Title: **PI Notification of Review Outcome and Response Requirements**	*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 ensure decisions of the Institutional Review Board (IRB) regarding new studies, progress reports/continuing review, amendments to previously approved studies, on-site unanticipated problems (UP) and protocol deviations, are communicated to principal investigators (PI) in writing, per federal guidelines. The Beaumont Health (Beaumont) IRB serves as the IRB for all human participants research conducted at Beaumont. According to the Bylaws of the Research Institute, the IRB operates under the authority of the Beaumont Board of Directors. Research cannot commence until final IRB approval has been granted.

II. GENERAL:

Decisions of the IRB will be communicated to the PI via a letter by email, and will contain the following information:

1. Results of the IRB review
2. When modifications are required, comments, request for revisions and clarifications, or more specific types of information required before the IRB can take action.
3. When a submission is approved, the details of the approval, i.e., type of submission (initial review, continuing review, amendment request, etc.), approval date, and for amendments, what changes are being approved (key personnel addition, changes to informed consent, sponsor communication, etc.).

The PI may not proceed with a new or amended protocol until written notification of final approval has been issued by the IRB. It is the goal of the IRB to generate letters within one (1) week following their determination.

III. NEW OR AMENDED PROTOCOL APPROVAL:

If a protocol is approved, the IRB approval letter will indicate the date approval was granted, the date approval will expire (which will not exceed one year from date of approval), and the required progress report submission date. Approval expires at 2359 hours (or 11:59 p.m.) on the date of expiration listed on the approval letter. The protocol may commence only upon written notice of approval from the IRB. This approval does not replace or serve in place of any departmental or other approvals which may be required (e.g., Research Administration).

IV. MODIFICATIONS REQUIRED:

A. Modifications Required status for new or amended protocols indicates a protocol requires minor revisions and/or clarifications which must be rectified prior to approval. The new or amended protocol may NOT commence until the final, written IRB approval has been granted.

B. This Modifications Required determination, and the specific revisions and clarifications required, will be communicated to the PI in writing. The PI must respond in writing to each of the IRB concerns, questions, and requested changes. The full committee, the IRB Chair or his/her designee (as determined at the time of initial review) will review the PI's response. Depending on the nature of the responses to the requested changes, the Chair or designee may grant approval or refer the protocol to the full committee.

C. If the IRB requires modifications, the date of approval is the date the conditions were determined to be met. The study expiration date will be no later than one year from the date the study was first reviewed (i.e., IRB meeting date). If the PI has not responded to the concerns of the IRB within a reasonable period of time (e.g., 90 days), the IRB reserves the right to terminate their review of the new or amended protocol.

V. DEFERRED – Substantive Revisions Required:

A. The IRB may defer a new or amended protocol any time the study fails to meet the regulatory criteria for approval or when there are a number of significant questions and concerns which could not be resolved at the IRB meeting. Reasons for deferral include, but are not limited to:
   - questions regarding the risk/benefit ratio,
   - inequitable recruitment,
   - inadequately described consent process and documentation,
   - insufficient safety monitoring,
   - questions concerning the protection of privacy or confidentiality,
   - the potential for coercion,
   - inadequate scientific justification or review,
   - insufficient credentialing and training for protocol required procedures,
   - failure by anyone listed as key personnel on the study to submit the required annual research conflict of interest disclosure.

B. When substantive revisions are required, the PI is notified of this determination and provided a list of the issues to be addressed before the IRB will further review the protocol submission.

C. The PI must respond in writing to each of the IRB concerns, comments, recommendations and/or questions. All forms originally submitted for the project (e.g., protocol application, informed consent and authorization form, assent form, information sheet, and/or advertisement, if applicable), must be revised, labeled with a new version date and re-submitted to the full IRB. The resubmission will preferably be submitted to the same IRB committee that originally reviewed the protocol, to review adequacy of the requested revisions.

D. The PI may not initiate the new or amended protocol until his/her response has been received in the IRB Office, the revisions have been reviewed and approved, and final IRB approval has been communicated to the PI in writing.

E. If the PI has not responded to the concerns of the IRB, in writing, within a **reasonable period of time (e.g., 90 days)**, the IRB reserves the right to terminate their review of the new or amended protocol.

VI. DISAPPROVED:

The IRB may disapprove a new or amended research protocol based on concern for a human participants safety, which the IRB determines cannot be remedied by the PI, such as:

a. a lack of key information by which to evaluate study objectives, or methods,
b. unidentified or unclear endpoints, benefits or risks,
c. failure to clearly address protection of the research participants,
d. risks to the research participants appearing to outweigh potential benefits of the research study,
e. the study lacks merit or is designed in a way that the methodology is unlikely to yield useful data toward meeting the stated objectives.

The IRB will notify the PI via letter through iMedRIS, outlining the reasons for IRB disapproval. If the investigator wishes to pursue the research, the protocol must be revised and submitted to the IRB as a new application and protocol. The new protocol must address the IRBs' original concerns, comments, recommendations, and/or questions.

VII. CONTINUING REVIEW:

The IRB will notify the PI in writing if continuing approval is being granted, or if additional information is necessary to grant continuing approval. Approval letters will include the approval period, which may not exceed one year, and the required date of the next progress report. IRB approval expires at 2359 hours (or 11:59 p.m.) on the date of expiration listed on the continuing approval letter.

VIII. AMENDMENTS:

All amendments will be approved or acknowledged by the IRB in writing. Amendments to the protocol include, but are not limited to: data safety monitoring board reports, unanticipated problems, key personnel changes, communication from the sponsor, changes to the protocol, closure of enrollment, and any other change or communication related to the trial to be reviewed by the IRB.

IX. ON-SITE UNANTICIPATED PROBLEMS:

The PI will receive a letter acknowledging IRB review of unanticipated problem reports. Any request for additional information or recommendations, such as modifying the informed consent and authorization process, will be noted in the letter.

X. PROTOCOL DEVIATIONS:

The PI will receive a letter acknowledging the IRB review of reported protocol deviations and will be notified if the reported protocol deviation requires further information regarding the health and safety of a research participant or of any action required by the PI.

XI. REGULATORY REFERENCES:

21 CFR 56.109(e) IRB Review of Research
45 CFR 46.109(d) IRB Review of Research and Investigator Notification of Decision

XII. ASSOCIATED POLICIES:

IRB Policy *IRB Initial Review of Research Protocols*
IRB Policy *Continuing Review and Renewal of a Protocol*
IRB Policy *Reporting an Unanticipated Problem Involving Risk to Participants or Others*
IRB Policy *Protocol Deviations*

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.