

# **The University of New England Institutional Biosafety Committee Policies and Procedures Manual**

Approved and Adopted by the UNE Institutional Biosafety Committee

6/1/2013

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## Section 1: Introduction

### 1.0 Purpose

It is the responsibility of The University of New England (UNE) Institutional Biosafety Committee (IBC) to review, approve and oversee the use of recombinant DNA (rDNA), biohazardous agents, materials and toxins in all research or teaching activities conducted by UNE facilities or research personnel. Together, *The Institutional Biosafety Committee Policies and Procedures Manual* (IBC Policies) and the UNE Policy *Use of Recombinant DNA and Biohazardous Agents, Materials and Toxins* set forth the relevant regulatory and local requirements. Because laboratory work can involve exposure not only to rDNA, biohazardous agents, materials and toxins, but also to chemical and radiological hazards, the IBC Policies should be used in conjunction with any other pertinent UNE policies and procedures.

### 1.1 Mission Statement

Ensure that UNE safeguards human health and the environment by maintaining an adherence with the *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)* and the *Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th ed.* Through a balance of outreach and support for research personnel, the IBC will:

- Assure activities meet the ethical and legal requirements for the responsible use of rDNA, biohazardous agents, materials and toxins.
- Establish policies and make recommendations to UNE regarding such activities.
- Minimize risks to the research personnel, community and the environment by educating the UNE community regarding the regulatory requirements for the use of rDNA, biohazardous agents, materials and toxins.

### 1.2 Authority of the IBC

The UNE IBC is responsible for the review, approval and oversight of research involving rDNA and biohazardous materials, agents and toxins in research **and** teaching activities. IBC responsibilities include assessing facilities, procedures, practices and training of research personnel to assure compliance with National Institutes of Health /Office of Biotechnology Activities (NIH/OBA) and other pertinent guidelines and regulations. To successfully carry out these responsibilities, the IBC is appointed to achieve sufficient knowledge and expertise in biomedical research and biosafety. The IBC has the authority to approve, require modifications to secure approval, disapprove, suspend or terminate research activities as required to assure adherence to the appropriate regulations and guidelines.

The UNE IBC is responsible for the planning and implementation of the campus Biosafety program with a purpose to ensure the health and safety of all personnel working with rDNA and biohazardous materials, agents and toxins. The IBC responsibilities include:

- Ensuring that research conducted at the Institution is in compliance with the *NIH Guidelines*, *BMBL*, and United States Department of Agriculture (USDA) regulations;
- Drafting campus policies and procedures; and
- Reviewing individual research proposals using rDNA and biohazardous materials, agents and toxins.

To the extent that UNE receives NIH funding for research involving rDNA molecules, **all** activities involving rDNA must follow the *NIH Guidelines*. Failure to adhere to these guidelines can result in suspension or termination of NIH funding, or to a requirement for prior NIH approval of any or all rDNA projects at the institution. The IBC is therefore responsible for establishing and implementing policies that provide for the safe conduct of research involving rDNA and biohazardous materials, agents and toxins to ensure adherence with *NIH Guidelines*, regardless of funding status or source. IBC responsibilities with regards to activities involving rDNA and biohazardous materials, agents and toxins are specified in the *NIH Guidelines*. The IBC has the authority to oversee all research and teaching activities involving rDNA and biohazardous materials, agents and toxins including suspension or termination of research that does not comply with IBC Policies.

### **1.3 Committee Composition**

The President of UNE delegates the Institutional Official (IO) authority to appoint the chair, IBC members and alternates as needed. All members are voting members, and consist of faculty, research personnel, and the community. At least one member each of the UNE Institutional Review Board (IRB) and the UNE Institutional Animal Care and Use Committee (IACUC) shall be members of the UNE IBC.

The Chair shall be **either**:

- a scientific researcher with experience in rDNA and biohazardous materials, agents and toxins; **or**
- the Director of Environmental Health & Safety, if the latter has appropriate experience monitoring and evaluating research and teaching activities involving rDNA or biohazardous materials, agents and toxins.

The UNE Director of Environmental Health and the UNE Director of Research Integrity shall be voting members *ex officio*. All other IBC membership terms are staggered for one or two years and are renewable upon mutual agreement. Members will be evaluated annually by the IO and Director of Research Integrity, on the basis of satisfactory attendance, their preparation for each meeting by reviewing the submitted research, and if they have effectively contributed to the functions of the IBC.

Members will collectively have appropriate expertise and experience in the use of rDNA and biohazardous materials, agents or toxins. They must have expertise in assessment of risk to environment and public health along with knowledge of institutional commitments and policies, applicable law, professional standards, community and environment. The IBC will have no fewer than five members whose expertise will be in the following areas, as determined by the UNE research agenda:

- At least one expert in rDNA technology.
- At least one member expertise in biological safety and physical containment.
- At least one expert in select agents and toxins (use, storage, transfer, and disposal).
- At least one member with expertise in animal containment principles.
- At least one member expertise in plant, plant pathogen, or plant pest containment principles. An individual representing laboratory technical staff (at present, this requirement is waived because UNE does not engage in this line of research).
- The Biological Safety Officer.
- At least two members from the surrounding community, and not affiliated with UNE, to represent the interests of the community in regards to health and protection of the environment.

Consultants may be invited to meeting for their expert advice when necessary but will not be allowed to vote on any protocol.

#### **1.4 Scope**

The IBC policies apply to all UNE personnel engaged in teaching activities and/or research involving rDNA, biohazardous agents, materials and toxins that are:

- Sponsored by UNE;
- Conducted by UNE personnel;
- Conducted using UNE's property or facilities;
- Received, stored, used, transferred or disposed of at any of UNE's facilities;
- Research at other institutions conducted on behalf of UNE.

#### **1.5 Federal Registrations**

The UNE IBC is registered with the Office of Biotechnology Activities<sup>1</sup> (OBA) for purposes of rDNA research. The UNE IBC will renew its registration annually in February. Annual renewal takes the form of a report that the Director of Research Integrity files with OBA. This report includes an updated list of IBC members indicating the role of each member and biosketches for each member.

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<sup>1</sup> For more information visit <http://www4.od.nih.gov/oba/>.

Additionally, the Director of Research Integrity will notify OBA of any changes in IBC membership when they occur. Such notice shall include a revised list of members, contact information and a biosketch for each new member. These annual reports and periodic updates serve three primary purposes:

- To assure OBA that local review of Biosafety risks takes place;
- To indicate the UNE point of contact for Biosafety matters; and
- To provide a census of the field by informing OBA where rDNA research is being conducted.

## 1.6 Regulations and Guidelines

The IBC Policies are based upon the following regulations and guidelines:

- **NIH Guidelines** This document specifies practices and provides guidelines for constructing and handling rDNA molecules and organisms containing rDNA molecules. Institutions conducting or sponsoring rDNA research covered by *NIH Guidelines* are responsible, through established policies and its IBC, for ensuring that such research is conducted in compliance with the *NIH Guidelines* are available online at [http://oba.od.nih.gov/oba/rac/guidelines\\_02/NIH\\_Guidelines\\_Apr\\_02.htm](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm).
- **BMBL** is published by Centers for Disease Control and Prevention (CDC) and the NIH – This document contains guidelines for microbiological practices, safety equipment, and facilities that constitute the four established biosafety levels. The BMBL is considered the standard for biosafety. The BMBL is available online at <http://www.cdc.gov/biosafety/publications/bmb15/index.htm>.
- **Select Agents and Select Agent Toxins** – The Department of Health and Human Services (HHS), Center for Disease Control and Prevention (CDC) regulations, 42 CFR Part 73, and the United States Department of Agriculture (USDA) regulations, 9 CFR Part 121, establish requirements regarding the possession, use, receipt, and transfer of listed select agents and select agent toxins. The regulations set forth the requirements for registration of listed select agents and select agent toxins, security risk assessments, safety plans, security plans, emergency response plans, training, transfers, record keeping, inspections, and notifications. For more information visit <http://www.selectagents.gov/>.
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- **For Research Involving Animals and Plants** -The Animal and Plant Health Inspection Service (APHIS) regulates genetically engineered (GE) organisms and certain GE organisms that may pose a risk to plant or animal health. APHIS uses the term biotechnology to mean the use of recombinant DNA technology, or genetic engineering



to modify living organisms. Permits are required for the importation, transit, domestic movement and environmental release of organisms that impact plants. For more information visit:

- **Biotechnology:** <http://www.aphis.usda.gov/biotechnology/index.shtml>
- **Permits:** [http://www.aphis.usda.gov/plant\\_health/permits/index.shtml](http://www.aphis.usda.gov/plant_health/permits/index.shtml)

## 1.7 Definitions

- **Biohazardous Materials, Agents and Toxins:** Infectious biological or synthetic agents, biologically derived materials and toxins that present a risk or potential risk to the health of humans, animals, or plants either directly through exposure or infection or indirectly through damage to the environment. Categories of potentially infectious biological materials include, but are not limited to, the following:
  - Human, animal, and plant pathogens (bacteria, parasites, fungi, viruses, prions);
  - All human and non human primate blood, blood products, tissues, and certain body fluids (use of human blood and body fluid for clinical diagnostic and treatment purposes is excluded);
  - Cultured cells and potentially infectious agents these cells may contain;
  - Infected animals and animal tissues.
- **Recombinant DNA (rDNA):** In the context of the *NIH Guidelines* recombinant and synthetic nucleic acids are defined as (1) recombinant nucleic acid molecules that are constructed by joining nucleic acid molecules and that can replicate in living cells, (2) synthetic nucleic acid molecules that are chemically, or by other means, synthesized or amplified nucleic acid molecules that may wholly or partially contain functional equivalents of nucleotides, or (3) molecules that result from the replication of those described in (1) or (2) above. Synthetic DNA segments that are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent) are considered as equivalent to their natural DNA counterpart.

## Section 2: Responsibilities

The *NIH Guidelines* will never be complete or final because all conceivable experiments involving rDNA cannot be foreseen. Therefore, it is the responsibility of UNE, the UNE research community and all those associated with it to adhere to the intent of the *NIH Guidelines* as well as the specifics. Good judgment is of key importance along with the assistance of the UNE IBC and OBA. The potential consequences of noncompliance with the *NIH Guidelines* consist of:

- Suspension, limitation or termination of NIH funds for rDNA research at UNE; and/or
- A requirement for prior NIH approval of any or all rDNA projects at UNE.

## 2.0 Institutional Official (IO) and the University Responsibilities

The responsibility for Biosafety Program at UNE rests with the Associate Provost for Research and Scholarship, who is the IO. The IO:

- Appoints IBC members;
- Annually evaluates IBC members with input from the IBC Chair and the Director of Research Integrity;
- Oversees the IBC and research personnel who obtain, possess or use rDNA and biohazardous materials, agents and toxins;
- Annually evaluates allocation of resources to the IBC and adjusts as necessary.

The IO bears ultimate institutional responsibility to

- Ensure that the IBC (See Section 1.2) reviews, approves and provides oversight and guidance to those research personnel who seek to use rDNA and biohazardous materials, agents and toxins in experiments or teaching; and .
- Ensure that any possession and/or use of rDNA and biohazardous materials, agents and toxins at UNE complies with appropriate safeguards, UNE policies and federal guidelines and regulations.

## 2.1 Institutional Biosafety Committee (IBC) Responsibilities

The responsibilities of the IBC include, but are not limited to, the following:

- Reviewing, approving and overseeing new research or teaching activities utilizing rDNA and biohazardous materials, agents and toxins, conducted at or sponsored by UNE, for adherence with the *NIH Guidelines* and the BMBL.
- Periodically reviewing, approving and overseeing ongoing research or teaching activities utilizing rDNA and biohazardous materials, agents and toxins research, conducted at or sponsored by UNE, for adherence with the *NIH Guidelines* and the BMBL.
- Notifying Principal Investigators in writing of the results of the IBC's review, approval, or disapproval.
- Making final determination of physical and biological containment for rDNA and biohazardous materials, agents and toxins research and modify containment levels as necessary.
- Assessing the facilities, procedures, practices, training and expertise of personnel involved in research utilizing rDNA and/or biohazardous materials, agents and toxins.
- Reviewing and reporting any significant problems, violations of the *NIH Guidelines* and any significant research-related accidents or illnesses to the IO and to the NIH/OBA per the *NIH Guidelines*.
- Directing development of appropriate procedures as required by NIH/OBA, CDC, and USDA regulations to oversee the possession and/or use of rDNA and biohazardous

materials, agents and toxins.

- Suspending or terminating protocol approval for the possession or use of rDNA and biohazardous materials, agents and toxins, where the IBC finds noncompliance or that such use or possession poses undue risk to research personnel or a threat to the health and safety of the community.
- Periodically reviewing the IBC policies and procedures and modify them as necessary to ensure appropriate biosafety measures and adherence with federal and state requirements.
- Conducting an independent assessment of the containment levels (BSL-1, BSL-1N, BSL-2 and BSL-2N), as required by the *NIH Guidelines* or the BMBL.
- Conducting an assessment of the facilities, procedures, practices, training, and expertise of personnel conducting research involving rDNA and biohazardous materials, agents and toxins.
- Ensuring adherence with all surveillance, data reporting, and adverse event reporting requirements set forth in the *NIH Guidelines* for rDNA research and the select agents and toxins regulations.
- Obtaining specific review, registration and/or approval from NIH/OBA for research that fall under Sections III-A, III-B, III-C and Appendix M.

## **2.2 Institutional Biosafety Committee (IBC) Chair Responsibilities**

The IBC Chair responsibilities include:

- Serving as one of three contacts for all regulatory agencies (in addition to IO who may delegate this function).
- Acting as liaison between the research personnel and IBC.
- Approving the agenda for the convened meeting of the IBC.
- Calling the meeting and directs the meeting deliberations, requests motions and seconds, and closes the meeting once it has concluded business.

## **2.3 Biological Safety Officer (BSO) Responsibilities**

The BSO shall be a member of the IBC. The BSO responsibilities include:

- Performing periodic inspections of laboratories conducting research using rDNA and biohazardous materials, agents and toxins to ensure that laboratory standards are rigorously followed;
- Reporting any problems, violations, research-related accidents or illnesses to the UNE IBC and the IO;
- Performing and reviewing the required risk assessment to determine appropriate Biosafety level for handling an organism;
- Developing emergency plans for handling accidental spills and personnel contamination

and investigating laboratory accidents involving rDNA and biohazardous materials, agents and toxins;

- Providing advice on laboratory security to the IBC research personnel; and
- Providing technical advice to research personnel and the IBC on research safety procedures.

The principal function of the BSO is to advise the research personnel, the IBC and the laboratory worker concerning the most appropriate safety practices that will assure the safe conduct of research with rDNA and biohazardous materials, agents and toxins.

#### **2.4 Principal Investigator Responsibilities**

The key Principal Investigator responsibility is to follow the *NIH Guidelines*, the BMBL and IBC Policies when using rDNA and biohazardous materials, agents and toxins. Along with this understanding, the Principal Investigator will also have the following responsibilities:

- Making the initial risk assessment and determination of required levels of physical and biological containment in accordance with the *NIH Guidelines* and the BMBL. The list is available online at <http://www.cdc.gov/biosafety/publications/bmb15/BMBL.pdf>;
- Being adequately trained in good microbiological techniques;
- Obtaining IBC approval prior to initiating or modifying any research involving use of rDNA and/or biohazardous materials, agents and toxins, even if federal regulations allow exemption of the proposed research or teaching activity, so the IBC can verify that they are exempt;
- Providing laboratory research personnel with protocols describing potential biohazards and necessary precautions;
- Instructing, training and supervising research personnel in (1) the practices and techniques required to ensure safety, and (2) the procedures for dealing with spills or potential exposures to the agents described in the research;
- Ensuring the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., purity and genotypic and phenotypic characteristics) and correct procedures or conditions that might result in release of or exposure to rDNA and/or biohazardous materials, agents or toxins;
- Developing and obtaining IBC approval of and adhere to biosafety plans for handling accidental spills and personnel contamination;
- Informing the research personnel of the Occupational Health & Safety Program and provisions for any precautionary medical practices advised or requested, e.g., vaccinations<sup>2</sup>;

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<sup>2</sup> See Section 8

- Ensuring all research personnel, including students, have the required training in the accepted procedures for laboratory practices and safety<sup>3</sup>;
- Maintaining IBC approval for use of rDNA and biohazardous materials, agents and toxins through timely submission of annual updates;
- Immediately reporting any significant problems or any research-related accidents and/or illnesses to EHS and any other UNE committees (*e.g.*, IRB or IACUC) that have reviewed and approved the research activity; and
- Complying with permit and shipping requirements for biohazardous materials;

## **2.5 Office of Biotechnology Activities (OBA) Responsibilities**

OBA serves as the focal point for information on recombinant DNA activities and provides advice to all within and outside NIH/OBA. OBA's responsibilities include, but are not limited to, the following:

- Serving as the focal point for all aspects of gene transfer experiments;
- Reviewing and approving experiments in conjunction with ad hoc experts involving the cloning of genes for toxin molecules that are lethal for vertebrates at an LD50 of less than or equal to 100 ng/kg body weight in organisms other than *Escherichia coli* K-12;
- Publish proposed changes to rules or guidelines in the Federal Register;
- Reviewing and approving the membership of an Institution's Biosafety Committee, and where it finds the IBC composition to meet the requirements set forth in the NIH Guidelines, giving approval for the IBC membership.

## **2.6 Office of Research Integrity Responsibilities**

The Director of Research Integrity will provide overall administrative support, and will coordinate IBC reviews and meetings. The Director's responsibilities include, but are not limited to, the following:

- Providing the necessary liaison between the research personnel, the IBC, federal and regulatory agencies;
- Serving as the office of record for documentation involving IBC;
- Providing all necessary documentation, forms, regulatory guidelines and regulations, to Principal Investigators;
- Maintaining IBC registration forms and records; Assisting the IO in filing annual updates and other reports to the NIH/OBA;
- Communicating with IRB or IACUC when protocols involve human subjects or animals;

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<sup>3</sup> See Section 7

- Monitoring Federal and state regulations, draft revised policies and procedures to remain in compliance with those regulations; and
- Providing administrative support for the IBC by scheduling meetings, arranging for meeting space and taking meeting minutes.

### **Section 3: Protocol/Modification Submission and Review**

#### **3.0 Submissions**

The UNE IBC is responsible for overseeing and evaluating all aspects of research and teaching activities involving rDNA and biohazardous materials, agents and toxins. To this end, the UNE IBC will review proposals that involve rDNA and biohazardous materials, agents and toxins to ensure that the criteria established in the IBC Policy and the federal regulations and guidelines are implemented. In its review, the IBC's primary goal is to facilitate research personnel compliance with applicable laws, regulations, guidelines and policies consistent with the performance of appropriate and productive scientific endeavors.

The Principal Investigator is responsible for submitting all IBC protocols (new, renewal or amendment) submissions to the Director of Research Integrity for IBC review and approval. No research involving rDNA and biohazardous materials, agents and toxins can be initiated until the Principal Investigator has received the approval of the IBC.

Although federal regulations allow exemptions for some types of rDNA used, the Principal Investigator must submit an application for all projects using rDNA and biohazardous materials, agents and toxins so that the IBC is aware of the activities and can verify that they are exempt. For more information about OBA exemptions visit [http://oba.od.nih.gov/oba/ibc/FAQs/FAQs\\_about\\_Experiments\\_that\\_are\\_Exempt\\_from\\_the\\_NIH\\_Guidelines.pdf](http://oba.od.nih.gov/oba/ibc/FAQs/FAQs_about_Experiments_that_are_Exempt_from_the_NIH_Guidelines.pdf).

No one shall obtain or use rDNA and biohazardous materials, agents and toxins until the protocol has been approved by the IBC. Modifications to approved protocols shall not be implemented until approved by the IBC.

#### **3.0.1 Who can be a Principal Investigator?**

Principal Investigators (PI) can submit applications to the IBC to work with rDNA and/or biohazardous materials, agents, and toxins. In general, a PI is a tenured, tenure track, or research faculty or research staff with assigned research space. Should a PI not have assigned space to conduct the research, the PI must submit the statement below, signed by the person who is responsible for the research space. Exceptions to this policy will be considered by the IBC on a case-by-case basis.

## Acknowledgement Statement

I, [insert name of person with assigned research space] am aware of the attached research of [insert name of PI without assigned space] that will be conducted in space assigned to me. I acknowledge my responsibility for ensuring that this research will be conducted in a safe manner and in accordance with institutional and federal regulations.

### 3.1 Experiments Requiring IBC Review

Experiments that require IBC review include, but are not limited to:

- Recombinant studies that are not exempt from the *NIH Guidelines*;
- The deliberate transfer of a drug resistance trait to micro-organisms that are not known to acquire the trait naturally<sup>4</sup>;
- The deliberate transfer of rDNA, or DNA or RNA derived from rDNA, into human research participants (human gene transfer);
- The deliberate formation of rDNA containing genes for the biosynthesis of toxin molecules;
- The use of Risk Group 2 agents as host-vector systems;
- The use of human etiologic and animal viral etiologic agents;
- The cloning of DNA from Risk Group 2 agents into non-pathogenic prokaryotes or lower eukaryotic host-vector systems;
- The use of infectious or defective Risk Group 2 agents;
- Whole animals in which the animal's genome has been altered by stable introduction of rDNA or DNA derived into the germ-line (transgenic animal)<sup>5</sup>;
- Viable rDNA-modified micro-organisms or cell lines tested on whole animals;
- Genetically engineered plants by rDNA methods;
- More than 10 liters of rDNA culture in a single vessel;
- The formation of rDNA molecules containing one-half or more of the genome of a eukaryotic virus or from the same virus family;
- Experiments using BSL-2 or BSL-2N containment;
- Non-recombinant research using biohazardous materials, agents or toxins;
- All research using biological toxins or bioactive derivatives or subunits of toxins;
- Research and non-clinical teaching collecting or analyzing human or non-human primate cell lines, tissues, fluids or other potentially infectious material.

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<sup>4</sup> Such actions may require review and approval from the Secretary of Health and Human Services.

<sup>5</sup> Projects involving certain transgenic animals may be exempt.

### 3.2 New Submissions

The online applications for both Biosafety and rDNA must be accurately completed and submitted for review and IBC approval. Applications will be assigned a protocol number upon receipt by the Director of Research Integrity.

For Biosafety Applications:

- To facilitate the approval of the research all BSL-2 and BSL-3 laboratories are required to be inspected and develop a Lab Biosafety Manual.
- The BSO, as agent for the IBC, will assist the Principal Investigator in completing this step of the application.
- The protocol will be reviewed by the IBC Program Coordinator and the BSO.
- To ensure a complete submission, it may be necessary for the Principal Investigator to submit additional information if requested by the IBC Program Coordinator or BSO.
- If the research is rDNA exempt a Biosafety application may still be required.
- Approval/Non-approval will be determined by the IBC.
- The online application is available at: [\[REDACTED\]](#)

For rDNA Applications:

- For non-exempt rDNA research a current approved Biosafety application number must be included in the application. The protocol will be reviewed for completeness by the Director of Research Integrity.
  - The Principal Investigator may need to submit additional information, to ensure a complete submission, if requested by the IBC Program Coordinator.
- The application will be circulated to IBC members for review prior to a convened IBC meeting.
- Approval/Non-approval will be determined by the IBC.
- The online application is available at: [\[REDACTED\]](#)

### 3.3 Continuing Review / Renewal

The Principal Investigator is required to resubmit all active protocol(s) annually. **The Principal Investigator is ultimately responsible for ensuring timely annual renewal.** As a courtesy, Principal Investigators will be notified of pending expiration of approval at 60 and 30 days prior to expiration of study approval. These resubmissions are reviewed in the same manner as new protocol submissions. Research cannot be continued if protocol renewal is not approved prior to the expiration date from the previous approval.



### **3.4 Failure to Submit Renewal/Respond to IBC Requirements**

If the Principal Investigator fails to provide a renewal form to the IBC by the anniversary date, the IBC Chair or the Director of Research Integrity will send an administrative suspension letter to the Principal Investigator, copied to the Chair/Dean of the department. All research activities pertaining to the research described in the expired protocol must cease. If the Principal Investigator does not provide a completed application for renewal by the next regularly scheduled IBC meeting, the protocol is subject to termination. Termination of the IBC protocol may require termination of any related IACUC or IRB protocols, and notice to the appropriate Chair/Dean, the Institutional Official and the Office of Sponsored Programs.

### **3.5 Modification Process**

Changes or modifications to approved protocols (*e.g.* changing/adding research personnel, room changes, new procedures or agents) must be reviewed and approved by the IBC prior to initiation. If the changes are extensive, or change the scope of the review, a new submission should be made.

### **3.6 Protocol Termination**

The Principal Investigator will provide written notice to the IBC, through the Director of Research Integrity, when a research involving rDNA and biohazardous materials, agents and toxins is completed or no longer active. The IBC shall contact the Principal Investigator if there are any questions or concerns regarding Termination of Approval.

As stated in Section 3.4 above, failure to renew a previously approved IBC protocol may result in protocol termination. Additionally, non-compliance with institutional and federal regulations, policies and guidelines or requirements of the IBC that are either serious or ongoing will be evaluated and the IBC may determine that the incidents require protocol termination.

### **3.7 Relationships to IACUC and IRB**

Occasionally, IBC protocols may involve human or animal subjects. In such cases, IBC review and approval can be made prior to, and as a condition of, approval by the UNE IRB or UNE IACUC.

## **Section 4: IBC Meeting Process**

### **4.0 Requirements for Quorum**

The conduct of official IBC business occurs at convened meetings that must include a quorum of members in order for the meeting to be held. The IBC defines a “quorum” as half the regular voting members, plus one. A protocol is approved only if a quorum is present, and if more than

50% of the quorum votes in favor or protocol approval. For reasons other than conflict of interest, abstentions from voting do not alter the quorum or change the number of votes required. Members are expected to attend the convened meetings unless they have notified the IBC Chair and the Director of Research Integrity in advance of their absence. Members who fail to attend half the scheduled meetings in any given calendar year may be removed from the committee.

#### **4.1 Protocol Review**

IBC members will be provided with electronic copies of all IBC protocol applications prior to the convened meeting at which the protocol will be considered. The IBC Chair or Director of Research Integrity, if asked, will relate any pre-meeting questions or comments from committee members to the Principal Investigator. This allows for the Principal Investigator to respond to any queries or questions prior to the convened meeting.

#### **4.2 Procedures**

IBC meetings are routinely held quarterly, on dates that will be announced at the start of each academic year. Special meetings can be called if the protocol volume requires, or if matters arise that require immediate resolution. The Director of Research Integrity is responsible for assuring that a meeting room is located and scheduled and that all other arrangements for the meeting are made.

At the scheduled time and upon reaching a quorum, the IBC Chair will call the meeting to order and follow an agenda prepared prior to the meeting. The typical order of the agenda is as follows:

- Call to order and Chair's reminder to members of conflict of interest requirements.
- Approval of the previous meeting's minutes.
- IBC related announcements.
- Protocol Review.
- Educational items for discussion.
- Next meeting announcement.
- Meeting adjournment.

The UNE IBC must complete the following when reviewing protocols for initial review or periodic review of ongoing research activities:

- Determine the containment levels required by the *NIH Guidelines*;
- Assess the facilities, procedures, practices, training and expertise of personnel involved in research with rDNA and/or biohazardous materials, agents or toxins; and
- Ensure compliance with the *NIH Guidelines* and the BMBL.

Sections II and III of the *NIH Guidelines* require the IBC to consider the following when reviewing any proposal for activities involving rDNA:

- Agent characteristics (e.g. virulence, pathogenicity, environmental stability);
- Types of manipulations planned;
- Source(s) of the inserted DNA sequences (e.g., species);
- Nature of the inserted DNA sequences (e.g., structural gene, oncogene);
- Host(s) and vector(s) to be used;
- Whether an attempt will be made to obtain expression of a foreign gene, and if so, the protein that will be produced;
- Containment conditions to be implemented;
- Applicable section of the *NIH Guidelines* (e.g., Section II-D-1. Section III-E-1, etc.).

#### 4.3 Possible Review Outcomes

All non-exempt protocols are presented and discussed individually and the IBC votes on the disposition of the protocol. Possible outcomes include:

- **Approval** – When the IBC has determined that all review criteria, based on the IBC Policies and federal-mandated regulations have been adequately addressed by the Principal Investigator, the IBC may approve the research, thus providing the Principal Investigator permission to perform the research;
- **Approval with conditions** – When there are minor items which prevent a final approval, but which do not require the Principal Investigator to provide details explanations or significant detailed additional information (e.g. where proof of training for a staff member needs clarification or a letter of agreement or collaboration is needed);
- **Tabled** – If the IBC is unable to complete its review because the protocol requires clarification, if significant issues or questions regarding the safety of the protocol need to be resolved, if committee members with certain expertise are not present, if the IBC wishes to seek external consultation, or if anything else prevents the IBC from concluding its review, the IBC may defer consideration, tabling review.
- **Withhold Approval**- When the IBC determines that a protocol has not adequately addressed all of the requirements of the IBC Policies and regulations as applicable, the IBC may withhold approval. The IBC Subcommittees may not withhold approval; this action may only be taken if the review is conducted using the IBC method of review.

#### **4.4 Conflict of Interest**

Both the *NIH Guidelines* and the IBC Policies state that no IBC member who has a direct or indirect conflict of interest in a project may participate in the IBC review or approval of that project. Examples of direct conflict of interest include, but are not limited to:

- Serving as the Principal Investigator for the project;
- Serving as faculty mentor to a student proposing the project; and/or
- Having a direct financial interest in the project.

Examples of indirect conflict of interest include, but are not limited to:

- Being related to the Principal Investigator;
- Serving as an advisor or consultant to the investigator(s); and/or
- Having an indirect financial interest in the project.

An IBC member who declares a conflict of interest with a research protocol:

- Does not count toward meeting quorum;
- May provide information about the protocol;
- Is excluded from discussion and voting; and
- May be asked to leave the meeting room for discussion and voting.

#### **4.5 Minutes**

Review of protocols by the IBC invokes a deliberative process, and section IV-B-2-b of the *NIH Guidelines* require that the IBC meeting minutes should offer sufficient detail about the discussion of the matters that were discussed in order to document the IBC rationale for particular decisions. The IBC has some latitude in the degree of detail in these minutes.

Recorded minutes of IBC meetings are intended to reflect the substantive discussion of protocols. Minutes are intended to contain sufficient information that a reasonable person could understand the nature of the discussion. In general, the minutes should offer sufficient detail to serve as a record of major points of discussion and the Committee's rationale for particular decisions, documenting that the IBC has fulfilled its review and oversight responsibilities as outlined under Section IV-B-2-b of the *NIH Guidelines*.

Meeting minutes are not intended to provide a verbatim transcript of discussion nor do they reiterate shared knowledge of the Committee such as recent discussions about a protocol in previous minutes. Historical evidence of compliance or non-compliance would be recorded in the minutes if it were germane to the discussion. Minutes may include reference to historical discussion by the IBC from members who have

- Served on the Committee and observed the procedures being proposed;
- Served as reviewers for protocols involving similar procedures (where their questions were answered);
- Participated in past IBC discussions about the procedures.

Guidance and clarification concerning the preparation of, and the public access to, minutes of the IBC meetings has been issued by NIH/OBA:

[http://oba.od.nih.gov/oba/IBC/IBC\\_Minute\\_Q\\_A.pdf](http://oba.od.nih.gov/oba/IBC/IBC_Minute_Q_A.pdf) and

[http://oba.od.nih.gov/oba/ibc/IBC\\_Minutes\\_Guidance\\_Feb\\_23\\_2007.pdf](http://oba.od.nih.gov/oba/ibc/IBC_Minutes_Guidance_Feb_23_2007.pdf)

Minutes of each IBC meeting are recorded in writing and contain:

- Time, date and place of meeting;
- Individuals in attendance;
- Whether and why the meeting was open or closed;
- All major motions, major points of order, and if motions were approved, the vote count; and
- Protocols reviewed (identified by protocol number and protocol title)

In order to document the adequate fulfillment of the Committee's review and oversight responsibilities described in Section IV-B-2-b of the NIH Guidelines, the meeting minutes must also document the IBC's consideration of the matters described in Section II and Section III of the NIH Guidelines (see Section 4.2).

#### **4.6 Principal Investigator Notification**

Upon completion of the review process (Section 3), the IBC Chair or the Director of Research Integrity will notify the Principal Investigator in writing of the IBC review decision (approved/not approved), including whether any special conditions for approval of work is required. The written notice will include the IBC's biocontainment/biosafety determination, any special safety considerations, applicable sections of the *NIH Guidelines*, along with the approval period (begin/end dates).

#### **4.7 Reports to the IO**

Copies of minutes and reports of laboratory incidents, accidents, spills, potential or actual exposure to infectious or biohazardous materials, and incidents of non-compliance, protocol suspensions or terminations will be forwarded to the IO at least annually.

## **4.8 Meeting Frequency**

Convened meetings of the IBC occur quarterly. The annual meeting schedule will be set by the Director of Research Integrity, in consultation with the IBC Chair. The Chair may call an emergency meeting of the IBC as necessary to address such issues as noncompliance or serious and/or unexpected events involving rDNA and biohazardous materials, agents and toxins, or protocols requiring “just in time” consideration.

## **4.9 Attendance of Non-Members**

Portions of the UNE IBC meetings are considered open and, as such, members of the UNE community and the public at large may attend an IBC meeting. The IBC will conduct most non-protocol business and protocol discussion in an open session. Discussion directly relating to biosecurity measures and actual protocol deliberation will be held in executive session. When the IBC goes into executive session, the meeting becomes closed to the public, and non-member guests will be asked to leave until the work of the executive session is complete.

## **Section 5: Reporting Requirements**

### **5.0 Reportable Incidents and Violations**

Incidents/problems involving rDNA and biohazardous materials, agents and toxins must be immediately reported to the Biological Safety Officer (BSO) and the Director of Research Integrity.

#### **5.1 The Principal Investigator Reporting**

Certain events trigger Principal Investigator reporting duties. Reports may need to be filed internally or externally.

##### **5.1.1 Principal Investigator Internal Reporting**

The Principal Investigator and their personnel must report any significant incident, violation of the *NIH Guidelines*, or any significant research or teaching-related accidents and illnesses immediately by contacting the BSO and the Director of Research Integrity. Examples of incidents and violations include, but are not limited to:

- Any overt human exposure, such as a needle stick, injection, splash, spill, aerosol exposure or contamination due to equipment failure;
- Any potential exposures with a high risk of contamination, such as spills, containment failure while working with the agent or equipment failure that may produce aerosols.
- A containment breach, which may be subsequently determined to pose either an overt or potential exposure individuals;

- The occurrence of any illness that may be caused by the agents used in the laboratory incidents involving the improper disposal of rDNA.
- Mishandling of biohazardous waste, such as incidents involving improper disposal of rDNA or other biohazardous materials;
- Conducting new or ongoing research without appropriate federal or institutional registration, review, approval or oversight; and
- Other failure by research personnel to follow federal and institutional regulations, guidelines, policies and/or procedures.

### **5.1.2 Principal Investigator External Reporting**

Principal Investigators have a duty to file reports externally with OBA in the following cases:

- Submitting information to support a new host-vector system.
- Submitting petitions for proposed exemptions to the NIH Guidelines.
- Submitting petitions for approval to conduct experiments specified in Sections III-A-1 and III-B.
- Submitting petitions for determination of containment for experiments not covered by the NIH Guidelines.

### **5.2 BSO Reporting**

The *NIH Guidelines* require the BSO to report to the IBC:

- All violations of the *NIH Guidelines* and significant incidents.
- Any significant research or teaching related accidents or illnesses.

### **5.3 IBC Reporting**

The IBC, through the IO, will file an annual report with OBA that includes:

- A roster of all IBC members clearly indicating the Chair, contact person, BSO, plant and animal expert(s).
- Biographical sketches of all IBC members.

The IBC is required, by the *NIH Guidelines*, to report to the appropriate UNE official and to the NIH/OBA within 30 days any significant incidents, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses. The IBC will be responsible for determining what remedial actions, if any, are necessary. For example the IBC may choose to change the frequency of lab inspections, or change the Biosafety Level of the protocol, based on results of the incident. The IBC is required to prepare a final copy of the Biological Incident Reporting Form which it will be signed and dated by the IO, IBC Chair and the BSO.

Other IBC reporting requirements (to OBA and other agencies) include but are not limited to:

- Research involving rDNA and biohazardous materials, agents and toxins without prior IBC approval;
- Lax security, unsafe procedures used in a laboratory setting, improper disposal of recombinant waste; and
- Significant changes to proposed research risk without prior notification and approval by IBC.

### **5.3.1 Expedited Reporting Duties**

Certain types of incidents must be reported to OBA on an expedited basis. Spills or accidents in BSL-2 or BSL-2N laboratories (involving rDNA) resulting in an overt exposure must be immediately reported to OBA. In the event of any such incident, the IBC will report to the appropriate institutional official, who, in turn will report to OBA.

### **5.3.2 Internal Reporting to Deans**

Institutional violations that will be reported to the appropriate Dean include but are not limited to:

- Lapses in protocol approval.
- Willful or repeated failure to comply with institutional and federal regulations, guidelines, and policies.

### **5.4 IO Reporting**

Upon receiving a report from the IBC, the IO will report to OBA in writing the following:

- Public comments on IBC actions, the IBC, through the IO, will forward both the public comments and the IBC's response to the Office of Biotechnology Activities.
- Any problems with or violations (non-compliance) of the *NIH Guidelines* any significant incident, accidents, or illnesses related to rDNA to the NIH/OBA within 30 days or immediately for overt exposure to a BSL-2/BSL-2N agent;

The IO will immediately notify the CDC/USDA of any incidents involving Select Agents and/or Select Toxins. The IO will also immediately notify, and fully cooperate with, state and local public health departments in the event that any significant research-related illness or accident occurs that that may be hazardous to the public.



## **5.5 Response to External Requests for Information**

In accordance with the NIH Guidelines, upon request, the institution will make available to the public all IBC meeting minutes and any documents submitted to or received from funding agencies which the latter are required to make available to the public. Redaction of proprietary and private information is allowed but “must be done so judiciously and consistently for all requested documents.”

## **Section 6: Non-Compliance**

### **6.0 Allegations**

Any allegations of non-compliance or unsafe working conditions may be made to the IBC Chair, to any member of the IBC, the Director of Research Integrity (ORS) to the IO, or to the UNE Compliance Hotline<sup>6</sup> at 1 866 587-6636. In all instances, allegations shall be immediately forwarded to the IBC Chair and the IO. The IBC Chair and the IO are responsible for investigation and resolution of all allegations of non-compliance. The allegations and resulting investigations will remain confidential to the extent possible.

### **6.1 Investigation and Review Process**

The IO and the IBC Chair will appoint a subcommittee to investigate the allegation. The subcommittee will inform all persons involved in the investigation of the purpose and the manner in which it will be conducted. The subcommittee, in its investigation, will examine all documents and procedures relating to the allegation and will interview individuals who are named in the allegation and others who may have knowledge of the circumstances surrounding the allegation and determine if there is a basis in fact to support the allegation. The subcommittee will report its findings to the full IBC for final determinations and recommendations (see Section 6.2).

### **6.2 IBC Determination**

At a convened meeting, the IBC will discuss the subcommittee report and determine whether there is a consensus that the allegation of non-compliance is substantiated and, if so, determine the seriousness of the incident. All persons involved in the allegation of non-compliance will be given the opportunity to appear to respond to the allegation and/or findings. Deliberations and voting on the report and recommendations will take place in a closed executive session. The IBC will inform all parties involved, including the complainant, if known, of the committee’s findings.

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<sup>6</sup> For more information about the UNE Compliance Hotline, see <http://www.une.edu/compliance/hotline.cfm>

### **6.3 Possible Outcomes**

The IBC has the authority to address non-compliance with the NIH Guidelines, the BMBL, UNE policies and procedures and other legal requirements. Findings of non-compliance may result in one or more of the following actions:

- Suspension of use of rDNA and/or biohazardous materials agents or toxins;
- Temporary or permanent termination of approval for use of rDNA and/or biohazardous materials agents or toxins;
- Confiscation of the rDNA and/or biohazardous materials agents or toxins;
- Proper destruction of the rDNA and/or biohazardous materials agents or toxins; and
- Any other action necessary to protect the public and/or UNE, including restricting access to the laboratory in order to suspend activities.

### **Section 7: Training**

Training is required for all research personnel working with rDNA and biohazardous materials, agents and toxins, as well as all IBC members. Approved training for investigators and protocol personnel is a prerequisite for protocol approval. All existing training materials and course content required by the IBC will be reviewed every two years by the IBC members, and any new training material or course content will be reviewed and approved prior to release.

#### **7.0 IBC Member Training**

All IBC members will complete the online IBC training available through the CITI program ([www.citiprogram.org](http://www.citiprogram.org)). The ongoing training program for all members consists of information provided at each IBC meeting. The objectives of providing ongoing training for IBC members is to increase their knowledge, understanding and awareness of current laws and regulations, new directives, best practice guidelines and institutional policies. It also provides a regular forum for the IBC to discuss concerns or questions brought forth by the faculty and research personnel. Information provided for these sessions will include questions and concerns brought to the attention of the IBC, official directives, relevant publications, conference announcements, seminar proceedings, and compliance issues. It will be the responsibility of the IBC Program Coordinator to document all training.

#### **7.1 BSO Training**

The Biosafety Officer BSO is either the Director of Environmental Health & Safety or a Certified Biosafety Professional (CBSP), a certification requiring continuing education in biosafety.

#### **7.2 Principal Investigator and Research Personnel Training**

General biosafety training is mandatory for all Principal Investigators and research personnel.

NIH Guidelines training is mandatory only for Principal Investigators and research personnel performing rDNA research that is non-exempt. It is the Principal Investigator's responsibility to complete and ensure all research personnel has received the required training prior to protocol review by IBC. Documentation of successful completion of training is required in order to receive IBC approval. The IBC training courses can found at [www.citiprogram.org](http://www.citiprogram.org).

## **Section 8: Occupational Health Services Program - Laboratory Animals and Biomedical Services (OHPLABS)**

### **8.0 Overview**

UNE provides occupational health and safety services to ensure appropriate occupational health and safety surveillance (and if necessary care) for lab personnel involved in research approved by the IBC. These services are provided through Concentra, and are provided free of charge to research personnel and all information collected will maintained in a confidential manner, as required by law. Alternatively, lab personnel are free to consult with their own physicians.

### **8.1 Enrollment Requirement**

All personnel who may be potentially exposed to biohazardous materials are strongly encouraged, and in some instances may be required, to make use of the services offered through Concentra.

### **8.2 Services Provided**

Concentra services include:

- Medical Evaluation
- Vaccinations
- Serum Banking
- Respirator Fit Testing
- Case Management
- Consultation for medical issues