Title: **Review by an External Institutional Review Board**	*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: **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 establish a procedure for requesting authorization for an approved, external (non-Beaumont) institutional review board (IRB) to serve as the IRB of record for review of certain types of research to be conducted at Beaumont Health (BH).

II. SCOPE:

This policy applies to research administrators, investigators, research staff, Institutional Review Board (IRB) members and IRB staff.

III. BACKGROUND:

Initial and continuing review and approval of clinical research by an IRB is required per federal regulations in order to protect the rights and welfare of human research participants. The Beaumont Health IRB serves as Beaumont's local IRB. When research meets certain criteria, Beaumont researchers may select either Beaumont's IRB or a Beaumont-approved, AAHRPP (Association for the Accreditation of Human Research Protection Programs) accredited external IRB. As of this policy date, Beaumont's approved external IRBs are Chesapeake IRB (CIRB), Western IRB (WIRB), Quorum, SMART IRB (additional paperwork will be needed) and the National Cancer Institute Central Institutional Review (NCI CIRB- for oncology studies only).

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IV. POLICY:

A. A principal investigator (PI) may consider utilizing an approved, external IRB when a study is:
   1. Multicenter
   2. Industry sponsored
   3. Phase II-IV drug study
   4. Pivotal or post market device study.
   5. Federally funded, when the funding agency requires use of an external IRB
   6. Multicenter Investigator Initiated Research (requirements need to be reviewed by Beaumont Research Institute and Beaumont IRB)

B. The following types of studies are **not** eligible for review by an external IRB and must be reviewed by Beaumont's IRB:
   1. Internally funded
   2. Investigator initiated, Beaumont as single site
   3. Phase I drug
   4. Pilot device
   5. Expedited studies not considered clinical trials (chart reviews, survey studies, etc.).

C. Beaumont's Research Institute is responsible for administrative review whenever external IRB review is sought. Administrative review is comprised of confirming the study qualifies for external IRB review, assuring educational requirements are met, assuring conflict of interest review, and assuring safety committee requirements are met, including Biosafety, Pharmacy, and Radiation Safety. The external IRB serves as the IRB of record for the single study in question. Budget and contract approval must be confirmed before study activities commence.

V. PROCEDURE:

A. **Initial Review - To initiate review of BH research by an external IRB:**
   1. The PI submits an Administrative Application through iMedRIS, requesting approval to use an external IRB. As part of the submission, the researcher is required to upload relevant study documents, including the protocol, the sponsor consent(s), the investigators brochure, IDE or IND FDA letters where applicable, a Curriculum Vitae for any researcher new to Beaumont, and Research Conflict of Interest Disclosures forms (COIDs) for each key personnel.
   2. Local safety review is required for studies involving a study-specific drug, an increase in or addition of radiation, or the use of gene therapy. These reviews will be initiated based upon

questions in the Initial Administrative Application and must be completed prior to issuance of the IRB's Administrative Acknowledgment letter for the external IRB.

3. Positive COID disclosures are routed to the RI Compliance Coordinator and, if determined to represent a conflict, a Management Plan (MP) is developed. In the event a positive conflict of interest disclosure requires a MP the IRB will provide a Submission Response to the researcher with the MP attached. The PI must return the MP to the IRB with required signatures before the IRB's Administrative Acknowledgement letter will be issued. When using an External IRB, the signed MP must be submitted to the External IRB. Any additions or changes to the MP by the External IRB will require review by the RI Compliance Coordinator and the BH IRB.
4. CITI training is verified for each key personnel listed on the study. Researchers are responsible for contacting Research Education for consent, phone script and other training needs.
5. Patient recruitment information including the Beaumont name, logo, address or phone number must be reviewed by Marketing Communications. Researchers are responsible for contacting Marketing Communications directly. Materials must then be submitted to the external IRB for review and are not reviewed by Beaumont's IRB.
6. When Administrative Review is complete, the IRB will provide an Acknowledgement letter to the PI and study contacts. The PI will include this letter in the external IRB submission.
7. External IRB approval, Beaumont budget and contract approval are required before study activities may begin.

B. **Amendment Requests -** Amendment requests involving addition or deletion of the PI or key personnel, or changes to the study medications, biologics, radiation or gene therapy must be submitted in iMedRIS for review by the Beaumont IRB prior to submission to the external IRB. The IRB will facilitate the review of training, conflicts of interests, pharmacy, radiation safety and Biosafety. An IRB Amendment Acknowledgement letter will be sent to the PI and the contacts listed in iMedRIS. This letter is provided to the external IRB by the researcher. All other types of amendment requests may be submitted directly to the external IRB.

C. **Changes which Impact Study Costs or Patient Care Billing –** If a protocol revision involves changes which increase Beaumont's cost to conduct the study (e.g., additional staff time, research specific procedures, etc.) or changes in procedures being billed to a patient's insurance, the Clinical Research Manager and Grants and Contracts Analyst must be notified in order to update the study budget, re-negotiate with the sponsor and/or request changes to Reveal or DDOTS.

D. **Changes in Study Status -** When the protocol status changes in any way, the PI or designee must submit the change in status (i.e. open, closed to enrollment, or closed) to the IRB via the

iMedRIS system. This will ensure accurate tracking and oversight of ongoing Beaumont clinical research.

E. **IRB Ceding Authority to an External IRB -** If the IRB allows a non-BH IRB to be recognized as the IRB of record for oversight of a study, this arrangement must be documented in writing between the two institutions using an IRB Authorization Agreement (IAA). The Office for Human Research Protections (OHRP) has a sample "IRB Authorization Agreement" on its website at http://www.hhs.gov/ohrp/assurances/forms/iprotsup.rtf. Master agreements are in place for the currently approved external IRB's.

F. **Quality and Safety Registries Managed by BH Department of Quality, Safety and Clinical Effectiveness -** Quality Assurance or Quality Improvement projects must be submitted to the Quality, Safety and Clinical Effectiveness Department, who will determine if the project is appropriate to conduct at BH. If the Quality Measures Department agrees the project would be of interest to the organization, the IRB, IT Privacy, IT Security and Legal will review the request and related submission documents.
   1. If a quality registry involves collection of prospective data, the IRB must review to determine if the data collection is intended for research purposes. If the intent is for research purposes, the IRB will determine if Beaumont is actively engaged in research or if the prospective data collection is for quality improvement purposes only.
   2. If a Beaumont investigator requests collection of data variables not originally included by the sponsor of the QA/ QI project or data registry, the project will be considered research and require Beaumont IRB review prior to the collection of the additional BH specific data variables.
   3. National or regional quality registries conducted through Beaumont Health's Quality, Safety and Clinical Effectiveness department may request an exception from the requirement to use only an approved, external IRB when all three of the following are met:
      a. The project is federally funded,
      b. The project requires use of a designated external IRB, and
      c. The required central IRB is AAHRPP accredited or is a government IRB i.e. NIH IRB.
   4. To initiate this exception request, the Quality, Safety and Clinical Effectiveness department initiates a written request to the IRB in SharePoint. The request details the reason for the request, identifies the requested IRB, provides evidence of the external IRB's current Federal Wide Assurance and the study specific IRB approval letter or letter granting exemption of the project. The request must be approved in writing by the IRB Chairperson or his designee (as documented in SharePoint). The Institutional Official (Research Institute Vice President or Administrative Director) must concur with the decision of the IRB Chairperson, as evidenced by their signature on the IRB Authorization Agreement.

Please see Appendix A: *National or Regional Quality Registry and Reliance on IRB of Lead Organization Determination Checklist*, to confirm your project meets criteria for review by the parent/lead organization IRB.

G. **NIH Single IRB Mandate**-Effective January 25, 2018, the NIH single IRB (sIRB) policy requires single IRB review for most multisite research using the same research protocol and supported through NIH grants, cooperative agreements, contracts, or the NIH Intramural Research Program. The policy applies to all awardees in the United States and all participating research sites in the United States. The NIH sIRB policy does **not** apply to foreign research sites, Exempt human subjects research or certain types of awards (career development, research training, or fellowship awards). The NIH Single IRB (sIRB) policy requires the Lead Researcher for the multi-center project to name the selected sIRB in the grant application and to confirm each participating site has agreed to rely upon the selected sIRB. **Research Administration is the sole entity permitted to approve and confirm Beaumont's agreement to rely on another organization's IRB for a particular project.** The Research Institute will conduct an Administrative Review to determine whether research is eligible/appropriate for review by the selected sIRB. Awardee organizations are responsible for ensuring authorization agreements are in place and that documentation is maintained; this will be confirmed during the Beaumont Administrative Review process. A single reviewing IRB takes on all IRB oversight responsibilities while Beaumont, as a Relying Institution, provides the reviewing IRB with local context regarding state law, study team member training/qualifications information, and conflict of interest information, when applicable. The Beaumont principal investigator is responsible for being knowledgeable about the reviewing IRB's policies and complying with its determinations. Beaumont IRB may serve as the single reviewing IRB in some instances, with other organizations relying upon Beaumont IRB oversight.

Beaumont has joined the SMART IRB Reliance Initiative. The SMART IRB (Streamlined, Multisite, Accelerated Resources for Trials IRB) Reliance platform is designed to harmonize and streamline the IRB review process for multisite studies, while ensuring a high level of protection for research participants. Beaumont's point of contact for SMART IRB is the Beaumont IRB nurse manager. Researchers should contact the Beaumont IRB at 248-551-0662 to learn more about working with SMART IRB and their responsibilities related to sIRB review.

VI. REFERENCES:

21 CFR 56.107 - IRB Membership
21 CFR 56.108 - IRB Functions and Operations

21 CFR 56.111- Criteria for IRB Approval of Research
45 CFR 46.107- IRB Membership
45 CFR 46.108 - IRB Functions
45 CFR 46.114- Cooperative Research
Guidance on Engagement of Institutions in Human Subjects Research October 16, 2008
Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research June 21, 2016

VII. ASSOCIATED POLICIES:

IRB and Clinical Research Policy 241 *Use of the National Cancer Institute Central IRB*
IRB and Clinical Research Policy 260 *International Research*

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.

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National or Regional Quality Registry and Reliance on IRB of Lead Organization Determination Checklist

The checklist below is used only by the Quality, Safety and Clinical Effectiveness department to help determine whether a multi-center registry managed within that department may qualify for review and oversight by an external IRB i.e., serve as the IRB of record for the project.

Project Title:
Date:
Form Completed By:

Qualification for Central Registry IRB Review and Oversight: Applies only to multi-center national or regional registries managed by the Beaumont Quality, Safety and Clinical Effectiveness Department.	**YES**	**NO**
1. Is the database/registry overseen by the Beaumont Quality, Safety and Clinical Effectiveness Department?	☐	☐
2. Is the primary Beaumont interest benchmarking?	☐	☐
3. Has the lead organization obtained IRB approval from an AAHRPP accredited IRB? (AAHRPP = Association for the Accreditation of Human Research Protection Programs)	☐	☐
4. The holder of the database/PI agrees there will be no alteration in the data variables required by the national registry (e.g., adding Beaumont only variables, for Beaumont use).	☐	☐
5. The holder agrees any Beaumont use of the database/registry data outside of the registry purpose will require Beaumont IRB review and approval.	☐	☐

ANSWER KEY:
- If the answer to **ALL** of the questions is **YES**, IRB approval may be granted by the registry parent/lead organization.
- **The IRB granting approval must be AAHRPP accredited.** Please contact the IRB to initiate an IRB Authorization Agreement between Beaumont and the parent/lead organization. A copy of this checklist and the IRB approval letter from the parent/lead organization must be provided to the IRB along with your request.
- If the answer to **ANY** of these questions is **NO**, the project must be submitted to the Beaumont IRB for review.
  Keep a dated copy of this checklist in your files.