Title: **Scientific 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 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 Scientific Review Committee to conduct a formal assessment of investigator initiated, greater than minimal risk (i.e., full board IRB review) clinical trials, and Beaumont investigator-initiated, multi-center trials. This process will be required for all Beaumont Health clinical research.

II. POLICY:

All investigator-initiated (IIR) clinical research requiring IRB full board review will require Scientific Review Committee (SRC) assessment prior to protocol completion and submission to the Beaumont IRB. The PI or a co-investigator is required to participate in the IRB meeting introduction of the project and to answer committee questions, in order to facilitate IRB review. Multi-center trials with a Beaumont Principal Investigator (PI) as Lead Researcher, both minimal risk and greater than minimal risk will require SRC review prior to Beaumont IRB submission. SRC review will include significance, approach, study population, measurement, sample size and statistical analysis, safety monitoring, researcher qualification and experience, environment for conducting the research and operational feasibility. The standardized *Scientific Review and Protocol Feasibility Checklist* will be used to document SRC review activities.

III. PROCESS:

A. **Parent/Corporate SRC:**

A duly constituted parent or **corporate SRC** will evaluate the following types of Beaumont investigator-initiated studies:

1. All greater than minimal risk (qualify for full board IRB review)
2. Minimal risk, multi-center, with a Beaumont PI as Lead Researcher.

Extramurally funded, peer reviewed, competitively awarded studies are exempt from SRC review, as they have undergone rigorous scientific review prior to funding e.g., NIH, DOD.

B. **Membership of the corporate SRC** will include the following:

1. Vice president of research
2. IRB chairperson
3. Researchers experienced in sound scientific design
4. Senior biostatistician
5. Clinical research managers
6. Ad hoc members may be used as deemed necessary by the SRC chair e.g., research pharmacist, research accountant, research compliance or patient billing, clinical engineering or intellectual property, experts in the specific field being researched, etc.

C. **Corporate SRC Meetings:**

The corporate SRC will meet monthly or less frequently depending on the number of studies for review. Additional meetings may be held as needed. SRC meetings will be held on the Royal Oak campus. Meetings may take place in a face-to-face setting or via phone participation. Email round-robin is not a suitable format for SRC review. Research Institute support staff will coordinate the meeting scheduling, minutes, etc.

1. **Project review -** At the meeting, the PI or co-investigator will present the project to the SRC membership for review. A primary or primary and secondary reviewer system may be utilized at the discretion of the SRC chair.

   A quorum of SRC members will be required for voting, and will be documented on the *Scientific Review and Protocol Feasibility Checklist.* Outcome of SRC review may be:

   1. Scientific Approval
   2. Modifications Required (SRC chair review of response to Modifications)
   3. Deferred- Major Modifications (full SRC review of changes required)
   4. Denied - indicating significant re-work of the protocol is required.

D. **Review Process - Steps in the Scientific Review Process:**

1. Investigator submits protocol to the SRC chair, who then assesses the protocol and returns it to investigator if inadequate. Any modifications are returned to the SRC chair.

2. SRC chair forwards adequate protocol to full SRC for review.
3. SRC review will include completion of the *Scientific Review and Protocol Feasibility Checklist.*
4. Once vetted by the SRC, investigator submits protocol to the Beaumont IRB and includes SRC completed checklist.
5. If the IRB has concerns with SRC review, protocol is sent back to the SRC.
6. Substantive IRB revisions will require re-review by the SRC.

E. **Elements of SRC Review:**

1. **Significance**
   a. Does the research address a problem of scientific, medical public health and/or practical importance?
   b. If the aims of the research are achieved, how will scientific/medical knowledge be advanced, or is the study likely to make a significant contribution to the literature?
   c. Is the research question articulated with clarity and precision? Are the study objectives and hypotheses articulated with clarity and precision?
   d. Is the literature review of prior work relevant and adequate?
   e. Does the proposed study address questions not already addressed adequately by previous studies?

2. **Approach**
   a. Are the conceptual framework, design, methods and analyses adequately developed, feasible, well-integrated and appropriate to the aims of the study?
   b. Does the researcher acknowledge potential problem areas and consider alternative tactics?

3. **Study Participants/Population**
   a. Are the controls appropriate? Is the definition of the study groups (controls and/or intervention) clear?
   b. Are the inclusion/exclusion criteria appropriate? Is the method of selecting study subjects appropriate?

4. **Measurement**
   a. Does each aim/hypothesis have a clear measurable outcome variable (operational guidelines on measurement/quantification, measurement scale)? Are the measurement times for primary outcomes specified?
   b. Is specification of baseline and demographic information being collected, adequate?
   c. Is the description of study instruments (questionnaires, laboratory tests) adequately addressed?

d. Is the participant timeline clear and consistent throughout the protocol (schedule of enrollment, intervention, assessment, visits)?

5. **Sample Size and Statistical Analysis**
   a. Is the proposed sample size adequate for the study goals?
   b. Was the sample size calculated based on power calculations or confidence interval width?
   c. Were references given for the choice of parameters used in the sample size calculation?
   d. Were any clinical and statistical assumptions behind the calculations stated?
   e. Are the proposed statistical analyses appropriate and able to address the research question(s) i.e., is it compatible with the outcome variables? Is it compatible with the study design and data collection method? Does it address the analysis of both primary and secondary outcomes?
   f. Is potential dropout a concern in this study? If so, is the treatment of dropouts clear and appropriate?

6. **Safety and Monitoring**
   a. Adverse events: Is there a clear definition of all adverse events? Is the quantification of such events described?
   b. Safety reporting/monitoring: Is the plan for reporting Unanticipated Problems (Ups), Adverse Events (AEs), and Serious Adverse Events (SAEs) clear and appropriate? Based on the study risks, is the type of monitoring appropriate (i.e., medical monitor, internal safety monitoring committee, data safety monitoring board)?
   c. Data Safety Monitoring Board (DSMB) if needed: Are the review plan and triggers requiring the DSMB to take action made clear? Is the composition/expertise of the DSMB appropriate?
   d. Is the protocol's assessment of risks, benefits and measures used to minimize risk scientifically accurate?
   e. Are there any other issues that might affect the scientific validity of the study?
   f. Does the proposal clearly /accurately identify and describe *risks* to participants or others? Does the study use appropriate methods or procedures to minimize risks?
   g. Does the protocol clearly/accurately identify and describe potential *benefits* to the subjects or others.
   h. Is review of concomitant medications addressed (e.g., how to collect and are there any which do not need to be captured)?
   i. Does the protocol schedule/table of events include all protocol required activities?

7. **Researcher Qualifications and Experience**
   a. Are study personnel qualified to perform the research (i.e., PI, co-investigators, clinical research staff)?

8. **Environment**
   a. Does the scientific environment in which the study will be done contribute to the probability of success?
   b. Will any collaborating investigators/institutions provide scientific expertise, data, samples or other help in conducting the research?
   c. Are the personnel, facilities, funding and other resources adequate /appropriate to perform the research?

9. **Operational Feasibility**
   a. Complexity of study activities
   b. Degree of external department collaboration/support
   c. Ability to meet enrollment goals, likelihood of physician referrals
   d. PI has sufficient time and resources to main proper study oversight
   e. Presence of competing studies
   f. Clinical Trials Office resource availability

F. **Documentation of SRC Review:**
Completion of the *Scientific Review and Protocol Feasibility Checklist* by the SRC to reflect robust review is required as part of the protocol development process. The IRB must be provided with written documentation of the scientific review which summarizes scientific issues raised and addressed during the review, together with a statement which names and describes the reviewers. Examples of appropriate documentation include the *Scientific Review and Protocol Feasibility Checklist*, or a copy of a review summary from a federal agency for projects being exempted from in-house Scientific Review.

G. **Departmental Level SRC:**
1. The corporate SRC may grant authority to department level SRCs with appropriate membership composition. The same process and *Scientific Review and Protocol Feasibility Checklist* form will be used by all SRCs to document review. Department level committees will report to the corporate SRC periodically and their privileges may be revoked if not adhering to general process. The corporate SRC chair may determine departmental SRC review of a given project is not adequate, and require review by the full corporate SRC.

2. All multi-center studies in which a Beaumont PI is the Lead Researcher, require corporate SRC review and <u>not</u> department level review.

4. Studies which require Radioactive Drug Research Committee (RDRC) review will undergo scientific review, inclusive of the *Scientific Review and Protocol Feasibility Checklist* items, by the RDRC and documentation of the review on the *RDRC Protocol Review Checklist*.

IV. ATTACHMENTS: (See Attachment Tab Upper Right Corner)
Scientific Review and Protocol Feasibility Checklist
Scientific Review Process Flow Chart

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.