

William Marsh Rice University
STANDARD OPERATING PROCEDURES OF THE
INSTITUTIONAL BIOSAFETY COMMITTEE

I. PURPOSE

The Institutional Biosafety Committee (IBC) of William Marsh Rice University (Rice) conducts (1) the initial review and approval and (2) the continuing review of research involving recombinant DNA. These reviews are conducted in accordance with the provisions of the *NIH Guidelines for Research Involving Recombinant DNA*. The NIH Guidelines are available at the website of the Office of Biotechnology Activities: <http://www4.od.nih.gov/oba>, and shall apply to all recombinant DNA research performed at Rice University, whether funded by NIH or not. In addition to the NIH Guidelines, Rice University personnel are also referred to Rice University Policy #301. ([Policies and Procedures for the Management and Administration of Sponsored Projects](#)).

The IBC shall coordinate its activities with the Vice Provost for Research (VPR), the Office of Sponsored Research (OSR), the Environmental Health and Safety Office (EHS), and other oversight committees of the university [such as the Institutional Review Board for the Protection of Human Subjects from Research Risks (IRB) and the Institutional Animal Care and Use Committee (IACUC)].

II. DEFINITIONS

For the purposes of this document:

A. **Recombinant DNA:** In accordance with the *NIH Guidelines, Section 1-B*, recombinant DNA molecules are defined as either: “(i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above.”

B. **Biosafety Level (BL):** A description of the degree of physical containment being employed to confine organisms containing recombinant DNA molecules and to reduce the potential for exposure of laboratory workers, persons outside of the laboratory, and the environment. In [Appendix G](#) of the *NIH Guidelines*, these are graded from BL-1 (the least stringent) to BL-4 (the most stringent).

C. **Biological Safety Officer (BSO):** An individual appointed by an institution to oversee management of biosafety risks.

D. **Office of Biotechnology Activities (OBA):** The NIH office responsible for developing, implementing, and monitoring NIH policies and procedures for the safe conduct of recombinant DNA activities, including human gene transfer.

- E. Risk Group 1 (RG1): Classification for agents that are not associated with disease in healthy adult humans.
- F. Risk Group 2 (RG2): Classification for agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are *often* available.
- G. Risk Group 3 (RG3): Classification for agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions *may* be available (high individual risk, but low community risk).
- H. Risk Group 4 (RG4): Classification for agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk).

III. MEMBERSHIP

A. Composition

IBC members shall be appointed by and shall serve at the discretion of the University President. The IBC shall consist of a minimum of five voting members so selected that they collectively have experience and expertise in recombinant DNA technology and the capability to assess the safety of recombinant DNA research and to identify any potential risk to public health or the environment. At least two members shall be unaffiliated with Rice University (except as members of the IBC) and shall represent the interest of the surrounding community with respect to health and the protection of the environment. At least one member shall be a scientist with expertise in plant, plant pathogen, or plant pest containment principles for studies requiring approval by the IBC. At least one member shall be a scientist with expertise in animal containment principles for studies requiring approval by the IBC. The Director of the Environmental Health and Safety Office/Biological Safety Officer (BSO) and the Animal Resource Facility Manager shall also be voting members. A representative of the Office of Sponsored Research (either the Director or Assistant Director) and the Compliance Administrator shall be appointed as non-voting ex officio members.

B. Conflict of Interest

No member may participate in the IBC's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IBC.

C. Appointment of Members

Members shall be appointed by and shall serve at the discretion of the University President. A Curriculum Vitae and a list of the membership shall be maintained in OSR. The IBC files shall also contain the following information for each member: earned degrees, area of expertise, employment and any other relationship between each member and Rice University.

A Chair will be appointed by the University President. The Chair shall serve as a regular member of the IBC and must fully understand all functions, policies and procedures relevant to the IBC. One or more Vice Chairs may be appointed by the University President. Each Vice Chair shall serve as a regular member of the IBC and must fully understand all functions, policies and procedures relevant to the IBC.

D. Attendance Requirements

Each member of the IBC shall be required to attend meetings of the IBC on a regular basis. Failure to attend regularly could result in the removal of the member from the IBC.

IV. IBC AUTHORITY AND OPERATIONS

The IBC shall have the authority to assess the risks associated with undertaking recombinant DNA research and based on their findings, to exempt, approve, require modifications to, or disapprove all research activities under its jurisdiction as set forth in this document. The IBC shall also have the authority to suspend or terminate a study for failure to meet the requirements as set forth herein or as a result of a serious adverse event. Any notification of suspension or termination of a study shall be given in writing to the principal investigator of a study and shall include a statement giving the reason(s) for the suspension or termination. The IBC shall also notify the appropriate university official(s) and funding source, if the project is funded by an external source; and as appropriate the Office of Biotechnology Activities. The IBC may also place restrictions on studies as it may deem appropriate and necessary.

A. Applicability

The NIH Guidelines shall apply to all recombinant DNA research performed at Rice University unless such research falls within categories that are exempt from the Guidelines. The decision to classify research as exempt shall be made by the IBC Chair or a member designated by the Chair. The following types of recombinant DNA molecules are exempt from the NIH Guidelines, as provided in Section III-F:

1. Those that are not in organisms or viruses.
2. Those that consist entirely of DNA segments from a single nonchromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent.
3. Those that consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well-established physiological means.

4. Those that consist entirely of DNA segments from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).
5. Those that consist entirely of DNA segments that are known as exchangers, and are identified on a list provided by the NIH director.

All recombinant DNA molecules, including those that are exempt, that are not recognized as exempt as provided in Items 1-5 above, shall be registered through the process as provided in these Standard Operating Procedures, using the "Recombinant DNA Registration Form, hereby incorporated as Appendix A to the IBC Standard Operating Procedures.

B. Responsibility

1. Review

On behalf of the institution, the IBC is responsible for the initial and continuing review of recombinant DNA research conducted at or sponsored by the institution for compliance with the [NIH Guidelines](#) as specified in [Section III, Experiments Covered by the NIH Guidelines](#), and approval of those research projects that are found to conform to the *NIH Guidelines*. The review shall include: (1) an independent assessment of the containment levels required by the NIH Guidelines for the proposed research; (2) assessment of the facilities, procedures, training, and expertise of the personnel involved in the research; and (3) ensuring compliance with all adverse event and problem reporting as required by the NIH Guidelines. The IBC shall be authorized to seek expertise outside its membership in cases where members of the committee have insufficient knowledge to assess risks associated with the proposed research.

Continuing review of recombinant DNA research studies shall be conducted at least annually.

2. Notification

On behalf of the institution, the IBC is responsible for notifying the Principal Investigator of the results of the Institutional Biosafety Committee's review and approval in a timely manner.

3. Setting Containment Levels

On behalf of the institution, the IBC is responsible for setting containment levels as specified in the *NIH Guidelines*, [Sections III-D-4-b, Experiments Involving Whole Animals](#), and [III-D-5, Experiments Involving Whole Plants](#).

4. Adopting Emergency Plans

On behalf of the institution, the IBC is responsible for adopting emergency plans covering releases, accidental spills and personnel contamination involving recombinant DNA, following the basic elements as provided in the NIH publication “[Laboratory Safety Monograph](#)”.

5. Reporting

In an annual report to the NIH/OBA, if there is no change in the membership, the IBC will submit on behalf of the institution, an updated roster of all IBC members clearly indicating the Chair, contact person, Biological Safety Officer (if applicable), plant expert, animal expert, and human gene therapy expertise or *ad hoc* consultant (if applicable). If there is a change in the membership at any time during the reporting year, a revised roster and biosketches for any new members shall be submitted to the NIH/OBA at the time of the change. If public comments are received concerning actions taken by the IBC, such comments shall also be submitted by the IBC to the OBA, along with any institutional response to such comments.

On behalf of the institution, the IBC is responsible for reporting any significant problems with or violations of the *NIH Guidelines* and any significant research-related accidents or illnesses to the VPR and to the NIH/OBA within 30 days of their occurrence.

A copy of all reports submitted by the IBC on behalf of the institution shall be sent to the VPR.

6. Meetings

The IBC shall have regularly scheduled convened meetings at least three times during the academic year. In the event that there are no new protocols for review and no requirements for a continuing review of a currently approved protocol, the IBC will not be required to meet. The IBC shall meet no less frequently than once every 12 months. All voting at a convened meeting of the IBC with regard to protocol approval shall require a quorum of members to be present and a majority vote of the quorum.

7. Review Process

- a. Prior to each meeting of the IBC, electronic copies of the following shall be provided to each member:
 - minutes of the previous meeting of the IBC,
 - for new submissions: registration form and any other supporting documents; if applicable include the research protocol and/or Federal grant application,

- for protocol modifications: requested modification and any supporting documents,
- for annual review of continuing registrations: annual review registration form; serious adverse event (SAE) report form(s), if applicable; appropriate supporting documents for continuing approval.

b. A primary and secondary reviewer will be appointed by the Chair or his/her designate for each new protocol registration.

c. The protocol registration file maintained in the Office of Sponsored Research will be available at the meeting for each agenda item and will also be available to any IBC member for review upon request prior to the meeting.

d. Submissions of New Protocol Registrations

All submissions of new protocol registrations will be received by the Compliance Administrator in electronic form with a hard copy of the required signed certification page. The following shall be required of all new submissions: (1) a protocol registration; (2) relevant grant proposal, if applicable; (3) supporting documents as applicable. These materials must be forwarded to the Compliance Administrator with the current Rice registration form.

e. Voting

After presentation by the two designated reviewers for each new protocol registration and thorough discussion by the IBC membership, a vote will be taken on the approval of the research project. A majority of the membership must be present to transact this business. This majority should include at least one unaffiliated member. Only members present during the vote may vote (i.e., no proxy votes are permitted). An IBC member may not vote on his/her own study. Any member having a conflict of interest must recuse him/herself from both the discussion of the research study and from the voting process. A majority of the votes cast is needed for study approval. This majority must be maintained even if a member(s) have recused him/herself.

f. Communication of IBC Decisions

The Compliance Administrator will notify each investigator of the IBC's decision regarding each registration. Decisions of the IBC may be:

- Approved. If the study is approved, the Compliance Administrator will forward to the PI an approval letter signed by the IBC Chair or the Chair's designee and a copy of the approved registration form.
- Disapproved. If a research study is disapproved by the IBC, a written statement including the reason(s) for the disapproval shall be sent to the investigator. The investigator will be given an opportunity to respond to this statement. His/her response may be given either in person or in writing.
- Approved Contingent. The IBC may approve a study contingent upon minor and specific changes or modifications being made to the registration form. Once the appropriate changes have been made, the investigator must forward the documents to the Compliance Administrator who will forward them to the Chair for approval. Once approval is given, the Compliance Administrator will provide the written approval, as noted above.
- Approval Deferred. If the IBC requires additional information to make an appropriate decision regarding the study, the Compliance Administrator will so inform the investigator in writing, identifying the specific documentation required. This documentation, along with the initial submittal, will be reviewed at the next meeting of the IBC following receipt of such documents. The investigator may be invited to present the additional information to the IBC in person.

8. Appeal of an IBC Decision

If an investigator wishes to appeal a decision of the IBC, the appeal must be made in writing and submitted to the Compliance Administrator. The appeal will be considered at the next meeting of the IBC.

9. Exempt from further IBC Review

Certain categories of research are exempt from the *NIH Guidelines*, as provided in [Section III-F](#). However, such determination is made by the IBC Chair or a member designated by the IBC Chair, not the researcher. Exempt registrations for new or renewing studies or modifications to existing approved studies may be reviewed and approved by the Chair or his/her designate and reported to the Committee.

10. Expedited Review

Minor changes i.e., anything other than changes to the approved host/vector systems or a change in principal investigator, may be approved by the Chair or his/her designate and reported to the IBC.

11. Continuing IBC Review

For all approved research, including that granted exempt status (see IV.B.9. above), a review is required at least once per year. Prior to the date that approval expires, the Compliance Administrator will send a reminder notice for the continuing review of the research project. This notice will request that the investigator complete a continuing review registration form to be returned to the Compliance Administrator within at least two weeks of the next scheduled meeting of the IBC.

For continuing review, the IBC shall be provided with: (1) a protocol summary and status report on the progress of the research, (2) a summary of any amendments or modifications to the research since the last review, (3) a summary of any relevant recent literature or interim findings that would have affected the original registration were it to be submitted at this time, and (4) any other relevant information.

The Board may take any of the following actions for protocols undergoing continuing review: (1) approval to continue without change to the registration (2) approval to continue with changes to the registration (3) approval to continue contingent upon changes requested by the IBC, or (4) termination of the registration. Notification of approval or reasons for disapproval or termination of research will be given to the PI within five business days of such decision. The PI will have the right to appeal.

For continuing review registrations that are submitted without changes to the existing approved protocol or that are submitted with minor changes such as personnel additions or deletions; study location, contact information, funding agency information, the Chair or his/her designate may review and approve the changes. Such approval must be reported to the IBC. Any change of principal investigator or any change to the host/vector system requires review by the full committee at a convened meeting.

Each protocol registration may be active for a maximum of three (3) years. After the second continuing review (and the third year of active status of the protocol registration), an application must be resubmitted to the IBC for new registration. The old registration number will be inactivated at this time and the Compliance Administrator will assign a new protocol registration number to the study.

V. RECORD REQUIREMENTS

On behalf of the IBC, the IBC Administration shall retain records in the Office of Sponsored Research for at least 3 years. These records shall include:

- protocol records, viz., copies of all research proposals, reports of serious adverse events (SAE), and any scientific evaluations and/or progress reports submitted by researchers;
- records of continuing review activities;

- copies of all correspondence between the IBC and the researchers; and
- Minutes of IBC meetings showing attendance and actions taken. For each protocol registration, actions will include voting (1) for approval or for approval pending modifications, (2) frequency of continuing review. The minutes shall also document the basis for requiring any change in the protocol or for its disapproval, and will summarize the discussion of controverted issues and their resolution.

In addition, the Board shall require the PI to retain all records relating to the research for at least three years after its completion.

These Policies and Standard Operating Procedures shall also be maintained in the Office of Sponsored Research.

VI. ALLEGATION OF NONCOMPLIANCE

Unless deemed by the Chair to be transparently without merit, an allegation of researcher noncompliance shall be investigated by the Chair, the Compliance Administrator, and others at the discretion of the Chair. This ad hoc committee shall meet with the researcher(s) within 5 working days of the allegation to determine its seriousness. The allegation may be (1) dismissed as unjustified, (2) referred to a more appropriate office (*e.g.*, Environmental Health and Safety Office, Vice Provost for Research and Graduate Studies, or Provost), (3) resolved through corrective or educational measures where the violation of biosafety regulations is minor or inadvertent, or (4) where the allegation appears founded and serious, submitted to the full IBC for a formal investigation.

Any determination of noncompliance will be recorded in the researcher's IBC registration file. If the full IBC is convened and determines the allegation to be founded and of a serious nature, the Vice Provost for Research and Graduate Studies, other appropriate University official(s), and OBA will be notified in writing within three working days.

Any issues not specifically addressed in this document shall be governed by the *NIH Guidelines*.