

Institutional Biosafety Committee Governance and Operating Policies

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1.0 URI IBC

The University of Rhode Island (URI) Institutional Biosafety Committee (IBC) serves as the IBC for the URI. The IBC includes specific review and oversight of Biological Research activities as defined in Section 4.0.

2.0 MISSION

The mission of the IBC is to promote safety and minimize the risks of performing Biological Research to URI investigators, study participants, the community, and the environment by providing scientific review and oversight to Biological Research at URI. The IBC is committed to following the letter and the spirit of biosafety guidelines, guidance, and regulations. The IBC shall operate in full compliance with all applicable federal, state, and local regulations.

3.0 APPLICABLE GUIDELINES AND REGULATIONS

As a condition for National Institutes of Health (NIH) funding of recombinant DNA (rDNA) research, URI shall ensure that such research conducted at or sponsored by the institution, irrespective of the source of funding, shall comply with the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines). The relevant guideline is:

 The NIH Guideline for Research Involving Recombinant DNA Molecules (NIH Guidelines), http://oba.od.nih.gov/rdna/nih_guidelines_oba.html

4.0 SCOPE

The IBC policies and procedures apply to all investigators, staff, students and visitors engaged in Biological Research, as defined below, conducted at or sponsored by URI.

4.1 Biological Research

Any activity that is laboratory research involving rDNA, biological agents, human or non-human primate materials, or biological toxins.

4.2 Recombinant DNA

The NIH Guidelines define rDNA molecules 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. Synthetic DNA segments which are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent) are considered as equivalent to their natural DNA counterpart. If the synthetic DNA segment is not expressed in vivo as a biologically active polynucleotide or polypeptide product, it is exempt from the NIH Guidelines.

Genomic DNA of plants and bacteria that have acquired a transposable element, even if the latter was donated from a recombinant vector no longer present, are not subject to the NIH Guidelines unless the transposon itself contains recombinant DNA (NIH Guidelines Section I-B).

4.3 Biological Agents

Viable infectious microorganisms (including prions) regardless of their pathogenicity to humans.

4.4 Human and Non-human Primate Materials

Human or non-human primate blood, unfixed human or non-human primate tissues, and human and non-human primate cell lines (established or primary).

4.5 Biological Toxins

Biological toxins are subject to the National Select Agents Registry Program managed by the U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA). The current list of toxins are identified at: http://www.selectagents.gov/index.html.

5.0 GOVERNANCE

The IBC carries out the review of Biological Research and oversight activities on behalf of URI and reports directly to the URI Institutional Official (IO).

6.0 KEY ROLES AND RESPONSIBILITIES

6.1 Institutional Official

The URI Institutional Official (IO) is responsible for:

- Serving as the responsible institutional official for applicable government entities.
- Providing the IBC with the necessary local resources through the institution's annual budgeting process.
- Reporting to NIH and other relevant federal, state and local agencies, as required.
- Investigating reports of noncompliance and reports of IBC concerns and taking corrective actions as needed.
- Holding investigators and study staff accountable for their responsibilities.
- Ensuring effective institution-wide communication and guidance on Biological Research and biological safety issues.
- Promoting an institutional culture of safety when conducting Biological Research.
- Appointing IBC members from their institution.

6.2 Chairperson

The IBC Chairperson is a voting member of the IBC and in collaboration with the URI Director of Research Compliance is responsible for:

- Ensuring that all IBC members are appropriately trained.
- Determining whether review can be conducted at a convened meeting or administratively.
- Presiding at convened IBC meetings.
- Reviewing and approving Biological Research that can be administratively reviewed.
- Overseeing investigations.
- Attending meetings with the IO.
- Participating in the development of IBC policies and procedures.
- Performing other activities, as needed, to fulfill institutional responsibilities set forth in the *NIH Guidelines* and other federal, state, and local regulations.
- Delegating the authority to preside over a convened IBC meeting.
- Recommend the appointment of members to the committee.

6.3 Director of Research Compliance

The Director of Research Compliance is responsible for the administrative leadership of the IBC. The Director of Research Compliance or designee is responsible for:

- Reviewing membership of the IBC to ensure scientific expertise, adequate representation, diversity, etc.
- Assessing IBC policies and developing new policies or changes to current policies.

- Attending IBC meetings, preparing IBC meeting agendas, preparing meeting minutes, and making minutes available to the public upon request.
- Notifying investigators of the results of IBC reviews and providing guidance to ensure compliance.
- Completing annual reports to the NIH per stipulated guidelines.
- Communicating with the institutional review boards (IRB) and institutional animal care and use committees (IACUC) regarding research requiring review by multiple committees and developing processes by which appropriate projects are reviewed by the IBC.
- Ensuring that PI has appropriate training approvals prior to registration approvals.
- Serving as a resource to the regulated community (i.e., investigators, staff, biosafety officer).
- Monitoring national, state and local regulatory trends and communicate regulatory changes to institutional officials and institutional biosafety officer as necessary.
- Assisting URI EHS to develop procedures for robust laboratory safety inspections and training programs.
- Reviewing investigations conducted by the IBC.

6.4 IBC

The IBC is registered with the NIH OBA. As the IBC is responsible for the review and approval of all biological research conducted at or sponsored by URI, the IBC will adhere to all requirements of the IBC set forth in NIH Guidelines related to the composition and responsibilities of the IBC.

Of behalf of the institution, the IBC is responsible for:

- Approving, requiring modifications to secure approval, and disapproving all biological research
 overseen and conducted by URI for compliance with adopted policies, regulations and
 guidelines. This review shall include an independent assessment of the biological containment
 required, and an assessment of the facilities, training and expertise of personnel involved in the
 research. All biological research must be approved by the IBC.
- Determining the necessity for health surveillance for research study staff involved in Biological Research; and if appropriate, recommending the establishment of a health surveillance program for such projects.
- Reviewing and approving IBC policies.
- Participating in reviews of unanticipated problems, including serious adverse events that are unexpected and related to the research, significant violations of policies, practices and procedures, violations of the NIH Guidelines, or any significant research-related accidents, potential exposures, and illnesses.
- Reviewing any findings of significant violation of policies, practices and procedures; participate
 in an investigation of any significant research related accidents or illnesses; suspend or rescind
 registration approvals as necessary, and recommend to the IO, limitations or conditions on an
 investigator's or research study staff's privilege to conduct Biological Research.

In addition to the review of Biological Research, the IBC shall be responsible for:

- Establishing and monitoring policy, practices and procedures for Biological Research at URI.
- Ensuring that adopted policies, practices and procedures for Biological Research meet applicable regulatory standards and guidelines.

- Reporting any significant problems with or violations of the NIH Guidelines and any significant research-related accidents or illnesses to the IO and NIH/OBA as specified in Section 14.2
- Lowering containment levels for certain experiments (as specified in Section III-D-2-a of the NIH Guidelines).
- Adopting emergency plans covering accidental spills and personnel contamination resulting from rDNA research.
- Reviewing design specifications and criteria for containment facilities.
- Reviewing and certifying use of Biosafety Level 3 laboratories.
- Reviewing and approving policies and procedures related to select agents, including access, strain verification, inventory management, laboratory protocols and emergency response plans.
- Reviewing and assessing compliance with permit-related requirements for work with materials from USDA Animal and Plant Health Inspection Service (APHIS): Veterinary Services (VS), and other applicable requirements.

6.5 Environmental Health and Safety

A representative from URI Environmental Health and Safety (EHS) is responsible for institution specific biosafety training, laboratory inspection and biosafety programs. To this end, the URI EHS is responsible for:

- Reviewing all institutional IBC registrations, assessing the risk of proposed laboratory research
 and providing recommendations to the IBC as to appropriate containment, procedures and
 personal protective equipment.
- Ensuring that IBC approved modifications or stipulations are implemented.
- Immediately reporting to the IBC any significant problems, violations, or any significant research-related accidents or illnesses.
- Developing emergency plans and procedures for handling accidental spills and personnel contamination and investigating laboratory accidents resulting from biological material research.
- Developing and overseeing training on biosafety and laboratory safety and ensuring compliance with training requirements.
- Providing advice and guidance on laboratory security.
- Providing technical advice and guidance to investigators and the IBC on research safety procedures and personal protective equipment.

6.6 Investigators

Primary responsibility for protecting the safety of their research study staff, study subjects, the community, and the environment rests with the principal investigator (PI). Pls may not commence Biological Research prior to obtaining IBC approval, and, as appropriate, other institutional approval of their research activities. For each research activity submitted to the IBC for approval, the PI must certify that s/he accepts responsibility for assuring adherence to the NIH Guidelines (if applicable) and applicable federal, state and local research regulations and institutional policies.

Specifically, investigators are responsible for:

- Following all IBC policies and procedures.
- Following all IBC requirements and PI responsibilities described in the NIH Guidelines.
- Completing all IBC and institutional training requirements prior to engaging in research and ensure research study staff have done so.

- Ensuring all Biological Research is appropriately reviewed and approved prior to initiation of the work.
- Ensuring research study staff is appropriately trained. This includes training on specific procedures and policies used in a given registration (i.e., registration-specific training) and documentation of this training.
- Ensuring IBC registrations are kept up to date, including but not limited to registration of all biological materials and listing of research study staff.
- Complying with IBC requirements associated with each registration (e.g. biosafety precautions).
- Complying with all determinations and additional requirements of the IBC, the IBC chairperson, and the IO.
- Reporting any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses to the IBC and URI EHS per Section 14.0.

6.7 Research Study Staff

Staff, including all URI employees (faculty, staff, and students), participating in Biological Research is responsible for:

- Following all IBC policies and procedures.
- Completing all IBC and institutional training requirements prior to engaging in research.
- Complying with IBC requirements associated with each registration (e.g. biosafety precautions).
- Complying with all determinations and additional requirements of the IBC, the IBC chairperson, and the IO.
- Reporting incidents or violations of IBC policies to the IBC.

7.0 DISCIPLINARY ACTIONS

The IBC can launch investigations, and suspend or rescind registrations based on noncompliance and/or unacceptable risk. In addition, the IO may place limitations or conditions on an investigator's or research study staff's privilege to conduct Biological Research upon recommendation of the IBC, where such actions are required to maintain the compliance with federal, state, local, and/or institutional requirements.

8.0 TRAINING OF RESEARCHERS

8.1 Principal Investigators

PIs conducting Biological Research are responsible to complete laboratory safety and biosafety training offered by URI EHS. PIs without current training will not be allowed to submit biological research for IBC review. The IBC may terminate approved biological research projects should investigators fail to maintain current training.

8.2 Research Study Staff

Laboratory research study staff is responsible to complete laboratory safety and biosafety training offered by URI EHS. Research study staff without current training may not engage in biological research activities until training is complete. It is the responsibility of the PI to ensure that all research study staff is compliant with training requirements. Additionally, research study staff must also be trained by the PI on the specific laboratory procedures and policies that will be used in each laboratory research registration.

9.0 IBC MEMBERSHIP

The IBC shall be comprised of no fewer than five (5) members so selected that they collectively have experience and expertise in recombinant DNA (rDNA) technology and Biological Agents and toxins and together have the capability to assess the safety of rDNA and Biological Agent and toxin research and are able to identify any potential risk to public health or the environment.

The IBC membership will be composed of the following:

- At least two individuals with expertise in rDNA technology, and/or biological safety, and/or physical containment.
- At least one individual with expertise in animal containment principles.
- At least two members not affiliated with the institution (apart from their membership on the IBC) and represent the interests of the surrounding community with respect to health and protection of the environment.

9.1. Recruitment and Selection of Members

Affiliated candidates for IBC membership shall be identified by the Director of Research Compliance and Chairperson of the IBC through the department chairs, IO, or through current IBC members. Unaffiliated members shall be identified through current IBC members or various community agencies or groups. Additionally, individuals who are affiliated or unaffiliated may self-refer to the IBC for consideration to be a new member.

New members shall be recruited as needed to ensure that the membership of the IBC continues to include individuals with varying backgrounds and the necessary experience and scientific or scholarly expertise to review the scope of Biological Research conducted at URI. In addition, new members shall be recruited as needed to replace the scientific or scholarly expertise of members who resign and, when needed, to provide additional scientific or scholarly expertise to review new research programs.

Candidates for membership must be able to participate in a majority of the IBC meetings. Please see Section 11.5 for IBC Member attendance requirements. Appointments of new members shall follow the steps outlined in Section 9.6.

9.2 Member Designations

Voting members shall be designated as either: (1) affiliated or unaffiliated; and (2) voting member or alternate voting member. The IBC will be composed of the following:

9.2.1 Affiliated

Members, or their immediate family members, who are affiliated with URI shall be considered affiliated. "Immediate family member" is defined as spouse, domestic partner, child, parent, or sibling. "Affiliated" is defined as having an employment relationship with, a professional relationship with, a paid consultant relationship with, or a trustee/governing board member relationship with, or being a student of URI.

9.2.2 Unaffiliated

Members or their immediate family members, who are not affiliated with URI shall be considered unaffiliated. "Immediate family member" is defined as spouse, domestic partner, child, parent, or sibling.

9.2.3 Voting Member

Voting members shall be required to vote or abstain from voting on each research activity considered by the IBC when they are present for the discussion and vote.

9.2.4 Alternate Voting Member

Each voting member shall identify an alternate voting member that has similar scientific and scholarly expertise. Alternate members shall be required to vote or abstain from voting on each research activity considered by the IBC when they are present for the discussion and vote, and the voting member for whom they are a designated alternate is not present.

9.3. Periodic Review of the Membership

The membership of the IBC shall be reviewed at least annually to ensure that membership includes individuals with varying backgrounds and the experience and scientific or scholarly expertise needed to review the scope of biological research conducted at URI. The Director of Research Compliance shall be responsible for compiling information about research registrations reviewed at convened meetings to assess the scope of biological research reviewed by the IBC. The Director and Chairperson of the IBC shall review the report, conduct the membership review and present results of the review to the IO.

9.4 Term of Appointment

Appointments to the IBC shall be made by the IO. Members shall be appointed for terms of three (3) years; however, members may be removed by the IO for cause as described elsewhere in this document.

9.5 Equal Opportunity

The membership shall include individuals who provide a specific expertise in biological research. No qualified individual shall be rejected from the membership on the basis of race, gender, creed, religion, color, national origin, age, disability, or sexual orientation.

9.6 Procedures for Appointment and Reappointment

Prospective members shall be asked to: (1) attend a meeting of the IBC; (2) provide a copy of their curriculum vitae or resume, and (3) complete the IBC member orientation program. Based on the information provided and the membership requirements of the IBC, the Director of Research Compliance and Chair shall recommend membership appointment of individuals to the membership of the IBC. The IO shall be responsible for inviting the individual, in writing, of his/her appointment and, when applicable, the relevant Department Chair.

9.7 Resignation

Any member may resign from the IBC by a written resignation submitted to the Director and Chairperson of the IBC.

9.8 Suspension or Removal of Members

Any member may be asked by the IO to step down or may be replaced for failure to fulfill their responsibilities as an IBC member.

9.9 Membership Records

The URI Office of Research Compliance shall maintain a roster of IBC members and alternate members to include the following information:

- Name;
- Earned degrees;
- Experience and expertise, such as board certifications, licenses;
- Affiliation, if any, with URI;
- Alternate members; and
- The primary member or class of primary members for whom the alternate could substitute.

The URI Director of Research Compliance, or designee, shall be responsible for updating the membership roster and IBC registration information as needed when membership changes and submitting the updated information to NIH OBA as required. IBC rosters shall be retained for at least seven (7) years and shall be made available upon request, when applicable. Individual membership records shall be retained by the IBC for at least seven (7) years from date of last service.

9.10 Use of Ad hoc Consultants

The IBC or IBC Chairperson may invite ad hoc consultants, when needed, to supplement or provide scientific review to the IBC. Additionally, the IBC may vote to table action and require an expert in a scientific area or discipline to review the research and provide consultation to the IBC. In such cases, the Chairperson or Director of Research Compliance shall be responsible for identifying the consultant and for requesting such consultation.

Ad hoc reviewers may provide reviews in writing or orally at a convened meeting. Ad hoc reviewers shall not be considered members and, as such, shall not vote on biological research before the IBC; however, ad hoc consultants shall be subject to the IBC policy on Member Conflicts of Interest. Ad hoc consultants shall be reminded that the discussions that take place at the meeting are confidential and should not be disclosed to others. Ad hoc consultants may be either affiliated or unaffiliated with URI as defined in Section 8.9.

9.11 Member Orientation, Training and Education

New IBC member orientation consists of reviewing the following with the Director of Research Compliance: a description of the IBC and responsibilities; *NIH Guidelines*; criteria for membership; authority of the IBC; registration review process; periodic review; registration modifications; records; roles and responsibilities; and federal regulations. IBC members shall be required to complete training in biosafety offered by URI EH&S. Documentation of training is maintained through the use of IBC member files.

The objectives of providing this information are the following:

- To introduce members to the role of the IBC and its evolution;
- To provide the basic information necessary for IBC members to discharge their responsibilities;
 and
- To provide a forum for response to, and discussion of, members' concerns and questions.

In addition, new IBC members will not be asked to serve as a primary reviewer until they have attended at least one meeting. Additionally, the Director of Research Compliance or designee will conduct periodic training during sessions within convened meetings.

10.0 CONFLICTS OF INTEREST

All members of the IBC and ad hoc consultants shall be required to disclose conflicts of interest and recuse themselves from participating in the discussion and vote on biological research with which they have a conflict of interest as defined in the IBC Member Conflict of Interest Policy. In preparation for each meeting, the Director of Research Compliance shall remind members that they must recuse themselves from discussing and voting on registrations if they are involved in the conduct or evaluation of the research or have significant financial interests (i) that would reasonably be affected by the research for which IBC approval is sought, and/or (ii) in entities whose financial interests would reasonably appear to be affected by the research. When members recuse themselves, they shall leave

the room for the discussion and vote on the research, except to provide information at the IBC's request prior to the discussion and vote. Recusals shall be documented in the minutes of the meeting as not present for the discussion and vote.

11.0 CONVENED MEETINGS

11.1 Meetings

11.1.1 Regular Scheduled Meetings

The IBC shall meet regularly. Meetings will occur in person or via conference call as required by NIH Office of Biotechnology Activities. Meetings shall be scheduled in advance and shall be posted on the IBC internet website. The agenda shall be prepared by the Director of Research Compliance and approved by the IBC Chair taking into consideration the nature and complexity of the biological research activities on the agenda and members attending the meeting. The agenda shall be limited as needed to allow sufficient time for discussion of each research activity before the Committee. Members shall be contacted prior to the meeting to determine attendance. From among those members planning to attend the meeting, the Director of Research Compliance and Chairperson shall assign reviewer(s) to each Biological Research activity on the agenda requiring review.

When making review assignments, the Director of Research Compliance and Chairperson shall take into consideration the experience and scientific or scholarly expertise required to review the research. In general, registrations shall be scheduled for review by date of receipt by the Office of Research Compliance; the IBC reserves the right to reschedule registrations for review based on the experience and expertise of the members planning to attend the meeting or to request the use of a consultant to supplement or provide scientific or scholarly expertise not available on the IBC. The agenda and materials related to the Biological Research scheduled for review at the meeting shall typically be provided to members at least seven (7) days in advance of the meeting to allow sufficient time for review.

11.1.2 Emergency Meeting

The IBC Chairperson or Director of Research Compliance may call an emergency meeting of the IBC as necessary.

11.2 Primary Reviewers

The primary reviewer(s) shall perform an in-depth review of all materials provided to them relevant to the biological research that they are assigned to review including, when applicable, the investigational drug brochure, study protocol, and informed consent document. The primary reviewer(s) shall be responsible for notifying the Director of Research Compliance if s/he has a conflict of interest as defined in the IBC policy on IBC Member Conflicts of Interest. In such cases, the Chairperson or designee shall reassign review of the research activity to another member.

11.3 Members not assigned as a Primary Reviewer

Members who are not assigned as the primary reviewer shall perform review of all materials provided to them relevant to the biological research in sufficient depth to vote on the research activity at the convened meeting.

11.4 Quorum

Biological Research that cannot be administratively approved shall be reviewed at a convened meeting of a quorum of the membership of the IBC. Reasonable efforts will be made to ensure that at least one unaffiliated member is present at each meeting. The presence of more than one-half plus one of the

voting membership shall constitute a quorum. Alternate voting members can be counted towards a quorum when they are attending as a replacement to a voting member. A quorum shall be maintained for the discussion and vote on each research activity on the agenda. Members not present for or recused due to a conflict of interest from the discussion and vote on a research activity shall not be counted towards the quorum. The Chairperson, Director, or designee shall be responsible for ensuring that quorum is achieved before the meeting begins and is maintained throughout the meeting when each research activity on the agenda is voted upon. The Director or designee shall be responsible for recording attendance and vote on each research activity.

11.5 Attendance

Voting members are expected to attend the majority of IBC meetings. Voting members that anticipate an absence should contact their alternate voting member to ensure that their alternate member can attend in their absence. Anticipated absences from an IBC meeting should be communicated to the Director of Research Compliance at least seven (7) days prior to the meeting.

11.6 Guests

Normally, IBC meetings are closed to the public, although on occasion, and at the discretion of the IBC Chairperson and Director of Research Compliance, individuals may attend IBC meetings as guests. In such cases, guests shall be reminded that the discussions that take place at the meeting are confidential and should not be disclosed to others. Guests are not members of the IBC by virtue of their attendance and are not eligible to vote. Guests are required to notify the Director of Research Compliance prior to the meeting of their desire to attend the meeting.

PIs (or their designees) may be asked by the Chairperson or Director of Research Compliance to attend the meeting to describe proposed research under review and answer questions. They will be asked to leave prior to the vote.

11.7 Discussion and Vote

The reviewer(s) will present their reviews. The IBC Chairperson will open the review for discussion by the members. At the end of the discussion, any member may make a motion to approve, require modifications in the research (to secure approval), table action for more information, or disapprove the research. A vote on the motion shall be taken by show of hands or voice vote, and the number of votes for, against, and abstentions from voting shall be recorded in the minutes. All motions shall be decided by majority vote of the members present for the review.

The IBC vote may result in one of the following:

- Approve the registration without modification;
- Approve the registration subject to modification;
- Table the decision pending additional information;
- Disapprove the registration.

11.8 Appeal of an IBC Decision

The decision of the IBC to disapprove the research cannot be overruled by any other institutional body or individual(s); however, an investigator may appeal the decision of the IBC in writing directly to the IBC Chairperson. The IBC Chairperson is responsible for reviewing the appeal with the Director of Research Compliance. The appeal is then scheduled for review at a convened meeting of the IBC that disapproved the research. The investigator may appeal the decision of the IBC in person at the convened meeting.

12.0 REGISTRATION REVIEW PROCEDURE

The IBC has the authority to and shall be responsible for determining appropriate biological safety requirements for Biological Research submitted to the IBC. The IBC shall be guided by the CDC-NIH Biosafety in Microbiological and Biomedical Laboratories, 5th Edition (or any updates as available) and the NIH Guidelines. The IBC shall conduct reviews of submitted rDNA research that are not exempt from the NIH Guidelines consistent with the requirements set forth in the NIH Guidelines. Registrations are valid for five (5) years (or less depending on IBC vote) and must be reviewed annually by the Principal Investigator.

Registration review procedures are described briefly below. Details regarding the registration review procedure can be found in the following IBC policies:

- Defining Review Procedures for Categories of Biological Research. (Attachment I)
- Review of Biological Research. (Attachment II)

12.1 Registration Approval Procedures

Registrations are submitted through IRBnet. After a registration is submitted, the Office of Research Compliance and/or Chairperson will decide whether more information is necessary and, if so, will contact the PI. Biological Research may be either reviewed by the full IBC or administratively by the Director of Research Compliance. Research involving rDNA that is not exempt from the *NIH Guidelines* is required to be reviewed at a convened meeting by the full IBC.

Once IBC review is complete, the IBC may do one or more of the following:

- Approve the registration without modification;
- Approve the registration subject to modification or stipulations;
- Table the decision pending additional information;
- Disapprove the registration.

12.2 Registration Approval Notification

The IBC shall provide email notification of the IBC decision to the PI. Email notifications will also be provided to staff identified on registration listed as requesting said notification (e.g., laboratory safety contacts, laboratory mangers, study coordinators).

12.3 Length of Approval

IBC approvals are valid for five (5) years. However, the IBC reserves the right to approve the research for periods less than 5 years if deemed necessary.

12.4 Amendments

Changes to the registration must be made through the amendment process in IRBnet. Amendments must be submitted and approved by the IBC prior to the implementation of the changes. Scientific changes (e.g., addition or removal of biological materials, new procedures, addition of animal studies) may require IBC review at a convened meeting. If possible, scientific changes will be administratively approved. Changes to staff, laboratory location, funding source, title are administratively approved.

12.5 Annual Review

Biological Research must be reviewed annually by the PI to ensure that the registration accurately describes the Biological Research. The annual review process includes submission of a short review form to the IBC. Registrations that are not reviewed annually will be terminated by the IBC.

12.6 Five Year Resubmission

Registrations that are at the end of their five year approval period must be resubmitted for review by the IBC or terminated.

12.7 Voluntary Registration Termination

Registration approvals may be terminated by the PI at anytime if the Biological Research activities described in the approved registration have concluded through IRBnet.

13.0 IBC RECORDS

The IBC records include:

- IBC meeting minutes.
- IBC registrations and attachments thereto.
- IBC membership.
- IBC policies and procedures.
- IBC documentation related to unanticipated problems, including serious adverse events that are
 unexpected and related to the research, significant problems, violations of the NIH Guidelines,
 or any significant research-related accidents, potential exposures, and illnesses.

13.1 Meeting Minutes

The minutes shall include the following:

- Voting members present;
- Presence of unaffiliated member(s);
- Voting members absent;
- Staff and guests, including consultants present for each Biological Research Activity reviewed at the meeting;
- Action voted on by the IBC;
- Number of votes for, against, and the number of abstentions from voting (documentation of quorum);
- Members attending the meeting but not present for the discussion and vote;
- Recusals of voting members due to conflicts of interest;
- When applicable, summary of information presented by IBC member(s), ad hoc consultants, or guest(s);
- Summary of the discussion of issues and their resolution, if any;
- Modifications required and/or additional information requested by the IBC; and
- Basis for requiring changes or disapproving the research.

Minutes shall be made available to the IBC members for review and approval and shall not be altered once approved. Minutes shall be retained by the IBC Office for at least seven (7) years and shall be maintained in a secure area within the IBC Office or secure shared filed area on the URI network.

13.1.1 Access to Meeting Minutes

In accordance with the *NIH Guidelines*, the IBC shall allow for public review of its actions through the provision of meeting minutes to those that have requested such documentation. The IBC, in consultation with the URI Office of General Counsel, shall review and respond to all written public requests for meeting minutes in a manner consistent with any redaction policy noted in Section 13.1.2. Public comments and the IBC response shall be forwarded to the NIH OBA by the Director of Research Compliance.

13.1.2 Redaction of Meeting Minutes

Consistent with Section IV-B-2-a-(6) of the *NIH Guidelines* as well as subsequent letters of interpretation from NIH OBA, the IBC reserves the right to redact proprietary or private information when minutes are released to the public, but will do so judiciously and consistently for all requested documents. This information may include trade secret information, confidential commercial information, personal information of IBC members, and specific information whose disclosure would directly compromise institutional security.

13.2 Retention

The IBC shall retain the following records for at least seven (7) years after the completion of the research activity:

- IBC meeting minutes.
- IBC registrations and attachments thereto.
- IBC Membership.
- IBC policies and procedures.
- IBC documentation related to unanticipated problems, including serious adverse events that are unexpected and related to the research, significant problems, violations of the NIH Guidelines, or any significant research-related accidents, potential exposures, and illnesses.

13.3 Access

All IBC records, as outlined above, shall be available for inspection by the Institutional Officials and their designees and designated federal agencies. As described in Section 13.1.1, IBC shall make available all IBC meeting minutes, per the *NIH Guidelines*.

14.0 INCIDENTS, VIOLATIONS AND SERIOUS ADVERSE EVENTS

14.1 Investigations

Investigations of laboratory incidents and violations of the NIH Guidelines or IBC policies may be requested by the IO, IBC Chair, or IBC members. The IBC Chair will identify the appropriate group or individual to conduct the investigation. Results of investigations will be reported to the IBC during a convened meeting.

14.2 Reporting

As part of the PI's responsibilities, PIs are required to notify the URI EHS and Research Compliance as soon as possible in the event of a potential or overt exposure to rDNA, a biological agent, human or human primate material or biological toxin, suspected laboratory acquired infection, or violation of the NIH Guidelines. This is required even if the staff was not seen by Occupational Health or the Emergency Department. Of behalf of the PI, the IBC will report to the appropriate agency as required. Additional information regarding reporting is provided below.

14.2.1 National Institutes of Health Office of Biotechnology Activities

Annual Report

The IBC shall submit an annual report on the activities of the IBC to NIH OBA consistent with the requirements set forth in NIH Guidelines.

Violations of the NIH Guidelines

The IBC, in collaboration with URI EHS, shall report any significant problems with or violations of the NIH Guidelines to the Institutional Official and NIH OBA within 30 days. Reports to NIH/OBA shall be sent to

the following address: Office of Biotechnology Activities National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985 Bethesda, MD 20892-7985, (20817 for non-USPS mail), Phone: 301-496-9838. Fax: 301-496-9839.

Laboratory Incidents

The IBC, in collaboration with URI EHS, shall report research related incidents to Institutional Official and NIH OBA in the following manner:

- Significant research-related accidents and illness will be reported within 30 days.
- Spills and accidents in biosafety level 2 laboratories resulting in overt exposures to organisms containing rDNA molecules will be reported immediately.
- Spills or accidents occurring in biosafety level 3 laboratories resulting in an overt or potential exposure will be reported immediately.

Reports to NIH OBA shall be sent to the following address: Office of Biotechnology Activities National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985 Bethesda, MD 20892-7985, (20817 for non-USPS mail), Phone: 301-496-9838, Fax: 301-496-9839

15.0 MONITORING AND AUDITS

In order to monitor and ensure compliance, internal or external auditors who have expertise in federal, state, and local statutes, regulations and institutional requirements may conduct periodic audits. Audits will focus on areas of concern that have been identified by any entity, i.e., federal, state or institutional. Random audits may also be conducted.

16.0 CONFIDENTIALITY

Proprietary or private information and information that is critical to institutional security that is discussed during the IBC review proceedings and records of review activities shall be considered confidential and protected from access except as provided in Section 13.1.1. IBC members or others with access to proprietary or private information and information that is critical to institutional security shall not use them for any purpose other than to carry out their review responsibilities and shall not disclose them to others who are not authorized under these procedures to have access. Such protection is essential to encourage open discussion by the IBC in review of proposed research, maintain the integrity of the deliberative process, safeguard the privacy and confidentiality of participants in research and avoid disclosure of information that is proprietary to the research sponsor or another third party and which the institutions may be contractually obligated to keep confidential.

Without limiting any of the above, the Director of Research Compliance shall specifically prohibit distribution of documents and records containing confidential and proprietary information of URI or of a third party without prior written approval by URI or the third party involved, as applicable.

17.0 POLICIES AND PROCEDURES

The IBC shall adopt such Policies and Procedures and develop such guidance as may be necessary for the review of biological research in compliance with federal, state, and local laws and regulations. Policies concerning IBC operations shall be developed by the Director of Research Compliance and IBC Chairperson and reviewed by the IO. Policies intersecting with or affecting other institutional offices or processes may be developed in consultation and coordination with those offices or institutional research leadership and are generally approved by the IO. The IBC Policies and Procedures, including IBC guidance documents and significant policy-related communications to the research community, shall be made available on the URI Office of Research Compliance website and shall be maintained by the URI

Office of Research Compliance for at least seven (7) years from the date of their adoption/distribution and shall be made available upon request to authorized representatives of the sponsor and, when applicable, authorized representatives of NIH and other federal agencies.

18.0 REPORTING AND MANAGEMENT OF CONCERNS

Questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the IBC may be reported orally or in writing. Employees are permitted to report concerns and may do so on an anonymous basis. Concerns may be reported to the IBC Chair, IO, or Research Compliance.

The IBC is responsible for investigating allegations and findings of non-compliance and taking corrective actions as needed. The IO is responsible for investigating reports of IBC non-compliance and taking corrective actions as needed.

Employees who report in good faith possible compliance issues shall not be subjected to retaliation or harassment as a result of the reporting. Concerns about possible retaliation should be immediately reported to the IO.

Contact information for the Institutional Official is as follows:

Peter Alfonso, Ph.D., Vice President for Research and Economic Development
Division of Research and Economic Development
Carlotti Administration Building, Suite 001
75 Lower College Road
Kingston RI 02881
401 874-4576

Contact information for the Director of Research Compliance is as follows:

Theodore A. Myatt, Sc.D.

Division of Research and Economic Development
70 Lower College Road
Kingston, RI 02881
401 874-2636

ATTACHMENT I

Title: Defining Review Procedures for Categories of Biological Research

Department: University of Rhode Island Institutional Biosafety Committee

Applies to: Employees, Staff or Other Agents of University of Rhode Island

Approval Date: December 4, 2012

Effective Date: December 4, 2012

Revision Date(s):

Next Review Date: December 4, 2013

Contact Person: Director, URI Research Compliance

1.0 KEYWORDS

IBC, Institutional Biosafety Committee, Full Board Review, Administrative Review

2.0 PURPOSE

The purpose of this policy is to define the procedures the University of Rhode Island Institutional Biosafety Committee (IBC) follow when conducting initial review and five (5) year resubmission of Biological Research and review of proposed changes (amendments) in approved research. This policy covers:

- Research involving recombinant DNA (rDNA)
- Research involving Biological Agents
- Research involving Human and Nonhuman Primate Materials
- Research involving Biological Toxins

3.0 DEFINITIONS

See Definitions of Biological Research, rDNA, Biological Agents, Human and Nonhuman Primate Materials, and Biological Toxins in the IBC Governance and Operating Policies.

4.0 POLICY STATEMENT

The IBC must review all Biological Research that involve rDNA, Biological Agents, Human and Nonhuman Primate Materials, and Biological Toxins as defined in the IBC Governance and Operating Policies. Registrations may be either reviewed at a convened meeting of the IBC (Full Board Review) or reviewed administratively (Administrative Review).

5.0 PROCEDURES

The procedures for review of Biological Research are dependent on the category of Biological Research. Sections 5.1 through 5.4 outline the procedures by research category. If the registration includes multiple types of materials, the more stringent review procedure will apply.

5.1 Research Involving Recombinant DNA

Research involving rDNA is covered under one of six sections (Sections III-A through III-F) of the *National Institutes of Health (NIH) Guidelines for the Use of Recombinant DNA Molecules (NIH Guidelines).* Per the *NIH Guidelines*, the review procedures differ depending on which section the research falls under. The

Principal Investigator (PI) is responsible for submitting the IBC registration and to make an initial determination of which section of the NIH Guidelines (if any) the research falls under. The Chairperson and/or the Director of Research Compliance verify that the PI's initial determination of the NIH Guideline section is correct.

For human subject research involving rDNA, the PI is responsible for submitting materials to the NIH Recombinant DNA Advisory Committee (RAC), if necessary. The URI Director of Research Compliance can assist in reviewing materials for the RAC and/or provide guidance on the RAC review process, if needed.

NIH Section III-A

NIH Guidelines Section III-A covers experiments that involve the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.

Initial Registrations, Five Year Resubmissions, or Amendments that fall under Section III-A require review by the NIH RAC, approval by the NIH Director, and approval by the IBC using the Full Board Review procedure.

NIH Section III-B

NIH Guidelines Section III-B covers experiments that involve the deliberate formation of rDNA containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD_{50} of less than 100 nanograms per kilogram weight.

Initial Registrations, Five Year Resubmissions, or Amendments that fall under Section III-B require approval by the NIH Office of Biotechnology Activities (OBA) and approval by the IBC using the Full Board Review procedure.

NIH Section III-C

NIH Guidelines Section III-B covers experiments that involve the deliberate transfer of rDNA or DNA or RNA derived from rDNA into one or more human research participants.

Initial Registrations, Five Year Resubmissions, or Amendments that fall under Section III-C require review by the NIH RAC (if subject to Appendix M of the NIH Guidelines), approval by the institutional review board (IRB) assigned to the review, and approval by the IBC using the Full Board Review procedure.

NIH Section III-D

NIH Guidelines Section III-D covers experiments that involve:

- 1. Experiments that involve the introduction of rDNA into Risk Group 2 agents (or higher) (Section III-D-1)
- 2. Experiments in which DNA from Risk Group 2 or Risk Group 3 agents is transferred into nonpathogenic prokaryotes or lower eukaryotes (Section III-D-2)
- 3. Experiments involving the use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems (Section III-D-3)
- 4. Experiments involving whole animals in which the animal's genome has been altered by stable introduction of recombinant DNA, or DNA derived there from, into the germ-line (transgenic animals) and experiments involving viable recombinant DNA-modified microorganisms tested on whole animals (Section III-D-4)

- 5. Experiments to genetically engineer plants by recombinant DNA methods where BL3-P containment is recommended. (Section III-D-5)
- 6. Experiments Involving More than 10 Liters of Culture (Section III-D-6)
- 7. Experiments with some strains of influenza viruses generated by recombinant methods (Section III-D-7)

Initial Registrations, Five Year Resubmissions, or Amendments that fall under Section III-D require approval by the IBC using the Full Board Review procedure.

NIH Section III-E

NIH Guidelines Section III-E covers experiments that involve:

- 1. Experiments involving the formation of recombinant DNA molecules containing no more than two-thirds of the genome of any eukaryotic virus (Section III-E-1)
- 2. Experiments involving recombinant DNA-modified whole plants, and/or experiments involving recombinant DNA-modified organisms associated with whole plants where BL2-P or lower containment is recommended (Section III-E-2)
- 3. Experiments involving transgenic rodents Section III-E-3)
 - a. This section includes the generation of rodents in which the animals' genomes have been altered by stable introduction of recombinant DNA, or DNA derived there from, into the germ-line (transgenic rodents). Only experiments that require BL1 containment are covered under this section; experiments that require BL2, BL3, or BL4 containment are covered under Section III-D-4.

Initial Registrations, Five Year Resubmissions, or Amendments that fall under Section III-E require approval by the IBC using the Full Board Review procedure. However, the NIH Guidelines allows Section III-E research to commence as soon as the IBC is notified (through the submission and initial review of a registration). Notification of the IBC is confirmed through an email from the IBC to the investigator.

NIH Section III-F

NIH Guidelines Section III-F covers experiments that are exempt from the NIH Guidelines. The following rDNA molecules are exempt from the NIH Guidelines:

- 1. Those that are not in organisms or viruses (Section III-F-1).
- 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 (Section III-F-2).
- 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 (Section III-F-3).
- 4. Those that consist entirely of DNA from an 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) (Section III-F-4).
- 5. Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent (Section III-F-5)
- 6. Those that do not present a significant risk to health or the environment, as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment (Section III-F-6 and Appendix C).

Based on a risk assessment conducted by the Director of Research Compliance and/or the IBC Chairperson, Initial Registrations, Five Year Resubmissions, or Amendments may be approved by either the Full Board Review or Administrative Review procedure.

5.2 Research Involving Biological Agents

Research involving infectious microorganisms (including prions) that are or potentially are pathogenic to humans is reviewed and approved by the IBC. Research involving infectious microorganisms (including prions) that are not pathogenic to humans, but have the potential to cause disease in other animals will be evaluated to determine if a formal review is warranted. The review process is dependent on the risk assessment conducted by the Director of Research Compliance and/or the IBC Chairperson.

Initial Registrations, Five Year Resubmissions, or Amendments initially determined by the IBC Chairperson and/or Director of Research Compliance to warrant biosafety level 1 (BL1) practices and procedures may be approved by the Administrative Review procedure. Initial Registrations and Five Year Resubmissions initially determined to be conducted at biosafety level 2 (BL2) or higher or those that involving introducing biological agents into human subjects require approval by the IBC using the Full Board Review procedure. Amendments to research approved at BL2 may be approved by either the Full Board Review procedure or the Administrative Review procedure depending on the risk assessment conducted by the Director of Research Compliance and/or the IBC Chairperson.

5.3 Research Involving Human and Nonhuman Primate Materials

Research involving Human or non-human primate blood, unfixed human or non-human primate tissues, and human and non-human primate cell lines (established or primary) is reviewed and approved by the IBC. The review process is dependent on the risk assessment conducted by the Director of Research Compliance and/or the IBC Chairperson.

Based on a risk assessment, Initial Registrations, Five Year Resubmissions, or Amendments may be approved by the IBC using either the Full Board Review or Administrative Review procedure.

5.4 Research Involving Biological Toxins

Research involving biological toxins subject to the National Select Agents Registry Program managed by the U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) is reviewed and approved by the IBC. The review process is dependent on the risk assessment conducted by the Director of Research Compliance and/or the IBC Chairperson.

Based on a risk assessment conducted by the Director of Research Compliance and/or the Chairperson, Initial Registrations, Five Year Resubmissions, or Amendments may be approved by the IBC using either the Full Board Review or Administrative Review procedure.

6.0 OTHER APPLICABLE URI POLICIES

1. Review of Biological Research

7.0 DEVELOPMENT AND CONSULTATION

For consultation on this policy, please refer to the Director of Research Compliance.

ATTACHMENT II

Title: Review of Biological Research

Department: University of Rhode Island Institutional Biosafety Committee

Applies to: Employees, Staff or Other Agents of University of Rhode Island

Approval Date: December 4, 2012

Effective Date: December 4, 2012

Revision Date(s):

Next Review Date: December 4, 2012

Contact Person: Director, URI Research Compliance

1.0 KEYWORDS

IBC, Institutional Biosafety Committee, Full Board Review

2.0 PURPOSE

The purpose of this policy is to define the procedures the University of Rhode Island (URI) Institutional Biosafety Committee (IBC) follows when conducting review of Initial and five year resubmissions of Biological Research and review of proposed changes (amendments) in approved research of the IBC.

3.0 DEFINITIONS

See Definition of Biological Research, rDNA, Biological Agents, Human and Nonhuman Primate Materials, and Biological Toxins in the IBC Governance and Operating Policies.

4.0 POLICY STATEMENT

All Biological Research registrations must be reviewed at an IBC convened meeting at which more than half the members are present unless the research is eligible for review using the Administrative Review procedure (See Section 6.0). When reviewing Biological Research, the IBC Chairperson and IBC members are subject to the policy on IBC Member Conflicts of Interest.

5.0 CONVENED MEETING PROCEDURES

Meeting Dates

The IBC meeting dates and times are scheduled in advance. The meeting dates are posted on the IBC website.

Quorum

Biological Research registrations that cannot be reviewed using the Administrative Review procedure are reviewed at a convened meeting consisting of a quorum of the membership of the IBC. Alternate voting members can be counted towards a quorum when they are attending as a replacement to a voting member. In addition, reasonable efforts will be made to ensure that at least one unaffiliated member representing the views of the surrounding communities are present at each meeting. A quorum is defined as more than one-half the voting membership.

Determining Agenda, Attendance and Assigning Reviewers

- 1. Prior to each convened meeting, members are asked to confirm that they will attend the meeting. This is necessary to determine that the requirement for a quorum will be met and that members with the appropriate scientific expertise will be in attendance.
- 2. The Director of Research Compliance, the IBC Chairperson, and the IBC Specialist review the agenda and list of members expected to attend and at their discretion assign reviewers. Generally, registrations are scheduled for review by receipt date; however, the IBC reserves the right to reschedule registrations for review based on the experience and expertise of the members planning to attend the IBC meeting.
- 3. The Director of Research Compliance and IBC Specialist are responsible for ensuring that one member attending the meeting has the necessary knowledge and expertise to review each of the registrations listed on the agenda.
- 4. When making reviewer assignments, the IBC Chairperson takes into consideration the scientific discipline and study procedures described in the registration and the experience and expertise of the members attending the meeting.
- 5. The qualifications, experience, and expertise of each member, are documented in the IBC roster. Member CVs are also on file in the URI Office of Research Compliance. The IBC Chairperson and Director of Research Compliance have access to the IBC roster and member CVs when making reviewer assignments.
- 6. The primary reviewer is typically an individual with expertise in the type of research under consideration. The primary reviewer is responsible for performing an in-depth review of all aspects of the registration, standard operating procedures, and when applicable, consent form and associated materials, the investigational drug brochure, and study protocol.
- 7. Reviewers are encouraged, although not required, to contact the principal investigator (PI) (through the IBC Specialist) prior to the meeting if they have questions about the study, particularly if they have significant concerns about the study or believe additional information is needed for the IBC to assess the risks and anticipated benefits, if any, to subjects.

Use of Consultants

- Ad hoc consultants may be used to supplement or provide expertise not available on the IBC.
 The IBC Chairperson, reviewing the draft agenda to make primary and secondary reviewer
 assignments, is responsible for determining whether the IBC membership includes the necessary
 expertise to review the registration and/or whether the expertise of an ad hoc consultant would
 be advisable.
- When, in the opinion of the IBC Chairperson, the IBC membership lacks the expertise needed to review the registration, the IBC Chairperson, in consultation with the Director of Research Compliance, identifies potential expert consultants.
- 3. Additionally, the IBC may vote to defer action on a registration and may require an expert in the scientific area or discipline to review the research and provide consultation to the IBC.
- 4. Ad hoc consultants are subject to the Policy on IBC Member Conflicts of Interest and must confirm in writing that they have no conflict of interest. If the ad hoc consultant agrees to

- review the research and the consultant has no conflict of interest, s/he is provided with all of the forms and documents submitted to the IBC for review.
- 5. Ad hoc consultants are asked to attend the meeting to present their findings relative to the safety of the study and the risks and potential benefits, and to answer questions. If the consultant is unavailable to attend the meeting, s/he may provide written comments for distribution or communication to the IBC members. Ad hoc consultants are not voting members, and their attendance is recorded in the Minutes as guests (consultant).

Distribution of Materials and Review by Members

- 1. Investigators who rely upon the IBC for IBC review of Biological Research are required to complete application forms and provide all required information and documents to the IBC Office for review by the IBC as described in the IRBNet Registration Submission Instructions.
- 2. Typically 10 days prior to the meeting, access to the forms and documents submitted for IBC review for each item on the agenda are provided to all members planning to attend the meeting either by distributing copies and/or granting access to the IBC members to materials on the IRBNet system. For initial review, five year resubmissions, and review of proposed changes in approved research, the agenda also includes references to relevant regulatory documents and IBC policies and procedures.
- 3. Assigned reviewers are responsible for an in-depth review of all of the materials provided to them relevant to the research. Members who are not assigned to review the registration are expected to review all of the materials provided to them relevant to the research in sufficient depth to discuss and to vote on the research at the convened meeting.
- 4. For initial review, all members attending the meeting receive a copy of all materials submitted by the investigator.
- 5. For five year resubmissions, every member attending the meeting receives copies of the required forms and documents submitted by the investigator. All members also receive a summary report that provides an overview of the registration and list of all IBC reviews. The entire registration file and minutes of meetings at which the registration was reviewed previously are available to all members upon request.
- 6. For review of amendments to approved research, every member attending the meeting receives copies of the required forms and documents submitted by the investigator for the proposed change. The entire registration file is available to all members upon request.

Conflicts of Interest

- 1. IBC members are subject to the policy on IBC Member Conflicts of Interest. The agenda for every meeting includes a reminder about the conflicts of interest policy.
- 2. Any member with a conflict of interest is asked to recuse him/herself and leave the room while the registration is being reviewed. Exceptions may be made by the IBC Chairperson to allow for the conflicted member to provide information to the IBC after the nature of the conflict is disclosed. After the member relates the factual information, the member must leave the room for the discussion and vote on the registration.

- 3. The names of those voting members who were recused from voting due to a conflict of interest are recorded in the Minutes.
- 4. Recused members are not counted towards the quorum requirement; therefore, if a quorum of the membership is not present for the review of any registration, no vote is taken and the registration is held over for review at the next meeting.

Discussion and Vote

- 1. The Director of Research Compliance or designee takes attendance at the meeting and records voting members present and absent for each review. Late arrivals, early departures, and individuals recused or out of the room for whatever reason during the vote on each registration are recorded in the Minutes.
- 2. The IBC Chairperson and assigned reviewers lead the discussion of each new registration, five year resubmission, or amendment listed on the meeting agenda.
- 3. The primary reviewer presents a brief synopsis of the research registration, with the expectation that the other members have reviewed the registration materials.
- 4. Secondary reviewers are asked to present any additional clarifications or commentary on the registration, and any questions or concerns, or modifications s/he would require for approval.
- 5. If human subjects research and if applicable, both the primary and secondary reviewers are expected to provide an in-depth review of the consent form and study protocol and make recommendations for changes to these documents.
- 6. Reviewers are encouraged to provide written comments so that the IBC Chairperson and/or IBC Specialist can convey the questions and concerns raised by the reviewers and the IBC, and/or specific modifications or stipulations required by them accurately and precisely.
- 7. After the primary reviewer has presented the study and their review comments, the IBC Chairperson opens the registration up for discussion by the membership. The IBC Chairperson and members may direct specific questions to the assigned reviewers or to other members with specific expertise.
- 8. At the end of the discussion, any member may make a motion to approve, require modifications or stipulations in the research (to secure approval), defer action on (pending receipt of additional information), or disapprove the registration. A vote on the motion is taken (for, against, or abstain) by show of hands or voice vote and recorded in the Minutes. All motions are decided by majority vote of the members present for the review. A quorum of the members of the IBC (more than one-half the members) must be present in order for the IBC to take a vote.
- 9. Approvals for initial reviews are granted for a period of five years (or less if committee deems appropriate). The approval period begins the date the registration is approved (or approved with modifications) at the convened meeting and expires five years after the approval date. Amendments to approved research do not change the initial expiration date.

Amendments (Proposed Changes)

1. Amendments to approved research are required for administrative changes (e.g., changes to staff, laboratory location, funding source, and title) and scientific changes. Scientific changes that require amendments include i) addition of new Biological Agents (including new strains or

- subtypes), rDNA, or Biological Toxins, ii) addition or changes to laboratory procedures, iii) additional of new animal studies, iv) anything that alters the risk of the biosafety assessment.
- 2. For human subject research, amendments are required for changes to the study product, dosing levels, dosing groups, or any other change that will alter the biosafety risk assessment of the research.
- 3. Amendments to previously approved research may be conducted using the Administrative Review procedure for the following:
 - a. Change to administrative items, such as changes to staff, laboratory location, funding source, or registration title.
 - b. Addition or change to non-rDNA laboratory research such that no additional risks have been identified since the initial review.
 - c. Addition or change to research involving rDNA subject to Section III-F of the NIH Guidelines.

Five Year Resubmission

- Five Year Resubmission review of the research is required until the research has been completed
 or has been closed prior to completion. The investigator must submit the resubmission review
 form to document that the study has been completed or is being closed prior to completion. For
 human subject research, the research may be considered completed or may be closed prior to
 completion when the investigator at this site is no longer collecting or receiving identifiable
 data.
- 2. Five Year Resubmission review of research previously approved by the convened IBC may be conducted using the Administrative Review procedure as follows:
 - a. Laboratory research such that no additional risks have been identified since the last review.
 - b. Human subjects research such that (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (iv) where no subjects have been enrolled and no additional risks have been identified.

Requiring Modifications, Deferring Action, or Disapproving Research and Responses to Review Notification Letters

Require modifications or stipulations in research to secure approval
 When the IBC votes to require modifications or stipulations in the research (to secure approval),
 the PI is notified in writing of the action voted on by the IBC and the required modifications or
 stipulations to the research.

The IBC Specialist and/or URI Environmental Health and Safety (EHS) will ensure that the PI or their designee has implemented the required modifications or stipulations. If they have not, the IBC Specialist and/or URI EHS will report back to the Director of Research Compliance and the issue will be discussed at the next convened meeting of the IBC.

An investigator may appeal modifications/stipulations included in the IBC approval in writing directly to the IBC Specialist and IBC Chairperson. The Director of Research Compliance is responsible for reviewing the appeal with the IBC Chairperson. The appeal is then scheduled for review at a convened meeting of the IBC. The investigator may appeal the decision of the IBC in person at the convened meeting.

Proposed changes submitted with the response are reviewed in accordance with the policies and procedures for review of proposed changes, i.e., either at a convened meeting or, if minor, using the Administrative Review procedure.

2. Defer research for more information

When the IBC votes to defer action pending receipt of additional information, the PI is notified in writing of the action voted on by the IBC and any questions and concerns that need to be addressed as well as modifications required to the research. The PI is asked to submit a point-by-point response and revised documents to the IBC within 60 days of the review date. Unless the PI requests an extension or there are extenuating circumstances, the registration is withdrawn from further review at the end of the 60-day period if no response is received.

When received, the PI's response, including revised documents, is scheduled for review at the next convened meeting of the reviewing IBC.

3. Disapprove

When the IBC disapproves the research, the PI is notified in writing of the action voted on by the IBC and the basis for the disapproval. Disapproval means that the study as designed cannot be approved.

The decision of the IBC to disapprove the research cannot be overruled by any other institutional body or individual(s); however, an investigator may appeal the decision of the IBC in writing directly to the Director and Chair of the IBC. The Director of the IBC is responsible for reviewing the appeal with the IBC Chairperson. The appeal is then scheduled for review at a convened meeting of the IBC that disapproved the research. The investigator may appeal the decision of the IBC in person at the convened meeting.

Approval Notification to Principal Investigator and the Institution

- 1. PIs are notified in writing of IBC approval of initial, five year resubmissions and amendments. The approval letter includes the date of IBC approval and the date upon which IBC approval expires.
- 2. All registration documentation (i.e., completed forms, attachments, approval letter) are stored within the IRBNet system and available to the PI.
- 3. Minutes of IBC meetings are made available electronically to the Institutional Officials.

6.0 EXPEDITED REVIEW PROCEDURES

Investigators relying on the IBC for IBC review of Biological Research are required to complete application forms and provide all required information and documents to the URI Office of Research

Compliance for review by the IBC. Based on the type of activities described in the registration, the registration may be either scheduled for review at a convened meeting of the IBC or reviewed through the Expedited Review procedure. Certain types of research, including research that is covered by Sections III-A through III-E of the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) are not eligible for Expedited Review per the NIH Guidelines. Additionally, the Director of Research Compliance or any member of the IBC may request that a registration be reviewed at a convened meeting regardless of the type of activities. The IBC Chair may approve, require modifications or stipulations (to secure approval) or defer action pending receipt of additional information from the Principal Investigator (PI). The IBC Chair may not disapprove a registration using the Expedited Review procedure; registrations can only be disapproved by the IBC at a convened meeting.

The IBC Chairperson may consult another IBC member(s) or an ad hoc consultant; however the IBC Chairperson is responsible for the review and approval of research using the Expedited Review procedure. When an ad hoc consultant is used, the IBC Chairperson or designee is responsible for communicating with the ad hoc consultant and for verifying that the consultant does not have a conflict of interest as defined in the Conflicts of Interest Policy for IBC Members.

When the IBC Chairperson requires modifications or stipulations in the research to secure approval or defers action pending receipt of additional information, the IBC Office notifies the PI in writing of the required modifications or additional information required for review. The PI is asked to submit a point-by-point response and revised documents to the IBC within 60 days of the review date. Unless the PI requests an extension or there are extenuating circumstances, the research is withdrawn from further review at the end of the 60-day period if no response is received.

When received, the IBC Chairperson reviews the Pl's response, including revised documents, and determines whether the modifications or stipulations have been made as requested and the research can be fully approved. The IBC Chairperson may continue to request additional modifications or information until the research is approved or referred for full board review at a convened meeting of the IBC.

Initial Review

Research activities that <u>may</u> be initially reviewed by the IBC through the Expedited Review procedures include:

- 1. Research that is determined by the IBC Chairperson and/or Director of Research Compliance to be covered by Section III-F of the NIH Guidelines.
- 2. Research involving Biological Agents that is initially determined by the Chairperson and/or Director of Research Compliance to warrant biosafety level 1 (BL1) practices and procedures.
- 3. Research involving only the human or nonhuman primate materials.
- 4. Research involving use of biological toxins.

Research in any of these categories may require review at a convened meeting of the IBC if a risk assessment determines identifies unique aspects of the research that should be discussed by the IBC.

Amendments (Proposed Changes)

Amendments to research activities that <u>may</u> be reviewed by the IBC through the Expedited Review procedures if the proposed changes include:

- 1. Research that is determined by the IBC Chairperson and/or Director of Research Compliance to be covered by Section III-F of the NIH Guidelines.
- 2. Research that is determined by the IBC Chairperson and/or the Director of Research Compliance to be covered by Section III-D or III-E of the NIH Guidelines and does not include any substantial changes in the biosafety risk assessment.
- 3. Research involving Biological Agents that is initially determined by the IBC Chairperson and/or and Director of Research Compliance to warrant BL1 or biosafety level 2 (BL2) practices and procedures, if current approval is for same or higher biosafety level.
- 4. Research involving only the human or nonhuman primate materials.
- 5. Research involving use of biological toxins.

Five Year Resubmissions

Research activities that are reviewed as part a five year resubmission that <u>may</u> be reviewed by the IBC through the Expedited Review procedures include:

- 1. Laboratory research such that no additional risks have been identified since the last review.
- 2. Human subjects research such that (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (iv) where no subjects have been enrolled and no additional risks have been identified.

7.0 OTHER APPLICABLE URI POLICIES

- 1. IBC Member Conflicts of Interest.
- 2. Defining Review Procedures for Categories of Biological Research.

8.0 DEVELOPMENT AND CONSULTATION

For consultation on this policy, please refer to the Director of Research Compliance.