Title: **HIPAA and Research**	*Applicable to: **Beaumont Health**	Effective Date: **03/16/2018**
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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 describe "The Privacy Rule" section of the Health Insurance Portability and Accountability Act (HIPAA) as it applies to human participant research conducted at Beaumont Health.

II. SCOPE:

This policy applies to investigators, key personnel, research staff, Institutional Review Board (IRB) members and IRB staff. This policy pertains to all Beaumont clinical research, including studies overseen by Beaumont IRB or an approved external IRB.

III. DEFINITIONS:

A. **Covered Entity -**Under HIPAA, a covered entity is a health plan, a health care clearinghouse, or a health care provider who transmits Protected Health Information (PHI) in electronic form related to certain transactions.

B. **Disclosure -** To release, transfer, provide access to, or divulge PHI outside of Beaumont. Disclosure also includes providing information or access to another individual (internally or externally) for purposes other than the original research purpose for which the information was gathered.

C. **Individual -** The person who is the subject of the PHI.

D. **Limited Data Set -** A subset of individually identifiable health information to be used for a specific research purpose, with certain direct identifiers removed, but containing some elements of PHI that could potentially identify the individual. All attempts to limit the amount of PHI utilized in a study will be exercised. A limited data set is not considered de-identified data.

E. **Limited Data Release and Use Agreement (LDUA) -** Written agreement between a covered entity or health care component and a researcher or research institution requesting a disclosure of PHI contained in a Limited Data Set. The LDUA must include a description of who will have access to the data and how it will be used.

F. **Protected Health Information (PHI) -** Health information transmitted or maintained in any form or medium which:

1. Identifies or could be used to identify an individual, **and**
2. Is created or received by a healthcare provider, health plan, employer or healthcare clearinghouse, **and**
3. Relates to the past, present or future physical or mental health or physical condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of healthcare to an individual.

G. **Research -** A systematic investigation, including development, testing and evaluation designed to develop or contribute to generalizable knowledge.

H. **Use -** To employ, apply, utilize, examine or analyze PHI originating from, belonging to, or maintained by Beaumont.

IV. BACKGROUND:

A. HIPAA was enacted on April 14, 2003 and establishes conditions under which researchers and investigators may access and use an individual's PHI for research purposes. This regulation requires a signed authorization from the participant prior to the use of PHI for research, unless the IRB has determined the research meets the legal requirements for a waiver or alteration of HIPAA authorization. The HIPAA Privacy Rule directly applies to covered entities. Researchers who obtain, create, access, use, and/or disclose individually identifiable health information must comply with the HIPAA rules pertaining to use and disclosure of PHI for research.

B. The HIPAA regulations are separate and distinct from the Common Rule, Food and Drug Administration (FDA) regulations or the International Commission on Harmonization (ICH

GCP) guidelines. The IRB will apply the HIPAA requirements to studies whenever individually identifiable PHI is involved independent of the research funding source.

V. POLICY:

All research conducted at Beaumont will comply with the HIPAA regulations to assure protection of participants' PHI. The IRB merges the regulatory requirements of informed consent and the HIPAA laws requiring authorization for use and disclosure of PHI into a single document (Informed Consent and Authorization).

VI. PROCEDURE:

A. **Use and Disclosure of PHI for Research -** In the course of conducting research, Beaumont investigators may obtain, create, access, use, and/or disclose individually identifiable health information. Under the Privacy Rule, investigators are permitted to use and disclose PHI for research with individual authorization, or without individual authorization under limited circumstances set forth in the Privacy Rule and defined in this policy.

B. **Individual Authorization -** To use or disclose PHI with authorization from the research participant, the investigator (or designee) must obtain the individual's authorization using an IRB approved Informed Consent and Authorization document. The IRB approved Informed Consent and Authorization is specific to each study and describes what information will be used, how it will be used and who will have access to the information. Unlike other healthcare authorizations which may pertain to a single visit or procedure, a research use authorization may be for a longer period of time. Statements in the consent and authorization document may indicate "the authorization continues until the end of the research study," "the authorization does not expire", or "there is no expiration date or event".

C. **Required Core Elements of a HIPAA Authorization -** A valid HIPAA authorization (not to be confused with required elements of Informed Consent) must contain **all** of the following core elements:
   1. A description of the PHI to be used or disclosed, identifying the information in a specific and meaningful manner.
   2. The names or other specific identification of the person or persons (or class of persons) authorized to make the requested use or disclosure.
   3. The names or other specific identification of the person or persons (or class of persons) to whom the covered entity may make the requested use or disclosure.
   4. A description of each purpose of the requested use or disclosure.

5. Authorization expiration date or expiration event that relates to the individual or to the purpose of the use or disclosure ("end of the research study" or "none" are permissible for research, including for the creation and maintenance of a research database or repository).
6. Signature of the individual and date. If the individual's legally authorized representative signs the Authorization, a description of the representative's authority to act for the individual must also be provided.

A valid Authorization will also contain the following required statements:

1. A statement of the individual's right to revoke his/her Authorization and how to do so, and, if applicable, the exceptions to the right to revoke his/her Authorization or reference to the corresponding section of the covered entity's notice of privacy practices.
2. Whether treatment, payment, enrollment, or eligibility of benefits can be conditioned on Authorization, including research-related treatment and consequences of refusing to sign the Authorization, if applicable.
3. A statement of the potential risk that PHI will be re-disclosed by the recipient. This may be a general statement that the Privacy Rule may no longer protect health information disclosed to the recipient.

The authorization must be written in lay language easily understood by the research participant and a signed copy must be provided to the individual signing the document. Any research protocol which involves more than minimal risk treatment for a participant to be enrolled will require execution (signing) of an authorization as a condition. Refusal to execute an authorization will exclude the individual from study participation.

D. **Use or Disclosure of PHI with Waiver or Alteration of Authorization -** To use or disclose PHI for research purposes without authorization by the individual, the investigator or other covered entity must obtain a Waiver of Authorization from the IRB. **A request for waiver of authorization is incorporated into the electronic initial IRB application for all IRB's. The following three criteria must be satisfied for the IRB to approve a waiver of authorization under the Privacy Rule:**

1. The use or disclosure of PHI involves no more than minimal risk to the privacy of individuals based on the presence of the following elements:
   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 opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; **and**
   c. Adequate written assurances the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or

for other research for which the use or disclosure of PHI would be permitted by this subpart.

2. The research could not practicably be conducted without the waiver or alteration; **and**
3. The research could not practicably be conducted without access to and use of the PHI.

The IRB waiver of authorization approval must include the following:

1. Identification of the IRB number and the date on which the alteration or waiver of authorization was approved;
2. A statement that the IRB has determined the alteration or waiver of authorization satisfies the three criteria in the Privacy Rule;
3. A brief description of the PHI for which use or access has been determined to be necessary by the IRB;
4. A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures; and
5. The signature of the IRB chairperson.

E. **Accounting for Research Disclosures -** In general, the Privacy Rule gives individuals the right to receive an accounting of certain disclosures of PHI made by a Covered Entity. Among the types of disclosures exempt from this accounting requirement are:
   1. Research disclosures made pursuant to an individual's authorization;
   2. Disclosures of the limited data set to researchers with a data use agreement under 45 CFR 164.514(e).

   For studies with a waiver of authorization and less than 50 records accessed, the following documentation must be maintained by the principal investigator and made available to the participant upon request:
   1. Date of the disclosure;
   2. Name of person/entity or the study involved in receiving the PHI;
   3. Description of what PHI was disclosed;
   4. Brief statement regarding the purpose of the disclosure.

   For disclosures of PHI for research purposes without the individual's authorization pursuant to 45 CFR164.512(i), and which involve at least 50 records, the Privacy Rule allows for a simplified accounting of such disclosures by covered entities. Under this simplified accounting provision, covered entities may provide individuals with a list of all protocols for which the patient's PHI may have been disclosed under 45 CFR 164.512(i), as well as the researcher's name and contact information. Screening logs must be maintained by researchers in order to assure this accounting can take place.

F. **Preparatory to Research -** The preparatory to research provision permits the investigator to use or disclose PHI for purposes preparatory to research, such as the development of research questions; the determination of study feasibility (in terms of the available number and eligibility of potential study participants); the development of eligibility (inclusion and exclusion) criteria; and the determination of eligibility for study participation of individual potential participants. Activities considered preparatory to research require representation from the researcher, either in writing or orally:

1. The use or disclosure of the PHI is solely to prepare a research protocol or for similar purposes preparatory to research,
2. The researcher will not remove any PHI from the Covered Entity, and
3. PHI for which access is sought is necessary for the research purpose.

Contacting potential participants for a research study remains a research activity and requires an IRB approved informed consent and authorization or HIPAA waiver of authorization.

G. **Research on Protected Health Information of Decedents -** The use or disclosure of PHI of the deceased, for research purposes, does not require investigators to obtain an HIPAA authorization from the personal representative or next of kin, a waiver or an alteration of the Authorization, or an LDUA. However, the researcher seeking access to any decedent's PHI must provide the IRB with the following representations:

1. The use and disclosure is sought solely for research on the PHI of the decedent(s);
2. The PHI for which use or disclosure is sought, is necessary for the research purposes; and
3. Documentation, at the request of the covered entity, of the death of the individual(s) whose PHI is sought by the researchers.

H. **De-identified Health Information -** The Privacy Rule does not cover de-identified information. Under the Privacy Rule, de-identified is defined as information which does not identify the individual and where there is no reasonable basis to believe the individual can be identified from the information.

Method 1: Health information is de-identified if a set of specific identifiers is deleted before the information is released by the covered entity to the researcher. These identifiers are as follows:

1. Names
2. Address (including all geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geo-codes, except for the initial three digits of most zip codes)
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, and date of death. All ages over 89 and all

elements of dates (including year) indicative of age over 89, except when ages over 89 are aggregated into a single category of "age 90 or older"

4. Telephone number
5. Fax number
6. E-mail address
7. Social security number
8. Medical record number
9. Health plan beneficiary number
10. Account number
11. Certificate/license number
12. Vehicle serial number
13. Universal Resource Locators (URLs)
14. Device Identifiers and serial numbers
15. Internet Protocol (IP) address numbers
16. Biometric indicators such as fingerprints or voiceprints
17. Full-face photographic images and any comparable images
18. Any other uniquely identifying number, characteristic, or code.

In addition, the covered entity or the researcher must not have reasonable basis to believe the information could be used alone, or in combination with other information, to identify an individual.

Method 2: The second method of de-identifying under HIPAA allows a person with appropriate knowledge and experience to apply generally acceptable statistical and scientific principles and methods for rendering information not individually identifiable to make and document a determination there is a very small risk the information could be used by others to identify a participant from the information. Documentation of the above must be submitted with the IRB application.

I. **Disclosing Data Using a Limited Data Set -** Individual PHI may be disclosed by a Beaumont investigator to a researcher who has no relationship with the participant by developing a Limited Data Set and executing a Limited Data Use Agreement. IRB Policy 249 *Limited Data Use Agreements* for additional information.

J. **Use of Social Security Numbers in Research** - The collection of the last four (4) digits of a study participant's social security number does not require additional action for approval on the investigators part. If the full social security number is deemed necessary for the research protocol, **all** of the following are required in the IRB submission:

1. A rationale for use of the full social security number;

2. Approval from the Corporate Privacy Officer
3. An additional written consent statement within the informed consent and authorization document regarding the use of the participant's social security number, requiring the participants' signature. The statement must indicate consent to the use of full Social Security number is optional and **not** a condition for study participation; and
4. A detailed security plan to protect the social security numbers from improper use or disclosure.

K. **Additional Disclosures -** The Privacy Rule permits, but does not require, the disclosure of PHI for specified public policy purposes, such as: to report communicable diseases, child abuse or neglect; to report adverse events involving investigational articles; or for tracking individuals for notification of recall, repair or replacement of investigational or approved devices. With a few exceptions, the Hospital or investigator may choose to limit disclosure of information created for a research study which includes treatment to purposes narrower than those permitted by the rule, in accordance with the individual or institution's professional standards.

VII. REFERENCES:

Title 45 Code of Federal Regulations, parts 160 and 164 (Privacy and Security Rule)
The Privacy Rule and Research - http://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html last updated June 2013

VIII. ASSOCIATED POLICIES:

IRB Policy *Expedited Review of Research*
IRB Policy *IRB Initial Review of Research Protocols*
IRB Policy *Research Exempt from Full IRB Review*
IRB Policy *Using Databases, Repositories and Registries in Research*
IRB Policy 249 *Limited Data Use Agreement*
IRB Policy *Review by an External Institutional Review Board*

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.