Marine Biological Laboratory

THE UNIVERSITY OF CHICAGO

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) POLICY & PROCEDURES MANUAL

FEBRUARY 2018

APPROVAL:

DAVID MARK WELCH	DIRECTOR, DIVISION OF RESEARCH	2/9/18 DATE
JOSHUA ROSENTHAL	INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) CHAIR	2/9/18 DATE
SIMON N MUCHOHI	BIOSAFETY OFFICER	02/09/2018 DATE

TABLE OF CONTENTS

1 PURPOSE AND SCOPE

The Marine Biological Laboratory (MBL) Institutional Biosafety Committee (IBC) is responsible for review and approval of research conducted at the MBL involving recombinant or synthetic nucleic acid molecules, other biohazardous materials, and the creation and/or use of genetically altered organisms, or other organisms, that present a risk to human health or the environment.

1.1 Purpose

The purpose of this document is to outline the policies and procedures that the IBC will follow in reviewing research protocols involving recombinant or synthetic nucleic acid molecules, biohazardous agents, biological toxins and organisms that present a risk to human health or the environment. The IBC ensures that research and teaching activities using these materials and conducted at MBL are in compliance with Federal, State and local laws and regulations, and MBL policies.

1.2 Scope

The IBC Policy and Procedures apply to all research and teaching activities conducted at MBL (regardless of source of funding) involving recombinant or synthetic nucleic acid molecules, biohazardous materials, biological toxins, and organisms that present a risk to human health or the environment.

The MBL currently does not have Animal Biosafety Level 2 (ABSL2) and Biosafety Level 3 (BSL3) containment facilities. Research work with Risk Group 2 (RG2) agents or higher requiring ABSL2 or BSL3 containment facilities cannot be conducted at the MBL.

2 ROLES AND RESPONSIBILITIES

2.1 MBL

- Establish an Institutional Biosafety Committee (IBC) that meets the requirements outlined in the *NIH Guidelines*.
- Establish and implement policies, in consultation with the IBC, for safe conduct of research involving biohazardous materials.
- Ensure appropriate training for the IBC Chair and Committee members, Biosafety Officer, Principal Investigators and laboratory personnel.
- Ensure compliance with the *NIH Guidelines* and other applicable Federal, State and local regulations by PIs and laboratory personnel conducting research at MBL that involves the use of biohazardous materials.

2.2 IBC

- Review research conducted at MBL involving recombinant or synthetic nucleic

acids or biohazardous materials to ensure compliance with the *NIH Guidelines* and IBC's policies.
- Notify the PI of the results of the IBC's review and approval.
- Determine containment levels as outlined in *NIH Guidelines.*
- Report any significant problems with or violation of the *NIH Guidelines* and any significant research-related accidents or illnesses to the Institutional Official (IO) and NIH Program for Biosecurity and Biosafety Policy (NIH PBBP) within 30 days, unless the IBC determines that a report has already been filed by the PI.
- The IBC may not authorize initiation of experiments that are not explicitly covered by the NIH *Guidelines* until NIH establishes the containment requirement.

2.3 Principal Investigator

The PI is responsible for full compliance with the *NIH Guidelines* in the conduct of recombinant or synthetic nucleic acid molecules research, the use of biohazardous materials, the creation or maintenance of organisms that pose a risk to human health or the environment, and adherence to IBC policies and procedures. The PI should:

- Make initial determination of the required biological containment levels in accordance with the *NIH Guidelines* and *Biosafety in Microbiological and Biomedical Laboratories* (BMBL).
- Submit an IBC application, together with IACUC or IRB applications.
- Restrict research activities to those which have been approved by the IBC.
- Limit access to laboratories and work areas where recombinant or synthetic nucleic acid molecules, biological agents and organisms that pose a risk to human health or the environment are used or stored.
- Select appropriate microbiological practices and laboratory techniques to be used for the research and provide adequate details to enable IBC to conduct proper risk assessment.
- Ensure personnel listed on the IBC protocol have sufficient knowledge, are properly trained, and have demonstrated the appropriate competence to safely perform the responsibilities for which they have been assigned.
- Ensure lab personnel involved in IBC research protocol fully understand procedures for managing spill or personnel exposure with biohazardous agents.
- Supervise lab personnel and ensure proper safety practices are used.
- Provide proper personal protective equipment to lab personnel.
- Provide an updated lab-specific Biosafety Manual to IBC, and make it readily accessible to lab personnel.
- Adhere to MBL's Biosafety Manual policies and procedures.
- Notify the IBC of any proposed changes to approved research registrations.
- Report any significant accidents and illnesses associated with research activities to the IBC within 30 days.

2.4 Biosafety Officer (BSO)

- Serving as a voting Member of IBC.
- Conduct laboratory safety inspections to ensure that appropriate laboratory procedures as determined by the IBC are rigorously followed.
- Report to the IBC and MBL senior management any significant problems, violations of the *NIH Guidelines*, and any significant research-related accidents, incidents or illnesses of which the BSO becomes aware, unless the BSO determines that a report has already been filed by the PI.
- Develop emergency plans for handling accidental spills and personnel contamination
- Participate in accident investigations involving recombinant/synthetic nucleic acids or biohazardous agents.
- Develop and manage a comprehensive Biosafety program for the MBL.
- Collaborate with investigators and lab personnel on biosafety issues.

3 PROTOCOLS REQUIRING IBC REGISTRATION

(a) **Recombinant and Synthetic Nucleic Acid Molecules**
To ensure compliance with *NIH Guidelines for Research Involving Recombinant DNA Molecules*, the MBL requires all investigators to register research projects that involve the use of recombinant or synthetic nucleic acid molecules.

(b) **Research Involving Infectious, Parasitic or Other Biohazardous Agents or organisms**
Including but not limited to prions, viruses, bacteria, protists, fungi, or animals capable of infecting or parasitizing humans, other animals housed in MBL research facilities, or that pose a risk to the local environment should they escape.

(c) **Select Agents and Toxins (including Exempt Quantities)**
Limited quantities of a regulated Select Agent or Toxin may be possessed per PI without the full regulatory burden of registration with the CDC/USDA and the concomitant security requirements (https://www.selectagents.gov/). The PI/Course Director must register research protocols using Select Agents and Toxins, including exempt quantities, with the IBC. The IBC will review and approve, if appropriate, all protocol registrations describing research with Select Agents and Toxins at a convened meeting.

(d) **Human Subject Materials**
These includes human or non-human primate blood, body fluid, cell lines, fixed and unfixed tissue or Other Potentially Infectious Materials (OPIM), and any other work requiring Institutional Review Board approval.

4 PROTOCOL/AMENDMENT SUBMISSION AND REVIEW

4.1 Protocol Submission Process

(a) Protocol submission forms are available on the IBC webpage: http://www.mbl.edu/services/biosafety-committee/

(b) All IBC protocol submissions, including new protocols, protocol amendments or resubmissions of approved protocols must be submitted to the IBC (biosafety@mbl.edu).

(c) Once IBC protocols are approved by the IBC, they are valid for a period of three years.

(d) Changes to approved protocols (e.g., room changes, new procedures or agents) must be reviewed and approved by the IBC prior to initiation of the protocol.

4.2 Tracking of IBC Research Protocols

Upon receipt of the duly completed IBC Protocol Registration Form, it is assigned a protocol Registration Number (e.g. **2017_R-DNA-05** or **2017_Para-05**) that will be used for tracking. Any protocol amendments or modifications received shall be numbered sequentially upon approval. The protocol Registration Number shall be referenced on all subsequent IBC correspondence.

4.3 Protocol Resubmission

A PI who intends to continue conducting the research described in a current approved IBC protocol is required to resubmit that protocol so that it can be reviewed and approved by the IBC prior to the three year expiration. The protocol resubmission shall be reviewed in the same manner as new protocol submission. The PI shall be sent reminders of the need to resubmit at least three months prior to expiration and reminded monthly to do so until the resubmission is received by the IBC Office.

4.4 Expiration of protocols

All IBC protocols are only approved for three years. If a protocol resubmission has not been submitted by the PI or if one has been resubmitted and is not approved by the IBC prior to the three year expiration date that protocol is automatically expired. No research described in such protocol may be conducted until the resubmission is approved by the IBC. Expiration of the IBC protocol may require termination of any related IACUC and IRB protocols, and notification of other agencies (e.g., OLAW and funding agencies).

5 PROTOCOL REVIEW PROCESS

5.1 Initial Administrative Review

1. The Associate Administrator to the Director of Research shall review each submitted research protocol for completeness. Any incomplete protocol shall be returned to the PI for completion prior to being presented to the IBC for review. Copies of all protocols to be reviewed by the IBC shall be provided to each member of the IBC.
2. If the IBC protocol involves the use of vertebrate animals, the Associate Administrator will confirm if there is a current approved IACUC protocol that corresponds to the IBC protocol. If not, the Associate Administrator shall inform the PI that IACUC protocol approval is also required.
3. If the IBC submission involves the administration of biohazardous agents or recombinant or synthetic nucleic acid molecules to humans or the collection of tissues or fluids from humans, the Associate Administrator will confirm with the *New England Independent Review Board* (NEIRB) if there is an associated approved IRB protocol. If not, the PI will be informed that IRB approval is also required.
4. Failure to obtain the required IACUC or IRB approval may delay approval of the IBC protocol submission.

5.2 Expedited Review (IBC Chair Review/Approval)

1. Amendment submissions indicating a minor change that has no impact on risk or biosafety level are reviewed by the IBC Chair. The Chair may request additional information or clarification from the PI, approve the submission with no modifications, or send it to the full Committee review if the Chair has determined that such review is warranted.
2. IBC protocols or amendments merely involving transgenic animal generation requiring BSL1 containment facilities are initially reviewed by the IBC Chair or BSO. Following satisfactory resolution of any issues raised during the review, the submission is considered to be "registered" and the PI may proceed with the generation of the animals, unless IACUC approval is also required. The submissions approved by the Chair are presented to the IBC at the next regularly scheduled convened IBC meeting for final approval.
3. The full Committee is informed semi-annually of all submissions that have been approved by the IBC Chair.

5.3 Full Committee Review

Following Initial Administrative Review, if Full Committee Review is required, the IBC protocol shall be reviewed by at least one member of the IBC. Any questions or concerns raised during the IBC member preliminary review must be adequately addressed prior to placing the protocol on the agenda of the next convened meeting of the IBC.

6 IBC DECISIONS FOR PROTOCOL REGISTRATIONS

The IBC shall make one of the following determinations regarding the protocol registration:

1. **Approved or Approved With Comment**
   The protocol submission satisfactorily addresses all issues and the submission is fully approved with no modification by the PI required.

2. **Approved With Stipulations**
   The protocol submission is approved, but the approval is limited pending satisfactory resolution to specific issues (e.g., Animal work may not begin until IACUC has approved the corresponding animal protocol).

3. **Pending-Conditions**
   Minor issues remain that must be addressed by the PI prior to approval. The revised protocol submission is reviewed by the IBC Chair who may have follow-up questions, may request the response to be evaluated by another member of the Committee or require full Committee Review if the response is not sufficient.

4. **Deferred**
   Significant issues remain requiring the full committee to review the PI response.

5. **Rejected**
   The protocol submission is not approved and has been withdrawn from further consideration by the committee.

6. **Suspended**
   The approval of the IBC protocol is temporarily suspended. None of the activity that is described in the IBC protocol involving IBC-regulated materials may be performed during the period in which the protocol is suspended. The IBC may suspend a protocol during instances of serious or continuing non-compliance with IBC or institutional policies and guidelines or with the *NIH Guidelines*. The activity of protocol suspension can only be executed in a convened meeting of the IBC. However, in circumstances involving an immediate threat to health and safety, the IBC empowers the Biosafety Officer to immediately suspend the hazardous activity.

7. **Terminated**
   The IBC protocol is no longer approved and will not be reconsidered for approval by the IBC Committee. All activities described in the protocol utilizing IBC-regulated materials must cease upon receipt of the notice of termination. The IBC will not reconsider re-approving the IBC protocol and it may not be re-submitted by the PI for IBC review. The IBC may terminate a protocol during instances of serious or continuing non-compliance with IBC or institutional policies, guidelines or with NIH *Guidelines*. The activity of protocol termination can only be executed in a convened meeting of the IBC.

7 DELINQUENT RESPONSES TO IBC REVIEW LETTERS BY PI

Failure to respond to submission review letters (e.g., administrative, preliminary or full committee) within 30 days will result in a Final Notice letter from the IBC Chair. If the PI fails to respond to the Final Notice in 30 days, this will result in withdrawal of the original submission. The PI should contact the IBC Chair or BSO if the PI is unable to respond to the review letters in a timely manner.

8 IBC RELATIONSHIPS TO OTHER INSTITUTIONAL COMMITTEES

8.1 Institutional Animal Care and Use Committee (IACUC)

The IBC and IACUC will collaborate to ensure ongoing review of research involving both animals and recombinant or synthetic nucleic acids or other potentially biohazardous agents or toxins. IBC protocol submissions involving the use of live vertebrate animals require IACUC review and approval before they can be approved by the IBC. A current IACUC protocol number must be included on the IBC submission.

8.2 Institutional Review Board (IRB)

IBC protocol submissions involving the administration of r/s DNA and biohazardous materials, biological agents or toxins to humans, or involve the collection of tissues or fluids from humans, require IRB review and approval prior to initiation. The MBL contracts with the *New England Independent Review Board* (NEIRB) (http://neirb.com/) to review any research protocols involving human subjects.

The IBC will verify with the NEIRB staff if the protocol has been approved for all IBC submissions that indicate IRB approval is required. Only after IRB approval is confirmed will IBC approval be granted for the protocol submissions. A current IRB protocol number must be included on the IBC protocol submission.

8.3 Grants

The Office of Sponsored Programs (OSP) provides assistance to the MBL research community by identifying funding opportunities, reviewing and approving proposals, negotiating awards, and managing the requirements and terms of those awards under the direction of the Director of Research Administration and Sponsored Programs. Upon receipt of funding proposals, the OSP reviews to determine if an IBC protocol is indicated or seems warranted. If funding is awarded OSP notifies the PI of the PIs responsibility to obtain IBC approval before the research is initiated.

9 BIOSAFETY TRAINING REQUIREMENTS

It is the policy of the MBL's IBC that all investigators, laboratory personnel, and students

involved with research activities described in a given IBC protocol be appropriately trained. The training will enable risks associated with research activities to be minimized, and ensure compliance with applicable Federal, State and local regulations and guidelines. The PI or Course Director/Faculty is responsible for ensuring all laboratory personnel and students involved with research activities described in a specific IBC protocol are trained appropriately.

9.1 Biosafety Level 1 (BSL-1) and rDNA Training

This course covers the difference between risk groups and biosafety levels, NIH Guidelines, and MBL policies on recombinant DNA, and research activities conducted in Biosafety Level 1 laboratory.

Laboratory personnel working with recombinant or synthetic nucleic acids or biohazardous materials determined to require BSL-1 containment must take this training. The training is conducted by the Biosafety Officer. Each individual shall complete this course every 2 years unless a significant change in regulatory requirements or institutional policy or biosafety guidelines mandate a shorter training interval.

9.2 Biosafety Level 2 (BSL-2) and rDNA Training

This course covers the difference between risk groups and biosafety levels, NIH Guidelines, and MBL policies on recombinant DNA, research activities conducted in BSL-2 laboratory, biosafety cabinets, and biohazardous spill response. Lab personnel working with rDNA or biohazardous materials determined to require BSL-2 containment must take the BSL-2/rDNA Training. The training is conducted by the Biosafety Officer. Each individual shall complete this course every two (2) years unless a significant change in regulatory requirements or institutional policy or biosafety guidelines mandate a shorter training interval.

9.3 Viral Vectors Training

This training module is required for all personnel listed on an IBC protocol that describes work using viral vectors (both replication competent and incompetent) regardless of the biosafety level used to manage them. Each individual shall complete this course every two (2) years unless a significant change in regulatory requirements or institutional policy or biosafety guidelines mandate a shorter training interval

9.4 OSHA Bloodborne Pathogens Training

Laboratory personnel working with human source materials, including blood, blood components, tissue, bodily fluids, cells or cell lines must complete the OSHA Bloodborne Pathogens Training. The training is conducted by the Biosafety Officer. Each individual shall complete this training annually in compliance with the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030).

9.5 Select Agents and Toxins (Exempt Quantities) Training

This training module is required for all laboratory personnel listed on an IBC protocol that describes work with any of the Select Agents and Toxins regulated by the Federal Select Agent Program. Each individual shall complete this course every two (2) years unless a significant change in regulatory requirements or institutional policy or biosafety guidelines mandate a shorter training interval.

9.6 DOT/IATA Shipping of Infectious Substances

This training is required when shipping infectious substances categorized as ***Class 6.2 Dangerous Goods*** by the US Department of Transportation (USDOT) and the International Air Transport Association (IATA). Anyone shipping Category A, Category B or Exempt samples will be required to receive this training module. Each individual responsible for shipping infectious substances shall complete this course every two (2) years as required by the **IATA *Dangerous Goods Regulations***.

9.7 Autoclaving Biohazardous Waste Training

Biohazardous waste generated at research and teaching labs at the MBL must be treated either by chemical disinfection or steam sterilization (autoclave) before disposal. Laboratory personnel are required to follow the specific guidelines outlined in the MBL Biosafety Manual document when handling biohazardous waste. All laboratory personnel responsible for autoclaving biohazardous waste must complete training for proper use of the autoclave. The training is offered by the Biosafety Officer.

9.8 Lab-Specific Training

Laboratory-specific training will be provided by the PI for each of their IBC research protocols. It is the responsibility of the PI to assess risks associated with the protocol. The PI must also ensure that all lab personnel listed on the IBC protocol are sufficiently trained to safely work with the biohazardous materials and that each staff member is aware of what to do in the event of spills or exposures to potentially infectious materials.

10 PROVIDING MINUTES OF IBC MEETINGS TO THE PUBLIC

Section IV-B-2-a-(7) of the NIH Guidelines states: "*Upon request, the institution shall make available to the public all Institutional Biosafety Committee meeting minutes and any documents submitted to or received from funding agencies which the latter are required to make available to the public.*"

Upon written request, the MBL will provide copies of minutes from meetings of its IBC.

The meeting minutes will be made available to the public only after they have been approved at a convened meeting of the IBC. Information restricted to protect institutional property, personnel and proprietary interests shall not be released to the public. Information to be redacted includes locations (laboratories, animal facilities and offices), proprietary or commercial information, and specific information whose disclosure would directly compromise personal, institutional or national security.

11 EMERGENCY RESPONSE

Spills of biohazardous material or release to the environment must be reported to the PI/Lab Supervisor or Course Director/Faculty, and the IBC Cahir or Biosafety Officer immediately.

12 INCIDENTS/ACCIDENTS

If an individual working on a project is injured or exposed to a biohazardous material, the incident must be reported to the PI/Lab Supervisor or Course Director/Faculty and Biosafety Officer immediately (x7645 or safety@mbl.edu). If personnel are exposed to recombinant materials, reporting to the NIH may be required and must be evaluated by the PI and IBC Chair/BSO. A sharps injury log must be completed by the BSO in compliance with the recordkeeping requirements outlined in OSHA Bloodborne Pathogens Standard.

13 RESOURCES

1. **MBL Biosafety Manual**
   http://www.mbl.edu/wp-content/uploads/2017/07/Biosafety-Manual_11-JULY-2017.pdf

2. **MBL Exempt Quantities of Select Agent Toxins Policy**
   http://www.mbl.edu/wp-content/uploads/2017/12/Select-Agents-and-Toxins-Policy_12.13.2017.pdf

3. National Institutes of Health (NIH): ***NIH Guidelines for Research Involving Recombinant DNA Molecules*** *(NIH Guidelines).*
   http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines

4. Centers for Disease Control and Prevention (CDC)/National Institutes of Health (NIH). ***Biosafety in Microbiological and Biomedical Laboratories (BMBL)***, 5th Edition, 2009. https://www.cdc.gov/biosafety/publications/bmbl5/bmbl.pdf

5. United States Department of Agriculture (USDA): ***Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins.*** http://www.selectagents.gov/

6. OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030). https://www.osha.gov/SLTC/bloodbornepathogens/standards.html

7. Commonwealth of Massachusetts Regulations (105 CMR 480.000). "***Minimum Requirements for the Management of Medical or Biological Waste***" (State Sanitary Code Chapter VIII). http://www.mass.gov/eohhs/docs/dph/regs/105cmr480.pdf.