

Operating Procedures of the Marquette University  
Institutional Biosafety Committee (IBC)

I. Functions

The IBC is responsible for the following functions on behalf of Marquette University (M.U.).

- A. Review all recombinant DNA (rDNA) research conducted at or sponsored by M.U. for compliance with NIH Guidelines (Guide) published April 2002 (<http://www4.od.nih.gov/oba>). Review shall include the following:
  - 1. An independent assessment of risk and the proposed containment levels.
  - 2. An assessment of the procedures, facilities, training and expertise of personnel involved in rDNA research.
- B. Approve those research projects that are found to conform to NIH Guidelines (Guide).
- C. Inform the Principal Investigator (P.I.) of the results of the IBC review.
- D. Periodically review rDNA research conducted at or sponsored by M.U. to ensure compliance with the Guide.

II. Composition of the IBC

The IBC shall have a minimum of five members. The Compliance Officer recommends members to the Vice Provost for Research and Graduate Studies. The Vice Provost makes the official appointment. Members collectively shall have experience and expertise in rDNA technology and the ability to assess the safety of proposed rDNA research. Two members of the committee shall not be affiliated with M.U. other than through membership on the IBC. At least one member shall have expertise in plants, plant pathogens or plant pest containment and one member shall have expertise with rDNA work in animals. The committee members elect the chair.

III. Operating Procedures

A. Exempt Research

All research utilizing rDNA must be registered with the Office of Research Compliance (ORC). Exempt status, as defined in the Guide, shall be determined by the Chair or a designated member of the IBC. When a principal investigator (PI) requests exempt status on the registration form, he/she must list the appropriate section of the Guide on which the exempt status is based. The chair or the designated member may request a review by all members of the IBC. In such case, the ORC will transmit by e-mail a copy of the registration form to all members. If the chair, the designated member or a majority of the members (when requested) disagree with the PI's claim that the research is exempt, the proposed research will be approved only at a convened meeting of the IBC. Under no circumstance may the PI make the final exempt designation. Exempt protocols will not be subject to further IBC review.

B. Non-exempt Research

All registered protocols that do not qualify for exempt status must be reviewed by the IBC and acted on at a convened meeting of the committee. A quorum of the committee must be present to vote on a submitted protocol. A quorum shall consist of a majority of the members. Such a convened meeting may take place with the personal presence of the members or by conference call. In either case, minutes shall be recorded and shall include all minority opinions. A protocol must be approved by a majority of the members present at the meeting. The IBC shall also determine the appropriate biosafety level (e.g. BL1, BL2, BL1-P or BL2-P) per the NIH Guidelines (Guide). The PI is invited to the meeting when his/her protocol is discussed in order to answer questions that may arise regarding the proposed research. However, the PI cannot be present when a vote is taken by the IBC. The P.I. will be informed in writing of the IBC decision. If the protocol is not approved, the P.I. will be informed of the reasons. If the P.I. decides to resubmit the protocol, he/she will be expected to make appropriate changes and/or address the items on which the denial was based. When a protocol is submitted by a member of the IBC, he/she may be present during the meeting to answer questions, but must leave the room when a vote is taken on the protocol. Non-exempt protocols will receive periodic re-review.

C. Amended protocols

If the P.I. finds it necessary to change experimental procedures involving rDNA, he/she must file an amended protocol with the IBC. The amended protocol and a copy of the original protocol will be sent to all members of the IBC. If any member considers the changes to be significant and raise the risk level, the amended protocol will be reviewed and voted on at the next convened meeting of the IBC.

D. Records

All records are maintained in the Office of Research Compliance. Minutes of the IBC meetings are available to the public upon written request and the payment of a \$5.00 handling fee.