Title: **Processing Data and Material Sharing Agreements**	*Applicable to: **Beaumont Health**	Effective Date: **03/19/2018** Last Periodic Review Date: **03/19/2018**
Policy Owner: **Administrative Director**	Document Type: **Policy**	Functional Area: **Research Administration, 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 procedure is to provide guidelines for the processing of non-financial research agreements (Agreements) including all sharing of Beaumont Health research data, materials or resources outside of Beaumont.

II. SCOPE:

This procedure applies to the sharing of Beaumont data, specimens or other non-monetary resources (collectively referred to as "Data") outside of Beaumont. This procedure covers data use agreements (de-identified and limited data), material transfer agreements, research collaboration acknowledgements and any other type of non-financial agreement developed specifically to protect Beaumont research Data. This procedure does not cover non-disclosure (NDA's) or confidentiality agreements (CDA's), sponsored clinical trial agreements (CTA's), contracts or sub-contracts.

III. GENERAL:

The Beaumont Research Institute is committed to supporting research collaborations to further advances in translational and biomedical science and to provide continued opportunities for our patients to benefit from improved clinical care. In doing so, Beaumont is responsible to assure use of patient data, specimens and other non-monetary resources is consistent with regulations and Beaumont policy. All sharing of Data outside of Beaumont must be documented in the form

of a legal agreement between Beaumont and the recipient individual or institution. The Vice President of Research and the Administrative Director of the Research Institute, or their designees, are the only authorized signatories for agreements involving research activities at Beaumont. Data may not be shared until an agreement is fully executed by Research Administration (RA) and the recipient institution, and Institutional Review Board (IRB) approval obtained (when applicable).

The Beaumont Research Institute is *not* responsible for initiating inter-institutional agreements for data, specimens or other non-monetary resources *provided to* Beaumont but will cooperate in the review and execution of agreements presented to us from other institutions or organizations.

VI. AGREEMENT TYPES:

A. **Confidentiality Disclosure Agreement (CDA)**
An agreement completed at the beginning of collaborative discussions and/or before confidential information is shared, in order to protect against unauthorized disclosure of confidential information.
These are also known as non-disclosure agreements (NDA). CDA's and NDA's are outside the scope of this policy. See Research policy 107 *Processing of Confidentiality Disclosure Agreements*.

B. **Clinical Trial Agreement (CTA)**
A comprehensive agreement between Beaumont and a Sponsor or their designee describing the rights, responsibilities and payments associated with the conduct of a sponsored clinical trial. CTA's must be managed by a clinical research manager (CRM) in conjunction with the Sponsored Programs Administration (SPA) office. CTA's may be referred to as master research agreement, research services agreement, clinical research agreements, etc. A CTA must be fully executed prior to the initiation of any research.

C. **De-Identified Data Use Agreement (DDUA)**
An agreement between an institution sharing de-identified data and an individual or institution receiving the data. The agreement must describe the data to be shared, the intended use for the data and the terms and conditions upon which the recipient accepts the data. In order for data to be considered de-identified, there must be no identifiers, including dates or addresses, in the dataset.

D. **Federal Sub-Contract**
An agreement between an institution awarded a federal grant and other institutions working on the grant describing the rights and responsibilities of each party and the payments

associated with the conduct of the work to be done. By regulation, federal sub-contracts include a number of provisions not typically included in a CTA, specific to compliance with federal grants management policies. Federal sub-contracts must be managed by a CRM in conjunction with the SPA Office.

E. **Limited Data Release and Use Agreement (LDUA)**
An agreement required by the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule between a covered entity and a person or entity that receives a limited data set. The LDUA must include:
1. A description of the specific permitted uses and disclosures of the limited data set by the recipient, consistent with the purpose for which it was disclosed. Note: A data use agreement cannot authorize the recipient to use or further disclose the information in a way which, if done by the covered entity, would violate the Privacy Rule.
2. Identify who is permitted to use or receive the Limited Data Set.
3. Stipulate the data recipient will:
    a. Not use or disclose the information other than permitted by the agreement or otherwise required by law.
    b. Use appropriate safeguards to prevent the use or disclosure of the information, except as provided for in the agreement, and require the recipient to report to the provider any uses or disclosures in violation of the agreement of which the recipient becomes aware.
    c. Hold any agent of the recipient (including subcontractors) to the standards, restrictions, and conditions stated in the data use agreement with respect to the information.
    d. Not identify the information or contact the individuals. The LDUA must state the recipient will use or disclose the information in the limited data set only for specific limited purposes.

For more information, refer to IRB policy 249 *Limited Data Release and Use Agreements*

F. **Materials Transfer Agreement (MTA)**
An agreement which governs the transfer of tangible research materials between two organizations, when the recipient intends to use the materials for his or her own research purposes. The MTA defines the rights of the provider and the recipient institution with respect to the materials and any derivatives. Examples of tangible research materials include biologic specimens (including but not limited to blood, urine, tissue) or specimen derivatives such as cell lines, proteins, genes, genetic mutations.

G. **Research Collaboration Acknowledgement (RCA)**
A Beaumont specific form used when a Beaumont investigator works with investigators from one or more institutions, ***sharing responsibilities for the overall project.***
The RCA includes provisions for:
1. Compliance with the approved research plan
2. Regulatory compliance
3. Rights to data
4. Budgetary requirements
5. Publicity
6. Publications
7. Intellectual property
8. Conflict of interests
9. Confidential information
10. Monitoring and reporting.

The RCA is not used for: 1) multi-center studies where the Beaumont investigator participates as a site and does not have overall responsibility for the project; or 2) as a data sharing agreement when a Beaumont investigator is sending data or specimens to another institution for use in that institution's research (or vice versa).

H. **Responsible Data Use and Disclosure Attestation**
An attestation by the Principal Investigator (PI) covering the use of Beaumont data for research or quality improvement purposes. The attestation includes the Beaumont users' responsibility to protect the privacy of the individuals who are the subjects of the data, to not use or disclose the data other than as permitted and to appropriately secure the data.

I. **Custom Project Research Agreement**
An agreement written by a Beaumont attorney to address unique characteristics of a research project or sharing of Data which goes beyond one of the agreements described above. Examples may include: when computers, software, or other resources are being shared in addition to data; when data being shared includes information about students, staff, physicians or other non-patient sources (i.e., surveys, educational assessments, observations); when data being shared includes any element of Protected Health Information (PHI); when staff from another institution will be participating in activities at Beaumont; or when the Beaumont PI is working with co-investigators from another institution but the rights and responsibilities related to the study remain with the Beaumont PI. The department specific research manager will provide study specific information to the Beaumont attorney to assure the agreement appropriately reflects the relationship between the parties.

V. PROCEDURE:

1. Prior to signing off on the IRB application, and as soon as the information is available, the PI or research manager determines the appropriate agreement required for the study by completing the **Data Use, Collaborations and Material Transfer Agreement Cover Sheet** (Cover Sheet) found on the Research Institute Forms web page. The Cover Sheet will help to identify the type of agreement needed (see Algorithm attached). The Cover Sheet also includes links to each of the following types of agreement: DDUA, LDUA, MTA, and RCA. Processing of the agreement may be done concurrent with IRB review.
2. The appropriate agreement template is downloaded, the required information is copied or entered into the agreement template (i.e., description of data, intended use of the data).
3. The agreement is sent by the research manager to the recipient institution for review and signature.
4. Once returned by the recipient organization, the agreement is attached to the completed and signed Cover Sheet and returned to the RA designee. The designee will facilitate the remainder of the agreement process.
5. If the individual at the recipient organization signed the template agreement with no changes, the RA designee records the agreement in the Agreement Tracking Database, obtains the Administrative Director's signature and returns copies of the executed agreement to the recipient organization, the PI/research manager, and maintains a copy on file in RA.
6. If changes to the agreement template are requested by the recipient institution, the RA designee will refer the tracked changes version of the agreement to the Research attorney for review.
7. The RA designee will work with the Research attorney to complete negotiations and coordinate execution of the agreement.
8. The RA designee will maintain an electronic library of all executed agreements.

A. Sharing Research Data and Materials with Individuals Working Outside of an Institution

It is a general expectation that Beaumont research data and materials will only be shared with individuals working within an established institution (i.e., university, research center, healthcare provider). However, to further our research mission, data may on occasion be shared with an individual outside of an institutional affiliation. Examples include graduating medical students, residents or fellows with unfinished studies, attending physicians no longer practicing at Beaumont or individuals unaffiliated with Beaumont but possessing unique skillsets or established studies. Any data shared with an individual must be de-identified and stored/exchanged by using a Beaumont Research Institute SharePoint folder specific to the

collaboration. Projects requiring data be shared with an outside individual must have a qualified Beaumont PI to accept responsibility for the ongoing activities of the project. A De-identified Data Use Agreement must be completed before any data is shared. In circumstances where the individual has no prior affiliation with Beaumont, a copy of their Curriculum Vitae (CV) must be provided, demonstrating past research experience.

B. **CRM Verification of Agreements**
When signing off on IRB Initial Applications, the CRM will verify all necessary data or material sharing agreements have been initiated. These agreements must be executed prior to any data or materials being shared outside of the organization.

C. **IRB Notification of Data Sharing**
As part of the IRB review, the IRB will notify the RA designee whenever an investigator initiated study application indicates data will be shared outside of Beaumont. The RA designee will be responsible for following up with the research manager until an agreement is fully executed.

VI. ATTACHMENT: (see attachment tab, upper right corner)

Questionnaire for Determining the Correct Type of Data or Material Sharing/Use Agreement

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.