UNIVERSITY OF MIAMI
INSTITUTIONAL BIOSAFETY COMMITTEE GUIDELINES

An Institutional Biosafety Committee (IBC) is a committee created under the National Institutes of Health (NIH) that is responsible for providing institutional oversight of recombinant DNA research**.** The mission of the University of Miami Institutional Biosafety Committee is to ensure that all recombinant DNA research activities comply with the National Institute of Health Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines).

It is the Principal Investigator's responsibility to be familiar with and adhere to the NIH Guidelines . Investigators should also familiarize themselves with the Office of Biotechnology Activities Recombinant DNA and Gene Transfer and the University of Miami IBC websites.

OVERSIGHT SUMMARY

Approval/Registration body	**Oversight level 1**	**Oversight level 2**	**Oversight level 3**	**Oversight level 4**	**Oversight level 5**	**Oversight level 6**
IBC	Exemption granted by IBC chair	Approval (study can be initiated after PI received notice from IBC Chair. Full IBC reviewer takes place afterwards).	Approval before initiation	Approval before initiation	Approval before initiation	Approval before initiation
IRB				Approval		
NIH OBA			May need to Register*	Register	Register	Review
RAC				Review	Review	Review
NIH Director's office						Approval
Exempt	From NIH oversight					
Section in Guidelines	III-F	III-E	III-D	III-C	III-B	III-A
Description of Section	No Hazard, natural exchanges	Non-Pathogenic lower eukaryotes or prokaryotes	Use of various risk group agents as vectors, donors, or recipients	Human Gene Transfer	Experiments involving the cloning of Toxin Molecules with LD50 of less than 100 nanograms per kilogram body	Experiments that Require Institutional Biosafety Committee Approval, RAC Review, and NIH Director Approval Before Initiation

* NIH registration is only required for certain categories of Section III-D protocols.

Comparison of Local Oversight Roles

Committee	Isolation of Gene	In Vivo Studies	In Vivo Testing (animal)	Development of Animal Model	Preclinical Studies (marine, primate)	HGT & Xeno Clinical Trial
IBC (NIH)	+	+	+	+	+	+
IACUC (OLAW)	-	-	+	+	+	-
IRB (OHRP)	-	-	-	-	-	+

UM IBC Standard Operating Procedures

Membership Requirements
An IBC must consist of at least five members. There is no limit on the maximum number of members. Collectively, the membership of the IBC should include experience and expertise in recombinant DNA technology and biosafety and physical containment, knowledge of, institutional commitments and policies, applicable laws, standards of professional conduct and practice, community attitudes, and the environment, and the capability to assess the safety of recombinant DNA research, and identify potential risks to public health and safety. The IBC is required to have two members not affiliated with the institution who represent the interest of the surrounding community with respect to health and protection of the environment. These may be officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns in the community. Click here for more information on IBC membership requirements.

Meetings
An IBC meeting schedule is posted on the IBC website. Meetings typically take place on the third Monday of the month from 1:00-2:30 pm. If there is an insufficient quorum to call a meeting, the meeting will be cancelled. If a meeting is cancelled, the Director of Compliance will contact the investigator to inform him or her when the protocol will be reviewed. The IBC will meet at least once quarterly to review new Section III-D protocols.

Submission Deadlines
Materials must be received by the submission deadline in order to be considered for the next scheduled meeting.

IBC Review
In accordance with Section IV-B-2-b-(1) of the NIH Guidelines, IBC review shall include:

(i) Independent assessment of the containment levels required by the NIH Guidelines for the proposed research;
(ii) Assessment of the facilities, procedures, practices, and training and expertise of personnel involved in recombinant DNA research;
(iii) Ensuring that all aspects of Appendix M have been appropriately addressed by the Principal Investigator;
(iv) Ensuring that no research participant is enrolled in a human gene transfer experiment until the RAC review process has been completed, Institutional Biosafety Committee approval has been obtained, Institutional Review Board approval has been obtained, and all applicable regulatory authorizations have been obtained;
(v) For human gene transfer protocols selected for public RAC review and discussion, consideration of the issues raised and recommendations made as a result of this review and consideration of the Principal Investigator's response to the RAC recommendations;
(vi) Ensuring that final IBC approval is granted only after the RAC review process has been completed; and
(vii) Ensuring compliance with all surveillance, data reporting, and adverse event reporting requirements set forth in the NIH Guidelines.

Additional IBC Responsibilities
In accordance with Section IV-B-2-b-(2) through (7) of the NIH Guidelines IBCs should also:

(i) Notify the principal investigator of IBC review and approval;
(ii) Set containment levels and modify containment levels for ongoing experiments as warranted;
(iii) Periodically review rDNA research to ensure compliance with the *NIH Guidelines*;

(iv) Implement contingency plans for handling accidental spills and personnel contamination resulting from recombinant DNA research; and

(v) Report to OBA and institutional officials within 30 days any:
   a. Substantial problems or violations of the *NIH Guidelines*; and
   b. Significant research related accidents or illnesses.

UM IBC GUIDELINES

Exempt Research

All studies that qualify for an exemption under Section III-F must be submitted for review on the *"IBC Exemption Request Form"* which can be found on the IBC website. The IBC Chairman or designee will review these applications and determine if an exemption is in order. If any changes are made to a study that has received an exemption from the IBC, a new application must be submitted for review.

Non-Exempt Research

The IBC will review and approve **all** applications that do not meet the exemption criteria outlined in Section III-F. The application forms for non-exempt studies can be found on the IBC website and are entitled *"Recombinant DNA and Gene Transfer Form"* and *"Human Gene Transfer Submission Checklist."*

(i) Section III-E

Full IBC review is not required prior to the initiation of a Section III-E study. For studies meeting the requirements outlined in Section III-E, the IBC Chairman or designee will review the applications in order to determine if this section seems appropriate. The Investigator must receive notice of the Chairman's determination prior to the initiation of the study. After this, the full IBC will review and approve the study at the next available meeting. If the IBC requests that any changes be made, the PI must respond at that time.

Renewals/Continuing Review

Duration of IBC approval for BL-1 and BL-2 protocols is for three years. Duration of approval for BL-3 and human gene transfer trials is for one year. An annual update must be submitted ***for all studies***. Details are listed below.

(i) Renewal of Human Gene Transfer Studies:

The IRB will electronically inform the IBC regarding the Investigator's continuing report submission. IRB approval of the annual reports is contingent on IBC approval.

(ii) Renewal of BL-3 Studies:

In order for approval to be renewed, submit a copy of the currently approved IBC protocol form and the annual update form for IBC review. The study cannot be continued once IBC approval expires. The annual update form is posted on the IBC website.

(iii) Annual Update for BL-1 & BL-2 Studies:

Before beginning the second and third year of the study, the Investigator must submit an annual update to the IBC. The IBC office will notify the Investigator as this date approaches. The annual update form is posted on the IBC website.

(iv) Exempt studies (Section III-F):

The IBC does not require annual updates or renewals for protocols deemed exempt and that have not been altered.

Amendments

In accordance with Section IV-B-7-c-(3) of the NIH Guidelines, **all** changes that occur subsequent to IBC approval must be reported to the IBC. Any revised documents must be submitted to the IBC for review and approval prior to initiation. The amendment form is located on the IBC website.

Review Process for Research Involving Animals or Human Subjects

IACUC and IRB review can take place either before or concurrent with IBC review. However, the IACUC or IRB cannot grant final approval until IBC approval has been granted. A member of the IBC will attend an IACUC or IRB meeting at the Committee's request. The IBC Administrator will provide the IACUC or IRB Administrator with a copy of the IBC approval letter.

The IBC will notify the IACUC or IRB if they note any concerns. In addition, the IACUC or IRB can invite an IBC member to the meeting where the continuing report is reviewed if they have concerns about the protocol.

Whenever a protocol is resubmitted to the IACUC or IRB as a new protocol, that protocol must also be resubmitted for IBC review, even if the study procedures have not changed.

For human gene transfer studies, please note that IBC approval cannot be granted until Recombinant DNA Advisory Committee (RAC) review has been completed. IRB review *can* occur before or after RAC review.

Special Notes for Research Involving Human Subjects
Investigators conducting research that involves the transfer of recombinant DNA molecules into one or more human research subjects must review Appendix M*, Requirements for Protocol Submission*, *Review, and Reporting – Human Gene Transfer Experiments,* of the NIH Guidelines.

(i) Additional Reporting Requirements:
The Investigator must send one copy of all reports sent to the NIH Office of Biotechnical Activities to the IBC. Examples of such reports include but are not limited to adverse events and continuing reports.

(ii) Below is a summary of the Adverse Event reporting schedule:

a. Any serious adverse event that is fatal or life threatening, unexpected, and associated with the use of the gene transfer product.
    i. Report to IBC no later than 7 calendar days after the sponsor's initial receipt of the information.
b. Serious adverse events that are unexpected and associated with the use of the gene transfer product, but are not fatal or life-threatening,
    i. Report to IBC no later than 15 calendar days after the sponsor's initial receipt of the information.
c. If, after further evaluation, an adverse event initially considered not to be associated with the use of the gene transfer product is subsequently determined to be associated;
    i. The event must be reported to the IBC within 15 days of the determination.
d. Any follow-up information relevant to a serious adverse event must be reported to the IBC within 15 calendar days of the sponsor's receipt of the information. If a serious adverse event occurs after the end of a clinical trial and is determined to be associated with the use of the gene transfer product, that event shall be reported to the IBC within 15 calendar days of the determination.
e. Any finding from tests in laboratory animals that suggests a significant risk for human research participants including reports of mutagenicity, teratogenicity, or carcinogenicity must be reported to the IBC no later than 15 calendar days after the sponsor's initial receipt of the information.