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PURPOSE

The purpose of this policy is to provide guidelines for the regulatory review and approval process of research in which a Beaumont Health System (BHS) investigator or department is to serve as the Coordinating Center or Lead Researcher.

SCOPE

This policy applies to investigators, key research personnel, Human Investigation Committee (HIC) members and HIC staff.

BACKGROUND

A **Coordinating Center** is an institution, department or individual, designated in a research protocol, who holds responsibility regarding oversight, conduct and administrative operations of a research trial. The Coordinating Center responsibilities must be clearly defined in the research protocol. 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 always responsible for assuring Institutional Review Board (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 and submit a copy to the HIC. It is important to note when a BHS investigator serves as the director of a Coordinating Center, or when a BHS department functions as a Coordinating Center or Lead Researcher, the BHS HIC is <u>not</u> the IRB of Record for the non-Beaumont participating sites.

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 #120 *Engagement in Research* for additional guidance.

When BHS 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, BHS is considered "engaged" in research.

POLICY

When BHS serves as the Coordinating Center for a research trial, the HIC requires the Beaumont Research Coordinating Center or BHS department/Lead Researcher acting as the Coordinating Center, to provide a protocol for trial operations (separate from the clinical trial protocol) which includes safeguards to ensure adequate trial oversight. The HIC must receive documentation of IRB review and approval from each participating site prior to data collection from the site.

Coordinating Center or Lead Researcher activities do not involve direct interaction or intervention with study participants at non-Beaumont sites.

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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).

Beaumont Research Coordinating Center HIC Application Requirements

The Beaumont Research Institute has a designated department that functions as a coordinating center – the Beaumont Research Coordinating Center. When the Beaumont Research Coordinating Center is providing coordinating center activities for a Beaumont or non-Beaumont research trial, the *Beaumont Research Coordinating Center Application* must be submitted to the HIC for review and approval.

Other BHS Department or Investigator Acting as Coordinating Center or Lead Researcher

The HIC Application and study specific protocol, must be submitted to the HIC for review and approval and 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 Coordinating Center or Lead Researcher 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 how the DSMB will be selected, who the members are, and how it will operate, including how often it will convene and the reporting frequency to the HIC.
3. A description of the mechanism used to communicate safety data back to participating sites.
4. A description of the mechanisms for protecting privacy of participants and for maintaining confidentiality of data.
5. The study protocol and informed consent and authorization template to be distributed to participating sites.
6. Recruitment materials.
7. A list of each site and the IRB serving as the IRB of record for each site. Written approval from the HIC Chair and Institutional Official (IO) must be obtained for Beaumont to serve as the IRB of record for a non-Beaumont Health System site.
8. Each site's FWA number. If a site does not have an FWA, the HIC must be advised.
9. A copy of each sites IRB initial approval letter, including non-Beaumont sites using Beaumont's HIC as their IRB of record. The Coordinating Center or Lead Researcher is responsible for ensuring each participating site has IRB approval prior to enrollment of participants.
10. A description of mechanisms used to manage information flow and 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.

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11. A description of mechanisms used to communicate with all study participants, in the event it becomes necessary.

Enrolling BHS Participants when BHS is the Coordinating Center

When BHS plans to enroll participants in a multi-center research study being managed by a BHS Coordinating Center, the HIC discourages the principal investigator (PI) of the multi-center study to also function as the BHS Coordinating Center PI. When the BHS PI does function concurrently in the Coordinating Center or Lead Researcher and site PI roles, the HIC 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.

HIC Responsibilities

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

When the Coordinating Center or Lead Researcher submits an amendment of protocol changes for HIC review and approval, it is not necessary to submit participating site's IRB approval letters. However, the Coordinating Center or Lead Researcher may not allow a site to implement protocol changes without the sites' IRB approval of those changes.

The BHS Coordinating Center is responsible to ensure each active site's most recent IRB approval letter.

Coordinating Center or Lead Researcher Responsibilities

The Coordinating Center or Lead Researcher is responsible to submit all appropriate documents to the HIC for review and approval. Following initial HIC approval, an amendment must be submitted to add additional study sites. The Coordinating Center must follow all activities as described in the HIC approved protocol. 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 HIC Policy 205 *Continuing Review and Renewal of a Protocol* for details.)

The Coordinating Center or Lead Researcher is responsible to provide justification for any substantive modifications of the consent template by a participating site, related to risks or alternative procedures. Such modifications must be reviewed by the HIC as well as the participating site's IRB.

Submission of the HIC Application documents the PIs' acceptance of responsibility to ensure all participating sites have obtained IRB approval prior to initiation of research. The HIC staff will review and confirm each protocol application for a Beaumont coordinating site project

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includes the appropriate documentation from all participating institutions.

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

Reporting to the HIC 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 and submitting them to the Beaumont HIC as required.

Cooperative Group Studies

National cooperative groups 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 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 is acting as the lead and communicating with other PIs and researchers, please note this in the HIC Application. The lead researcher or national PI must understand their responsibilities.

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

ASSOCIATED POLICIES

RI Policy #120 *Institutional Engagement in Research*
HIC Policy #205 *Continuing Review and Renewal of a Protocol*
HIC Policy #213 *Expedited Review of Research*
HIC Policy #216 *HIC Initial Review of Research*

☐ Original ☒ Revision or Review

Research Institute Compliance Committee Review Date: _____

Corporate Administration Approval: _____ Date: _____
V.P. of Research or Chief Medical Officer

Research Institute Board Approval: _____ Date: _____

Research Administration Approval: _____ Date: _____
Administrative Director

Research Institute Administration