaumont must be maintained electronically with privacy and security measures in place. Examples of databases include the following:
   1. A set of observations (i.e., data) resulting from a research study;
   2. An electronic file of a medical provider's patients;
   3. A collection of diagnosis, treatment, and follow-up information for a clinical subset of patients;
   4. A file of outcomes information compiled for quality assurance activities;
   5. A list of potential research participants.

B. **Non-Research Databases, Registries, and Repositories -** Databases, registries, and repositories are often created and maintained for purposes unrelated to research. These may include diagnosis, treatment, billing, marketing, quality control, public health surveillance, etc. Because of the important information in these collections, non-research databases, registries and repositories can provide a great source of data for research studies. Although the primary purpose of the database, registry or repository is non-research related, IRB oversight is required when the information is used for research purposes.

C. **Registry -** A **registry** or "data bank" is a collection of information elements or databases which:
   1. Include information from multiple sources;
   2. Has some similar characteristics;
   3. Is maintained and used over time;

4. Has controlled access to and use of the information by multiple individuals and/or for multiple purposes.

D. **Repository -** A **repository** or "tissue bank" is a collection of biological specimens which:
1. Receives specimens;
2. Maintains the specimens over time;
3. Controls access to and use of specimens;
4. May be used by multiple individuals;
5. May be used for multiple purposes over time.

Repositories typically include a link to a database which houses demographic and/or medical information about the individuals from whom the specimens were obtained. The database often links the information and specimens to their donor's identity by a code rather than by name or medical record number.

V. POLICY:

It is the policy of Beaumont to protect the rights of all human participants in research, including those who may not have given informed consent. The Beaumont Health IRB serves as the primary Institutional Review Board for human participant research conducted at Beaumont (for information about the use of external IRB's, see IRB Policy *Review by an External Institutional Review Board)*. In accordance with federal regulations, IRB review and approval is required to protect the rights and welfare of human research participants. It is the policy of the IRB to review, approve, and provide guidance on the special ethical considerations when using or developing databases, registries, and repositories for research.

A. **Non-Research Databases, Registries or Repositories -** Generally**,** the creation or operation of **non-research** databases, registries, or repositories is not considered to be human participant research. However, when research is proposed using PHI or specimens held in a non-research database, registry or repository, IRB oversight is required. Each research use must receive prospective IRB review, approval and continued oversight. Examples of research involving information or specimens from non-research databases, registries, or repositories requiring IRB oversight include:
1. A project to identify disease-specific biomarkers using identifiable human tissue samples originally collected and stored solely for diagnostic purposes.
2. Use of a medical provider's patient database to identify and recruit potential research participants.
3. Use of quality assurance data containing identifiable PHI for an activity designed to develop or contribute to generalizable knowledge.

Researchers who wish to use information or specimens obtained from a non-research database, registry, or repository are required to submit an application for IRB review and obtain IRB approval before initiating the research in accordance with IRB Policy *IRB Initial Review of Research Protocols*. The IRB application should include all available information regarding the circumstances under which the information or specimens were originally collected.

Investigators who believe their research using information or specimens from a non-research database, registry, or repository may be Exempt from the human participant research regulations must complete and submit an application in iMedRIS, for IRB review. Prior to initiating any research use of the data obtained from non-research sources, the investigator must receive a letter from the IRB granting Exemption. IRB Exemption status applies only to information or specimens already existing in a non-research database, registry, repository at the time IRB Exemption is granted. IRB Exemption status generally does not cover the use of prospectively collected data or specimens, or if linking identifiers exist between the data/specimen and the identity of the participant/donor.

B. **Informed Consent/Waiver of Consent Using Non-Research Databases, Registries and Repositories -** Since research use was not anticipated at the time the information and/or specimens were entered into non-research databases, registries and repositories, typically, informed consent and authorization has not been obtained from the participants. The IRB may require researchers to obtain informed consent and authorization from participants for the research use of data or specimens from non-research databases, registries or repositories. Health care providers may be required to obtain permission from potential participants prior to releasing contact information from non-research databases or repositories to researchers for recruitment purposes.

Under circumstances described below, the IRB may waive informed consent of participants whose information and/or specimens were initially collected for non-research purposes. The IRB has the authority to waive or alter the informed consent requirements if it finds and documents **all** of the following apply:

1. The research involves no more than minimal risk to the participants;
2. The alteration or waiver will not adversely affect the participants' privacy, rights or welfare;
3. The research could not practicably be carried out without the alteration or waiver; and
4. Where appropriate, the participants will be provided with additional pertinent information after participation.

Investigators who believe the above criteria apply to their research must request a Waiver of Consent in their IRB application. Please refer to IRB Policy *Informed Consent and Authorization in Research* for additional information.

C. **Privacy Protections when Using Non-Research Databases, Registries or Repositories -** Under the Health Insurance Portability and Accountability Act (HIPAA) PHI in non-research databases, registries, and repositories may not be used or disclosed for research unless:
   1. Written authorization has been obtained from the patient for use and disclosure of PHI in research, **or**
   2. The IRB approves and documents a formal waiver of the authorization requirement, **or**
   3. The holder of the PHI receives and documents the HIPAA required representations from the investigator and determines the research involves **only** one or more of the following:
      a. Decedents' information
      b. De-identified information
      c. Limited data sets review preparatory to research.

      For additional information refer to IRB Policy *HIPAA and Research*.

D. **Waiver of Authorization -** The most flexible mechanism for obtaining PHI without individual authorization is through a waiver, which the IRB may approve if it finds and documents, per Health and Human Services (HHS) Privacy Rule Regulations:
   1. The use or disclosure of PHI involves no more than minimal risk to the privacy of the individuals based on at least the following:
      a. An adequate plan to protect the identifiers from improper use and disclosure, **and**
      b. An adequate plan to destroy the identifiers at the earliest possible opportunity, unless there is a health or research justification for retaining the identifiers (or retention is required by law), **and**
      c. Adequate written assurances the PHI will not be reused or disclosed to another person or entity, except as required by law.
   2. The research could not practicably be conducted without the alteration or waiver.
   3. The research could not practicably be conducted without access to and use of the PHI.

   Investigators who believe all three (3) criteria above apply to their research would complete questions requesting a Research Waiver of Authorization within their IRB application for review. If the investigator's research involves solely de-identified information, this should be indicated at the appropriate section of the IRB application, whether for Exempt, Expedited or Full Board IRB review.

E. **Research Databases, Registries and Repositories -** Researchers who wish to develop or maintain a **research** database, obtain IRB approval prior to collecting data or initiating any database-related activities per IRB Policy *IRB Initial Review of Research Protocols*.

1. The advantage for investigators to create, maintain and/or use a research database, registry, or repository lies in the ability to collect both retrospective and prospective data. The intent of the research database, registry, or repository is to control access and use of the information/ specimens and to allow use for multiple research projects, many of which could not be specifically identified and described when the database was created. If the database has a new research question which is different from the originally approved application, a new IRB application must be submitted, **prior to collection of data**.
2. Given the intended use for multiple, yet-to-be-identified research projects and investigators, a research database, registry, or repository's operating procedures must include detailed mechanisms for controlling the collection, storage, use, and sharing of its information and specimens.
3. Investigators, who collect information and/or specimens to be entered into the research database, registry, or repository, as well as investigators receiving information and/or specimens from the database, must agree to specific conditions required by the IRB.
4. A research database, registry, or repository protocol must be submitted to the IRB with defined operating parameters. Operators of the research databases, registries, or repositories must implement physical and procedural mechanisms for the secure receipt, storage, and transmission of information and specimens. The IRB must ensure the IRB application describes sufficient protection of participant privacy and confidentiality of participant information, prior to granting approval.
5. When participant privacy and confidentiality protection mechanisms are sufficiently well-defined and implemented to assure participants' information and/or specimens cannot be identified by recipient investigators, the IRB may approve relatively broad parameters for sharing the information and/or specimens with researchers.
6. When properly developed, the research database, registry, or repository incorporates a series of protections which permit multiple uses of the information and/or specimens by multiple investigators for multiple research projects, with minimal additional IRB review.
7. When the research involves a repository, questions in the IRB application (iMedRIS) submission will need to be answered for the IRB to ensure data security. For any database, registry, or repository, **all** of the following information must be included in the IRB application:
   a. The specific conditions under which data/specimens may be accepted into the database, registry, or repository;

b. A detailed description of the physical and procedural mechanisms for the secure receipt, storage, and transmission of information and specimens to ensure the protection of participant privacy and the confidentiality of participant data/specimens;
c. The specific conditions under which data and/or specimens may be shared with or released to researcher;
d. An Informed Consent and Authorization Document (ICAD) which includes, in addition to the usual elements of consent, a clear description of the following:
   1) The general concept, purpose, and name of the database, registry, or repository for which consent is being solicited,
   2) As specifically as possible, the types of research the database, registry, or repository will support,
   3) The physical and procedural mechanisms for protecting participant privacy and the confidentiality of data/specimens,
   4) The conditions and requirements under which information or materials will be shared with recipient investigators,
   5) Specific risks related to a breach of confidentiality for the information being collected,
   6) Where human genetic research is anticipated, information about the consequences of DNA typing (e.g., regarding possible paternity determinations) and related confidentiality risks.

When a new research idea is identified which requires use of information or specimens in an existing database, repository, or registry, IRB review and approval of a new project submission must be obtained per IRB Policy *IRB Initial Review of Research Protocols* prior to initiating any research-related activities. When new investigators are added to existing research projects, an Amendment must be submitted to the IRB in accordance with IRB Policy *Amendment Requests to the IRB Approved Studies*.

F. **Information or Specimen Sharing -** The IRB is responsible for the regulatory oversight of any research database maintained at Beaumont, including their employees or agents, as well as use of data by investigators not directly affiliated with Beaumont.
   1. The use and disclosure of information or specimens from a research database, registry, or repository must be reviewed by both the IRB providing the information or specimens and the IRB or authority responsible for oversight at the site where the information and/or specimens will be used. Additionally, all sharing of data or specimens outside of Beaumont must be documented using the appropriate research collaboration or data

sharing agreement and approved by Research Administration. Templates for various data sharing (e.g., identifiable data, Limited Data Sets, de-identified data, material transfer agreements, collaboration agreement) are available on the Research Institute webpage. The agreement will have to be reviewed and signed by Research Administration. For questions please call 248-551-8550.

2. Under HIPAA, there are provisions for sharing a Limited Data Set outside of the organization. A Limited Data Set is defined as a data set in which the only elements of PHI that may be included are dates, town or city, state and/or zip code. By regulation a Limited Data Release and Use Agreement (LDUA) is required when a limited data set is being shared. When planning to share any Beaumont research data outside of the organization, complete a *Data Use, Collaborations and Material Transfer Agreement Cover Sheet* (available under Research Administration on the Forms page of the Research Institute website) to determine the type of agreement required and access the appropriate data sharing agreement template. Instructions on how to process data sharing agreements are included on the Cover Sheet.
3. Information or specimens from these databases may be accessed, used, shared, or disclosed only in accordance with the IRB approval, Informed Consent and Authorization document, waiver of authorization, and any additional approval conditions stipulated by the IRB. Once provided to recipient-investigators outside of Beaumont, use and disclosure of the information/specimens must also comply with any additional requirements of the recipient institution and its' IRB.

G. **Conversion of a Clinical Database, Registry or Repository to a Research Database, Registry or Repository -** Data and/or specimens stored in a database, registry or repository solely for clinical or quality assurance purposes, may be transferred into a research database, registry, or repository with prior approval from the IRB. This conversion from a clinical database, registry or repository to a research data database, registry or repository may occur once. If prospective collection of data is desired, the IRB will determine if informed consent and authorization is required (as described below).

H. **Conversion of a Research Study Protocol to a Research Database Registry or Repository Protocol -** An IRB-approved protocol may include a specific research study and a research database, registry, or repository to store data and/or specimens for future studies. When the research database, registry, or repository is maintained at Beaumont for use in future studies, the database must be submitted as a separate protocol with a separate informed consent and authorization document (ICAD) as required per IRB Policy *Informed Consent and Authorization in Research*. Re-consent of currently enrolled participants under the

combined protocol and database may not be required if the initial consent contains language identifying the study and potential future use of the participants' information/specimens. Use of prospective data and/or specimens collected from future participants enrolled only in the database, registry or repository research study must sign an ICAD, unless a Waiver of Authorization has been granted by the IRB.

VI. REFERENCES:

Research Repositories, Databases, and the HIPAA Privacy Rule, NIH publication number 04-5489, January 2004
45 CFR 46 Protection of Human Participants
21 CFR 50 Protection of Human Participants
21 CRF 56 Institutional Review Board
45 CFR 160 and 164 Privacy and Security Rule

VII. ASSOCIATED POLICIES:

IRB Policy *Amendment Requests to the IRB Approved Studies*
IRB Policy *Expedited Review of Research*
IRB Policy *IRB Initial Review of Research Protocols*
IRB Policy *HIPAA and Research*
IRB Policy *Informed Consent and Authorization in Research*
IRB Policy *Quality Assurance / Quality Improvement Projects*
IRB Policy *Research Exempt from Full IRB Review*
IRB Policy 232 *Research Record Retention*
IRB Policy 238 *IRB Review of Research Involving Tissue/Specimen Banking*
IRB Policy 247 *Limited Data Use Agreements-SOP*

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.