THE
UNIVERSITY
OF RHODE ISLAND
DIVISION OF RESEARCH
AND ECONOMIC
DEVELOPMENT

Institutional Biosafety Committee Governance and Operating Policies

December 2018

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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

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- The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines),* https://osp.od.nih.gov/biotechnology/nih-guidelines/

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 and Synthetic Nucleic Acids

The *NIH Guidelines* defines recombinant and synthetic nucleic acids are defined as: (i) molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids; (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or (iii) molecules that result from the replication of those described in (i) or (ii) above.

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 Integrity 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 Integrity

The Director of Research Integrity is responsible for the administrative leadership of the IBC. The Director of Research Integrity 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.

On 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). PIs 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 Biological Research (and recombinant or synthetic nucleic acid molecule technology) and together have the capability to assess the safety of Biological 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 recombinant or synthetic nucleic acid molecule 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 Integrity 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 IBC

The function of the IBC shall be reviewed at least annually to ensure that the committee is meeting the requirements of the NIH Guidelines and that the 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 Integrity shall be responsible for reviewing the actions of the IBC and 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 Integrity 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 Integrity 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 Integrity, 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 the 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 Integrity 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 Membership Orientation, Training, and Education

New IBC member orientation consists of reviewing the following with the Director of Research Integrity: 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 or complete biosafety training through the Collaborative Institutional Training Initiative (CITI Program). 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 Integrity 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 below. In preparation for each meeting, the Director of Research Integrity 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 Science Policy. 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 Integrity or designee 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 Integrity and/or Chairperson shall assign reviewer(s) to each Biological Research activity on the agenda requiring review.

When making review assignments, the Director of Research Integrity and/ or 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 Integrity; 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 Integrity 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, but not limited to, the IBC Registration Document, training records, and standard operating procedures. The primary reviewer(s) shall be responsible for notifying the Director of Research Integrity if s/he has a conflict of interest as defined in Section 10. In such cases, the Chairperson or designee shall reassign review of the research activity to another member.

11.3 Members not assigned as Primary Reviewers

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 votes on each research activity.

11.5 Attendance

Voting members are expected to attend the majority of IBC meetings. Anticipated absences from an IBC meeting should be communicated to the Director of Research Integrity or designee at least seven (7) days prior to the meeting.

11.6 Guests

As required by the NIH Guidelines, IBC meetings (when possible and consistent with protection of privacy and proprietary interests) are open to the public. 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 Integrity 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 Integrity 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 Integrity. 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 amended as needed.

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 Integrity 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 Integrity (i.e., Expedited Review). 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 (i.e., Expedited Review).

12.5 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.

12.6 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 Integrity.

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 Integrity **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 Science Policy

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 OSP within 30 days. Reports to NIH/OSP shall be sent to the following address: Office of Science Policy 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 OSP shall be sent to the following address: Office of Science Policy 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 Integrity 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 Integrity 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 Integrity website and shall be maintained by the URI Office of Research Integrity 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 Integrity.

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

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

Theodore A. Myatt, Sc.D.
Division of Research and Economic Development
70 Lower College Road
Kingston, RI 02881
401 874-2636

1.0 ATTACHMENT I: Defining Review Procedures for Categories of Biological Research

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):	August 31, 2016, December 6, 2018
Next Review Date:	December 6, 2019
Contact Person:	Director, URI Research Integrity

1.1 Keywords

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

1.2 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 or synthetic nucleic acid molecules (rDNA)
- Research involving Biological Agents
- Research involving Human and Nonhuman Primate Materials
- Research involving Biological Toxins

1.3 Definitions

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

1.4 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 (Expedited Review).

1.5 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.

1.5.1 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 Integrity 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 Integrity 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 Science Policy (OBA) and approval by the IBC using the Full Board Review procedure.

NIH Section III-C

NIH Guidelines Section III-C 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 institutional review board (IRB) assigned to the review, and approval by the IBC using the Full Board Review procedure. The IBC can, during its evaluation of human gene transfer protocols, request that the NIH RAC review the protocol and provide comment.

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).
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 (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 Integrity and/or the IBC Chairperson, Initial Registrations, Five Year Resubmissions, or Amendments may be approved by either the Full Board Review or Expedited Review procedure.

1.5.2 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 Integrity and/or the IBC Chairperson.

Initial Registrations, Five Year Resubmissions, or Amendments initially determined by the IBC Chairperson and/or Director of Research Integrity to warrant biosafety level 1 (BL1) practices and procedures may be approved by the Expedited 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 Expedited Review procedure depending on the risk assessment conducted by the Director of Research Integrity and/or the IBC Chairperson.

1.5.3 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 Integrity 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 Expedited Review procedure.

1.5.4 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 Integrity and/or the IBC Chairperson.

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

1.6 Other Applicable URI Policies

- Review of Biological Research

1.7 Development and Consultation

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

2.0 ATTACHMENT II: Review of Biological Research

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):	August 31, 2016
Next Review Date:	December 6, 2019
Contact Person:	Director, URI Research Integrity

2.1 Keywords

IBC, Institutional Biosafety Committee, Full Board Review

2.2 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.

2.3 Definitions

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

2.4 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 Expedited 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.

2.5 Convened Meeting Procedures

2.5.1 Meeting Dates

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

2.5.2 Quorum

Biological Research registrations that cannot be reviewed using the Expedited 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.

2.5.3 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 Integrity, 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 Integrity 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 Integrity. The IBC Chairperson and Director of Research Integrity 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.

2.5.4 Use of Consultants

1. 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.
2. 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 Integrity, 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).

2.5.5 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.

2.5.6 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.

2.5.7 Discussion and Vote

1. The Director of Research Integrity 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.

2.5.8 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 Expedited 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.

2.5.9 Five Year Resubmission

1. 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 Expedited 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.

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

1. 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 Director of Research Integrity, IBC Specialist and/or IBC Chairperson will review modified materials to ensure the PI has sufficiently addressed the required modifications or stipulations. If they have not, the PI will be notified in writing that additional modifications are needed to secure approval. If requested by the IBC, the IBC Specialist and/or URI EHS will conduct an inspection of modifications or stipulations to ensure they have been implemented. The IBC Specialist and/or URI EHS will report back to the Director of Research Integrity 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 Integrity 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 Expedited 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.

2.5.11 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.

2.6 Expedited Review Process

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 Integrity 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 Integrity 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 PI'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.

2.6.1 Initial Review

Research activities that may 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 Integrity 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 Integrity to warrant biosafety level 1 (BL1) practices and procedures.
3. At the discretion of the IBC Chairperson and/or Director of Research Integrity, research involving Biological Agents that warrant biosafety level 2 (BL2) practices

and procedures, when the Principal Investigator (PI) already has obtained approval for a separate application that involves BL2 Biological Agents.
4. Research involving only the human or nonhuman primate materials.
5. 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.

2.6.2 Amendments (Proposed Changes)

Amendments to research activities that may 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 Integrity 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 Integrity 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 Integrity 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.

2.6.3 Five Year Resubmissions

Research activities that are reviewed as part a five year resubmission that may 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.

2.7 Other applicable URI Policies

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

2.8 Development and Consultation

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

3.0 ATTACHMENT III: Institutional Oversight of DURC

Title:	Institutional Oversight of DURC
Department:	University of Rhode Island Institutional Biosafety Committee
Applies to:	Employees, Staff or Other Agents of University of Rhode Island
Approval Date:	May 25, 2016
Effective Date:	May 25, 2016
Revision Date(s):	August 31, 2016, December 6, 2018
Next Review Date:	December 6, 2019
Contact Person:	Director, URI Research Integrity

3.1 Keywords

IBC, Institutional Biosafety Committee, Full Board Review

3.2 Purpose

This policy sets forth instructions for individuals and committees at the University of Rhode Island (URI) who are responsible for the implementation of the University's requirements with respect to Dual Use Research of Concern ("DURC"). This policy is intended to strengthen the institutional review and oversight by the University of life sciences research to identify potential DURC and to develop and implement risk mitigation where appropriate, and as required by federal regulation. In so doing, this Policy is intended to preserve the benefits of life sciences DURC while minimizing the risk that the output of such research could be used for harmful purposes.

3.3 Definitions

A. **Dual Use Research.** Research conducted for legitimate purposes that can be utilized for both benevolent and harmful purposes.

B. **Dual Use Research of Concern ("DURC").** Life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat, with broad potential consequences, to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

C. **DURC Agents:** Agents and toxins specified by the U.S. Government as governed by its DURC policy. The below list of agents and toxins will be subject to revision to reflect future changes in federal DURC policy, but as currently defined, the following 15 agents and toxins, in any quantity, are governed by federal and University policy on DURC:

1. Avian influenza virus (highly pathogenic)
2. *Bacillus anthracis*
3. Botulinum neurotoxin (For purposes of this Policy, there are no exempt quantities of botulinum neurotoxin. Research involving any quantity of botulinum neurotoxin should be evaluated for DURC potential.)
4. *Burkholderia mallei*
5. *Burkholderia pseudomallei*
6. Ebola virus

7. Foot-and-mouth disease virus
8. *Francisella tularensis*
9. Marburg virus
10. Reconstructed 1918 Influenza virus
11. Rinderpest virus
12. Toxin-producing strains of *Clostridium botulinum*
13. Variola major virus
14. Variola minor virus
15. *Yersinia pestis*

D. **Experimental Effects of Concern:** the following 7 categories of experiments:
   1. Enhances the harmful consequences of the agent or toxin.
   2. Disrupts immunity or effectiveness of an immunization against the agent or toxin, without clinical and/or agricultural justification.
   3. Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies.
   4. Increases the stability, transmissibility or the ability to disseminate the agent or toxin.
   5. Alters the host range or tropism of the agent or toxin.
   6. Enhances the susceptibility of a host population to the agent or toxin.
   7. Generates or reconstitutes an eradicated or extinct agent or toxin listed in the definition of DURC Agents above.

E. **Principal Investigator. ("PI")** A PI is an individual who is designated by URI to direct a project or program and who is responsible to the funding agency or URI for the scientific and technical direction of that project or program. There may be more than one PI on a research grant or project.

F. **Institutional Review Entity ("IRE").** The committee charged with establishing and implementing internal policies and practices that allow for the identification and oversight of DURC, and that reviews proposed research that will utilize a DURC Agent. The URI Institutional Biosafety Committee (IBC) serves as the IRE for URI. The Vice President for Research and Economic Development, the IBC Chair, and the ICDUR (defined below) can request *ad hoc* consultants provide IRE expertise with regard to ethics and compliance, export controls regulations and other knowhow as needed.

G. **Institutional Contact for Dual Use Research ("ICDUR"):** The individual designated by the Vice President for Research and Economic Development to be the institutional point of contact for researchers' questions relating to compliance with this Policy and to serve as the liaison with the relevant U.S. Government funding agencies. The ICDUR for URI is the Director of Research Integrity.

H. **Risk Mitigation Plan:** A plan that describes the DURC-associated risks identified by the IRE, the specific risk mitigation measures to be employed, and how these measures address the identified risks.

I. **U.S. Funding Agency:** The U.S. Government agency that is funding the subject research. If a federal department or agency simply passes through funding from another federal department, agency or non-federal entity to support life sciences research involving one

or more of the DURC Agents, the agency originally providing the funding shall be considered the U.S. Funding Agency. Where the agency providing funding is a non-federal entity NIH shall be considered the U.S. Funding Agency.

3.4 Policy

3.4.1 Purpose and Scope of Policy

A. Purpose

This policy is intended to comply with federal requirements for review of Dual Use Research of Concern ("DURC") to:

- Strengthen the institutional review and oversight by URI of specifically defined life sciences research
- Identify potential DURC
- Develop and implement risk mitigation where appropriate
- Set forth instructions for individuals and committee at URI responsible for the implementation of the University's requirements with respect to DURC, and
- Preserve the benefits of dual use life sciences research while minimizing the risk that the output of such research would be intentionally used for harmful purposes.

B. Scope

This policy shall apply only to life sciences research conducted at URI that may constitute DURC.

3.4.2 Investigator Responsibilities

A. Before commencing research with DURC Agents, the Principal Investigator ("PI") must first make a determination about whether:
    1. The research directly involves non-attenuated forms of one or more of the potential DURC Agents; or
    2. The research with non-attenuated forms of one or more of the DURC Agents also produces, aims to produce, or can reasonably be anticipated to produce one or more Experimental Effects of Concern; or
    3. His/her research may meet the definition of DURC. If research is determined not to meet the DURC criteria, it is the responsibility of the PI to monitor his or her research on an ongoing basis and notify the IRE if anything changes that may alter the IRE determination.

B. The PI's assessment in regarding the above should be summarized in writing and this summary shall be registered and retained with the IRE via the ICDUR. The PI will provide the ICDUR with documentation, indicating the reasons for concluding that his/her research involves, or does not involve potential DURC, along with sufficient data to permit the IRE to complete the review.

C. If the IRE determines that the proposed research is DURC, the PI will be expected to:
    1. Collaborate with the IRE to develop the Risk Mitigation Plan.
    2. Conduct DURC in accordance with the final Risk Mitigation Plan;
    3. Notify the ICDUR of any substantive change in the on-going conduct of the DURC;
    4. Notify the ICDUR if for whatever reason (e.g., changes in the research, new discoveries), he/she feels that the research should no longer be considered DURC;

5. Ensure that laboratory personnel (i.e., those under the supervision of laboratory leadership, including graduate students, postdoctoral fellows, research technicians, laboratory staff and visiting scientists) conducting research with one of more of DURC Agents have received appropriate education and training on DURC;
6. Be knowledgeable about and comply with all URI and federal policies and requirements for oversight of DURC; and
7. Communicate about the DURC in a responsible manner and in compliance with the approved risk mitigation plan.

3.4.3 Institutional Responsibilities

A. The University shall ensure that no research with DURC Agents will be conducted unless the Principal Investigators conducting research with one of more of DURC Agents have received education and training on DURC. This education and training must be sufficient to allow them to undertake an initial assessment to determine whether the research they wish to undertake is potentially DURC.

B. The ICDUR will be the institutional point of contact for researchers' and administrators' questions relating to compliance with this Policy and will also be the liaison with the relevant U.S. Funding Agencies.

The ICDUR shall:

- As necessary, advise the PIs in conducting the life sciences research in accordance with federal and University policies when questions arise about whether their research may require further review of oversight as DURC.
- On behalf of the IRE, conduct an initial assessment of information provided by the PI to determine whether the research involves one or more of the 15 listed agents and if it involves one of the seven experimental effects.
- Upon determining that the research does involve one of the seven experimental effects, the ICDUR will notify the members of the IRE which will then convene to assess the research to determine if it meets the DURC criteria. If the research is determined to not involve one of the seven experimental effects, the ICDUR will notify the IRE accordingly.
- Notify the relevant U.S. Funding Agency as to whether or not research involving one or more of the 15 agents and one or more of the seven experiments effects meets the definition of DURC within 30 calendar days.
- Ensure that the IRE reviews each DURC Risk Mitigation Plan annually;
- Ensure that education and training on DURC is available for individuals conducting research with one or more of the DURC Agents and that records of such education and training are retained for the term of the research grant or contract plus three years after its completion;
- Ensure that records of institutional DURC reviews and completed Risk Mitigation Plans are retained for no less than eight years, unless a shorter period is permitted by law or regulation;
- Notify the relevant Program Officer of the applicable U.S. Funding Agency within 30 calendar days of any change in the status of any DURC, including whether such research has been determined by the IRE to no longer meet the definition of DURC. The notification should include details of any changes to an approved Risk Mitigation Plan, which must be approved by the U.S. Funding Agency.

- Report within 30 calendar days to the applicable U.S. Funding Agency instances of noncompliance with this Policy, as well as mitigation measures undertaken to prevent recurrences of similar noncompliance.
- Liaison with the National Institutes of Health ("NIH") on DURC that is non-federally-funded.
- Ensure that URI can certify that it is, or will be, in compliance with the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern when applying for or accepting federal funding for life sciences research.

C. IRE Review Process: Based on the materials provided by the PI and ICDUR, along with any other relevant information, the IRE shall first determine whether the subject research directly involves non-attenuated forms of one or more of the DURC Agents. Guidance on points to consider while making this assessment can be found in NIH's "Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern (the "Companion Guide"). The ICDUR may, on the IRE's behalf, consult the applicable U.S. Funding Agency or, if support for research does not come from a U.S. Funding Agency, consult the NIH Office of Science Policy, for advice about DURC. In making its assessment, the IRE should examine descriptions of the research, the PI's assessment and other relevant information such as the project proposal, any project reports, any previous outcomes of Dual Use reviews and examples of similar research in the literature. When considering whether the research in question meets the definition of DURC, the IRE should identify the risks associated with the potential misuse of the knowledge, information, technologies or products (collectively, the "Research Output") that may be generated and assess the following:
    - The ways in which the research output could be misused to harm public health and safety, agriculture, plants, animals, the environment, materiel or national security;
    - The ease with which the research output might be misused and the feasibility of such misuse; and
    - The magnitude, nature and scope of the potential consequences of misuse.

    Guidance on points to consider while making this assessment can be found in the Companion Guide.

    1. <u>If the IRE determines the research is not DURC</u>, the Director of Research Integrity shall promptly advise the PI in writing that the research is not subject to DURC oversight under this policy or federal policy, and the ICDUR shall, within 30 days of the IRE's determination, notify the relevant U.S. Funding Agency.
    2. <u>If the IRE determines the research meets the definition of DURC</u>, the Director of Research Integrity will promptly so notify the PI and within 30 calendar days, the applicable US Funding Agency, and shall proceed to develop a Risk Mitigation Plan.

    In order to determine the acceptable level of risk and the best mitigation strategies, the IRE should assess the potential benefits of the research and then weigh the risks and benefits.

The IRE may consider the PI's input in developing a draft Risk Mitigation Plan. The Plan should indicate the DURC-associated risks, the specific risk mitigation measures to be employed and how these measures address the identified risks. Strategies for mitigating risks could include:

- Applying additional biosafety or biosecurity measures
- Modifying the experimental design or methodology
- Planning for medical countermeasures
- Educating and training research staff
- Developing a specific monitoring plan
- Not conducting certain aspects of the research, if doing so would result in a U.S. Funding Agency's imposition of publication or citizenship restrictions that contravene UC policy protecting freedom to publish or disseminate research results. For example, including such restrictions in a Risk Mitigation Plan could potentially jeopardize URI's Fundamental Research Exclusion (FRE) under export control regulations and require imposition of export controls requirements to the research, in violation of the above URI policies.

At the conclusion of its review of research that the IRE determines meets the definition of DURC, the IRE will submit its findings and its recommendations as to the elements of the draft Risk Mitigation Plan to the PI and to the Vice President for Research and Economic Development.

The PI shall have the right to make a timely appeal to the Vice President for Research and Economic Development or designee regarding the IRE's recommendation. In the event the PI appeals the IRE's recommendation, the Vice President for Research and Economic Development or designee shall be authorized to determine the merits of the PI's appeal and communicate that decision to the PI and the IRE.

The Vice President for Research and Economic Development or designee shall determine whether to act on the recommendations of the IRE, and is authorized to approve the institutional determination that the research is DURC and the institution's recommended Risk Mitigation Plan that are conveyed by the ICDUR to the U.S. Funding Agency. Within 90 calendar days following the final institutional approval of the draft Risk Mitigation Plan by the Vice President for Research and Economic Development or designee, the ICDUR shall submit such draft plan to the applicable U.S. Funding Agency for final review and approval. The IDCUR and the PI will respond to any questions and concerns that the U.S. Funding agency may have regarding the draft Risk Mitigation Plan. Upon approval of the draft Plan by the U.S. Funding Agency, the IRE must communicate the final Risk Mitigation Plan to the PI and the ICDUR will collaborate with the PI to ensure its implementation.

For research determined to be DURC, the IRE shall review, at least annually, all active Risk Mitigation Plans at the University. The IRE, working with the PI shall modify the applicable Risk Mitigation Plan as needed to ensure that the Plan still adequately mitigates the risks associated with the DURC.

D. Subawards: Federal DURC policy requires that where elements of a potential DURC project are being carried out at multiple institutions through a subaward with a primary institution that directly receives the grant or contract from the U.S. Funding Agency, (the "Prime Institution"), the Prime Institution will be responsible for notifying the applicable U.S. Funding Agency of research that may constitute DURC and if such

research is determined to be DURC, providing copies of each institution's Risk Mitigation Plan. The Prime Institution should also ensure that DURC oversight is consistently applied by all entities participating in the collaboration. If the Prime Institution's procedures or standards are less rigorous than the subawardee's the more rigorous standard will be applied.

3.5 Compliance / Responsibilities

The Vice President for Research and Economic Development is responsible for ensuring compliance with this policy.

3.6 Procedures

Not Applicable

3.7 Related Information

- United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern (2012): http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf
- United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (2014) http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf
- Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern (the "Companion Guide"): http://www.phe.gov/s3/dualuse/Documents/durc-companion-guide.pdf
- Implementation of the U.S. Government Policy for Institutional Oversight of Life Sciences DURC: Case Studies: http://www.phe.gov/s3/dualuse/Documents/12-case-studies-durc.pdf
- Training on the US Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern: http://www.phe.gov/s3/dualuse/Documents/durc-us-policy-trng.pdf
- National Institutes of Health ("NIH") Notice NOT-OD-15-017: NIH Implementation of the US Government Policy on Institutional Oversight of Life Sciences Dual Use Research of Concern issued on November 21, 2014: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-017.html