NMC
Institutional Biosafety Committee
Policies and Procedures

Revision 6

December 2022

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New Mexico CONSORTIUM

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SECTION 1. INTRODUCTION

The New Mexico Consortium (NMC) Institutional Biosafety Committee (IBC) is in the IBC Registration Management System (IBC-RMS) of the National Institutes of Health (NIH) Office Science Policy, Biosafety, Biosecurity, and Emerging Biotechnology Policy Division (BPD) for purposes of recombinant or synthetic nucleic acid molecules research.

1.1 Purpose.

The NMC IBC is to review, approve and oversee the use of recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins in all research activities sponsored by the NMC.

1.2. Mission Statement.

To ensure that the NMC safeguards human health and the environment and 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 recombinant or synthetic nucleic acid molecules, biohazardous agents, materials and toxins.
- Make recommendations to the PI and NMC management regarding such activities.
- Minimize risks to the research personnel, community and the environment by educating the NMC researchers and management regarding the regulatory requirements for the use of recombinant or synthetic nucleic acid molecules, biohazardous agents, materials and toxins.

1.3. Charge and Authority of the IBC.

The NMC Chief Executive Officer (CEO) has charged the committee with review, approval and oversight of research involving recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins in research and teaching activities. Responsibilities of the IBC include assessment of facilities, procedures, practices, and training of research personnel to assure compliance with NIH/BPD and other pertinent guidelines and regulations. The IBC has the authority to approve, require modifications to secure approval, disapprove, suspend, or recommend termination of research activities to assure adherence to the appropriate regulations and guidelines.

The IBC reviews individual research proposals using recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins and makes certain that research conducted by NMC is in compliance with the *NIH Guidelines*, *BMBL*, and the Health and Human Services (HHS)(45 CFR 46 and Human Subjects Regulations Decision Charts) and U.S. Department of Agriculture (USDA) regulations *(APHIS-BRS).*

1.4. Appointment of Members and Committee Composition.

The Chief Executive Officer (CEO) appoints the Chair and the Members of the NMC IBC. Each IBC Member signs the NMC Employee Conflict of Interest (COI) Form and the IBC Code of Conduct and Member Acknowledgement, included as Attachment A.

NMC IBC includes NMC staff, researchers, and members of the community. The Chair shall be a scientific researcher with experience in recombinant or synthetic nucleic acid molecules and biohazardous materials, agents, and toxins. The term of membership may vary and is renewable upon mutual agreement.

Members will collectively have the appropriate expertise and experience in the use of recombinant or synthetic nucleic acid molecules and biohazardous materials, agents, and toxins. They must have expertise in assessment of risk to the environment and public health along with knowledge of institutional commitments and policies, applicable laws, professional standards, community attitudes and the environment.

The IBC will have no fewer than five (5) members and will be composed of the following:

- One (1) member with expertise in recombinant or synthetic nucleic acid molecule technology, biological safety and physical containment.
- At least one (1) member with expertise in plant, plant pathogen, or plant pest containment principles.
- At least one (1) member who represents the laboratory technical staff.
- At least two (2) members shall not be affiliated with the NMC (apart from their membership on the IBC) and shall represent the interest of the surrounding community with respect to the health and protection of the environment.

The IBC may engage consultants who are knowledgeable in institutional commitments and policies, applicable laws, standards of professional conduct and practice, community attitudes and the environment. Consultants may be invited to meetings for their expert advice when necessary but will not be allowed to vote on any protocol.

1.5 Scope.
These IBC Policies and Procedures shall apply to all research personnel engaged in activities and/or research involving recombinant or synthetic nucleic acid molecules, and biohazardous agents, materials and toxins that are:

- Sponsored by the NMC
- Conducted by NMC research personnel

1.6. Regulations and Guidelines.
This IBC Policy is based upon the following regulations and guidelines:

- NIH *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines);*
- CDC's *Biosafety in Microbiological and Biomedical Laboratories 6th Ed.*
- *USDA Animal and Plant Health Inspection Service Biotechnology Regulatory Services (APHIS-BRS).*

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 the following:

- Human, animal, and plant pathogens (bacteria, parasites, fungi, viruses, prions, archea, etc.).
- All human and nonhuman 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 plants or spores.
- Contaminated soil/water.
- Infected animals and animal tissues.

Recombinant or Synthetic Nucleic Acids. In the context of the *NIH Guidelines,* recombinant and synthetic nucleic acid molecules are defined as (1) recombinant nucleic acid molecules that are constructed by joining nucleic acid molecules and that can replicate in a living cell, i.e., recombinant nucleic acids, (2) 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 (3) molecules that result from the replication of those described in (1) or (2) above. Synthetic nucleic acid molecule 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 counterparts.

SECTION 2. RESPONSIBILITIES

The NMC (and the IBC acting on its behalf) is responsible for ensuring that all research with recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins sponsored by NMC is conducted in compliance with the *NIH Guidelines*.

2.1. NMC Management Responsibilities.

In addition to the responsibilities detailed in Section 1.3. (Appointment of Members and Committee Composition) above, the CEO oversees the IBC and research personnel who obtain, possess, or use recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins. The Research Administrator shall notify the PI of their responsibilities regarding the NMC's IBC Policy and Procedures.

2.2. IBC Member Responsibilities.

The following actions are the responsibilities of all IBC Members, including the IBC Chair:

- Review recombinant or synthetic nucleic acid molecule research and biohazardous materials, agents and toxins sponsored by the NMC (as specified in Section 1.4. Scope) for compliance with the *NIH Guidelines* and approve those research projects that are found to conform with the *NIH Guidelines*.

Note: This pertains to the initial and continuing periodic reviews and modifications to the currently approved research.

- Notify the PI of the results of the IBC's review and approval.
- Make a final determination of physical and biological containment for recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins research and modify containment levels, as necessary.
- Adopt emergency plans covering accidental spills and personnel contamination resulting from recombinant or synthetic nucleic acid molecule research.
- Assess the facilities, procedures, practices, training, and expertise of personnel involved in research utilizing recombinant or synthetic nucleic acid molecules and/or biohazardous materials, agents, and toxins.
- Report any significant problems with or violations of the requirements of the *NIH Guidelines* and any significant research-related accidents or illnesses to NMC CEO or HR and NIH/BPD within 30 days, unless the IBC determines that a report has already been filed by the PI. Incident Reports shall be sent to the Office of Science Policy, Biosafety, Biosecurity and Emerging Biotechnology Policy Division, NIH, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20817, Tel. 301-496-9838, Fax 301-496-9839.
- Suspend or terminate protocol approval for the possession or use of recombinant or synthetic nucleic acid molecules 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.
- Review the IBC Policies and Procedures (this document) annually and modify the document as necessary to ensure appropriate biosafety measures and adherence with federal and state requirements.
- Obtain specific review, registration and/or approval from NIH/BPD for research experiments that fall under *NIH Guidelines* Sections III-A, those that require NIH Director and IBC approval before initiation; III-B, those that require NIH OSP and IBC approval before initiation, and Appendix M.

Furthermore, the IBC may not authorize initiation of experiments which are not explicitly covered by the *NIH Guidelines* until NIH (with the advice of the Recombinant DNA Advisory Committee [RAC] when required) establishes the containment requirement.

2.3. IBC Chair Responsibilities.

Along with functioning as an IBC Member, outlined in Section 2.2. (IBC Member Responsibilities) above, the following actions are the responsibilities of the IBC Chair:

- Serves as a contact for all regulatory agencies, in collaboration with the NMC Biosafety & Compliance Specialist (BCS), including o NIH/BPD per General Responsibilities, Section IV-B-7-a-(4).

Note: Incident Reports shall be sent to the Office of Science Policy, Biosafety, Biosecurity and Emerging Biotechnology Policy Division, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax).;

- Approves the agenda for the convened meeting of the IBC;
- Signs IBC meeting Minutes;
- Requests that a meeting be convened; and, during the meeting,
    - Directs the meeting's agenda and deliberations;
    - Requests motions and seconds to these motions; and,
    - Motions to adjourn the meeting when business has concluded.

2.4. PI Responsibilities.

On behalf of the NMC, the PI is responsible for full compliance with the *NIH Guidelines*, the *BMBL* and these Policies and Procedures when using recombinant or synthetic nucleic acid molecules and biohazardous materials, agents, and toxins.

PI or a designee shall prepare the IBC Biological Use Application Form (on the New Mexico Consortium Forms webpage). Upon approval of the IBC Biological Use Application Form, the PI shall complete the IBC Protocol and Approval Acknowledgement Form. The PI shall complete the IBC Activity Modification Form, for any modifications to the IBC-approved protocol or activity (e.g., personnel, biological materials, laboratory location, etc.).

2.4.1. General Responsibilities.

The PI shall:

- Not begin or modify recombinant or synthetic nucleic acid molecule research which requires IBC approval prior to initiation (see Experiments Covered by the NIH Guidelines) or the proposed modification has been approved by the IBC as needed and has met all other requirements of the *NIH Guidelines*.
- Provide enough information for all projects, both funded and unfunded, that use recombinant or synthetic nucleic acid molecules and/or biohazardous materials, agents and toxins, so that the IBC can verify that they are exempt, although federal regulations allow exemptions for some types of recombinant or synthetic nucleic acid molecules use per Appendix A. (Exemptions under Section III-F-6--Sublists of Natural Exchangers).
- Determine whether experiments are covered by Section III-E (Experiments that Require IBC Notice Simultaneously with Initiation) and ensure that the appropriate procedures are followed.
- Report any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses to NMC CEO, the IBC Chair, NIH/BPD and other appropriate authorities (if applicable) within 30 days per General Responsibilities, Section IV-B-7-a-(3).
- Report any new information bearing on the *NIH Guidelines* to the IBC Chair.
- Be adequately trained in good microbiological techniques per General Responsibilities, Section IV-B-7-a-(5).
- Comply with permit and shipping requirements for recombinant or synthetic nucleic acid molecules. per General Responsibilities, Section IV-B-7-a-(7).
- Ensure the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., purity and genotypic and phenotypic characteristics) per the Responsibilities of the PI during the conduct of research, Section IV-B-7-e-(4) and correct procedures or conditions that might result in release of or exposure to recombinant or synthetic nucleic acid molecules and/or biohazardous materials, agents, or toxins per the Responsibilities of the PI during the conduct of research, Section IV-B-7-e-(3).
- Develop and obtain IBC approval of and adhere to site-specific protocols for handling accidental spills and personnel contamination per General Responsibilities, Section IV-B-7-a-(6), and,

- Inform the research personnel of any precautionary medical practices advised or requested, e.g., vaccinations, per Responsibilities of the PI Prior to Initiating Research, Section IV-B-7-d-(3).

2.4.2. Submissions by the PI to the IBC.
The PI shall:

- Make an initial determination of the required levels of physical and biological containment in accordance with the NIH Guidelines per Submissions by the PI to the IBC, Section IV-B-7-c-(1).
- Select appropriate microbiological practices and laboratory techniques to be used for the research per Submissions by the PI to the IBC, Section IV-B-7-c-(2).
- Submit the Initial (New) IBC Biological Use Application Form and any subsequent changes (e.g., changes in the source of DNA or host-vector system), if covered under Sections III-A, III-B, III-C, III-D, or III-E (see Experiments Covered by the NIH Guidelines), using the IBC Activity Modification Form to the IBC for review and approval or disapproval per Submissions by the PI to the IBC, Section IV-B-7-c-(3).
- Remain in communication with the IBC throughout the conduct of the project per Submissions by the PI to the IBC, Section IV-B-7-c-(4).

2.4.3. Responsibilities of the PI Prior to Initiating Research.
The PI shall:

- Make available to all laboratory staff the protocols that describe the potential biohazards and the precautions to be taken per Responsibilities of the PI Prior to Initiating Research, Section IV-B-7-d-(1).
- Instruct and train laboratory staff, per Responsibilities of the PI Prior to Initiating Research, Section IV-B-7-d-(2) in
    - the practices and techniques required to ensure safety, and,
    - the procedures for dealing with accidents; and,
- Inform the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection) per Responsibilities of the PI Prior to Initiating Research, Section IV-B-7-d-(3).

2.4.4. Responsibilities of the PI During the Conduct of the Research.
The PI shall:

- Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed per Responsibilities of the PI During the Conduct of Research, Section IV-B-7-e-(1).
- Investigate and report any significant problems pertaining to the operation and implementation of containment practices and procedures in writing to the Facility Director and IBC Chair, per Responsibilities of the PI During the Conduct of Research, Section IV-B-7-e-(2).
- Correct work errors and conditions that may result in the release of recombinant or synthetic nucleic acid molecule materials per Responsibilities of the PI During the Conduct of Research, Section IV-B-7-e-(3).
- Ensure the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., purity and genotypic and phenotypic

characteristics) per Responsibilities of the PI During the Conduct of Research, Section IV-B-7-e-(4).

SECTION 3. IBC BIOLOGICAL USE APPLICATION FORM

3.1. Protocol.

No research involving recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins can be initiated until the PI has received the Approval of the IBC Biological Use Application Form (on the New Mexico Consortium Forms webpage).

Although federal regulations allow exemptions for some types of recombinant or synthetic nucleic acid molecules used, the PI must provide enough information for **all** projects using recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins so that the IBC is aware of the activities and can verify that they are Exempt from *NIH Guidelines* (Section III-F).

If the IBC Biological Use Application Form information indicates that the proposed experiments are Exempt from *NIH Guidelines* or only require Notification to, not approval from, the IBC, the BCS and IBC Chair will review the materials for confirmation of PI's assessment.

If the IBC Biological Use Application Form information indicates that either only local approval is required; or, both local and federal approvals are required, the IBC shall:

- Review the IBC Biological Use Application Form at a convened IBC meeting consisting of a quorum of Members;
- Determine the action (i.e., Approval or Non-approval) by a simple majority of votes;
- Notify the PI in writing of the IBC decision; and, if approved,
- Grant Approval for a maximum of three (3) years.

No one shall obtain or use recombinant or synthetic nucleic acid molecules and/or biohazardous materials, agents and toxins until IBC Biological Use Application Form has been reviewed and approved, as needed, by the IBC. Both major and minor modifications to approved IBC Biological Use Application Forms shall not be implemented until an IBC Activity Modification Form, is submitted and approved by the IBC.

IBC Biological Use Application Forms for IBC review and approval of new projects, and IBC Activity Modification Forms for modifications or renewals of approved projects, must be emailed to research@newmexicoconsortium.org.

3.2. Initial (New) IBC Biological Use Application Forms.

The PI submits the Initial (New) IBC Biological Use Application Form to research@newmexicoconsortium.org. The Research Administrator (RA), in consultation with the BCS, reviews the IBC Biological Use Application Form for completeness and requests additional information from the PI as needed. The BCS forwards the IBC Biological Use Application Form to the IBC Chair for review.

- If the IBC Chair approves an Application (i.e., determines that the work described in the Application may commence prior to IBC member approval of the Application), they will notify the PI; or,
- If the IBC Chair disapproves an Application (i.e., determines that the work described in the Application cannot commence prior to IBC member review and approval), then the Application will be forwarded to the IBC members prior to convening an IBC meeting.
- The IBC members will review all Applications for work that the IBC Chair determines to be above Biosafety Level (BSL) 1 regardless of the IBC Chair's initial determination (of when the work described in the Application can commence).
- In addition, the IBC Chair's initial determination to approve or disapprove the Application can be superseded by the IBC member's determination (e.g., if the IBC Chair approves the Application, thereby determining that the work can commence prior to the IBC member's approval, but then the IBC members disapprove the work upon review of the Application, then the work must stop until the PI satisfactorily addresses the IBC members' concerns such that the IBC members decide to approve the work described in the Application).

The IBC Chair and the IBC Members:

- Convene an IBC meeting
- Decide whether the research gains Approval or/Non-approval
- Notify the PI of the IBC's decision.
- Forward a copy of the signed and dated review (IBC Biological Use Application Form) with the determination to the RA at research@newmexicoconsortium.org.

3.3. Revised IBC Biological Use Application Forms.

If Section I, Category of Application, on the IBC Biological Use Application Form is marked 'Revised – Existing IBC approval will expire' but it is not approved **prior** to the 'Expiration Date' listed on the previously approved IBC Biological Use Application Form, research **cannot** be continued. The PI is required to resubmit a Revised IBC Biological Use Application Form **every three (3) years**. The Revised IBC Biological Use Application Form is reviewed in the same manner as the Initial (New) IBC Biological Use Application Form submission.

SECTION 4. IBC MEETINGS

4.1. Requirements for a Quorum.

A quorum of IBC Members must be present when conducting official IBC business at meetings. The IBC defines a "quorum" as more than half of the regular voting members. An IBC Biological Use Application Form is approved only if a quorum is present and when more than 50% of the quorum votes in favor of approving the protocol. For reasons other than a conflict of interest, abstentions from voting do not alter the quorum or change the number of votes required.

4.2. IBC Biological Use Application Review.

The IBC Biological Use Application will be reviewed by the IBC members prior to the meeting. In the process of the review, the members will contact the PI with any queries as needed.

4.3. Meeting Procedures and IBC Biological Use Application Review.

IBC meetings are held as needed.

The BCS coordinates the IBC Biological Use Application review and schedules the meetings. The BCS communicates the review outcomes to the RA and coordinates IBC recordkeeping with RA.

In reviewing proposed recombinant or synthetic nucleic acid molecules research, the *NIH Guidelines*, in Sections II and III, cite a number of matters that the IBC should consider that include:

- Agent characteristics (e.g. virulence, pathogenicity, environmental stability).
- Types of manipulations planned.
- Source(s) of nucleic acid molecules sequences (e.g., species).
- Nature or function of the gene encoded by recombinant or synthetic nucleic acid molecule 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.
- Change in biosafety risk for organism formed through combination of sequences from multiple sources or synergistic effect of combining transgenes resulting in new phenotype.
- Containment conditions to be implemented.
- Applicable section(s) of the *NIH Guidelines* (e.g., Experiments Using Risk Group 2, Risk Group 3, Risk Group 4 or Restricted Agents as Host-Vector Systems, Section III-D-1; Experiments Involving the Formation of Recombinant or Synthetic Nucleic Acid Molecules Containing No More than Two-Thirds of the Genome of Any Eukaryotic Virus, Section III-E-1, etc.).

4.4. Possible IBC Biological Use Application Review Outcomes.

The IBC Biological Use Application review outcomes shall be one of the following:

- **Approval** – When the IBC has determined that all review criteria, based on the IBC Policies and Procedures and federally-mandated regulations have been adequately addressed by the PI, the IBC may approve the research, thus providing the PI permission to perform the research.
- **Approval with Conditions** – When the IBC requires additional information and/or resolution of issues identified in the conditional approval, which may include but are not limited to answering questions on the safety of the research protocol or completion of required or recommended additional training. The PI shall have the permission to perform the research upon meeting all the conditions specified in the Approval with Conditions.
- **Withhold Approval** - When the IBC determines that the IBC Biological Use Application Form has not adequately addressed all of the requirements of the IBC Policies & Procedures and other requirements as applicable, the IBC may withhold approval. The individual IBC members may not withhold approval upon prior review; this action may only be taken if the review is conducted in an IBC meeting.

4.5. Conflict of Interest (COI).

In accordance with Section IV-B-2-a-(4). Membership and Procedures of the IBC in NIH Guidelines, no IBC member may be involved (except to provide information requested by the IBC) in the review or approval of a project in which he/she has been or expects to be engaged or has a direct financial interest. All IBC members are required to sign the NMC's Conflict of Interest Form.

Other examples of COI cases include:

- An IBC member is the PI of the project;
- An IBC member is involved in a potentially competing research program;
- An IBC member's personal biases may interfere with their impartial judgment; and,
- An IBC member has access to funding or intellectual information that may provide an unfair competitive advantage.

IBC members who may have a COI may not be counted toward a quorum and may not vote. IBC members are required to inform the IBC about the COI by sending an email to research@newmexicoconsortium.org.

4.6. IBC Meeting Minutes.

Section IV-B-2-b. Functions of the IBC in NIH Guidelines requires that the IBC meeting minutes should offer sufficient detail about the discussion of the matters that were considered to document the IBC rationale for particular decisions.

Section IV-B-2-a-(7) Membership and Procedures of the IBC in NIH Guidelines requires institutions to provide meeting minutes to the public upon request.

Keeping IBC meeting minutes is the responsibility of the BCS.

4.7. PI Notification.
Upon completion of the review process, the IBC Chair notifies the PI of the review outcome in writing. Included in the notification will be the IBC decision on the biocontainment/biosafety level to be used for the proposed research, any special safety considerations, applicable sections of the *NIH Guidelines* and the approval period (i.e., the Anticipated Start Date and Anticipated End Date, in Section I of the IBC Biological Use Application Form for the approved research).

The BCS forwards a copy of the reviewed and signed IBC Biological Use Application Form to the PI and to research@newmexicoconsortium.org for NMC records.

The PI acknowledges the receipt of the review outcomes by completing the IBC Protocol and Approval Acknowledgement Form and emailing it to research@newmexicoconsorium.org.

4.8. Attendance of Non-Members.
IBC meetings are considered open and, as such, members of the NMC community and the public at large may request to attend an IBC meeting. Those who wish to attend an IBC meeting must notify the RA in advance (505) 412-4200 or research@newmexicoconsortium.org about the desire to attend.

SECTION 5. REPORTING REQUIREMENTS

5.1. Reportable Incidents and Violations and Reporting Procedures.
Incidents/problems involving recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins must be immediately reported to the BCS and CEO or any available NMC administrator or manager. Examples of reportable incidents:

- Any overt exposure, such as a needle stick, splash, or contamination due to equipment failure.
- A containment breach, which may be subsequently determined to pose either an overt or potential exposure to individuals.
- Incidents involving improper disposal of recombinant or synthetic nucleic acid molecules.

These reports may be submitted using the NMC Incident Report Form found on the New Mexico Consortium Forms webpage.

Failure by research personnel to follow federal and institutional regulations, guidelines, policies and/or procedures may also require reporting to the appropriate institutional, local, state and/or federal agencies. Violations may include, but are not limited to, conduct of new or ongoing research without appropriate federal or institutional registration, review, approval or oversight.

5.2. PI Reporting Responsibilities
General Responsibilities of the PI, Section IV-B-7-a-(3). and Section IV-B-7-a-(4). indicate that the PIs must report any significant incident, violation of the NIH Guidelines, or any significant, research-related accidents and illnesses immediately by contacting the

NMC CEO, HR, BCS or any available NMC Admin or manager. Examples of incidents and violations include:

- Overt exposures are defined as exposures that result in direct personnel exposure to biohazardous materials such as injection, spills, splashes or aerosol inhalation.
- Potential exposures are defined as exposures that have a high risk of exposing personnel to biohazardous materials such as spills, containment failure while working with the agent or equipment failure that may produce aerosols.
- Overt exposure.
- Any illness that may be caused by the agents used in the laboratory incidents involving the improper disposal of recombinant or synthetic nucleic acid molecules.

In addition, PIs must report other information to the IBC as soon as they become aware of the information:

- Information to support a new host-vector system.
- Application for determination of containment for experiments not covered by the *NIH Guidelines*.

5.3. IBC Reporting Responsibilities

5.3.1. NIH/BPD Annual Reports per IBC Membership and Procedures.
Per Section IV.-B-2-a-(3), on behalf of the IBC, the BCS and/or the RA, shall:

- File annual reports with NIH/BPD that include,
    - A roster of all IBC members clearly indicating the Chair, contact person and applicable experts; and,
    - Biographical sketches of all IBC members.

5.3.2. Violation Report per IBC Functions.
Per Section IV-B-2-b-(7), the IBC shall:

- Report to the CEO, as soon as possible, and to the NIH/BPD within 30 days any,
    - significant incidents;
    - violations of the *NIH Guidelines*; or,
    - significant research-related accidents and illnesses.

5.3.3. Other Reports.
The IBC shall also report to the CEO:

- Research involving recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins without prior IBC approval (see Section III-D.)
- Lax security, unsafe procedures used in a laboratory setting, improper disposal of recombinant waste (see Appendix G.)
- Significant changes to proposed research risk without prior notification and approval by IBC (see Section IV-B-2-b.)

5.3.4 Public Comments.
Per IBC Membership and Procedures, Section IV-B-2-a-(7) in the NIH Guidelines, if public comments are made on IBC actions, the IBC, through the BCS or the RA, shall:

- Forward both the public comments and the IBC's response to the CEO.

5.4. Response to External Requests for Information.
Per IBC Membership and Procedures, Section IV-B-2-a-(7) in the NIH Guidelines, upon request at research@newmexicoconsortium.org, the NMC will make available to the public all IBC meeting minutes and any documents submitted to or received from funding agencies of which the latter are required to make available to the public.

SECTION 6. NON-COMPLIANCE

6.1. Allegations Investigation
Any allegations of non-compliance or unsafe working conditions shall be made to any member of the IBC by sending an email to research@newmexicoconsortium.org. The IBC will work with the CEO to investigate and suggest a resolution. The allegations and resulting investigations will remain confidential to the extent possible.

6.2. Possible Non-Compliance Outcomes.
Findings of non-compliance may result in one or more of the following actions:

- Suspension of use of recombinant or synthetic nucleic acid molecules and/or biohazardous materials agents or toxins.
- Termination of approval for use of recombinant or synthetic nucleic acid molecules and/or biohazardous materials agents or toxins.
- Any other action necessary to protect the public and/or NMC.

SECTION 7. TRAINING

7.1. IBC Member Training.
All IBC members are required to review:

1. Laboratory Safety Program;
2. *NIH Guidelines*;
3. NMC's IBC Policies and Procedures (this document); and,
4. IBC training through the Collaborative Institutional Training Initiative (CITI) program

7.2. PI and Research Personnel Training.
In addition to training that is mandatory for the facility, PIs and research personnel performing recombinant or synthetic nucleic acid molecules research that is non-exempt must review the *NIH Guidelines* and the other training requirements for their job category, Training Requirements. It is the PI's responsibility to complete and ensure all research personnel have received the required training prior to application review by IBC.

SECTION 8. REFERENCES

BMBL 6th edition, Revised June 2020

Collaborative Institutional Training Initiative (CITI) program

New Mexico Consortium Employee Conflict of Interest (COI) Form

New Mexico Consortium Forms webpage

New Mexico Consortium IBC Activity Modification Form

New Mexico Consortium IBC Biological Use Application Form (see New Mexico Consortium Forms webpage)

New Mexico Consortium IBC Protocol and Approval Acknowledgement

New Mexico Consortium Incident Report Form (see New Mexico Consortium Forms webpage)

New Mexico Consortium Laboratory Safety Program: https://newmexicoconsortium.org/wp-content/uploads/2021/09/LSP-and-Appendices-070119.pdf

New Mexico Consortium Training Acknowledgement (see New Mexico Consortium Forms webpage) or https://newmexicoconsortium.org/wp-content/uploads/2021/09/TrainingAcknowledgementForm090121copy.pdf

NIH Biosafety and Recombinant DNA Policy

NIH Guidelines

USDA APHIS Biotechnology Regulatory Services

U.S. Department of Health and Human Services, 45 Code of Federal Regulations (CFR) 46

U.S. Department of Health and Human Services, Human Subject Regulations Decision Charts

SECTION 9. CONTACTS

Biosafety and Compliance Specialist (BCS):
Shannon Flynn sflynn@newmexicoconsortium.org

Chief Executive Officer (CEO):
Steven Buelow buelow@newmexicoconsortium.org

Chief Operations Officer (COO):
Irina Izvekova izvekova@newmexicoconsortium.org

Human Resources Representative (HR):
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Attachment A: Institutional Biosafety Committee (IBC) Code of Conduct & Member Acknowledgement

The New Mexico Consortium's IBC carries out its mission through the work of its Members. The IBC Member owes a fiduciary duty to the IBC, which includes the duties of diligence, loyalty, ethics, and confidentiality. These duties supersede any obligation to any IBC Member's home institution or department.

IBC Members shall adhere to the following PRINCIPLES:

1. Will be familiar with and follow the IBC policies governing their responsibilities regarding their service on the IBC as set forth through the NIH and other Federal and State Regulations.
2. Will attend the IBC meetings and participate in the IBC reviews and official business.

3. Will preserve and protect the confidentiality of all information entrusted to them by the IBC and the researchers who have submitted an IBC application. All discussions that occur at any time among IBC members regarding the researcher(s) and/or their IBC application, all discussions conducted in the IBC meetings, and any phone calls or any discussions with the researcher(s) and/or general counsel are deemed confidential. An IBC Member may not disclose any confidential or sensitive information they receive to anyone beyond the IBC without the written permission of the IBC Chair and the Office of Compliance. The duty to maintain confidential information extends permanently after the IBC Member has concluded service on the IBC.

4. Will avoid actual or apparent conflicts of interest. The IBC Member shall be diligent in considering how their personal relationships and personal interests may affect or be perceived as affecting their work on the IBC.

5. Will refrain from accepting any gifts, including money, tangible property, favors or services that might be reasonably perceived to influence him/her in the discharge of his/her duties to the IBC.

6. Shall ensure that all IBC decisions are made in compliance with relevant regulatory and legal requirements.

7. In his/her individual capacity, shall refrain from any actions or public statements that could reasonably be perceived to be made on behalf of the IBC or the NMC.

8. Will not respond to media inquiries about IBC matters during or after the conclusion of his/her service on the IBC but will refer such inquiries to the Director.

9. Is responsible for reporting any situation that he/she knows or has reason to believe may have violated Federal Regulations/Policies and is responsible for assuring that the IBC Chair is made aware of the potential violation in a timely manner.

IBC Member Acknowledgement of the Code of Conduct

I acknowledge that I have read and understand the principles contained in the IBC Code of Conduct. I agree to comply with these principles. I understand that breaches of this Code of Conduct may result in my removal as an IBC Member.

Printed Name	Signature	Date

When complete, scan & email this page to: research@newmexicoconsortium.org Thank you.