Arizona State University
Institutional Biosafety Committee

POLICIES AND PROCEDURES MANUAL

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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. Arizona State University (ASU) must ensure that recombinant or synthetic nucleic acid research conducted at or sponsored by ASU, irrespective of the funding source, if any, complies with the *NIH Guidelines* as a condition for NIH funding of such research at ASU. To meet the requirements of these guidelines, all Principal Investigators using recombinant or synthetic nucleic acid molecules must submit a disclosure 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 or all recombinant or synthetic nucleic acid research at ASU; or a requirement for prior NIH approval of any or all recombinant or synthetic nucleic acid projects at ASU. The *NIH Guidelines* are available at: NIH Guidelines – Office of Science Policy

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. For more information visit http://www.selectagents.gov/. To meet these regulations, all Principal Investigators using select agents or toxins molecules must submit a disclosure to the Institutional Biosafety Committee for review.

1.3 Biosafety in Microbiological and Biomedical Laboratories

Biosafety in Microbiological and Biomedical Laboratories (BMBL) is published by CDC and the 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. The BMBL is available online at: Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition | CDC Laboratory Portal | CDC

The BMBL should be used as a resource for Principal Investigators in planning their work with

biohazards.

1.4 OHSA Bloodborne Pathogens Standard

The Occupational Safety and Health Administration's (OSHA) Bloodborne Pathogens Standard applies to work with human blood, tissue, organs, bodily 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 ASU Exposure Control Plan.

Handling and disposal of biohazardous waste is also regulated by OSHA under the OSHA Bloodborne Pathogens Standard and by state and federal statutes. The procedures for biohazardous waste handling are described in the ASU Biological Waste Handling Procedures.

The requirements described in the OSHA Bloodborne Pathogens Standard (29 CFR § 1910.1030)is available at: Bloodborne Pathogens - Standards | Occupational Safety and Health Administration (osha.gov)

1.5 ASU Biosafety Manual

The ASU Biosafety Manual is 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 in the Biosafety Manual also reflects the requirements and guidelines of federal and state regulations. It is intended that the Principal Investigator (PI) and supervisory personnel will supplement the information in the Biosafety Manual with instruction and guidance regarding specific practices and procedures unique to the work being done in their laboratories. The most current version of the Biosafety Manual is available on the ASU Environmental Health & Safety (EH&S) website.

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 ASU faculty members, staff employees, or students.

The IBC has oversight of all research and teaching 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 ASU 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, ASU's Institutional Biosafety Committee applies the following definitions to *recombinant or synthetic nucleic acid molecules* and *biohazards*.

A. Recombinant or Synthetic Nucleic Acid Molecules are defined as (per *NIH Guidelines* on Section I-B):

(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 the following:

- 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 bodily 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 for research and teaching must be approved by the IBC. If vertebrate animals are being utilized in activities with biohazards, the Institutional Animal Care and Use Committee 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 Senior Vice President for Knowledge Enterprise Development on policies and procedures relating to the use of infectious micro-organisms in research and teaching; the handling of infectious waste disposal; 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 Director – Knowledge Enterprise (KE) Operations 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, ASU 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 Institutional Biosafety Committee 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 Arizona State University rests with the Senior Vice President for Knowledge Enterprise who has delegated the responsibility to the Director-KE Operations who serves as the Institutional Official (IO). The IO:

- Appoints IBC members.

- Annually 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. 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 one year 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 Research Integrity and Assurance (ORIA) 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 disclosure (or amendment), it may choose to have a subcommittee review those details and provide a report to the committee-assigned Designated Reviewer (DR). Makeup of the subcommittee is determined on a case-by-case basis by either the committee as a whole or the assigned DR 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

As 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 disclosures, modifications, and annual reviews;
- Ensure that IBC committee members are adequately trained;
- Approve the agenda for the convened meeting of the IBC;
- Attends appropriate national meetings dealing with biosafety issues and the role of IBCs. The cost of attendance at these meetings will be funded by ORIA.

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:

A. Performing periodic inspections of laboratories conducting research using biohazards to ensure that laboratory standards are rigorously followed prior to commencement of research.
B. Reporting to 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*.
C. Performing and reviewing the required risk assessment to determine appropriate biosafety level and personal protective equipment (PPE) for handling and disposal of biohazards.
D. Assisting researchers in developing plans for preventing and handling accidental spills and personnel contamination.
E. Investigating laboratory accidents involving biohazards.
F. Providing technical advice to research personnel and the IBC on research safety procedures.
G. Providing training in the safe use and practices for those working with biohazards.
H. Reviewing IBC disclosures 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 Office of Research Integrity and Assurance and 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. A calendar of scheduled meetings is posted to the IBC website at: Disclosure Submission | Research Integrity and Assurance (asu.edu).

The IBC Chair may call an emergency meeting of the IBC as necessary. It is the general practice of the IBC to convene in person meetings attended by a quorum of members. However, in accordance with guidance from the NIH Office of Science Policy (OSP), the use of teleconferencing allows for participation by board members who are unable to physically attend in person (e.g. during pandemic conditions) or when 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 public request.

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 IBC Coordinator in advance, via email, regarding the desire to attend. While no one will be denied access to a meeting, the IBC Coordinator, ORIA Assistant Director 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 disclosure is approved only if a quorum is present, and if more than 50 percent of the quorum votes in favor of disclosure 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 ORIA 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 disclosures 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 NIH's Office of Science Policy (OSP). The annual report, required by OSP, is filed annually on behalf of the IBC by the Office of Research Integrity and Assurance, and includes an updated list of IBC members indicating the role of each member and biosketches for each member. ORIA notifies OSP of changes in IBC membership as they occur and submits an annual report on behalf of the University.

The purpose of registration and annual membership updates are:

- To provide assurance of ASU IBC review of biosafety risks to the Office of Science Policy (OSP)
- Indicates University point of contact.
- Demonstrates 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/OSP, CDC and USDA regulations to oversee the possession and/or use of biohazards.
G. Suspend or terminate disclosure 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 disclosures 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 the 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 as 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/OSP for research that falls under Sections III-A, III-B, III-C and Appendix M of the *NIH Guidelines*.

L. 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 Research Integrity and Assurance

The IBC is supported and administered by the Office of Research Integrity and Assurance (ORIA), which has offices in the Centerpoint Building (CTRPT). IBC meetings are held on Zoom.

4.2 Responsibilities of the Office of Research Integrity and Assurance

The Office of Research Integrity and Assurance is responsible for maintaining Arizona State University's registration with the NIH Office of Science Policy (OSP); reporting to OSP at least annually; updating the committee roster and biosketches; and facilitating the IBC's responsibilities for administrative, oversight, review and reporting functions. ORIA accepts, screens, and tracks biohazard disclosures and reviews material transfer agreements for compliance. They act as a liaison for the IBC with other University departments and committees (e.g. Environmental Health & Safety [EH&S], 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. ORIA supports University investigators by assisting with IBC submissions, training, and biosafety information.

ORIA has further responsibility for maintaining the official records of the Institutional Biosafety Committee, including correspondence with the Office of Science Policy, meeting minutes, disclosure records (both paper records and those in the Enterprise Research Administration (ERA) platform), and committee rosters and biosketches. The website for the Institutional Biosafety Committee, located at http://researchintegrity.asu.edu/biosafety, is maintained by this office.

4.3 Meeting Minutes

Minutes of IBC meetings shall be taken by a staff person from the Office of Research Integrity and Assurance 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.

Particular care shall be taken to record deliberation relative to the assessment of the containment level required, the facilities, procedures, practices, and training of personnel involved in biohazard research.

Minutes shall also document IBC actions taken on each disclosure reviewed; votes on actions; and required modifications for IBC approval. Members who are recused will be recorded, and the basis for disapproving any proposed disclosure, annual review, or modification shall be recorded.

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 ASU Office of General Counsel.

4.5 Records Retention

Records of the Institutional Biosafety Committee shall be retained by the Office of Research Integrity and Assurance.

ORIA will retain IBC disclosures, meeting minutes, and rosters of IBC members for a period of at least three years. For IBC disclosures, the three years begins after protocol 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 accessible for inspection and copying by authorized representatives.

5.0 IBC Disclosure Review Process

5.1 Lead Time for Review

Submission deadlines are four weeks prior to a scheduled IBC meeting. Submission deadlines and meeting dates are posted on the Institutional Biosafety Committee website located at: Disclosure Submission | Research Integrity and Assurance (asu.edu)

5.2 IBC Review Required

Research or teaching activities 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 microorganisms 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 etiologic agents.
G. Containment of animal etiologic agents.
H. The cloning of recombinant or synthetic nucleic acids from RG-2 or greater agents into non-pathogenic prokaryotes or lower eukaryotic host-vector systems.
I. The use of infectious or defective RG-2 or greater agents in the presence of a helper virus.
J. 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).
K. Viable recombinant or synthetic nucleic acid-modified microorganisms or cell lines tested on whole animals.
L. Genetically engineered plants by recombinant or synthetic nucleic acid methods.
M. More than 10 liters of recombinant or synthetic nucleic acid culture in a single vessel.
N. 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.
O. Non-recombinant research using biohazards, select agents or toxins.
P. All research using biological toxins or bioactive derivatives or subunits of toxins.
Q. Research collecting or analyzing human or nonhuman primate cell lines, tissues, blood, other blood products, or feces.

5.3 Scope of Review

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

- Conduct assessment of the containment levels required by the *NIH Guidelines*
- Assess 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)
- Nature of the inserted DNA sequences (e.g., structural gene, oncogene)
- Host(s) and vector(s) to be used
- Whether an attempt will be made to obtain expression of a foreign gene, and if so, the protein that will be produced
- Containment conditions to be implemented
- Applicable section of the *NIH Guidelines* (e.g., Section II-D-1. Section III-E-1, etc.)

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://cfo.asu.edu/ehs-biosafety.

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 disclosure or modification is reviewed by the ORIA IBC Coordinator, 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 disclosure or modification. All of the IBC members are electronically provided the disclosure 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 DR designation or call for full committee review. A quorum must agree to the use of the Designated Review process and if a single committee member calls for a full committee review, then the disclosure or modification is reviewed by the full IBC at the next convened meeting.

Alternately, a committee member can submit comments to the Designated Reviewer to include in his or her correspondence with the PI. If the Designated Reviewer and the Biosafety Officer are accepting of the disclosure or modification (or revised version based on their comments), they both inform the Chair and IBC Coordinator of their decision and the approval is processed. Alternately, the Designated Reviewer or Biosafety Officer upon acquisition of additional information, may themselves call for a full committee review.

The Designated Reviewer has the delegated authority to approve, request modifications, or request Full Committee Review.

The IBC Chair or Biosafety Officer can serve as the Designated Reviewer, but, as with any Designated Review, their assignment must be approved by a quorum of the committee via an electronic notification (email or in ERA). 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 disclosures are presented and discussed individually and the IBC votes on the disposition of the disclosure. 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 Principal Investigator, the IBC may approve the research, thus providing the Principal Investigator permission to perform the research.

2) **Approval with Required Modifications** – This status is used for disclosures 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 disclosure 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 decide to defer or table the review.

4) **Withhold Approval** -- When the IBC determines that a disclosure 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 disclosure is being reviewed. Failure to attend the IBC meeting to answer questions posed by the committee may result in the delay of the IBC approval.

5.5 Review of Disclosures

Principal Investigators must complete and submit a disclosure to the IBC for review using the IBC ERA platform, which assigns a disclosure number (known as "SPROTO" in the system) for reference. This can be used to reference the study with ORIA or Office for Research and Sponsored Projects Administration (ORSPA) for grant applications.

The type of review the disclosure receives will be determined by its classification as outlined in the table below.

Category	Review Type	Approval Period
BSL1 Disclosures Exempt from *NIH Guidelines*	Chair Review	No expiration
BSL2 Disclosures Exempt from *NIH Guidelines*	Designated Review or Full Committee Review (Chair determines review type)	3 years
Select Agent Disclosures	Full Committee Review	1 year
Disclosures Not Exempt from *NIH Guidelines*	Full Committee Review	3 years
Storage Forms	Designated Review	No expiration
All Other Disclosures	Full Committee Review	3 years

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 disclosure under review by the IBC, or state a conflict of interest with a research disclosure, the member(s):

- Is/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 during IBC discussion and voting.

5.7 Notice of IBC Action

The Office of Research Integrity and Assurance shall provide written notification of the Chair's/IBC's decision to the Principal Investigator and whether any special conditions for approval of work are required. 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, and the approval period (begin/end dates). If the disclosure contains recombinant or synthetic nucleic acid research, the notification will contain the *NIH Guidelines* classification of the proposed work. The Principal Investigator is responsible for understanding the NIH classification for the approved work and sharing that information with their staff.

5.8 Duration of Approval

Duration of approval depends upon category of disclosure. Article 5.5 above specifies the Approval Period by disclosure category.

5.9 Revisions to Approved Disclosures

Changes or modifications to approved disclosures require IBC approval prior to initiation. If the changes are extensive, a new submission may be required.

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

5.10 Renewal and Continuing Review

Disclosures are approved for no more than 3 years. During this 3 year period the Principal Investigator is responsible for submission of continuing review materials as required. Disclosures that are not renewed prior to the expiration date are closed and work may no longer continue. The Principal Investigator and other stakeholders (e.g. IRB, EHS) will be notified of the closure. As a courtesy, the IBC Coordinator will notify the Principal Investigator of pending continuing review and expiration dates prior to their submission due date. The Chair has the delegated authority to administratively approve continuing reviews or to refer them for Designated Review or Full Committee Review.

5.11 Notice of Termination

The Principal Investigator 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. Any unused agents that will need to be stored for future use must have a Storage Form submitted to the IBC for tracking purposes and to make sure that proper storage practices are used. A new disclosure 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 disclosure may result in termination of the disclosure. Notification will be sent to the Principal Investigator and copied to the Chair/Dean of the department. All research activities pertaining to the research described in the disclosure must cease. Termination of the disclosure may require notification of other compliance functions including the IACUC or IRB and notification by ORIA 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 disclosure termination and either storage or disposal of the agents in use.

6.0 Principal Investigator's Responsibility

6.1 General Responsibilities of the Principal Investigator Possessing or Using Biohazards

The Principal Investigator, a scientist trained and knowledgeable in appropriate laboratory techniques, safety procedures, and hazards associated with handling biohazards is responsible for the conduct of work with any biohazardous agents or materials. This individual should consult with EH&S Biosafety or other health and safety professionals 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 personnel infection for biohazards
    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. Correcting 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 the release of or exposure to biohazards.
F. Developing specific biosafety standard operating procedures (SOP) for biohazards used in the laboratory and maintain a copy in the laboratory. All research personnel should review these SOP documents and such review shall 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 (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 in the IBC ERA system for all projects using biohazards so the IBC can verify that they are exempt. At ASU only the IBC can determine the applicability of federally 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 disclosure information to the Office of Research Integrity and Assurance with sufficient lead time for review. New IBC disclosures must be submitted in the ERA system and PIs must be logged into their my.asu.edu account. All modifications and annual reviews for those disclosures currently in ERA must also be submitted through the platform. Forms to make changes to or submit an annual review for current disclosures that are still paper based can be found at http://researchintegrity.asu.edu/biosafety/forms.

The Principal Investigator shall:

A. Make an initial determination of the required levels of physical and biological containment in accordance with the *ASU Biosafety Manual* or in consultation with EH&S Biosafety;

B. Select appropriate microbiological practices and laboratory techniques to be used for the research;

C. Submit the initial disclosure information, annual reviews, and any subsequent modifications to the Institutional Biosafety Committee for review and approval or disapproval;

The Principal Investigator shall remain in communication with the Institutional Biosafety Committee 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 safety 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 for biohazards as well as precautionary medical practices advised or requested (e.g. vaccinations or serum collection)
    6) *NIH Guidelines* classification of work (if working with recombinant or synthetic nucleic acid molecules)

C. Secure approval from the Institutional Biosafety Committee 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 an access determination of individuals 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 Institutional Biosafety Committee requires that all personnel working with Biosafety Level 3 (BSL 3) biohazards, or any materials covered by the OSHA Bloodborne Pathogen Standard, to complete biosafety training prior to IBC approval and take refresher training annually. For all other work with Biosafety Level 2 (BSL 2) or below (e.g. BSL 1) biohazards, training must be completed prior to IBC approval and refresher training must be completed every four years. Disclosures that are both BSL 1 and Exempt from the NIH Guidelines, are only required to complete the ASU Biosafety and Bloodborne Pathogens Training initially. New disclosures and annual reviews will be screened by the Office of Research Integrity and Assurance to ensure that all personnel have completed the training requirement before letters of approval will be issued.

Registration for the online course, presented by Environmental Health& Safety (EH&S), may be accomplished online at https://cfo.asu.edu/ehs-training. There is no charge for the course.

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 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, as well as fully understanding the 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 the Principal Investigator and Lab Supervisor.

8.0 Review Requirements for Activities Taking Place at another Institution

In cases where an ASU faculty member, staff employee, or student is involved in work located at an off-campus site with an Office of Science Policy (OSP) registered Biosafety Committee, the ASU IBC may accept an approval statement from that other Biosafety Committee, in lieu of performing a duplicate review. The ASU IBC must be allowed to assess whether or not a separate registration should be submitted to the ASU IBC under these circumstances. The ASU IBC reserves the right to request additional information and to require modifications. Non- substantive issues will not be raised.

ASU 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 (IRB), the Institutional Animal Care & Use Committee (IACUC), or the Radiation Safety Committee (RSC). These committee reviews occur in parallel under the coordination of the Office of Research Integrity and Assurance.

10.0 Allegations of Noncompliance

Any allegations of noncompliance or unsafe working conditions shall be made to the IBC Chair, Office of Research Integrity and Assurance (ORIA), Biosafety Officer 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. Allegations can also be reported via email (research.integrity@asu.edu or by calling the ASU Hotline for Ethics and Compliance at 877 SUN DEVL (877-786-3385).

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 to the allegation and/or finding have left the proceedings, the report and recommendations will be further discussed and voted upon by the IBC. 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 the use of biohazards;
- Confiscation or destruction of the biohazards;
- 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 Biological Safety 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. It should be noted that 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 Institutional Biosafety Committee is required, by the *NIH Guidelines*, to report to the appropriate University official and to the NIH/OSP 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 OSP 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 OSP 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 OSP. 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 OSP. The IBC working through the IBC Chair and the BSO will report to the Institutional Official, who, in turn will oversee the report to OSP of any of the above-described incidents.

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

- Lapses in disclosure 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 OSP.

12.0 Resources

- **NIH/OSP** NIH Guidelines – Office of Science Policy
- **CDC/USDA Select Agents** Federal Select Agent Program (cdc.gov)
- **BMBL** Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition | CDC Laboratory Portal | CDC
- **IBC/ORIA Website** Institutional Biosafety Committee | Research Integrity and Assurance (asu.edu)
- **EH&S** Environmental Health and Safety | Business and Finance (asu.edu)
- **Employee Health** ASU Employee Health | Arizona State University
- **ASU Hotline for Ethics and Compliance** ASU Hotline

  877 SUN DEVL (877-786-3385)
- **ORIA** Home | Research Integrity and Assurance (asu.edu)