Title: **Protocol Review Committee Process**	*Applicable to: **Beaumont Health**	Effective Date: **01/12/2018** Last Periodic Review Date: **01/12/2018**
Policy Owner: **Administrative Director**	Document Type: **Policy**	Functional Area: **Research Administration, 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 standard operating procedure is to provide guidelines for use of a Protocol Review Committee to conduct a formal feasibility assessment of clinical trials and the ongoing review of open clinical trials. This process is required for all Beaumont Health clinical research.

II. POLICY:

All clinical research requiring Institutional Review Board (IRB) full board (or expedited review, which require resources in addition to the principal investigator, resident, fellow or student's time), will require review by a duly constituted Protocol Review Committee (PRC). Review will include scientific integrity (sponsored studies), operational feasibility and strategic/medical importance. Investigator-initiated studies with patient interaction will require full scientific review by a duly constituted Scientific Review Committee. Open clinical trials and their accrual will undergo review by a PRC six months following opening, and routinely thereafter. If no accrual, a study will be closed or a funding source from the department identified for the study to remain open. Certain exceptions may be made for studies targeting rare and life threatening illnesses e.g., rare cancers, humanitarian device exemptions, etc. The standardized *Protocol Review Checklist* will be used to document PRC review activities.

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III. PROCESS:

A. **Beaumont Health PRC -** The central **Beaumont Health Protocol Review Committee** will review protocols for departments without a PRC and grant authority to department-level PRCs for departments with the resources and research volume to manage their own PRC.

B. **Membership of the Beaumont Health PRC -** Members will include the following:
1. Chair of each department-level PRC
2. A standing member from each department with robust research volume who plan to use the central PRC in lieu of a department specific PRC
3. Other investigators
4. Research administrators
5. Clinical research managers
6. VP of Research (or designee) as PRC chair.

C. **Protocol Review Meetings** - Standing monthly meetings will be scheduled, and additional meetings held as needed. Meetings will be held on the Royal Oak campus. Research Institute support staff will coordinate the meeting scheduling, minutes, etcetera.

Following site selection by the sponsor, new protocols must be submitted one week prior to the scheduled meeting to assure adequate time for review. An agenda and meeting packet including all protocols to be reviewed will be sent to each PRC member. A primary reviewer may be used when there are several projects being reviewed per meeting. Otherwise all members are responsible for full review of protocols being assessed at the PRC meeting. At the meeting, the PI or co-PI will present the project to the PRC membership for review. A minimum of two representatives from each department requesting PRC review must participate in the PRC meeting. In addition to the PI or co-PI, it is recommended the clinical research manager participate to represent departmental resources available, competing trials, etc.

A quorum of PRC members is required for voting, and will be documented on the *Protocol Review Checklist*. Outcome of PRC review may be:
1. Approve – indicating the trial start up process may commence e.g., IRB submission, contract and budget negotiation, etcetera.
2. Request additional information from the prospective PI, with subsequent re-review by the PRC (full committee, chair or chair's designee).
3. Decline – indicating the department will not engage in the trial.

D. **Review Documentation -** The *Protocol Review Checklist* will be used by all PRCs to document review. The completed *Protocol Review Checklist* will be retained with the PRC minutes and a copy returned to the clinical research manager for uploading to SharePoint. These documents will be used for audits, metrics, etc.

Multi-center projects where a Beaumont PI is the Lead Researcher will be reviewed by the corporate Scientific Review Committee, and completion of the *Protocol Review Checklist* will occur in addition to the *Scientific Review Checklist*.

E. **Department-Level PRC Guidelines -** Authority to convene a **department-level PRC subcommittee** will be granted by the central Beaumont Health PRC. Membership will include a minimum of three voting members at each meeting. Required members:
1. Clinical research manager
2. Medical director of research (if applicable)
3. Department chair or designee
4. Other members may include researchers and research staff.

Any modifications to a subcommittee's membership, e.g., adding a department or a new chairperson, must be submitted to and approved by the central Beaumont Health PRC.

Departmental PRC's will function in a similar manner as the central Beaumont Health PRC. Protocols will be submitted by the PI or co-investigator, who will participate in the meeting to present the study and be available for questions from the committee. Meetings may take place in a face-to-face setting, videoconferencing, or via phone participation. Email round-robin is not a suitable format for PRC review. The project PI may not be included in the vote, but may be included in quorum. A co-investigator or a clinical research manager listed on a project may vote. Outcomes of the departmental PRC review are the same as those of the central Beaumont Health PRC: 1) approved, 2) additional information needed, or 3) declined. A department chair may veto a project approved by the PRC, but may not approve a project Declined by the PRC. The *Protocol Review Checklist* will be used by all PRCs to document review. The completed *Protocol Review Checklist* will be stored on SharePoint by the clinical research manager for each department, for use in audits, metrics, and etcetera.

Department-level PRCs will report periodically to the central Beaumont Health PRC and their privileges may be revoked if not adhering to general processes. Meeting minutes will be submitted to the central Beaumont Health PRC and include protocols reviewed, their disposition, and other business as appropriate. An annual review of department-level PRCs will be conducted by the central Beaumont Health PRC.

F. **Review of Enrollment Accrual -** Each PRC will be responsible for conducting ongoing review of enrollment accrual of open clinical trials. This assessment will be documented using the *Enrollment Review by PRC Checklist*. Guidelines and criteria developed by the Research Institute Executive Committee require quarterly detailed review of non-enrolling studies (no enrollment after 6 months) and low enrolling studies, (studies open > 1 year with < 50% of the targeted enrollment).

Research Administration will provide department chairs and the applicable PRCs with a quarterly list of non-enrolling and low enrolling studies. The list will be distributed during the first month of the quarter and all reviews must be completed by the end of the quarter. Each PRC may decide when during the quarter to complete their non-enrolling/low-enrolling review. The PRC Chair will distribute the list to each PI requesting completion of the "Study Information" section on the *Enrollment Review by PRC Checklist*. The PRC Chair will provide a deadline for return of the completed form in advance of the next PRC meeting. The completed checklist will include:

1. Medical director of research (if applicable)
2. Study demographic information (i.e., title, IRB #, PI name, location study is being conducted)
3. Reasons for no/low enrollment
4. Indication of whether they wish to close the study or keep it open
5. Plans to address lack of enrollment, including how ongoing study activities will be funded
6. Identify rare circumstances to make an exception to closing e.g., HUD/HDE, rare cancer population, sponsor hold, delayed opening to enrollment.

Each PRC will review completed *Enrollment Review Checklist* form(s) at the next meeting:

1. PRC will accept or decline the PI's response.
2. If PRC determines the study will be closed, Research Institute will review the clinical trial agreement for termination language and timing requirements.
3. For low enrolling studies with no active patients, the entire study will be closed. For studies with enrolled and active patients, the PRC will consider whether the study may be closed entirely or closed to new enrollments, allowing active patients to complete follow up.
4. If long term follow up is required, PRC may examine the feasibility of transferring patients(s) to other site(s) and closing the study at Beaumont (less desirable option).
5. PRC will notify the department Chair and PI of decision to close study, close the study to new enrollment, or require a re-negotiated budget with sponsor.
6. Research Institute will provide formal notification to sponsor of plan to close study or close study to new enrollment due to inability to enroll patients.

G. **Review Documentation -** The PRC will document the review of each study with no or low enrollment on the *Enrollment Review by the PRC Checklist* and in the meeting minutes. Copies of the minutes will be provided to Research Administration to facilitate review of termination language, budget re-negotiations and/or notices of enrollment closure or termination. The PRC will notify the PI, clinical research manager and department Chair, in writing, of committee determination. Copies of the non-enrolling/low enrolling list of studies, as well as a completed Enrollment Review by PRC form for each study, will be posted in SharePoint.

H. **Documentation of PRC Activities:**
All PRC activity documentation will be stored in the Protocol Review Committee SharePoint site. SharePoint sites should be organized as follows:

1. Each meeting should have a folder, labeled with the meeting date
2. Within each folder there should be:
   a. an agenda
   b. meeting minutes
   c. a folder for non-enrolling and low enrolling study review (if conducted during that meeting). The folder must include:
      a) the quarterly list of non-enrolling and low enrolling studies
      b) an *Enrollment Review by the PRC Checklist* for each study on the list
   d. a folder for each new study reviewed - each new study should have the following in the new study review folder:
      a) copy of the protocol
      b) the PRC Review Checklist
      c) a copy of the letter to the PI describing the outcome of the review any other items reviewed.

IV. ATTACHMENTS (See Attachment Tab Upper Right Corner)

Protocol Review Checklist
Enrollment Review by the PRC Checklist
Scientific Review Checklist
Flow Chart SRC & PRC

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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.