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| **Coordinating Center and Lead Researcher Requirements** | **Beaumont Health** | **04/03/2018** |
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| **Administrative Director** | **Policy** | **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 guidelines for the regulatory review and approval process for research in which a Beaumont Health (Beaumont) investigator or department is to serve as the Coordinating Center or Lead Researcher.

## II. SCOPE:

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

## III. BACKGROUND:

A **Coordinating Center** is an institution, department or individual designated in a research protocol to hold responsibility for oversight, conduct and administrative operations of a research trial. The Coordinating Center responsibilities must be clearly defined in the research protocol/plan. Utilization of a Coordinating Center may involve simple data compilation in a one-site trial or may include extensive data management and adverse event monitoring for a large multi-center trial. Generally, the Coordinating Center is the point of communication among the participating investigators, site personnel and the study sponsor.

The Coordinating Center of a multi-center trial is responsible for assuring IRB approval is granted at each participating site prior to the initiation of research at the site. In confirming IRB approval, the Coordinating Center must collect each site's IRB approval letter.

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It is important to note when a Beaumont investigator serves as the director of a Coordinating Center, or when a Beaumont department functions as a Coordinating Center or Lead Researcher, the Beaumont IRB is not the IRB of Record for the non-Beaumont participating sites.

A. **Engaged in Research**

Health and Human Services (HHS) regulations require each institution "engaged" in human participant research to provide an assurance of compliance with the regulations, unless the research is exempt. Refer to RI Policy *Institutional Engagement in Research* for additional guidance.

When Beaumont serves as the Coordinating Center or Lead Researcher for an observational study or clinical trial in which multiple sites are participating, or as a statistical center who obtains, receives or possesses private information from participant(s) that is individually identifiable (either directly or through coding systems) for research purposes, Beaumont is considered "engaged" in research. Thus IRB approval is required.

## IV. POLICY:

When Beaumont serves as the Coordinating Center for a research trial, the IRB requires the Beaumont Research Coordinating Center or Beaumont department/Lead Researcher acting as the Coordinating Center, to provide a plan for trial operations (separate from the clinical trial protocol) which includes safeguards to ensure adequate trial oversight.

Coordinating Center or Lead Researcher activities do not involve direct interaction or intervention with study participants at non-Beaumont sites. Risks associated with Coordinating Center activity include a potential breach of confidentiality, failure to provide adequate training and direction to investigators and research staff, failure to conduct adequate review of safety data and failure to adequately oversee research activities at each site (when appropriate).

A. **Beaumont Research Coordinating Center (BRCC) IRB Application Requirements**

The Beaumont Research Institute has a designated department that functions as a coordinating center – the Beaumont Research Coordinating Center. When the BRCC is providing coordinating center activities for a study not being conducted at Beaumont, an expedited review IRB application in iMedRIS must be submitted for review and approval. Information submitted will include those elements below, applicable to BRCC's contracted obligations for a given study:

1. A description of the database and data management and analysis plan designed to ensure participant safety.

2. A description for clinical and/or medical monitoring of data collected to ensure participant safety.
   a. If the BRCC will provide central analysis of adverse events, a detailed explanation of how this will occur, must be included.
   b. If the data will be monitored by a Data Safety Monitoring Board (DSMB), include who the members are, how it will operate, how often it will convene and the reporting frequency to the IRB.
3. A description of the mechanism used to communicate safety data back to participating sites.
4. A description of the mechanisms for protecting participant privacy and maintaining confidentiality of data.
5. The study protocol and informed consent and authorization template for participating sites.
6. A list of participating sites, each site's IRB of record, and the site's Federalwide Assurance (FWA) number.
7. A description of mechanisms used to manage information flow, including approval processes for protocol changes, reporting of unanticipated problems that are not adverse events, interim findings and other information which may affect the risk/benefit analysis of the study to participating sites.
8. A description of mechanisms used to communicate with all study participants, in the event it becomes necessary.

Changes to the BRCC role or obligations for a given study, must be submitted to the IRB as an amendment request. The BRCC may not allow a site to implement protocol changes without that sites' IRB approval of those changes.

When the BRCC is providing coordinating center activities for a study being conducted at Beaumont, the Beaumont PI's application in iMedRIS will include Coordinating Center/Lead Researcher information, and no separate BRCC submission to the IRB is required.

B. **Other Beaumont Department or Investigator Acting as Coordinating Center or Lead Researcher**

An IRB Application and study specific Coordinating Center/Lead Researcher plan must be submitted to the IRB for review and approval. This may be part of the original IRB submission when the Lead Researcher is also an enrolling site for the study. If the Beaumont department/investigator acting as Coordinating Center/Lead Research Beaumont is not also a participating site in the research being conducted outside of data management, an expedited

review IRB application in iMedRIS must be submitted. The iMedRIS application submission will include the following:

1. A description of the database and data management and analysis plan designed to ensure participant safety.
2. A description for clinical and/or medical monitoring of data collected to ensure participant safety.
    a. If the BRCC will provide central analysis of adverse events, a detailed explanation of how this will occur, must be included.
    b. If the data will be monitored by a Data Safety Monitoring Board (DSMB), include who the members are, how it will operate, how often it will convene and the reporting frequency to the IRB.
3. A description of the mechanism used to communicate safety data back to participating sites.
4. A description of the mechanisms for protecting participant privacy and maintaining confidentiality of data.
5. The study protocol and informed consent and authorization template for participating sites, and any recruitment materials.
6. A list of participating sites, each site's IRB of record, and the site's Federalwide Assurance (FWA) number. Note: Written approval from the IRB Chair and Institutional Official (IO) must be obtained for Beaumont to serve as the IRB of record for a non-Beaumont Health site.
7. A description of mechanisms used to manage information flow, including approval processes for protocol changes, reporting of unanticipated problems that are not adverse events, interim findings and other information which may affect the risk/benefit analysis of the study to participating sites.
8. A description of mechanisms used to communicate with all study participants, in the event it becomes necessary.

The Coordinating Center or Lead Researcher is responsible for ensuring each participating site has IRB approval prior to enrollment of participants. Changes to the Coordinating Center/Lead Researcher role or obligations for a given study, must be submitted to the IRB as an amendment request. The Coordinating Center or Lead Researcher may not allow a site to implement protocol changes without the sites' IRB approval of those changes.

C. **Enrolling Beaumont Participants when Beaumont is the Coordinating Center**

When Beaumont plans to enroll participants in a multi-center research study being managed by a Beaumont Coordinating Center/Lead Researcher, the IRB discourages the principal investigator (PI) of the multi-center study to also function as the Beaumont Coordinating

Center PI. When the Beaumont PI *does* function concurrently in the Coordinating Center or Lead Researcher and site PI roles, the IRB may require additional safeguards to ensure patient safety and research integrity (e.g., a plan to maintain blinding or external review of interim data), as appropriate.

D. **IRB Responsibilities**

The IRB is responsible for ensuring the PI has appropriately addressed the requirements listed above, using the iMedris IRB application.

When conducting multi-site research sponsored by the Department of Defense, a formal agreement between organizations is required to specify the roles and responsibilities of each party.

E. **Coordinating Center or Lead Researcher Responsibilities**

The Coordinating Center or Lead Researcher is responsible to submit all appropriate documents to the IRB for review and approval. Following initial IRB approval, an amendment must be submitted to add additional study sites. The Coordinating Center must follow all activities as described in the IRB approved protocol/plan. The Coordinating Center or Lead Researcher is responsible to monitor each site for current IRB approval. Research may **not** be conducted at a site whose IRB approval has lapsed, as the continuation of research after expiration of IRB approval is a violation of HHS and FDA regulations. (See IRB Policy *Continuing Review and Renewal of a Protocol* for details.)

Submission of the IRB Application documents the Coordinating Center/Lead Researcher's acceptance of responsibility to ensure all participating sites have obtained IRB approval prior to initiation of research

If a participating site does not have an IRB, the site may request the Beaumont IRB to serve as the IRB of Record. A written agreement must be reached between the participating site and the Beaumont IRB which clearly outlines the review and approval procedures. The IRB must issue an approval letter for that site, as IRB of record.

F. **Reporting to the IRB in Multi-Site Research**

As the Lead Researcher at the coordinating institution, the PI is responsible for receiving data and reports from participating sites in a timely manner, communicating to all participating sites as warranted, and submitting them to the Beaumont IRB as required.

G. **Cooperative Group or Commercially Sponsored Studies**

National cooperative groups or commercial entities may sponsor multi-center studies and

name a "lead researcher" or "national PI" - typically the researcher who developed and is most familiar with the protocol. As the sponsor, the cooperative group/commercial entity bears responsibility for coordinating center activities, and the lead PI assumes an advisory role (e.g., interpreting the protocol or leading the steering committee or advisory board). If the cooperative group/commercial entity is acting as the lead and communicating with other PIs and researchers, please note this in the IRB Application. The lead researcher or national PI must understand their responsibilities.

## V. REFERENCES:

21 CFR 50.3 Definitions
45 CFR 102 Definitions
21 CFR 56.108 (b) IRB Functions and Operations
45 CFR 46.108(b) IRB Functions and Operations
45 CFR 46.111 Criteria for IRB Approval of Research
21 CFR 56.111 Criteria for IRB Approval of Research

## VI. ASSOCIATED POLICIES:

RI Policy *Institutional Engagement in Research*
IRB Policy *Continuing Review and Renewal of a Protocol*
IRB Policy *Expedited Review of Research*
IRB Policy *IRB Initial Review of Research Protocols*

## 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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