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PURPOSE

The purpose of this policy is to define the organization and function of the Beaumont Health System (BHS) Institutional Review Board (IRB) and to establish procedures for determining membership needs including the addition or removal of members.

SCOPE

This policy applies to Research Institute (RI) staff, IRB members and IRB staff.

POLICY

In accordance with federal regulations, International Conference on Harmonization (ICH), Good Clinical Practice Consolidated Guidelines (GCP), BHS policies, and RI By-Laws, the IRB is responsible for the oversight of research involving human participants at BHS in order to protect the rights, safety and welfare of all individuals participating in clinical research. This oversight will include, but not be limited to, ethical, scientific and financial issues. All research proposals involving human participants (including medical records or specimens) must be evaluated and approved prior to implementation by an IRB of record. The IRB will have adequate medical and scientific expertise and community representation to fulfill this responsibility.

PROCEDURE

IRB Membership

There may be more than one IRB operating group, and the membership of each IRB group will consist of all of the following:

a) At least ten members from varying backgrounds who possess sufficient professional competence to safeguard the rights and welfare of human participants.
b) Members of both sexes and of more than one profession.
c) At least one non-scientist.
d) At least one member who is not affiliated with BHS and who is not part of the immediate family of a person who is affiliated with BHS.
e) At least one member whose primary concerns are in scientific areas.
f) At least one member who represents the perspective of research participants.
g) Alternate members may be nominated for membership following the same procedure as full members. Alternate members may attend any meeting, but may vote only when serving in the place of an absent full member. If the full member and alternate member are both present the full member will vote and the alternate member will be listed as a guest. The minutes of the meeting will indicate when an alternate member is voting in lieu of another IRB member.
h) Any appointed IRB member can serve as an alternate for another committee member who shares the same function.
i) A member may not participate in the review of a project in which the member has a potential conflict of interest, except to provide information as requested by the IRB. The member with a conflict will be recused from the vote.

The composite of the IRB group(s) will consist of the diversity of professional experience and expertise required to deal with a multiplicity

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of considerations prerequisite to the rendering of decisions which are compassionate and just, with sensitivity to participant's safety and standards of professional care, and knowledge of, or familiarity with, applicable research laws and regulations, community concerns and institutional commitments. Every effort will be taken to assure the membership balance of the group and voting on projects minimizes any unintentional specialty bias in reviewing and approving projects.

Individuals who are responsible for business development are prohibited from serving as members or ex-officio members on the IRB and/or carrying out day-to-day operations of the review process.

When the IRB reviews research involving participants likely to be vulnerable to coercion or undue influence, the IRB Chairperson or designee evaluates each protocol and ensures at least one IRB member knowledgeable about or experienced in working with such participants will be in attendance at the meeting. The IRB Chairperson or designee defers the research to another meeting, or obtains consultation if there is not appropriate scientific or representational expertise.

Appointment of IRB Members

Members of the IRB, alternate IRB members, the IRB Chairperson and Vice Chairperson, will be appointed by the Education, Innovation and Research Committee upon recommendation of the Vice President (VP) of Research/Medical Director of the RI to serve for a two year term. There is no limit to the number of terms a member may serve. Alternate member's confirmation will include the name(s) of full member(s) for whom the alternate may substitute.

Prior to full appointment by the Education, Innovation and Research Committee, an IRB member nominee will complete a conflict of interest disclosure, which will be submitted to the Corporate Compliance Office. Member nominees may be given interim IRB membership status by the VP of Research.

Membership needs may be identified by the IRB Chairperson, the IRB Manager, Research Administration or the Institutional Official (IO). Membership need and augmentation is based on maintaining an adequate number of members, maintaining adequate representation of expertise, and/or maintaining adequate representation of nonscientists or community representatives. The IRB Chairperson or designee evaluates each protocol to determine whether a consultant is needed. Expert consultants may be utilized to obtain review in an area where additional expertise is needed. Consultants are not considered IRB members and do not have the right to vote. Consultants may be obtained through recommendations of the Chairperson of the department submitting the protocol. The consultant will receive a study packet, reviewer checklist and RI Policy #105 *Conflict of Interest Disclosure for Research Approval Committee Members* at least seven (7) days prior to the meeting. The information provided by the consultant will be documented in the IRB minutes.

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Appointment of IRB Chairperson and Vice Chairperson

The Education, Innovation and Research Committee is responsible for the appointment of the IRB Chairperson and Vice Chairperson based on the recommendation of the VP of Research/Medical Director of the RI. Candidates must be a scientist member of the IRB with considerable IRB or research compliance experience. The Chairperson and Vice Chairperson must demonstrate leadership skills and be willing to commit the time necessary to provide oversight to the IRB and nominal direction to the IRB staff.

IRB Member Education

New IRB members will be oriented to the roles and responsibilities of IRB membership by the IRB Manager or designee. The orientation will include:

- Review of IRB policies and procedures, including the IRB reviewer checklists used to assist in project review.
- Review of IRB forms.
- A demonstration of the resources available on the IRB website.
- A copy of the *Institutional Review Board Member Handbook.*
- A review of packet material.

Ongoing education consists of IRB Brown Bag Series, bi-monthly *IRB Research and Human Ethics* newsletters, webinars, presentations and discussion at meetings as necessary.

Evaluation of IRB Chairperson and Vice Chairperson

The Administrative or Medical Director of the RI meets annually with the IRB Chairperson and Vice Chairperson for performance evaluation, and to assess the level of commitment to continue serving in this capacity.

Evaluation of IRB Members

Each member of the IRB is evaluated by the IRB Chairperson or IRB Manager at least annually, including assessment for continued suitability to fulfill specific representative capacities. For example, non-affiliated members must verify they or their family members have not acquired relationships with Beaumont over the past year. The written evaluation is signed by the Chairperson, and a copy is given to the IRB member. In addition to annual evaluations, the IRB Manager is responsible for monitoring the membership complement at convened meetings and to verify meetings are appropriately convened and member attendance is appropriate. The IRB Manager completes an evaluation of the IRB Chairperson and Vice Chairperson at least annually, and shares the documentation with the Administrative or Medical Director of the RI.

Maintenance of IRB Roster

The IRB membership roster will include the following information for each IRB member:

- Name
- Gender
- Earned degree(s)
- Representative capacity
  - Scientist or nonscientist
  - Affiliated or non-affiliated

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- Experience to determine expertise and contribution to IRB
- Representative capacities in terms of the vulnerable populations, if any, each member is knowledgeable about or experienced in working with
- Employment or other relationship between the IRB and BHS
- Alternate members
- The primary members or class of primary members for whom each alternate could substitute.

Each member's curriculum vitae and/or biosketch will be stored in the IRB Office. Changes in IRB membership are promptly reported to the Office of Human Research Protections (OHRP) by the IRB Manager.

IRB Staff

The Administrative Director of the RI is responsible for maintaining appropriate staffing, including an IRB Manager, to support the activities of the IRB and the IRB Office.

Training of IRB Staff

Training of the IRB staff is overseen by the IRB Manager. With completion of adequate training, select IRB staff may serve as IRB members and may be designated by the IRB Chairperson to approve expedited review initial applications, exemption requests, expedited progress reports, amendment requests and modifications received.

Evaluation of IRB Staff

Each IRB staff member is formally evaluated, per organizational policy, on an annual basis as well as on an ongoing basis, by the IRB Manager.

Functions of the IRB

Functions of the IRB include:

a) Reviewing requests for use of an AAHRPP accredited, Beaumont approved external IRB and authorizing the use, when appropriate.

b) Conducting preliminary review, by an IRB staff member, of submitted research protocol applications to identify gross application errors which must be corrected by the Principal Investigator (PI) prior to IRB submission.

c) Determining the level of review to be conducted (i.e., full board, expedited, or exempt).

d) Reviewing projects requesting determination of human participation research and providing concurrence, where applicable.

e) Reviewing projects requesting an exemption and providing concurrence as described in IRB Policy #231 *Research Exempt from Full IRB Review.*

f) Using an expedited review procedure for protocols which meet criteria for Expedited review as stated in IRB Policy #213 *Expedited Review of Research.*

g) Conducting a pre-review of all initial protocols submitted for full board review using a Pre-review Checklist. The review will be available in iMedRIS to all members, including the IRB primary reviewer. Assigning a primary reviewer for each protocol determined to require full board review. The primary reviewer analyzes the project in detail, requests further information from the PI if needed,

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and presents the project to the IRB at a regularly scheduled meeting. At the Chairperson's discretion, additional reviewers may be assigned to projects for which they have individual expertise, with the same responsibilities as those of the primary reviewer. An *IRB Reviewer Checklist* must be completed by each primary reviewer to facilitate a thorough review.

h) The Primary Reviewer may contact the PI, but the PI may not contact the Primary Reviewer unless the Primary Reviewer requests to be contacted.

i) Considering each new full board review protocol based on the protocol application form, accompanying documents and a detailed presentation of the project by the assigned primary reviewer at the next regularly scheduled meeting. A majority of IRB members must be present, including at least one non-scientific member. In order for the research project to be approved, it must receive the approval of a majority of members present at the meeting and this must be noted in the IRB minutes. Meetings will be scheduled as needed to meet the volume of submitted protocol applications (typically twice a month). The IRB will communicate the Committee's decision in writing to the PI of each study reviewed.

j) Conducting continuing review of each project at least annually, based upon information submitted by the PI on the Progress Report. The IRB may determine the review of certain protocols be conducted more frequently, appropriate to the degree of risk presented by the research, and may seek additional means or sources of verification to assure project compliance with the IRB-approved protocol and/or IRB policies.

k) Reviewing all Unanticipated Problem reports to determine if the event changed the risk/benefit exposure of the participants. The IRB may determine participants be notified of the event, require a protocol or informed consent and authorization document change and/or may halt the study until the risk/benefit ratio is determined acceptable.

l) Reviewing all Major Protocol Deviation Reports to determine if participant safety has been compromised. The IRB may determine the action plan submitted with the report is appropriate, require changes to the action plan, request additional information or stop the study until patient safety have been maintained. Minor protocol deviation logs will be reviewed along with the Progress Report.

m) Responsibility for reporting to the appropriate institutional and regulatory officials (e.g., OHRP or the Food and Drug Administration), any serious or continued non-compliance with IRB policies or applicable regulatory bodies.

IRB Authority

The IRB will review and have authority to approve, require modifications, defer, or disapprove any research activities involving human participants covered by federal, state and institutional regulations and polices. The IRB will:

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a) Require participants be consented appropriately in accordance with the elements of informed consent as outlined in IRB Policy #221 *Informed Consent and Authorization.*

b) Require documentation of informed consent and authorization or waive this requirement in accordance with IRB Policy #221 *Informed Consent and Authorization.*

c) Notify the PI in writing, of its decision to approve, request modifications, defer or disapprove the proposed research activity. If a project is disapproved or modifications are required, an explanation of the reasons for the IRB's decision will be given to the PI. The PI must respond in writing, and has the opportunity to respond in person.

d) Conduct continuing review of research covered by these regulations at intervals appropriate to the degree of risk, but not less than once per year, and shall have the authority to observe, or have a third party observe study conduct, including the consent process.

The IRB has the authority to suspend or terminate approval of research has not been conducted in accordance with IRB requirements or which has been associated with unexpected serious harm to participants. Any such suspension or termination of approval will include a statement of the rationale regarding the IRB action and be reported promptly to the PI, appropriate institutional officials, OHRP and the Food and Drug Administration as appropriate.

The IRB will determine all of the following requirements are satisfied in order to approve the research study:

a) Risk to the participants is minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and whenever appropriate, by using procedure already being performed on the participants for diagnostic or treatment purposes.

b) Risk to the participants is reasonable in relation to anticipated benefits.

c) Selection of participants is equitable.

d) Informed consent and authorization will be obtained in compliance with state, federal and institutional regulations and policies, as appropriate.

e) Participant signing of an informed consent and authorization document must be witnessed by an individual other than the consent provider.

f) Informed consent and authorization will be appropriately documented in accordance with state, federal and institutional regulations and policies, as appropriate.

g) Adequate provision is provided to monitor participant safety.

h) Participant privacy and the confidentiality of data will be protected.

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i) When vulnerable participants or those susceptible to coercion or undue influence are involved, additional safeguards are included in the study to protect the rights and welfare of these participants.

Undue Influence

It is the responsibility of the IRB to objectively review IRB submissions and implement IRB policies and procedures without undue influence over the deliberations or processes. IRB members, IRB staff, investigators or research participants who believe an attempt has been made to unduly influence the IRB, its review processes or application of its polices and procedures may contact the Institutional Official (IO), RI Compliance Coordinator, Corporate Compliance Office or Beaumont Health System compliance line. Complaints will be handled as described in RI Policy #116 *Complaints, Allegations of Non-Compliance and Confirmed Non-Compliance in Clinical Research.*

Documentation of IRB Activities

The IRB will prepare and maintain adequate documentation of its activities including the following:

a) Copies of all reviewed research protocols, informed consent and authorization documents, progress reports, amendments, protocol deviations, unanticipated problems and any other documentation accompanying these submissions related to the study.

b) Minutes of IRB meetings in sufficient detail, including meeting attendance, actions taken by the IRB (i.e., vote on actions, number of members voting for or against study approval, and those abstaining or recusing themselves from vote), justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the protocol with rationale for significant/non-significant risk at initial review (Refer to IRB Policy #209 *Determination of Significant Risk Device*) discussion or rationale when requiring changes in, deferring, or disapproving research, and a written summary of the discussion of controverted issues.

c) Records of continuing review activities.

d) Copies of all correspondence between the IRB and the PI and study staff.

REGULATORY REFERENCES

21 CFR 50 – Protection of Human Subjects
21 CFR 56 – Institutional Review Boards
21 CFR 312 – Investigational New Drug Application
21 CFR 600 – Biological Products: General
21 CFR 812 – Investigational Device Exemptions
45 CFR 46 – Protection of Human Subjects

ASSOCIATED POLICIES

RI Policy #116 *Complaints, Allegations of Non-Compliance and Confirmed Non-Compliance in Clinical Research*
IRB Policy #200 *Unanticipated Problem and Adverse Event Reporting*
IRB Policy #209 *Determination of Significant Risk Device*
IRB Policy #213 *Expedited Review of Research*

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IRB Policy #216 HIC *Initial Review of Research Proposals*
IRB Policy #221 *Informed Consent and Authorization in Research*
IRB Policy #222 *Institutional Authority*
IRB Policy #224 *Meetings of the Human Investigation Committee*
IRB Policy #231 *Research Exempt from Full HIC Review*
IRB Policy # 233 *Review by an External Institutional Review Board*
Beaumont Health System, Research Institute By-laws

☐ 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