NORTHERN ARIZONA UNIVERSITY

Environmental Health and Safety

Institutional Biosafety Committee (IBC) Policies and Procedures Manual 2025

Andrew Koppisch, PhD., IBC Chair
Shelley Jones, M.S., Biosafety Officer

Revised 1/2025

Table of Contents

1.0 Introduction

1.1 National Institutes of Health *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*

The National Institutes of Health *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH *Guidelines)* are applicable to all recombinant or synthetic nucleic acid research conducted within the United States at institutions that receive federal funding for research. Northern Arizona University (NAU) must ensure that recombinant or synthetic nucleic acid research conducted at or sponsored by NAU, irrespective of the funding source, if any, complies with the *NIH Guidelines* as a condition for NIH funding of such research at NAU. To meet the requirements of these guidelines, all Principal Investigators using recombinant or synthetic nucleic acid molecules must submit a protocol to the Institutional Biosafety Committee for review.

Failure to comply with the *NIH Guidelines* may result in suspension, limitation, or termination of NIH funds for any and all recombinant or synthetic nucleic acid research at NAU, or a requirement for prior NIH approval of any or all recombinant or synthetic nucleic acid projects at NAU. The NIH *Guidelines* are available at http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines.

1.2 Select Agent and Toxin Regulations

The Department of Health and Human Services (HHS), Centers 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 toxins. The regulations set forth the requirements for registration of listed select agents and toxins, security risk assessments, safety plans, security plans, emergency response plans, training, transfers, record keeping, inspections, and notifications http://www.selectagents.gov. To meet these regulations, all Principal Investigators using select agents or toxins must submit a protocol to the IBC for review.

1.3 Biosafety in Microbiological and Biomedical Laboratories

Biosafety in Microbiological and Biomedical Laboratories (BMBL) is published by CDC and NIH. This document contains guidelines for microbiological practices, safety equipment, and facilities for each of the four established biosafety levels. The BMBL is considered the standard for biosafety and should be used as a resource for Principal Investigators in planning their work with biohazards cdc.gov/labs/bmbl.

1.4 OHSA Bloodborne Pathogens Regulations

The requirements described in the Occupational Safety and Health Administration's (OSHA) Bloodborne Pathogens regulation (29 CFR § 1910.1030), available at https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030, apply to work with human blood, tissue, organs, body fluids, and cell cultures. Special training, medical surveillance, procedures, and equipment that must be in place for protection against bloodborne pathogens, needlesticks, and other sharps injuries, are described in the NAU Exposure Control Plan at http://nau.edu/Research/Compliance/Environmental-Health-and-Safety/Biological-Safety/. Handling and disposal of biohazardous waste is also regulated by OSHA under the OSHA Bloodborne Pathogens regulation and by state and federal statutes. The procedures for biohazardous waste handling are described in the NAU Biosafety Manual http://nau.edu/Research/Compliance/Environmental-Health-and-Safety/Biological-Safety/.

1.5 NAU Biosafety Manual

The NAU Biosafety Manual is intended as a resource for information, guidelines, policies, and procedures that will enable and encourage those working in the laboratory environment to work safely and to eliminate, or reduce, the potential for exposure to biological hazards. The information presented also reflects the requirements and guidelines of federal and state regulations. It is intended that the

Principal Investigator (PI) and supervisory personnel will supplement this information with instruction and guidance regarding specific practices and procedures unique to the work being done in their laboratories. The most current version of the Manual is available on-line on the NAU Environmental Health & Safety (EH&S) website at http://nau.edu/Research/Compliance/Environmental-Health-and-Safety/Biological-Safety/.

1.6 Scope of Coverage of These Policies and Procedures

All faculty members, staff employees, and students are included within the scope of these *Policies and Procedures*, as are collaborators and visitors from other organizations working with NAU faculty members, staff employees, or students.

The Institutional Biosafety Committee (IBC) has oversight of all activities involving recombinant or synthetic nucleic acids and biohazards, including those:

- Sponsored by the University,
- Conducted by University research personnel,
- Conducted using the University's property and/or facilities, or
- Received, stored, used, transferred or disposed of at any of the University's facilities.

The Institutional Biosafety Committee Policies and Procedures Manual (PPM) and the EH&S Biosafety Manual provide a review of the relevant regulatory requirements and University policies. The PPM should be used in conjunction with the Biosafety Manual and University policies and procedures.

1.7 Definitions

For the purposes of these policies and procedures, NAU's Institutional Biosafety Committee applies the following definitions to *recombinant or synthetic nucleic acid molecules* and *biohazards*.

A. Recombinant or Synthetic Nucleic Acid Molecules

Recombinant or synthetic nucleic acid molecules are defined as:

(i) molecules that a) are constructed by joining nucleic acid molecules, and b) can replicate in a living cell (i.e. recombinant nucleic acids),

(ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (i.e. synthetic nucleic acids), or

(iii) molecules that result from the replication of those described in (i) or (ii) above.

B. Biohazards

Biohazards are microorganisms, microbial toxins, or other biological agents that can infect and/or cause disease in humans, animals, or plants. Biohazards are often referred to as infectious agents or etiological agents. Categories of potentially infectious biological materials include:

- Human, animal, and plant pathogens (bacteria, bacterial toxins, parasites, fungi, viruses, rickettsia, prions, protozoans, genetically modified specimens)
- Select agents or toxins
- All human or nonhuman primate blood, blood products, tissues, and certain body fluids
- Cultured human cells and potentially infectious agents these cells may contain
- Infected animals, their tissues and bodily fluids
- Recombinant or synthetic nucleic acid molecules

Use or possession of biohazards must be approved by the IBC. If vertebrate animals are being utilized in activities with biohazards, the Institutional Animal Care and Use Committee (IACUC) must also review the proposed work.

2.0 Institutional Biosafety Committee

2.1 Mission of the Institutional Biosafety Committee

The Institutional Biosafety Committee is advisory to the Vice President for Research on policies and procedures relating to the use of infectious micro-organisms in research and teaching; the disposal of infectious waste; and the certification of University compliance with the National Institutes of Health *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* for all projects involving recombinant or synthetic nucleic acid molecules. The committee is appointed by and responsible to the Associate Vice President for Research who serves as the Institutional Official.

2.2 Authority Granted to Institutional Biosafety Committee

Each institution conducting or sponsoring recombinant or synthetic nucleic acid research that is covered by the NIH *Guidelines* is responsible for ensuring that the research is conducted in full conformity with the provisions of the NIH *Guidelines*. Therefore, NAU established the Institutional Biosafety Committee that meets those requirements and that carries out the functions, as set forth in Section IV-B-2-a and Section IV-B-2-b of the *NIH Guidelines.*

In addition to that authority, the IBC has established and implemented these policies and procedures to provide for the safe and ethical conduct of research and teaching activities involving all biohazards and to facilitate compliance with the NIH *Guidelines,* other applicable laws, and University policies. The IBC has the authority to approve, require modifications to secure approval, disapprove, suspend or terminate research activities as required to assure compliance with applicable regulations and guidelines.

Responsibilities of the IBC include:

- Reviewing research involving recombinant or synthetic nucleic acid molecules and biohazardous materials
- Assessment of facilities (in collaboration with EH&S)
- Developing procedures, practices and training of research personnel to assure compliance with NIH *Guidelines* and regulations.

2.3 Institutional Official and University Responsibilities

The responsibility for the Institutional Biosafety Committee at Northern Arizona University rests with the Vice President for Research who has delegated the responsibility to the Associate Vice President who serves as the Institutional Official (IO). The IO:

- Appoints IBC members.
- Evaluates IBC members with input from the IBC Chair.
- Names the membership and chairperson of the IBC to support oversight of research investigations for research to obtain, possess or use biohazards.
- Directs reporting of noncompliance.

2.4 Committee Composition

The Institutional Official has the authority to appoint the Chair, members and alternate members of the Institutional Biosafety Committee. Appointments are made formally in writing. In accordance with the NIH *Guidelines*, the IBC is comprised of at least five members with:

- At least one expert in recombinant or synthetic nucleic acid technology.
- At least one expert in biological safety and physical containment.
- At least one expert in select agents and toxins (use, storage, transfer, and disposal).
- At least one expert in plant, plant pathogen, or plant pest containment principles.
- At least one expert in animal containment principles.
- The Biological Safety Officer.
- At least two members from the surrounding community, and not affiliated with the

University, to represent the interests of the community in regard to health and protection of the environment. These will be chosen from:

- Representatives of community interests with respect to health and protection of the environment, e.g., officials of state or local public health or environment authorities, local government bodies, persons with medical, occupational, or environmental expertise.
- They can also be the individuals who represent community attitudes.

The Chair shall be a scientific researcher with experience in biohazards. With the exception of the community members, IBC members shall be faculty or staff of the University. The term of membership is three years and is renewable without limit upon mutual agreement.

Members will collectively have appropriate expertise and experience in the use of biohazards. They must have expertise in assessment of risk to environment and public health along with knowledge of University policies, applicable laws, and professional standards.

IBC members with a conflict of interest (i.e., are acting as a research investigator, have financial interest in the project, are related to a member of the research team, etc.) in a particular project being reviewed shall be recused during the IBC's deliberations. They may be asked to provide clarifying information to the IBC, but they shall not vote.

Members are expected to attend a majority of IBC meetings. Anticipated absences from an IBC meeting should be communicated to the IBC Chair and the Office of Biological Safety as soon as possible, preferably at least 24 hours before the meeting.

2.5 Specialized Expertise Requirements

2.5.A Subcommittees

If the committee determines that it does not possess the expertise necessary to evaluate some the details of the proposed protocol (or amendment), it may choose to have a subcommittee review those details and provide a report to the committee (assigned designated review). Makeup of the subcommittee is determined on a case-by-case basis by either the committee as a whole or the assigned designated reviewer to assure sufficient expertise is present. Subcommittee members may include members of the IBC, University faculty or staff that are not IBC members, or individuals from outside of the University. PIs are informed of the use of a subcommittee and are asked to work directly with the subcommittee.

2.5.B Consultants

Should an occasion arise when the IBC lacks the specialized expertise necessary to review proposed work, it may retain a suitable consultant to advise the committee and to assist in the review. The consultant may attend meetings but will not vote, nor will his/her attendance count toward quorum.

2.6 Chair of Institutional Biosafety Committee

A voting member of the committee, the Chair presides over the IBC meetings and, when necessary, designates a member of the committee to serve in his or her absence. In addition to providing committee leadership, the Chair performs an initial review of registration materials to ensure appropriate assignment of biosafety level. The Chair will also:

- Serve as a contact for all regulatory agencies,
- Act as liaison between the research personnel and IBC,
- Review submitted protocols, modifications, and annual reviews,
- Ensure that IBC committee members are adequately trained,
- Approve the agenda for the convened meeting of the IBC, and
- Attends appropriate national meetings dealing with biosafety issues and the role of IBCs.

2.7 Biosafety Officer

The Biosafety Officer (BSO) shall be a voting member of the IBC. The principal function of the Biosafety Officer is to advise research personnel, the IBC and University departments concerning the most appropriate safety practices that will assure the safe conduct of research with biohazards. The Biosafety Officer responsibilities include:

- Performing periodic inspections of laboratories conducting research using biohazards to ensure that laboratory standards are rigorously followed prior to commencement of research.
- Reporting to the IBC any problems, violations, research-related accidents or illnesses, or concerns; inspection findings for all IBC covered research; and all violations of the NIH *Guidelines*.
- Performing and reviewing the required risk assessment to determine appropriate biosafety level and personal protective equipment (PPE) for handling and disposal of biohazards.
- Assisting researchers in developing plans for preventing and handling accidental spills and personnel contamination.
- Investigating laboratory accidents involving biohazards.
- Providing technical advice to research personnel and the IBC on research safety procedures.
- Providing training in the safe use and practices for those working with biohazards.
- Reviewing IBC protocols before they can be considered for approval.

The BSO has the authority to suspend activities that are deemed to be an immediate threat to safety of personnel, environment, or the community at large. A suspension by the Biosafety Officer must be immediately reported to the IBC and will be discussed in a convened meeting of the IBC.

2.8 Select Agent Responsible Official

The Responsible Official is responsible for compliance with select agent registration and reporting requirements. The Responsible Official will report any concerns or violations in the select agent program to the IBC immediately and will communicate in a timely manner when there are issues that overlap with responsibilities of the IBC.

2.9 Education of IBC Members

New members of the IBC receive introductory training from Chair of the IBC with support from the Environmental Health & Safety to ensure they are familiar with the NIH *Guidelines*. IBC members shall receive updates at IBC meetings on changes affecting the possession and/or use of biohazardous materials and newsworthy items of interest to the Biosafety community. Other educational opportunities may include professional conferences and symposia.

2.10 Committee Meeting Schedule and Access

The Institutional Biosafety Committee meets as needed to review applications proposing use of biohazards. The IBC Chair may call an emergency meeting of the IBC as necessary. It is the general practice of the IBC to convene meetings attended by a quorum of members. However, in accordance with guidance from the Office of Biotechnology Activities, the use of teleconferencing allows for participation by board members who are unable to physically attend a meeting. On rare occasions, a meeting may be convened entirely by teleconference, should sufficiently time-sensitive or urgent matters arise. In these cases, the usual and customary procedures shall apply, i.e., a quorum shall be established; votes shall be taken; and minutes shall be recorded and made available upon request from the public.

Institutional Biosafety Committee meetings are considered open and, as such, members of the University community and the public at large may request to attend an IBC meeting. Those who wish to attend an IBC meeting should notify the Biosafety Officer in advance at (928)523-7268. While no one will be denied access to a meeting, the Biosafety Officer and IBC Chair must be made aware of additional attendees. Last minute requests may not be honored if the meeting room cannot accommodate additional attendees.

If the IBC determines an executive session is needed, guests may be excluded from that portion of the meeting and may return when the executive session has ended.

2.11 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 more than half the regular voting members. A protocol is approved only if a quorum is present, and if more than 50 percent of the quorum votes in favor of protocol approval. Abstentions from voting do not alter the quorum or change the number of votes required.

Members are expected to attend a majority of the convened meetings. Anticipated absences by the meeting should be communicated to the IBC Chair and Biosafety Officer as soon as possible, preferably at least 24 hours in advance of the meeting. Members who fail to attend meetings on a regular basis may be removed from the committee.

2.12 Materials Distributed to Committee Members for Review

Prior to the meeting, each member shall have access to all protocols and related documentation to be reviewed at the meeting. Minutes of the previous meetings will also be distributed in advance.

2.13 Institutional Biosafety Committee Registration

The IBC is registered with the National Institutes of Health's Office of Biotechnology Activities (OBA). The annual report, required by OBA, is filed annually on behalf of the IBC and NAU by the Office of Biological Safety, and includes an updated list of IBC members indicating the role of each member and bio-sketches for each member.

The purpose of registration and annual membership updates are to:

- Provide assurance of IBC review of biosafety risks to the Office of Biotechnology Activities (OBA).
- Indicate University point of contact.
- Demonstrate high standards of safety in conducting recombinant or synthetic nucleic acid molecule research.

3.0 Responsibilities of the Committee

On behalf of the institution, the Institutional Biosafety Committee responsibilities include, but are not limited to, the following:

A. Review, approve and oversee research utilizing biohazards, conducted at or sponsored by the University, for adherence with the NIH *Guidelines*, all applicable laws, and University policies. This pertains to the initial review, annual reviews, and modifications to the currently approved research.
B. Make final determination of physical and biological containment for biohazards and modify containment levels as necessary.
C. Assess the facilities, procedures, practices, training and expertise of personnel involved in research utilizing biohazards.
D. Determine necessity of health surveillance or vaccinations of personnel.
E. Review and report any significant problems, violations of the NIH *Guidelines* and any significant research-related accidents or illnesses to the IO and to the appropriate authorities.
F. Direct development of appropriate procedures as required by NIH/OBA, CDC and USDA regulations to oversee the possession and/or use of biohazards.
G. Suspend or terminate protocol approval for the possession or use of biohazards, where the IBC finds non-compliance or that such use or possession poses undue risk to research personnel or a threat to the health and safety of the community or environment.

H. Periodically review the IBC policies and procedures and modify them as necessary to ensure appropriate biosafety measures and adherence with federal and state requirements.
I. Review research protocols that include the possession and/or use of biohazards for compliance with NIH *Guidelines,* Select Agent Regulations*,* as well as applicable University policies, local, state, and federal regulations. As part of the review process, the IBC will do the following:
    1) Conduct an independent assessment of the containment levels (BSL-1 to BSL-3) in collaboration with EH&S.
    2) Conduct an assessment of facilities, procedures, practices, training, and expertise of personnel conducting research involving biohazards.
    3) Ensure adherence with all surveillance, data reporting, and adverse event reporting requirements set forth in the NIH *Guidelines*.
J. Coordinate with the Responsible Official (RO) to verify that all select agents and toxins work is in compliance with CDC or USDA regulations.
K. Obtain specific review, registration and/or approval from NIH/OBA for research that falls under Sections III-A, III-B, III-C and Appendix M of the NIH *Guidelines*. Review and approve architectural plans for new facilities or renovations to existing facilities where biohazard research may be performed. The IBC designates EH&S as their agent to review plans and approve on their behalf.

4.0 Administrative Support for the Institutional Biosafety Committee

4.1 Office of Biological Safety

The IBC is supported and administered by the Office of Biological Safety, which has offices in the Applied Research and Development (ARD) Building. Meetings are typically held in the ARD Building.

4.2 Responsibilities of the Office of Biological Safety

The Office of Biological Safety is responsible for maintaining NAU's registration with the NIH Office of Biotechnology Activities (OBA); reporting to OBA at least annually; updating the committee roster and bio-sketches; and facilitating the institution's responsibilities for administrative, oversight, review and reporting functions. The Office of Biological Safety accepts, screens, and tracks biohazard protocols and material transfer agreements. They act as a liaison for the IBC with other University departments and committees (e.g., Institutional Animal Care and Use Committee [IACUC], Institutional Review Board [IRB], Office of General Counsel [OGC]). In collaboration with the IBC Chair, they coordinate the committee's activities. The Office of Biological Safety supports University investigators by assisting with IBC submissions, training, and biosafety information.

The Office of Biological Safety has further responsibility for maintaining the official records of the IBC, including correspondence with the OBA, meeting minutes, protocol records, and committee rosters and bio-sketches. The website for the IBC is maintained by this office and located at http://nau.edu/Research/Compliance/Environmental-Health-and-Safety/Biological-Safety/

4.3 Meeting Minutes

Minutes of IBC meetings shall be taken by the IBC Secretary and shall, at a minimum, document the date and place of the meeting; attendees; whether minutes of the prior meeting were approved; whether and why the meeting was open or closed; all major motions and major points of order; whether motions were approved; and time of adjournment. Minutes shall be recorded in sufficient detail to serve as a record for major points of discussion and the committee's rationale for particular decisions; thus, documenting that the IBC fulfilled its review and responsibilities as outlined in Section IV-B-2-b of the NIH *Guidelines.* The minutes will give a brief summary of discussions that take place during executive session.

Minutes shall document deliberation relative to the assessment of the containment level required, the facilities, the procedures, practices, and training of personnel involved in biohazard research, IBC actions taken on each protocol reviewed, votes on actions, any required modifications for IBC approval, members who are recused, and the basis for disapproving any proposed protocol, annual review, or modification.

4.4 Access to Minutes and Other Official Records of the IBC

In accordance with the NIH *Guidelines* and the Freedom of Information Act (FOIA), 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." Requests for information will be coordinated through the Office of General Counsel.

4.5 Records Retention

Records of the IBC shall be retained by the Office of Biological Safety including IBC protocols, meeting minutes, and rosters of IBC members for a period of three years. For protocols, the three years begins after expiration or termination.

Principal Investigators are required to keep copies of research records for a period of three years after closure of the project. All records must be available to authorized representatives.

5.0 IBC Protocol Review Process

5.1 Timeline for Review

Meetings are schedule as needed to facilitate proposed research projects. Submission deadlines are two weeks prior to a scheduled IBC meeting.

5.2 IBC Review Required

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

A. The use of recombinant or synthetic nucleic acid molecules.
B. The deliberate transfer of a drug resistance trait to micro-organisms that are not known to acquire the trait naturally.
C. The deliberate transfer of recombinant or synthetic nucleic acids or RNA derived from recombinant or synthetic nucleic acids into human research participants (human gene transfer).
D. The deliberate formation of recombinant or synthetic nucleic acids containing genes for the biosynthesis of toxin molecules.
E. The use of Risk Group-2 (RG-2) or Risk Group-3 (RG-3) agents (per the NIH *Guidelines*) as host-vector systems.
F. The use of human and animal etiologic/biohazardous agents including select agents and toxins.
G. The cloning of recombinant or synthetic nucleic acids from RG-2 or greater agents into non-pathogenic prokaryotes or lower eukaryotic host-vector systems.
H. The use of infectious or defective RG-2 or greater agents in the presence of a helper virus.
I. Whole animals in which the animal's genome has been altered by stable introduction of recombinant or synthetic nucleic acids or DNA into the germ-line (transgenic animal).
J. Viable recombinant or synthetic nucleic acid-modified microorganisms or cell lines tested on whole animals.
K. Genetically engineered plants by recombinant or synthetic nucleic acid methods.
L. More than 10 liters of recombinant or synthetic nucleic acid culture.

M. The formation of recombinant or synthetic nucleic acid molecules containing one-half or more of the genome of a eukaryotic virus or from the same virus family.
N. All research using biological toxins or bioactive derivatives or subunits of toxins.
O. Research collecting or analyzing human or nonhuman primate cell lines, tissues, blood, other blood products, or feces.

5.3 Scope of Review

When reviewing protocols, there are several activities that the Institutional Biosafety Committee must carry out on behalf of the University:

- Assessment of the containment levels required by the NIH *Guidelines.*
- Assessment the facilities, procedures, practices, and training and expertise of personnel involved in research with biohazards, in collaboration with EH&S.
- Ensure compliance with the NIH *Guidelines*, University policy, and all applicable federal, state, and local regulations.

In reviewing proposed recombinant or synthetic nucleic acid molecule 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 the inserted DNA sequences (e.g., species)
- Whether an attempt will be made to express a foreign gene, and if so, the protein that will be produced
- Nature of the inserted DNA sequences (e.g., structural gene, oncogene)
- Host(s) and vector(s) to be used
- Containment conditions to be implemented
- Applicable section of the NIH Guidelines (e.g., Section II-D-1, Section III-E-1, etc.)

To assist with this review, all laboratories that are requesting to perform research with biosafety level 2 or 3 biohazards or containment are required to be inspected annually and to develop a Laboratory-Specific Biosafety Manual. The Biosafety Officer, as agent for the Institutional Biosafety Committee, will assist the Principal Investigator in completing these requirements. Information on this process can be found at http://nau.edu/Research/Compliance/Environmental-Health-and-Safety/Biological-Safety/.

5.4 Types of Review

Depending on the biohazards being used, the Institutional Biosafety Committee may utilize the following types of review:

A. Chair Review

During Chair Review, the protocol or modification is reviewed by the Biosafety Officer and the IBC Chair. After the review is complete, the Chair has the delegated authority to approve, request modifications, or request Designated Review or Full Committee Review.

B. Designated Review

The Designated Review process is an expedited committee review process where the IBC Chair appoints a committee member who, along with the Biosafety Officer, will review the protocol or modification. All of the IBC members are electronically provided the protocol or modification as well as informed of the member selected as the Designated Reviewer (DR). Committee members are given 2 business days to either accept the designation or call for full committee review. If a single committee member calls for a full committee review, then the protocol or modification is reviewed by the full IBC at the next convened meeting. Alternately, a committee member can submit comments to the DR to include in the correspondences with the PI. If the DR and the Biosafety Officer approve of the protocol or modification (or revised version based on comments), they both inform the Chair and IBC

Coordinator of their decision, and the approval is processed. Alternately, the DR or Biosafety Officer may call for a full committee review.

The DR has the delegated authority to approve, request modifications, or request Full Committee Review. The IBC Chair or Biosafety Officer can serve as the DR, but, as with any Designated Review, their assignment must be approved by the committee via an electronic notification. There cannot be blanket consent by IBC members for Designated Review approval; consent must be given for each Designated Review request individually. Designated Review approvals are documented in the consent agenda of the next IBC meeting.

C. Full Committee Review

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

1) **Approval** – When the IBC has determined that all review criteria, based on the IBC Policies 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.
2) **Approval with Required Modifications** – This status is used for protocols that the committee feels have met all regulations but may have one or two minor obligations to meet (e.g., training, equipment inspection, etc.) before approval can be issued.
3) **Tabled** – If the protocol requires clarification in order for the IBC to make judgment, certain committee members with certain expertise are not present, the IBC wishes to seek external consultation, or any of a number of other reasons prevents the IBC from conducting its review, then the IBC may wish to defer or table the review.
4) **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.

Principal Investigators are invited and strongly encouraged to attend the IBC meeting when their protocol is being reviewed. Failure to attend the IBC meeting to answer questions posed by the committee may result in a delay of the IBC approval.

5.5 Review of Protocols

Principal Investigators must complete and submit a protocol form to the IBC for review. The protocol will be assigned a protocol number for reference. The type of review the protocol receives will be determined by its classification:

Category	Review Type	Approval Period
Select Agent and Risk Group 3 Protocols	Full Committee Review	3 years
Protocols subject to NIH *Guidelines*	Full Committee Review	3 years
Protocols Exempt from NIH *Guidelines* (including work with human derived materials/cell cultures)	Designated Review or Full Committee Review (Chair determines review type)	3 years
Risk Group 1 Protocols Exempt from NIH *Guidelines*	Chair Review	No expiration

5.6 Conflict of Interest

The NIH *Guidelines* state that no Institutional Biosafety Committee member may participate in the IBC

review or approval who has a conflict of interest in the project (e.g., is acting as the Principal Investigator, has financial interest in the project). IBC members are required to disclose any conflicts of interest. Should an IBC member declare involvement in any way in a research protocol under review by the IBC, or state a conflict of interest with a research protocol, then the member(s):

- Are excluded from actively participating in the discussion and must abstain from voting.
- May provide information requested by the IBC.
- May be asked to leave the meeting room for discussion and voting.

5.7 Notice of IBC Action

The Office of Biological Safety shall provide written notification of the Chair's/IBC's decision to the PI and whether any special conditions for approval of work are required. Included in the notification will be the IBC's decision on the biocontainment/biosafety level to be used for the proposed research, any special safety considerations, along with the approval period (begin/end dates). If the protocol contains recombinant or synthetic nucleic acid research, the notification will contain the NIH *Guidelines* classification of the proposed work. The PI is responsible for understanding the NIH classification for the approved work and sharing that information with his/her staff.

5.8 Duration of Approval

Duration of approval depends upon the category of the protocol. Protocols that are biosafety level one and exempt from the NIH Guidelines do not expire. Select agent/toxin and risk group 3 protocols are valid for one year; all other protocols are valid for a period of three years.

5.9 Revisions to Approved Protocols

Changes or modifications to approved protocols require IBC approval prior to initiation and completion of the latest protocol registration form with all revisions/additions highlighted in the registration form.

Minor modifications, for instance, a change in personnel, change in locations, and addition of materials within the current scope of the protocol, may be approved administratively by the IBC Chair. The IBC Chair may delegate authority to approve personnel modifications to the IBC staff. Major modifications, such as new procedures, materials, or agents outside the scope of the current protocol, must be reviewed by the IBC either through the Designated Review process or by full committee review.

5.10 Annual Review or Renewal

The PI is required to submit a review of their protocol annually. At the expiration date of the protocol, a new protocol must have been approved by the IBC or the protocol will be closed. As a courtesy, the IBC Coordinator will notify the PI of pending annual review and expiration dates starting at ninety days prior to the review or expiration date. The Chair has the delegated authority to administratively approve annual reviews or to refer them for Designated Review or Full Committee Review.

5.11 Protocol Escalation and Notice of Termination

The PI will notify the IBC when research involving biohazards is completed or no longer active and inform the IBC of the disposition of any remaining materials. For research materials that are retained in storage, a new protocol must be approved by the IBC before the agents can be removed from storage for use.

Failure to submit a timely annual review or to renew a previously approved protocol may result in termination of the protocol. Notification will be sent by the IBC Chair and/or IBC Administrator to the PI and copied to the Chair/Dean of the department following the steps listed in the Protocol Renewal Timeline Chart below. All research activities pertaining to the research described in the

protocol must cease. Termination of the protocol may require notification of other compliance

functions including the IACUC or IRB, Office of Sponsored Projects, and notification by the Office of Biological Safety to the appropriate regulatory agencies.

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.

In addition, noncompliance 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 and either storage or disposal of the agents in use.

Protocol Renewal Timeline Chart

Protocol Category	Approval Period	1st notification	2nd notification	3rd notification	Protocol Escalation Steps
Select Agent protocols Protocols subject to NIH Guidelines	3 years	2 months prior to expiration date cc: IBC Administrator	1 month prior to expiration date cc: IBC Administrator	2 weeks prior to expiration date cc: IBC Administrator and Chair	Expiration date - IBC Administrator notifies Chair: 1. IBC Chair emails PI (copies IBC Administrator), and sets a submission deadline 2. Protocol not submitted by deadline, then IBC Chair and Administrator notify department Chair and Dean, Institutional Official, and the Office of Sponsored Projects and schedule an IBC meeting for protocol status decision 3. If a Notice of Protocol Termination is issued by IBC, then IBC Chair and Administrator will report decision to department Chair and Dean, Institutional Official/Associate Vice President for Research and Compliance, and Office of Sponsored Projects
Protocols exempt from NIH Guidelines (including work with human derived materials/cell cultures)	3 years	2 months prior to expiration date cc: IBC Administrator	1 month prior to expiration date cc: IBC Administrator	Expiration date cc: IBC Administrator and Chair	Two weeks past due date - IBC Administrator notifies Chair: 1. IBC Chair emails PI (copies IBC Administrator), and sets a submission deadline 2. Protocol not submitted by deadline, then IBC Chair and Administrator notify department Chair and Dean, Institutional Official, and the Office of Sponsored Projects and schedule an IBC meeting for protocol status decision 3. If a Notice of Protocol Termination is issued by IBC, then IBC Chair and Administrator will report decision to department Chair and Dean, Institutional Official/Associate Vice President for Research and Compliance, and Office of Sponsored Projects
RG1 protocols exempt from NIH Guidelines	No expiration	NA	NA	NA	NA
Protocol documentation never submitted to IBC	NA	Immediate			1. IBC Chair emails PI (copies IBC Administrator), and sets a submission deadline 2. Protocol not submitted by deadline, then IBC Chair and Administrator notify department Chair and Dean, Institutional Official, and the Office of Sponsored Projects and schedule an IBC meeting for protocol status decision

References: NIH Guidelines Section 2.2 *Authority Granted to Institutional Biosafety Committee,* Section 3.0 G. *Responsibilities of the Committee, Section* 5.5 *Review of Disclosures,* and Section 5.11 *Notice of Termination*, Section 10.0 *Allegations of Non-compliance*, Section 11.2 *Institutional Reporting Responsibilities,* NAU IBC Policies and Procedures Manual 2025

6.0 Principal Investigator's Responsibility

6.1 General Responsibilities of the Principal Investigator Possessing or Using Biohazards

A scientist trained and knowledgeable in appropriate laboratory techniques, safety procedures, and hazards associated with handling biohazards must be responsible for the conduct of work with any biohazardous agents or materials. This individual should consult with EH&S with regard to risk assessment. Responsibilities of the Principal Investigator (PI) include:

A. Following the NIH *Guidelines* for work with recombinant or synthetic nucleic acid molecules.
B. Recommending an initial determination of the recombinant or synthetic nucleic acid molecule category based on NIH *Guidelines* classifications, if applicable.
C. Instruct, train and supervise research personnel in
    1) Laboratory practices and techniques required to ensure safety
    2) Procedures for dealing with spills or potential exposures to the agents described in the research
    3) Aseptic technique
    4) Characteristics of the material(s) used
    5) Signs and symptoms of laboratory acquired infections in personnel
    6) NIH classification of work (if working with recombinant or synthetic nucleic acid molecules)
D. Supervising laboratory staff to ensure that the required safety practices and techniques are employed. Correct work errors and conditions that may result in accidents, injuries, or the release of biohazardous materials.
E. Ensure 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 biohazards.
F. Developing specific biosafety standard operating procedures for biohazards used in the laboratory and maintain a copy in the laboratory. All research personnel should review these documents and their review should be documented in writing.
G. Inform the research personnel of the Occupational Health & Safety Program, possible symptoms of illness relating to materials used, and provisions for any precautionary medical practices advised or required, (e.g., vaccinations or serum collection).
H. Ensuring compliance by laboratory personnel with relevant regulations, guidelines, and policies.
I. Obtaining IBC approval prior to initiating or modifying any research involving use of biohazards and maintain that approval through timely submission of annual reviews.
J. Immediately report any significant problems or any research-related accidents and/or illnesses to EH&S and any other university committees i.e., IBC, Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC) that have reviewed and approved the research activity. After initial report, a synopsis of the issue will be required to be submitted in writing.
K. Complying with permitting and shipping requirements for recombinant or synthetic nucleic acid molecules, transgenic, or biohazardous materials.
L. Submitting an application for all projects using biohazards so the IBC can verify that they are exempt. At NAU only the IBC can determine the applicability of federal allowances for exemption.
M. Maintain documentation of all safety related training for research personnel and records of vaccinations or declinations (if required).

6.2 Submissions by the Principal Investigator to the Institutional Biosafety Committee

Any faculty member who desires to possess or use biohazards must submit the appropriate IBC protocol form to the Office of Biological Safety with sufficient lead time for review. IBC forms can be

found at http://nau.edu/Research/Compliance/Environmental-Health-and-Safety/Biological-Safety/.

The Principal Investigator shall:

A. Make an initial determination of the required levels of physical and biological containment in accordance with the *NAU Biosafety Manual* or in consultation with EH&S Biosafety,
B. Select appropriate microbiological practices and laboratory techniques to be used for the research, and
C. Submit the initial protocol form, annual reviews, and any subsequent modifications to the Institutional Biosafety Committee for review and approval or disapproval.

The PI shall remain in communication with the IBC throughout the conduct of the project.

6.3 Responsibilities of the Principal Investigator Prior to Initiating Research

The Principal Investigator shall:

A. Make available to all laboratory staff the protocols that describe the potential biohazards and the precautions to be taken.
B. Instruct and train laboratory staff in:
    1) Laboratory practices and techniques required to ensure safety,
    2) Procedures for dealing with spills or potential exposures to the agents described in the research,
    3) Aseptic technique,
    4) Characteristics of the material(s) used,
    5) Signs and symptoms of personnel infection as well as precautionary medical practices advised or requested (e.g. vaccinations or serum collection), and
    6) NIH *Guidelines* classification of work (if working with recombinant or synthetic nucleic acid molecules).
C. Secure approval from the IBC before initiating any activities involving biohazards.

6.4 Responsibilities of the Principal Investigator during the Conduct of the Research

The Principal Investigator shall:

A. Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed.
B. Report any significant incident, violation of the NIH *Guidelines*, or any significant, research-related accidents and illnesses immediately by contacting the Biosafety Officer. Examples of incidents and violations include:
    1) Overt exposures (exposures that result in direct personnel exposure to biohazards such as injection, spills, splashes or aerosol inhalation)
    2) Potential exposures (exposures that have a high risk of exposing personnel to biohazards such as spills, containment failure while working with the agent or equipment failure that may produce aerosols)
    3) Any exposure (overt or potential) in a BSL-3 laboratory
    4) Overt exposure in BSL1 or BSL-2 laboratories
    5) Any illness that may be caused by the agents used in the laboratory
    6) Incidents involving the improper disposal of biohazards.
D. Ensure 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 biohazards.
E. Limit or restrict access to the laboratory when work with biohazards is in progress; this includes making a determination of who may be at increased risk.
F. Establish policies and procedures to limit access exclusively to those individuals who have been advised of the potential hazards and meet specific entry requirements.
G. Ensure that laboratory personnel are offered, at no cost, appropriate immunizations or tests for the infectious agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine, tuberculosis skin testing).

6.5 Requirement for Completion of Biosafety Training

The IBC requires that all personnel working with biosafety level 2 or 3 biohazards complete biosafety training prior to IBC approval. New protocols and annual reviews will be screened by the Office of Biological Safety to ensure that all personnel have completed the training requirement before letters of approval will be issued. Training is provided at no cost by EH&S.

7.0 Research Personnel Responsibilities

All research personnel that work in a laboratory have a responsibility to:

A. Participate in appropriate training and instruction to ensure that they are adequately trained and fully understand the instructions. This includes taking refresher courses as applicable.
B. Fully comprehend all biological agents and select agents and toxins being used in the laboratory and the potential risks associated with exposure and associated emergency response procedures.
C. Follow all laboratory practices and protocols and comply with all applicable policies, procedures, and guidelines.
D. Complete any necessary medical surveillance.
E. Report all thefts, security incidents, accidents, spills, or contamination incidents to supervisor.

8.0 Review Requirements for Activities Conducted at another Institution

In cases where an NAU faculty member, employee, or student is involved in work located at an off-campus site with an Office of Biotechnology Activities registered Biosafety Committee, the NAU IBC may accept an approval statement from that institution's Biosafety Committee, in lieu of performing a duplicate review. The IBC must be allowed to assess whether or not a separate registration should be submitted to the IBC under these circumstances. The committee reserves the right to request additional information and to require modifications.

NAU investigators in this situation must provide a copy of the registration submitted to the other reviewing institution, a copy of that institution's approval letter, and, if externally funded, a copy of the funding proposal statement of work.

9.0 Coordination with Other Compliance Committees

Coordination with other compliance committees may be necessary, as proposed research may require review by the Institutional Review Board, the Institutional Animal Care & Use Committee, or the Radiation Safety Committee. These committee reviews can occur in parallel.

10.0 Allegations of Noncompliance

Any allegations of noncompliance or unsafe working conditions shall be made to the IBC Chair, Office of Biological Safety or to the Institutional Official. In all instances, allegations shall be immediately forwarded to the IBC Chair and the Biosafety Officer. The allegations and resulting investigations will remain confidential to the extent possible.

The IBC Chair will investigate the allegation. All persons involved in the investigation will be informed of the purpose and the manner in which it will be conducted. All documents and procedures relating to the allegation will be examined and individuals who are named in the allegation will be interviewed

as well as others who may have knowledge of the circumstances surrounding the allegation. The Chair will determine if there is a basis in fact to support the allegation. The Chair will report his/her findings to the full IBC for the final determination.

At a convened meeting, the IBC will discuss the Chair's report and determine if there is a consensus that the allegation of noncompliance is substantiated and, if so, the seriousness of the incident. All persons involved in the allegation of noncompliance will be given the opportunity to appear to respond to the allegation and/or findings. After all persons who have appeared to respond have left, the report and recommendations will be further discussed and voted upon. The IBC will inform all parties involved, including the submitter of the allegations, if known, of the committee's findings. The IBC has the authority to resolve noncompliance. Findings of noncompliance may include but are not limited to:

- Suspension or termination of use of biohazards,
- Confiscation or destruction of the biohazards, or
- Any other action necessary to protect the public and/or University, including restricting access to the laboratory in order to suspend activities.

11.0 Reporting Requirements

11.1 Reportable Incidents and Violations

Incidents/problems involving biohazards must be immediately reported to the Biosafety Officer. Examples of reportable significant incidents include but are not limited to:

A. Any overt exposure, such as a needle stick, splash, and contamination due to equipment failure.
B. Any potential exposure in a BSL-3 facility.

A significant event may also occur from a containment breach, which may be subsequently determined to pose either an overt or potential exposure to individuals or the environment. Waste from recombinant or synthetic nucleic acid research is also considered biohazardous and incidents involving improper disposal of recombinant or synthetic nucleic acids must also be reported. Questions regarding reportable incidents should be directed to the Biosafety Officer.

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.

11.2 Institutional Reporting Responsibilities

The IBC is required, by the NIH *Guidelines*, to report to the appropriate University official and to the NIH/OBA within thirty days any significant incidents, violations of the NIH *Guidelines*, or any significant findings of research-related accidents and illnesses. The IBC will be responsible to determine what actions, if any, are necessary. For example, the IBC may determine the need to make changes to the frequency of laboratory inspections or biosafety containment level of the research, based on results of the incident.

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

- Research involving biohazards conducted without prior IBC approval
- Lax security, unsafe procedures used in a laboratory setting, improper disposal of recombinant or synthetic nucleic acid waste
- Changes to research risk that have been initiated without prior approval by IBC

Some incidents must be reported to OBA on an expedited basis. Spills or accidents in BSL-2

laboratories involving recombinant or synthetic nucleic acids that result in an overt exposure must be immediately reported to OBA. In addition, spills or accidents involving recombinant or synthetic nucleic acids occurring in high containment (BSL-3 or higher) laboratories resulting in an overt or potential exposure must be immediately reported to OBA. The IBC working through the IBC Chair and the BSO will report to the Institutional Official, who, in turn will oversee the report to OBA.

Institutional violations that will also be reported to the appropriate College or department head may include but are not limited to:

- Lapses in protocol approval
- Failure to comply with institutional and federal regulations, guidelines, and policies
- Unsafe work practices

As per Section IV-B-2-a-(7) of the NIH *Guidelines*, if public comments are made on IBC actions, the IBC, through the IO, will forward both the public comments and the IBC's response to OBA.

12.0 Resources

- **NIH/OBA** **http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines**
- **CDC/USDA Select Agents** **https://www.selectagents.gov/**
- **BMBL** **https://www.cdc.gov/labs/bmbl/?CDC_AAref_Val=https://www.cdc.gov/labs/BMBL.html**
- **IBC Website** **http://nau.edu/Research/Compliance/Environmental-Health-and-Safety/Biological-Safety**
- **EH&S** **http://nau.edu/Research/Compliance/Environmental-Health-and-Safety**