Policies and Procedures for the Marquette University Institutional Biosafety Committee (IBC):

Purpose of the IBC
The purpose of the Institutional Biosafety Committee at Marquette University is to review research with recombinant DNA (rDNA) being conducted at Marquette. Institutions that receive support from the National Institutes of Health (NIH) for rDNA research are required to establish and register an Institutional Biosafety Committee (IBC) with the NIH Office of Biotechnology Activities (OBA) in compliance with the *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines).*

Function of the IBC
The Marquette University IBC committee is responsible for the oversight, administration, and review of all MU projects involving research with rDNA that may pose safety, health, or environmental risks. The IBC will assist and advise Principal Investigators, and other researchers in meeting their responsibilities to ensure that the biological aspects of the research are conducted in a safe manner using Marquette University established biosafety standards and principles. The Office of Environmental Health and Safety and Office of Research Compliance also are included to make sure that safe research includes worker safety, public health, environmental protection, ethics, and compliance with applicable biosafety and university standards.

Committee Membership
The IBC shall have a minimum of five members. The Research Compliance Officer will recommend members to the Vice Provost for Research and Dean of 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 Marquette University 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. The Director of Environmental Health and Safety and the Research Compliance Officer are non-voting members.

Meetings
A. Frequency: year or more when deemed necessary.
B. Quorum: more than 50% of voting members.
C. Minutes will be taken, subject to approval at the next meeting, and kept on file for three years.

Duties of IBC
The IBC is responsible for the following functions on behalf of Marquette University
A. Review all recombinant DNA (rDNA) research conducted at or sponsored by Marquette University for compliance with NIH Guidelines published April 2002 (http://www4.od.nih.gov/oba). Review shall include the following

1. An independent assessment of 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.
C. Inform the Principal Investigator (PI) of the results of the IBC review.
D. Periodically review (re-review) rDNA research conducted at or sponsored by Marquette University to ensure compliance with NIH Guidelines.

Operating Procedures Protocol Review

A. Exempt Research

1. All research utilizing rDNA must be registered with the Office of Research Compliance (ORC). When a principal investigator (PI) requests exempt status on the registration form, the PI must list the appropriate section of the NIH Guidelines on which the exempt status is based. Exempt status, as defined in the NIH Guidelines, shall be determined by the IBC Chair or a designated member of the IBC. The IBC Chair or the designated member may request a review by all members of the IBC. In such a case, the ORC will transmit by e-mail a copy of the registration form to all members. If the IBC Chair or 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 be subject to further IBC committee review by the use of the IBC 3 year renewal letter sent by the Office of Research Compliance.

B. Non-Exempt Research

1. 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 member present at the meeting.
2. The IBC shall also determine the appropriate biosafety level (e.g. BL1, BL2, BL3, BL4) per the NIH Guidelines. For research that may be conducted under more stringet conditions that minimum required by the NIH Guidelines the IBC has created a BL1+ and a BL2+ containment level section that can be selected on the IBC protocol form. **NOTE: Marquette University will only approve BL1 or BL2 protocol requests. Marquette University is not equipped for the facilities for work with BL3 or BL4 projects.**
    a. 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.
2. Protocols are approved for a period of three years or until the termination of the project if earlier that the three year period. The PI will be informed of in writing of the IBC decision. Non-Exempt protocols will be subject to further IBC committee review by the use of the IBC 3 year renewal letter sent by the Office of Research Compliance.

3. If the protocol does not receive initial approval, the PI will be informed of the reasons. If the PI decided 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.
4. **Amended protocols**
    - **a.** If during the three-year approval period, the PI 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 member 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.
5. **Protocol Renewal/Continuation**
    - a. The Marquette University IBC committee agreed that a 3 year review cycle was an appropriate time frame for all research involving recombinant DNA (rDNA). Any PI that will continue research with rDNA whether exempt or non-exempt will need to complete the IBC 3-year renewal form. Please note that if your research remains non-exempt by NIH definitions and there is a significant change in operating protocol and/or organisms as originally filed with the IBC you must complete a new IBC Protocol Review Form for submission to the IBC.
6. **Miscellaneous information**
    - **a.** It is the PI's responsibility to notify the IBC committee in writing when rDNA organisms are no longer used, even if it is before the expiration or approved protocol period.
    - **b.** It is the primary responsibility of the PI to ensure the safety of lab workers and of others in the university environment and to be sufficiently proactive in notifying or requesting the Biosafety Committee for a decision regarding research operations.
    - **c.** All protocols will require review and/or renewal before expiration. For simplicity, renewal of a given protocol does not change the originally assigned protocol number. Conversely, a significant change in a protocol may be filed at any time and if approved will supplant and replace and reset the approved time period for the rDNA research.
    - **d.** The IBC recognizes that in many instances there may be a variety of different experiments that are done with different vectors and/or different organisms, all of which fall into the same BL category of experimental containment as defined by the latest NIH guidelines. The protocol that the PI's submit should be sufficiently broadly worded as to include all the experiments, vectors, and organisms that will be utilized. Good reporting practice would include addition – as appendix material – to an original approved protocol. Notification or updating does not change the end of the approved period for conducting the research.

e. Unauthorized and/or unapproved rDNA research, even when classified as exempt, is not allowed and the University Biosafety Committee can notify the Dean of the Graduate School in instances requiring corrective action.

f. The IBC will investigate and report any significant problems with or violations of the NIH guidelines and any significant research-related accidents or illnesses involving rDNA to the Principal Investigator, the Office of Research Compliance, the Vice Provost of Research/Dean of Graduate School, the Department of Environmental Health and Safety, and the NIH Office of Biotechnology Activities (OBA) as appropriate.