Title: **Meetings of the Institutional Review Board**	*Applicable to: **Beaumont Health**	Effective Date: **03/16/2018**
		Last Periodic Review Date: **03/16/2018**
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 setting agendas, calling to order, conducting, managing, adjourning and preparing minutes for meetings of the Beaumont Institutional Review Board (IRB).

II. SCOPE:

This policy applies to Beaumont IRB members and IRB staff.

III. POLICY:

The Beaumont Health (Beaumont) IRB serves as the primary Institutional Review Board for human participant research conducted at Beaumont (for information about the use of external IRB's, see policy *Review by an External Institutional Review Board*). The Beaumont IRB is responsible for the initial and continuing review and oversight of research involving human participants at Beaumont Health for which it serves as IRB of record. Use of the term "IRB" in the remainder of this policy refers to the Beaumont IRB. Written procedures will be approved to describe all functions and operations of the IRB, in accordance with:

1. 21 CFR 56.108 - IRB Functions and Operations
2. 45 CFR 46.108 - IRB Functions and Operations.

If a study sponsor contractually requires the principal investigator (PI) to conduct a study in accordance with ICH-GCP E6, or at the request of the investigator, the IRB will review protocols

in accordance with ICH GCP Consolidated Guidelines. When conducting such review, the IRB will be in accordance with ICH E6 Part 3.3 – Procedures (refer to IRB policy *Clinical Studies Conducted in Compliance with ICH-GCP Guidelines*.)

IV. DEFINITIONS:

A. **Primary Reviewer -** A Primary Reviewer has the appropriate scientific or scholarly expertise for making an in-depth critique of the IRB application, protocol, informed consent and authorization document, investigator brochures, advertisements, and other materials submitted for review of the research.

B. **Pre-reviewer -** An IRB staff member and an IRB member.

C. **Consultant -** A Consultant will assist the IRB with reviews when adequate expertise is not available within the IRB. A consultant has the appropriate scientific or scholarly expertise for making an in-depth critique of the IRB application, protocol, informed consent and authorization document, investigator brochures, advertisements and other materials submitted for review of the research.

V. PROCEDURE:

A. Beaumont has two committees (IRB 1 and IRB 2), and each meets monthly. The scheduling of meetings is generated annually and posted on the IRB website and in iMedRIS. Generally, one of the IRBs meets every two weeks to provide a timely review of the research. Prior to each convened meeting, the IRB staff will collect and compile the agenda, the previous month's meeting minutes, information regarding conflicts of interest, the studies undergoing initial Full Board review at the meeting, recently approved Expedited and Exempt protocols, protocol amendments, continuing review/progress reports, unanticipated problems, protocol deviations and any other announcements or business to be reviewed at the meeting. Members may review the agenda in iMedRIS in advance of the meeting in order to permit sufficient time to review the information. The Pre-reviewer will review the IRB application, protocol, informed consent and authorization document, investigator brochures, advertisements, and other materials submitted for review of the research. The Pre-reviewer will document their review on the Pre-review checklist and submit the checklist to the Primary Reviewer for further review.

   A Primary Reviewer will be assigned for each new protocol or protocol amendment to be presented at the meeting. The Primary Reviewer will not be listed as key personnel on the study or have a conflict of interest related to the study. The Primary Reviewer will be

responsible for making an in-depth critique of the IRB application, protocol, informed consent and authorization document, investigator brochures, advertisements, and other materials submitted for review.

B. **Consultants** - Additional reviewers, including Consultants who are non-affiliated experts, may be appointed by the IRB Chairperson to assure the required expertise or knowledge is available for adequate review of the risks and benefits of the research. Consultants may participate in any review activity, including but not limited to Full Board, Expedited initial reviews, Exempt initial reviews, amendments, continuing review, review of unanticipated problems involving risks to subjects or others, review of protocol deviations or non-compliance with regulations or laws or the requirements of the IRB.

   If additional expertise is needed to answer questions which arise before or during the IRB meeting, a Consultant may be engaged. The IRB will defer the review of the research if there are significant questions remaining after the meeting or if the submission does not meet the Regulatory Criteria for IRB Approval of Research. If a Consultant is needed, the IRB Consultant Reviewer Checklist will be completed in iMedRIS. The IRB Consultant will be required to verify they have no conflict of interest to the research study. If there is a conflict of interest, another Consultant will be selected.

   The need for a Consultant may be identified any time during the review process. For example, the need for a Consultant may be determined by the IRB Chairperson when assigning a Primary Reviewer, upon initial review of the project by the IRB Administrative Manager, by the Primary Reviewer if she/he determines additional expertise is needed or during a meeting if questions arise for which none of the members in attendance have the appropriate scientific or scholarly expertise to address.

C. **Conflicts of Interest -** IRB members or Consultants utilized by the IRB may not participate in review activity if they have a conflict of interest related to the research being reviewed. A conflict is defined as a financial interest of the Consultant or their immediate family member in the product or service being tested, or involvement of the IRB member, Consultant, or their immediate family in the design, conduct, or reporting of the research. Immediate family means spouse or domestic partner; birth or adoptive parent, child or sibling; stepparent, stepchild, stepbrother or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

D. **Conduct of the Meeting -** All meetings will be conducted by the IRB Chairperson. In the event the Chairperson is not in attendance, the Vice-Chair or a designated Co-Chair will lead the meeting.

1. A quorum of the membership must be present to conduct the official business of the Committee. A quorum shall be defined as a simple majority of the full membership, exclusive of non-voting members. At least one non-scientist must be present to make a quorum. At least one non-affiliated member (lay member), not otherwise affiliated with the institution, representing the general perspective of participants must be present at the meetings. If the IRB reviews research which involves categories of participants vulnerable to coercion or undue influence, one or more individuals knowledgeable about or experienced in working with such participants must be present.
2. A quorum must be maintained during the course of the meeting. In the event the number or qualifications of members in attendance does not meet the requirements defined above, either through the departure of a member or by a member being excused for potential conflict of interest, a quorum shall no longer exist and official actions of the Committee shall cease until a quorum is reestablished.
3. Once the meeting is called to order, guest introductions are made and any potential conflict of interest is addressed. This information is noted in the meeting minutes. Minutes from the previous meeting are presented for discussion. If changes are required, the changes are discussed and added to the minutes. If there are no changes, the Committee acknowledges the meeting minutes as presented.
4. Research approved through Exempt and Expedited Review since the last IRB meeting is available for review by IRB members via provision of IRB minutes and access to the studies within iMedRIS. Members discuss concerns or questions related to these reviews at the meeting. A brief review of any educational topics or audit updates are discussed prior to initiating review of the agenda items e.g., new protocol applications, protocol amendments, progress reports, unanticipated problems, etcetera.
5. The Primary Reviewer of a protocol or protocol amendment will present a brief summary of the protocol along with any comments regarding deficiencies or recommended clarifications. All Committee members will have an opportunity to comment on each submission. Non-members may participate in the discussion at the discretion of the Chairperson. If a Committee member has a conflict of interest with a study sponsor or is listed as key personnel on a study, the member will be recused prior to the final discussion and vote. The recusal and reason will be noted in the meeting minutes.
6. Following full board review and discussion of the merits, deficiencies, controverted issues and ethical issues of a protocol submission, the Chairperson will entertain a motion for action. Acceptable motions are: **Full Approval, Modifications Required, Deferral** or **Disapproved**. After each motion has been seconded, the Chairperson will conduct a voice vote of the voting membership. At convened meetings, a majority of the members present must vote in favor of approval in order for the research to be approved. The minutes will state if the voice vote is unanimous or without objection. When negative

votes, abstentions, or recusals are cast, the minutes will reflect the number of affirmative and negative votes and abstentions.

7. Reports of Unanticipated Problems (UP), Protocol Deviations (PD) and noncompliance will also be reviewed by the convened Committee. The Chairperson will invite discussion and the IRB will determine if reports of UP, PD or noncompliance (NC) meets the respective definitions, if actions by the PI are adequate or if further actions to protect participants are warranted. Additionally, for each UP or Level I Noncompliance, the IRB will make a determination if the event meets the criteria for reporting to the Institutional Official and outside regulatory authorities. (See Research policy *Contacts, Complaints, Allegations of Non-Compliance and Confirmed Non-Compliance in Clinical Research* , IRB policies *Reporting an Unanticipated Problem Involving Risk to Participants or Others* and *Protocol Deviations*).
8. After each meeting, PI's are sent written comments from the Committee regarding any deficiencies identified during the review along with any revisions or clarifications requested by the Committee. When a project is deferred, the modified protocol application and associated forms will return to the full IRB for review.
9. The date of the IRB meeting at which the protocol is presented and reviewed is considered the IRB review date. When the IRB requires modifications by the PI, the date of approval is the date all the conditions were determined to be met. The expiration date is reflective of the IRB meeting date, i.e. IRB meeting 1/2/17 requires modification, modifications are approved on 2/1/17 the expiration date of the approval will be 1/1/18. If the research expires before the conditions are reviewed and approved, all research activities must stop until approval is obtained. All continuing protocols will be reviewed prior to the annual anniversary of the review date. The IRB may require a progress report at intervals more frequently than annually, dependent upon the potential risks involved in the research.

E. **Minutes of the IRB Meetings**

The IRB Chairperson, IRB Vice-Chair and IRB Manager will review meeting minutes and correspondence to PIs to ensure all concerns presented at the meeting, as well as the number of members voting on each protocol, are accurate. This review is documented in written communication. Minutes of the IRB activities, including actions taken under an Expedited Review process, are available for review and discussion by IRB members via provision of IRB minutes and access to the studies within iMedRIS. Corrections to, and discussion of the previous meetings minutes will be recorded. Routine audits of the IRB minutes will be conducted by an impartial party who will attend meetings, take notes and audit minutes to monitor if discussion items and controverted issues are documented. IRB minutes will be maintained in the IRB office according to IRB Policy 247 *IRB Document Management.*

IRB meeting minute documentation includes:

- Attendance at the meeting.
- When an alternate member replaces a primary member.
- Actions taken by the IRB.
- Separate deliberations for each action.
- Voice votes for each protocol as numbers for, against, abstaining. The names of IRB members who leave the meeting because of a conflict of interest marked as recused, noting the specific nature of the conflict of interest (ex, key personnel) as the reason for recusal.
- The basis for requiring changes in research.
- The basis for deferral or disapproving research.
- A written summary of the discussion of controverted and/or ethical issues and their resolution.
- Findings of Risk/Benefit ratio.
- For initial and continuing review, the approval period.
- Required determinations and protocol-specific findings justifying those determinations for:
  - Waiver or alteration of the consent process.
  - Research involving pregnant women, fetuses, and neonates.
  - Research involving children.
- The rationale for significant risk/non-significant risk device determinations for initial review.

F. **Non-Compliance in DoD Research**

Records maintained that document compliance or non-compliance with DoD requirements will be made accessible for inspection and copying by representatives of the DoD at reasonable times and in a reasonable manner as determined by the supporting DoD component.

VI. 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
ICH E6 Part 3.3 – Procedures.

VII. ASSOCIATED POLICIES:

RI Policy *Institutional Conflict of Interest*
RI Policy *Conflict of Interest for an Individual Involved in Research*

RI Policy *Contacts, Complaints, Allegations of Non-Compliance and Confirmed Non-Compliance in Clinical Research*
IRB Policy *Reporting an Unanticipated Problem Involving Risk to Participants or Others*
IRB Policy *IRB Initial Review of Research Protocols*
IRB Policy *PI Notification of Review Outcome and Response Requirements*
IRB Policy *Protocol Deviations*
IRB Policy *247 IRB Document Management*
IRB Policy *Research Supported by the Department of Defense*
IRB Policy *Review by an External Institutional Review Board*

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.