Title: **Biosafety Committee Operations**	*Applicable to: **Beaumont Health**	Effective Date: **01/11/2018**
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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:

A. The purpose of this policy is to establish guidelines under which the Beaumont Institutional Biosafety Committee (IBC) operates. The Committee is responsible for overseeing the use of recombinant or synthetic nucleic acid molecules and pathogenic infectious agents in research and education at Beaumont Health (BH). The Committee may evaluate other protocols involving the use of any biologic agent(s) when the Committee, other committees (including the Institutional Review Board [IRB] and the Institutional Animal Care and Use Committee [IACUC]) or the Principal Investigator (PI) believes the protocol might be associated with biosafety-related risks.

B. When a BH-approved external IRB associated with a duly constituted and registered external IBC is the IRB of record for a study requiring biosafety committee review, the external IBC will serve as the IBC of record for the study. The only external IBC option is the combined Beaumont – Western Institutional Review Board (WIRB) IBC. All other IBC oversight will be provided by the Beaumont IBC as described in this policy.

II. DEFINITIONS:

A. **Recombinant or Synthetic Nucleic Acid Molecules**
   1. Molecules that are a) constructed by joining nucleic acid molecules and b) can replicate in a living cell (i.e. recombinant nucleic acids);

2. Nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (i.e., synthetic nucleic acids); or
3. Molecules that result from the replication of those described in I or II.

B. **Pathogenic Infectious Agents**
Agents used for clinical, diagnostic, teaching, research or production purposes which may pose a degree of hazard to the exposed personnel or to the environment.

III. RESPONSIBILITIES:

A. The responsibilities of the Biosafety Committee include the following:
1. To review and act in a timely manner on proposals using recombinant or synthetic nucleic acid molecules or pathogenic infectious agents in research or education at Beaumont.
2. To insure all activities associated with the use of recombinant or synthetic nucleic acid molecules or pathogenic infectious agents are carried out in compliance with policies of appropriate federal and state regulatory agencies.
3. To assure the welfare of Beaumont and the health and welfare of its personnel, as well as the general public, are not jeopardized by the use of recombinant or synthetic nucleic acid molecules or pathogenic infectious agents in research and education projects in the hospital.

B. The Biosafety Committee will provide guidelines to all investigators describing the standard operating procedures and facilities to be used when working with recombinant or synthetic nucleic acid molecules or pathogenic infectious agents. The Committee must review all proposed use of recombinant or synthetic nucleic acid molecules or pathogenic infectious agents for research or education. If approval is required from both the Committee and from federal or state regulatory agencies, then approval from the corresponding federal or state agency must be obtained prior to project initiation. The Committee will determine the category of approval required by a proposed use of recombinant or synthetic nucleic acid molecules or pathogenic infectious agents (see below).

IV. MEMBERSHIP:

A. The Beaumont IBC will be comprised of no fewer than five (5) members, selected so the Committee has sufficient experience and expertise in recombinant or synthetic nucleic acid technology and pathogenic infectious agents to assess the safety of proposed activities in

these areas, and to identify any potential risks to public health or to the environment that may result from these activities. At least two (2) members of the Committee will not be affiliated with Beaumont ("external members"); these individuals will represent the interests of the surrounding community with respect to the health and protection of the environment.

B. Prospective Committee members will be recommended by the Chair of the Committee to the Administrative Director of the Research Institute (RI), who may then nominate these individuals for approval by Vice President of Research. The Biosafety Committee Chair will be nominated by the Administrative Director of the RI and approved by the Vice President of Research. Replacement members may be added to the Committee at the request of the Committee Chair and the approval of the Administrative Director of the RI, pending Vice President of Research approval.

C. The Committee will require a quorum to participate in its meetings, in order to be able to vote. A quorum shall consist of a majority of the Committee members, and must include at least two (2) internal members and one (1) external member. If a member participates in the meeting via teleconference, the member can be counted toward a quorum, and will be allowed to vote at the meeting.

D. Any external IBC administered by the biosafety services of an external IRB (e.g., WIRB) must be duly constituted according to current NIH guidelines, and include on the roster at least one Beaumont institutional representative and at least two local external (non-affiliated, community) members. The Beaumont plus WIRB IBC must be registered with the NIH as an IBC for Beaumont studies.

V. FREQUENCY OF MEETINGS:

The Committee will meet at least once per year. Additional meetings will be held based on need, as determined by the Committee Chair.

VI. REVIEW OF PROPOSALS:

A. All new applications or amendments to previously-approved protocols involving human subjects also require IRB approval for the use of recombinant or synthetic nucleic acid molecules or pathogenic infectious agents will be submitted by the PI to the IRB via iMedRIS, using the IRB application or amendment form. The IRB will then notify the Chair of the Biosafety Committee, via e-mail, a new application or amendment has been submitted via iMedRIS and requires Biosafety Committee review.

New applications which require both IACUC and Biosafety Committee review will be sent by the PI concurrently to both committees; the Biosafety Committee-specific application will be used for the submission to the Biosafety Committee.

A new application or amendment to a previously approved application which requires Biosafety Committee approval only will use the Biosafety Committee-specific form and be submitted directly from the PI to the Biosafety Committee Chair.

The Chair will then send the new applications to each member of the Committee for review. The primary reviewer assigned to each application will prepare a written review of the application, which will be submitted to the Chair prior to the meeting in which the application will be reviewed. The PI or his/her representative submitting the proposal will be invited to attend the meeting at which his/her application will be discussed.

Committee members will be subject to RI policy *Institutional Conflict of Interest*. No member of the Committee may participate in the initial or continuing review of any project in which the member has a potential or perceived conflict of interest, except to provide information requested by the Committee. Committee members with a potential or perceived conflict of interest relating to a protocol or amendment under discussion by the committee must recuse themselves from voting and leave the room prior to the vote on the issue.

B. **Recombinant or Synthetic Nucleic Acid Molecules**

Each application involving recombinant or synthetic nucleic acid molecules will be assigned by the Committee Chair to one of the categories described in the "Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules" from the Department of Health and Human Services, National Institutes of Health (NIH) Biosafety NIH Guidelines. These categories are as follows:

1. Those requiring Institutional Biosafety Committee approval, NIH Recombinant DNA Advisory Committee (RAC) review and NIH Director approval before initiation.
2. Those requiring NIH/Office of Recombinant DNA Activities (ORDA) and Institutional Biosafety Committee approval before initiation.
3. Those requiring Institutional Biosafety Committee approval before initiation.
4. Those requiring Institutional Biosafety Committee notification simultaneous with initiation.
5. Those exempt from the NIH Guidelines (no research involving gene transfer is involved).

The description of experiments and procedures involving recombinant or synthetic nucleic acid molecules for each of the above categories will be taken from the "Guidelines for Research Involving Recombinant or synthetic nucleic acid molecules."

If an investigator indicates in his/her application the research falls under **category v** ("Exempt from NIH guidelines") above, and the application clearly does not involve recombinant or synthetic nucleic acid molecules or infectious agents, the Chair may classify the project as Exempt from NIH Guidelines without consulting the Committee. If the possible Exempt from NIH Guidelines status of the application is open to question, the Chair will poll Committee members via e-mail to determine concurrence with this classification. If all Committee members concur, the application may be classified Exempt from NIH Guidelines by the Committee without a convened meeting. A letter stating the Committee's determination of the application as "Exempt from NIH Guidelines" will be sent to the PI by the Committee Chair.

New applications indicating **category 1, 2, 3 or 4** classification, and applications assigned to these categories by the Committee Chair, will require review at a meeting of the Committee. If the Committee determines external approval from the Recombinant DNA Advisory Committee (RAC), the Office of Recombinant DNA Activities (ORDA), or the NIH Director is required, the PI will be informed in a timely manner so he/she may proceed with obtaining these approvals.

For applications in **categories 1** or **2**, approval from the required external agencies must be obtained, in addition to Biosafety Committee approval, before research may proceed.

C. **Pathogenic Infectious Agents**

Research and/or education related applications involving pathogenic infectious agents will be classified by the Committee Chair, after consulting with Committee members if necessary, following the Center for Disease Control/National Institutes of Health Guidelines "Biosafety in Microbiological and Biomedical Laboratories" 4th Edition, Section III.

1. **Biosafety Level 1 (BSL 1):** Well-characterized agents not consistently known to cause disease in healthy adult humans; these agents are considered to be of minimal potential hazard to laboratory personnel and the environment.
2. **Biosafety Level 2 (BSL 2):** Agents of moderate potential hazard to personnel and the environment.
3. **Biosafety Level 3 (BSL 3):** Indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route (applicable to clinical, diagnostic, teaching, research or production facilities).
4. **Biosafety Level 4 (BSL 4):** Dangerous and exotic agents which pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease.

   The proposal will subsequently be reviewed by the Committee. Research involving pathogenic infectious agents may also be subject to review by the Beaumont Infection Control Committee.

D. **Committee Actions New Project Submissions**

The Committee may take one of the following actions on new applications submitted for review:

1. **Approval:** PI may proceed, approval is effective immediately. No time limit is set for approved protocols, but annual progress reports are required (see below).
2. **Modification Required:** Minor modifications are required to secure approval. The PI must respond satisfactorily, in writing, to requests for minor changes and/or clarifications. Responses are sent to the Chair, or, in the event of the absence of the Chair, to another member of the Committee designated by the Chair or by the Administrative Director of the RI to serve in that capacity. The Chair may grant full approval to the protocol, or defer the application to the next Committee meeting if concerns still exist.
3. **Deferred:** Major revisions are required; the revised protocol application will be discussed at a subsequent Committee meeting.
4. **Denied Approval:** Major deficiencies exist, and a new application is requested from the PI.
5. **Exempt:** Committee grants the project an exemption from review.
   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. A Committee quorum will be required for voting purposes and a majority vote rules. Members voting not to approve an application that subsequently receives Committee approval will submit a written description of their reasons for dissent to the Committee Chair. These comments will be included in the approval letter sent to the PI and included in the Committee's Minutes. They will be part of the Committee's permanent records.
6. **Administrative Review of submissions for External IBC review and administration**: For human-subject protocols requiring review by both an External IRB and associated External IBC, the Study PI and/or study sponsor will be responsible for the completion of the External IBC forms transferring the study information to the External IBC. The Beaumont IBC Chair or designee will sign off on the initial submission in iMedRIS through the Internal Routing of the IBC application, acknowledging the study will be sent for external review and communicating such to the External IBC Biosafety Administrator. Once the Beaumont IBC Chair or designee administratively reviews the submission, the External IBC is responsible for the Biosafety review for any amendments, study continuation and any other study related activity going forward.

E. **Continuing Review:**

Research projects are approved by the Committee without regard to the expected length of the project; however, annual progress reports must be received for the Committee's approval to remain in effect. The due dates for these reports are the same as required by the IRB or the IACUC for projects which are also IRB or IACUC-approved; otherwise, reports are due annually on the anniversary of the date the project received initial full Committee approval. For projects which also require IRB approval, the Progress Report form or Final Report/Closure form will be submitted by the PI to the IRB via iMedRIS. The IRB will notify the Chair of the Biosafety Committee the appropriate document is in iMedRIS for the Biosafety Committee to review. For projects which also require IACUC approval, a copy of the IACUC Progress Report Form or Final Report/ Closure Form must be submitted to the Biosafety Committee by the PI at the time it is submitted to the IACUC. For studies which do not require IRB or IACUC approval, the Committee Chair will provide a Biosafety Committee annual report form to the PI for completion when the annual report is due and a Final Report form for projects being closed. A subcommittee consisting of the Chair and two additional members will review the annual progress reports and may, by unanimous vote, approve the reports, indicating that the project may continue. If a unanimous vote is not obtained, a meeting of the full Committee will be called to review the progress report in question. Progress reports approved by the subcommittee will be presented to the Committee for information only at the next Committee meeting.

For studies approved and administered by an External IRB and External IBC, the External IBC is responsible for Biosafety continuing review and renewal.

F. **Protocol Amendments**

1. Any amendment to protocols involving the use of recombinant or synthetic nucleic acid molecules or pathogenic infectious agents in a project previously approved by the Committee will require prior notification of the Committee Chair and submission of a revised application to the Committee. Submission of an IRB or IACUC Amendment Request Form will be required if the protocol is also IRB or IACUC approved; otherwise, the Biosafety Committee Amendment Request Form will be used. If the Chair determines the changes are of an essential nature, i.e., have the potential to negatively impact participant health or to increase risk to participants, researchers, or other hospital personnel, the Amendment Request Form will be reviewed by the full Committee at a convened meeting. If the Chair determines the changes requested are of a non-essential nature, the Amendment Request Form will be evaluated by a subcommittee of the Committee consisting of the Chair and at least two additional Committee members. An example of "non-essential" changes would be a change in the number of patients to be recruited and enrolled in a treatment protocol at Beaumont. If the subcommittee

unanimously approves the amendment, the Chair approves the amendment. If unanimous approval is not obtained from the subcommittee, the amendment will be discussed at a meeting of the full Committee.

2. An amendment denied approval may be resubmitted along with a statement from the PI describing the changes to the application and responses to the Committee's concerns. The amendment may be re-reviewed by the subcommittee that initially reviewed it, or, at the discretion of the Chair, it may be reviewed at a meeting of the full Committee.
3. The Committee's action on all applications and amendments it reviews will be communicated via e-mail from the Committee Chair to the PI. The e-mail will be copied to other relevant committees, i.e., the IRB or IACUC, for protocols which require IRB or IACUC approval. For protocols which require IRB as well as Biosafety Committee approval, the Committee's actions will also be communicated to the PI via iMedRIS.
4. New applications, Amendment Requests, and Progress Reports must be reviewed and approved by the Biosafety Committee prior to approval being granted by other oversight committees (e.g., the IRB or IACUC) with the exception that amendments requesting addition or removal of Key Personnel (other than the PI) do not require Biosafety Committee review.
5. For studies approved and administered by the external IRB and External IBC, these committees are responsible for Biosafety review and approval of all study amendments. The content of amendments and External IBC decisions will be communicated to the Beaumont Institutional Official, study sponsor, PI and Beaumont Institutional Representative, who will distribute the communication as necessary to other Beaumont stakeholders.

VII. CONSISTENCY OF SUBMITTED DOCUMENTS BETWEEN BIOSAFETY AND OTHER COMMITTEES:

The text of any document reviewed by the Biosafety Committee must be essentially the same, with regard to biosafety-related issues, as the document reviewed by other committees; and the PI must be the same. If the biosafety-related text of a document which has been submitted to the Biosafety Committee is subsequently changed when the document is submitted to another committee the PI is responsible for informing the Biosafety Committee of the changes at the time of document submission to the other committees. The Chair of the Biosafety Committee will review the changes to the document and may, at his/her discretion, submit the changes to a subcommittee for approval (if chair deems the changes not to be of a significant nature) or convene a meeting of the full committee to discuss the changes if he/she deems them to be of a significant nature.

VIII. FACILITIES AND EQUIPMENT:

The Committee will be responsible for insuring the facilities and equipment used for activities involving recombinant or synthetic nucleic acid molecules or pathogenic infectious agents are in compliance with institutional, state, and NIH regulations. The PI may be requested to provide certification of such facilities.
For studies submitted to and reviewed by the external IBC, facilities and equipment used for activities involving recombinant or synthetic nucleic acid molecules or pathogenic infectious agents will be inspected according to the policies of the External IBC to ensure compliance with institutional, state and NIH regulations. The Beaumont institutional representative or qualified external member(s) will take part in these in these inspections and communicate the results thereof to the External IBC.

IX. CONCERNS, ALLEGATIONS OF MISCONDUCT OR INAPPROPRIATE PROCEDURES:

All biosafety-related complaints or allegations of misconduct or inappropriate procedures will be promptly reported to the VP of Research and the Administrative Director of the RI by the Committee Chair. In case of concerns, allegations of misconduct or inappropriate procedures on studies reviewed and administered by an External IBC, the External IBC is responsible for notifying the VP of Research.

X. REVOCATION OF APPROVAL:

The Committee has the authority to revoke permission to perform recombinant or synthetic nucleic acid molecule or pathogenic infectious agent research or educational activities at Beaumont. Permanent revocation of a project requires a majority vote of a quorum of the Committee members. If any member of the Committee believes a project presents an imminent health hazard, he/she may immediately revoke the PI's permission to continue the project. The Committee member taking this action must inform the Committee Chair of his/her action within forty-eight (48) hours, and must communicate his/her concerns in writing to the Committee Chair within five (5) days. The Committee will then take action as soon as possible to confirm the revocation, reinstate the project, or take other action deemed necessary. The VP of Research and the Administrative Director of the RI must be informed of these actions. The PI for the project should be present, if possible, at the meeting in which the revocation of permission to

conduct the project is discussed. If the project involves human research subjects, the Chair of the IRB must be notified immediately of the revocation, and the project may not re-commence until approval has been granted by both the Biosafety Committee and the IRB.

Any revocation of the approval of a project reviewed and administered by the External IBC must be promptly communicated to the VP of Research by the Beaumont Institutional Official and/or the External IBC Chair.

XI. RECORDS AND REPORTS:

Records of submitted applications, reviews, Minutes of Committee meetings, correspondence, and other Committee-related activities will be maintained by the Committee Chair. The Chair will provide the VP of Research and the Administrative Director of the RI with a quarterly executive summary of Committee activities. This report will include a list of applications reviewed, the Committee action taken on each item reviewed, and other biosafety-related activities in which the Committee or the Committee Chair was involved.

The Chair will, on an annual basis, update the NIH Institutional Biosafety Committee Registration Management System with regard to members of the committee.

The External IBC is responsible for the minutes and records of that committee's activities. Updating the External IBC membership in the NIH Registration Management System and any other required communication with the NIH will be the responsibility of the External IBC.

XII. ABSENCE OF CHAIR:

In the event Committee-related activities must be transacted in the absence of the Chair, a Committee member previously designated by the Chair, or designated by the Administrative Director of the RI, may temporarily serve as Chair.

XIII. ASSOCIATED POLICIES AND GUIDELINES:

RI Policy *Institutional Conflict of Interest*
RI Policy *Contacts, Complaints, Allegations of Non-Compliance and Confirmed Non-Compliance in Clinical Research*
CDC/NIH Guidelines on "Biosafety in Microbiological and Biomedical Laboratories" 4th edition, 1999.
Review by an External Institutional Review Board

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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.