

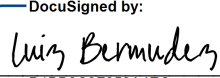


Oregon State University

Institutional Biosafety Committee

Policies and Procedures Manual

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By signing above, the IBC Chair affirms that this Policies and Procedures Manual has been reviewed and approved by the Institutional Biosafety Committee and represents the current, authoritative guidance for the safe and compliant conduct of biological research at Oregon State University.

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Scope and Purpose

The safe conduct of biological research is essential to protect the health and wellbeing of university personnel, students, visitors, the surrounding community, and the environment. Improper use or handling of biohazardous materials can result in accidental exposures, laboratory-associated infections, regulatory non-compliance, reputational and legal consequences for the university, and, in severe cases, broader public health impacts. This policy outlines the standards, responsibilities, and oversight mechanisms that govern the use of biological materials at Oregon State University. It establishes the framework for ensuring compliance with applicable federal, state, and institutional requirements, including the *NIH Guidelines* and other biosafety regulations and best practices.

The purpose of this document is to define the role and authority of the Institutional Biosafety Committee (IBC); identify the responsibilities of investigators, the Biological Safety Officer, and other institutional stakeholders; and describe the procedures for the review, approval, and ongoing oversight of biological research. Together, these policies support a safe research environment, promote responsible stewardship of biological materials, and ensure that all activities involving biohazards are conducted in a manner that minimizes risks to personnel and the broader community.

IBC Membership, Authority, and Composition

The IBC is established under the authority of the President for Research Integrity. The President for Research Integrity appoints and approves all voting members and alternate members of the committee. Member terms are typically three years and may be renewed to maintain needed scientific and community expertise.

Committee composition

The IBC maintains a membership structure that meets the composition requirements in the *NIH Guidelines*. The committee includes individuals with experience and expertise in areas such as microbiology, infectious disease, molecular biology, plant biology, animal studies, occupational health, environmental safety, and research administration. The committee also includes at least two members who are not affiliated with Oregon State University and who represent the interests of the local community. An Agricultural Research Service scientist serves as a member according to the cooperative agreement between OSU and USDA ARS.

A current list of IBC members, including roles, areas of expertise, and contact information, is maintained by the IBC Administrator and is available as a separate document on the IBC website or upon request. This list is updated whenever membership changes occur.

Ad hoc expertise

The IBC may invite ad hoc consultants to provide specialized expertise when needed. Consultants may participate in discussions but do not vote.

Quorum

A quorum consists of at least half of the current voting members listed on the roster filed with NIH. When possible, at least one nonaffiliated member should be present. Emergency meetings follow the reduced quorum procedures described in this manual.

Authority

The IBC is authorized to review, approve, require modifications to, or disapprove activities that involve recombinant or synthetic nucleic acids or other biohazardous materials. The committee may suspend activities that present safety or compliance concerns and may require corrective actions or refer concerns to institutional leadership.

Summary of Roles and Responsibilities

IBC

- Reviews, approves, and oversees all recombinant or synthetic nucleic acid (r/sNA) research and all biohazardous agent use at OSU.
- Ensures compliance with *NIH Guidelines*, including specialized oversight for gene drive modified organisms (GDMOs).
- Establishes containment levels, biosafety requirements, and risk-mitigation expectations.
- May delegate certain review tasks to the Biological Safety Officer (BSO), but may not delegate approvals for activities requiring full-committee review.
- Ensures the committee has access to appropriate scientific, ecological, and containment expertise.

IBC Chair

- Leads meetings, sets agendas, and ensures compliance with *NIH Guidelines* and institutional expectations.
- Determines attendance and confidentiality for meeting discussions.
- Oversees timely review of public comments and ensures compliance with federal transparency requirements.

Biological Safety Officer (BSO)

- Provides technical biosafety guidance to researchers and the IBC.
- Oversees biosafety training, risk assessments, inspections, and exposure control planning.
- Conducts investigations of laboratory accidents and exposures and coordinates emergency response.
- Provides required oversight and containment verification for GDMO research.
- Reviews and supports occupational health programs and OSHA Bloodborne Pathogen compliance.

Principal Investigators (PIs) / Laboratory Directors

- Ensure all applicable research is registered with the IBC before work begins.
- Train and supervise laboratory personnel and ensure adherence to biosafety

procedures.

- Report spills, accidents, exposures, or releases promptly.
- Maintain laboratory-specific training records and ensure personnel complete required training.
- Communicate with animal care, facility, or plant units as appropriate for their research.

Detailed Roles and Responsibilities

IBC. The IBC is appointed by the Vice President for Research and Innovation and includes faculty and staff with broad expertise in the biological sciences, as well as two community representatives who are not affiliated with OSU. Member qualifications are consistent with the expectations outlined in the *NIH Guidelines*. The IBC is responsible for the registration, review, approval, and oversight of all non-exempt recombinant or synthetic nucleic acid research and all biohazardous activities conducted at OSU.

The IBC also provides oversight for research involving gene drive modified organisms (GDMOs), ensuring that such work is conducted under appropriate containment (minimum BL2, BL2-N, or BL2-P), and that organism-specific and ecological risks are fully evaluated. The committee ensures that relevant expertise in gene drive technology, ecological risk assessment, and species-specific containment is available internally or through ad hoc consultants.

The IBC establishes biosafety and containment requirements based on risk assessments and may delegate certain oversight activities to the Biological Safety Officer (BSO); however, approvals for activities that must be reviewed by the full committee under the *NIH Guidelines* may not be delegated.

Principal Investigators / Laboratory Directors. Principal Investigators (PIs) may include instructors, emeritus faculty, professors at all academic ranks, and courtesy faculty. PIs are responsible for supervising all personnel involved in their research and ensuring that all individuals receive appropriate biosafety, recombinant or synthetic nucleic acid, and human-materials training as applicable to their work.

PIs must ensure that all required research is registered with the IBC before work begins and that biosafety recommendations and containment practices established by the IBC or BSO are consistently followed. They are responsible for maintaining laboratory-specific training records, ensuring staff competency, and implementing required safety procedures.

PIs must promptly report all accidents, spills, exposures, or potential releases involving biological hazards or r/sNA to the Biological Safety Officer. When required, PIs must also meet NIH reporting obligations in accordance with institutional procedures.

Biological Safety Officer. The BSO provides professional biosafety guidance to researchers and to the IBC. The BSO supports the safe conduct of biological research by

offering technical advice, conducting risk assessments, evaluating facilities and equipment, and assisting with the development of exposure control plans and emergency procedures.

The BSO has institutional oversight responsibilities for research involving gene drive modified organisms (GDMOs), ensuring that such work meets or exceeds the minimum containment requirements and supporting the IBC in evaluating organism-specific and ecological risks. The BSO coordinates access to necessary expertise in gene drive technology and environmental risk evaluation when specialized consultation is needed.

The BSO conducts inspections, investigates biological incidents or exposures, and prepares reports for the IBC and institutional leadership. Additional responsibilities include supporting occupational health programs, ensuring compliance with the OSHA Bloodborne Pathogen Standard, and guiding investigators in developing and maintaining appropriate biosafety practices and documentation across their research programs.

General Policy

This policy applies to Oregon State University (OSU) and all affiliated facilities. Affiliated facilities are defined as those that report directly to an OSU administrative unit or receive any extramural funding through the OSU Office of Sponsored Programs.

In recognition of the necessity for conducting research utilizing potentially hazardous biological materials in a safe and secure manner, all biological research at OSU will be conducted in accordance with accepted biological safety practices and in full compliance with this and other existing university policies and all applicable federal rules and regulations relating to such activities. The OSU IBC shall review biohazardous research conducted for any purpose by OSU personnel or in any OSU facility. The IBC has full authority to impose containment requirements or procedural safeguards, audit programs, and inspect facilities to ensure that biohazards are handled, used, and disposed of in a safe and compliant manner.

OSU recognizes that some federal guidance uses BL notation and some uses BSL or ABSL notation. For purposes of safety requirements, OSU treats these terms as equivalent. BL2 corresponds to BSL2. BL2 N corresponds to ABSL2. BL2 P corresponds to plant BSL2. The containment expectations, facility requirements, and work practices are the same regardless of notation.

Further, OSU will comply with the requirements set forth in the current version of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines April 2024)* and all other policies promulgated by the National Institutes of Health, Office of Science Policy (NIH / OSP) and with Oregon Revised Statutes (ORS 431.805 and 431.810) for all work involving r/sNA as defined below.

Specific Policies

Policy on Public Comments

Members of the public or OSU community may comment on IBC actions by sending written comments to Biological Safety Officer, Oregon State University, Oak Creek Building, Corvallis, OR 97331 or electronically to ibc@oregonstate.edu. The IBC will review and discuss all comments at the next regularly scheduled meeting and prepare a formal response at the first opportunity. All comments received, along with IBC responses, will be forwarded to NIH / OSP.

To support federal transparency requirements, OSU will publicly post the current IBC roster and approved IBC meeting minutes. Public posting will begin no later than June 2025 and will continue on an ongoing basis. Any proprietary, personal, or sensitive information will be redacted as required. This posting requirement is consistent with the *NIH Guidelines* and federal efforts to increase public access to institutional biosafety oversight.

Policy on Conflict of Interest

Members of the IBC may not be involved in the review or approval of any project or program if that member expects to be engaged in the work or has a direct financial interest, or if the protocol under review is from a spouse or close relative. Members will be asked to leave the room during discussion and voting, but may address questions or provide other information requested by the IBC.

Conflicts of interest and recusals will be documented in the meeting minutes, including the name of the member, the nature of the conflict, and confirmation that the member did not vote on the affected item. Conflicted members may be counted toward quorum for the meeting as a whole but are considered abstaining and non-voting for the specific proposal under review.

Policy on Public Attendance of IBC Meetings

Meeting dates and times will be published on the IBC Website. Non-members of the IBC, including members of the public, who wish to attend an IBC meeting, are directed to contact the IBC administrator. Meetings or certain discussions within a meeting may be limited to members and invited guests where sensitive or proprietary information are under discussion; the Chair shall make the final decision of what topics under discussion are appropriate for a wider audience. Principal Investigators may request that certain items in their proposals be considered for discussion only by IBC members. If a meeting or discussion is deemed sensitive, then the Chair can call an Executive Session in which the non-members will be asked to leave.

Policy for Reporting Accidents, Exposures or Illnesses

Spills or accidents which result in possible exposures to pathogenic or potentially

pathogenic microorganisms or recombinant / synthetic nucleic acids must be reported immediately by the research principal investigator to the institutional Biological Safety Officer (BSO), who shall take responsibility for appropriate reporting of such incidents. As described in this document, all incidents, exposures and illnesses involving the use of r/sNA will be documented and reported to NIH / OSP.

Policy for Training Researchers Working with Biological Hazards

Training is essential to working safely with biological hazards. Training must be appropriate to the work being conducted in the laboratory, and comply with federal, state and university requirements. Laboratory personnel must have specific training in the procedures conducted in the laboratory and must be supervised by a scientist with training in a discipline related to the research being conducted in the laboratory. This policy addresses the various requirements and responsibilities for minimum training of workers in laboratories handling biological hazards.

Training Requirements for Laboratory Workers

Laboratory – Specific: All workers must be trained in laboratory procedures, safe use of equipment and information about potential biological hazards present in the lab to include: routes of exposure, signs and symptoms of illness, effective methods to minimize the risk of exposures, and laboratory – specific exposure response procedures.

Recombinant or Synthetic Nucleic Acids (r/sNA): All principal investigators and workers who conduct research utilizing non-exempt r/sNA, regardless of the containment level, must complete the training module for *NIH Guidelines* available through SciShield. The April 2024 revision of the *NIH Guidelines* requires updated *NIH Guidelines* training for all principal investigators and laboratory personnel conducting non-exempt recombinant or synthetic nucleic acid research.

Gene Drive Modified Organisms (GDMOs): Principal investigators and laboratory personnel working with gene drive modified organisms must complete GDMO-specific training. This training must include:

- GDMO containment principles and minimum BL2/BL2-N/BL2-P requirements
- Ecological and environmental risk considerations
- Genetic stability and gene-drive propagation risks
- Emergency procedures for unintentional release or exposure
- Additional requirements described in the *NIH Guidelines* Section III-D-8

This training is required in addition to *NIH Guidelines* training and BSL-2 training. GDMO-specific training may be provided by Environmental Health & Safety (EHS), the BSO, or qualified subject matter experts approved by the BSO. Principal Investigators are responsible for ensuring that all GDMO personnel have completed and documented this training before initiating GDMO work. At OSU, completion of GDMO-specific training is documented and tracked through the institutional training management system (SciShield) and is required prior to initiating any GDMO-related work.

BSL-2 Laboratories: All principal investigators and workers who conduct research in a BSL-2 or equivalent laboratory must attend Laboratory Biosafety training provided by EHS. Training for personnel working at BSL-2 must address the hazards and containment practices relevant to the work being conducted. Personnel who conduct research involving gene drive modified organisms (GDMOs) must complete additional GDMO-specific training, which is tracked separately from general BSL-2 laboratory biosafety training.

Human Source Biological Materials: All principal investigators and workers who conduct research in a laboratory where human source biological materials are handled must attend Bloodborne Pathogen training provided by EHS or other qualified individuals.

Re-Training Frequency for Laboratory Workers

Laboratory-Specific: Workers must receive annual updates or additional training when procedural or policy changes occur.

r/sNA: No specific re-training frequency required. Major revisions to the *NIH Guidelines* may necessitate re-training; principal investigators will be notified by the IBC if re-training is necessary. The April 2024 *NIH Guidelines* revisions, including new requirements for gene drive modified organisms, constitute a major revision that requires updated training for affected personnel.

Gene Drive Modified Organisms (GDMOs): Re-training for work involving GDMOs is required whenever GDMO methods, containment strategies, or experimental protocols change. Re-training is also required when new personnel join a GDMO project, and whenever the NIH updates or revises requirements related to GDMO oversight.

BSL-2 Laboratories: Principal investigators and workers who conduct research in a BSL-2 or equivalent laboratory must receive retraining every 3 years; the exception is for those workers who work in a BSL-2 laboratory where human source biological materials are handled (see below).

Human Source Biological Materials: Principal investigators and workers who conduct research in laboratories where human source biological materials are handled must receive re-training annually, in accordance with OSHA requirements.

Documentation

Principal investigators are responsible for creating and maintaining documentation of any laboratory-specific or program-specific training provided to workers. Training records must be available for review during laboratory inspections.

Institution-provided trainings, including Laboratory Biosafety, Bloodborne Pathogens, NIH Guidelines, and GDMO-specific training, are tracked centrally through SciShield.

Principal Investigators remain responsible for ensuring completion of all required training prior to work initiation and for documenting any additional laboratory-specific or procedure-specific training not captured in institutional systems.

EHS is responsible for maintaining records of training provided by EHS and training required for compliance with federal and state regulations.

Training for IBC Members

IBC members must maintain familiarity with the current *NIH Guidelines*, federal DURC and Gain-of-Function research policies, and this manual. Initial IBC member orientation and periodic refresher training will be coordinated by the BSO or IBC Administrator and may include online modules, workshops, or distribution of updated guidance documents. Training completion will be documented and maintained with IBC records.

Definitions

Workers – any student, student employee, staff or faculty member affiliated with Oregon State University who works in a research laboratory.

Biohazard – any agent, toxin, or recombinant material of biological origin capable of causing infection, disease, or other detrimental effects to humans, animals, or plants.

r/sNA– as defined by the *NIH Guidelines* as:

- molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids;
- 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
- molecules that result from the replication of those described in (i) or (ii) above.

Synthetic nucleic acid segments which are likely to yield a potentially harmful polynucleotide or polypeptide are considered as equivalent to their natural NA counterpart. If the synthetic nucleic acid segment is not expressed in vivo as a biologically active polynucleotide or polypeptide product, it is exempt from review.

Gene Drive Modified Organism (GDMO) – An organism that has been genetically engineered using recombinant or synthetic nucleic acid techniques to bias the inheritance of a specific genetic trait, such that the trait is transmitted to a greater proportion of offspring than would be expected under Mendelian inheritance. GDMOs include, but are not limited to, CRISPR-based homing drives, split gene drive systems, and other engineered inheritance-biasing systems as described in the *NIH Guidelines*.

Pathogen – a microorganism, virus, or other infectious agent capable of reproduction within a living host, and as a consequence of that reproduction, causing persistent infection or acute disease within that host.

Biological toxin – all are poisons, predominantly proteins, of natural origin but increasingly accessible by modern synthetic methods, which may cause death or severe incapacitation at relatively low exposure levels.

Risk Groups (RG-1, RG-2, RG-3, RG-4) – microorganisms capable of causing human disease are assigned to one of four risk groups, in increasing order of their capacity to cause disease in humans. Risk group assignments will follow the most current *NIH Guidelines* Appendix B and ABSA risk group listings, as well as *CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th ed (2025)*.

Biosafety Levels (BSL) – Designations for containment requirements for safety equipment, facilities and work practices as defined by either the *NIH Guidelines* or the current *CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)*. There are four biosafety levels. The *NIH Guidelines* refer to laboratory biosafety levels as BL1–BL4, with plant (BL1-P–BL4-P) and animal (BL1-N–BL4-N) containment levels (Appendices G, L, M).

Biosafety Level Terminology -- OSU uses either BSL or BL terminology depending on the context of the work. In the *NIH Guidelines*, containment levels for laboratory, plant, and animal work are described as BL1 through BL4, BL1 P through BL4 P, and BL1 N through BL4 N. In other institutional materials and in the CDC and NIH publication *Biosafety in Microbiological and Biomedical Laboratories*, containment levels are described as BSL1 through BSL4 and ABSL1 through ABSL4.

At Oregon State University, BL2 is equivalent to BSL2, BL2 N is equivalent to ABSL2, and BL2 P is equivalent to plant BSL2. Containment requirements are the same regardless of whether BL or BSL terminology is used.

Human source biological materials – unfixed biological materials derived from the human body, including blood and body fluids (except sweat, urine or saliva unless these fluids are visibly contaminated with blood); primary cells, cell strains or cell lines; tissues or organs. Vomit and feces are not subject to OSHA requirements but should be handled with precautions.

Plant Biosafety Levels – The containment levels as described in the *NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules* are applicable for containment of recombinant plants (BL1-P, BL2-P, BL3-P, BL4-P).

Animal Biosafety Levels – The containment levels for housing and manipulations involving infected animals as described in the CDC Publication *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* (ABSL-1, ABSL-2, ABSL-3, ABSL-4) or recombinant nucleic acids (BL1-N through BL4-N).

Exposure – Any eye, nose, mouth or other mucous membrane, parenteral or inhalation contact with potentially infectious materials.

Research Activities Requiring IBC Registration and Oversight

r/sNA. r/sNA research is the use of recombinant or synthetic nucleic acids, as defined above, for any purpose, including the construction or breeding of transgenic plants and animals. All non-exempt r/sNA research projects must be registered with the IBC. Those projects determined to be exempt do not require registration; criteria for exempt status are restricted to those deemed exempt by the current *NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules*. The IBC will have the final decision on which projects are exempt, review non-exempt projects, establish appropriate containment levels, and make other biosafety requirements as deemed necessary and appropriate for the protection of OSU personnel, students, agricultural or natural ecosystems, and the community from potential biological hazards being used for research activities at the university. The r/sNA oversight activities of the IBC will be conducted according to the most recent edition of the *NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules*.

Gene Drive Modified Organisms (GDMOs). Research activities involving gene drive modified organisms generated by r/sNA molecules must be registered with and reviewed by the IBC. Consistent with the *NIH Guidelines* (Section III-D-8), such experiments must be conducted at a minimum of BL2, BL2-N (Animals), or BL2-P (Plants), with additional containment or risk mitigation as determined by risk assessment. The IBC will ensure that appropriate expertise in gene drive technology and ecological/environmental risk is available (including *ad hoc* consultants when needed).

Additional requirements and training expectations for GDMO work are described in the “Policy for Training Researchers Working with Biological Hazards” and “Detailed Roles and Responsibilities” sections of this manual.

Experiments involving GDMOs may not be conducted at BL1 or field conditions and must, at a minimum, meet BL2, BL2-N, or BL2-P containment as specified in the *NIH Guidelines*.

Human Source Materials. Human source materials include unfixed biological materials derived from the human body, such as blood, tissues, organs, body fluids, primary human cells, and human cell lines not certified as non-infectious, as well as environmental samples reasonably expected to contain human biological material (e.g., wastewater influent or effluent, sewage, septage, and biosolids). Research involving human source materials must be registered with and reviewed by the Institutional Biosafety Committee when there is potential for exposure to infectious agents. The IBC evaluates biosafety risks, assigns appropriate containment and safety controls, and ensures compliance with the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030) and the OSU Exposure Control Plan, as applicable; IBC review does not replace or supersede Institutional Review Board review when human subjects regulations apply.

Microbial Pathogens and Biological Toxins. Research activities involving pathogenic microorganisms of animals, humans or plants and with toxins of biological origin must be

registered and approved by the IBC according to the policies described below. The IBC will review projects, set appropriate containment levels, and make other safety requirements and recommendations. The IBC may delegate some of these activities to the BSO, as allowed by federal requirements. Guidance for pathogen containment comes from the CDC publication *Biosafety in Microbiological and Biomedical Laboratories* (the BMBL), but requirements are established by a risk assessment process. Microbial pathogens include viruses, fungi, protozoans, helminth parasites, and bacteria that are capable of replicating in and / or causing disease in humans, animals, or plants. Non-microbial agents of disease, such as those causing spongiform encephalopathy in animals or humans must also be registered and reviewed by the IBC.

- **Biological Toxins.** Research that makes use of toxins of biological origin requires registration with the BSO or the IBC. If the research involves r/sNA expressing toxic polypeptides, the work must be reviewed and approved by the IBC. If the principal investigator does not conduct other activities requiring registration with the IBC, the toxin work may be registered directly with the BSO. Some toxins are select toxins and may not be used at OSU at this time in quantities above federally mandated limits.
- **Human Pathogens.** All projects which make use of agents of human infection classified as Risk Group 2 or 3, or the culture or handling of organisms requiring BSL-2 or BSL-3 facilities and practices by the Centers for Disease Control and Prevention, must be registered and approved. Risk Group 1 organisms are not known to cause disease in healthy humans and registration of projects with these agents is not required unless they also fall into one of the animal, plant categories below, or they contain non-exempt r/sNA. The use of Risk Group 4 organisms or r/sNA requiring level 4 containment, is prohibited at OSU due to lack of suitable containment facilities for such research. OSU relies on the most current *NIH Guidelines Appendix B* and the CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* for authoritative human pathogen risk group classifications and containment guidance so that the university does not maintain agent specific risk classifications locally. Research involving possible contact with bloodborne human pathogens must be conducted in accordance with the additional requirements established in 29 CFR 1910.1030 (OSHA Bloodborne Pathogen Standard) and the OSU Exposure Control Plan, and must be done at BSL-2 containment.
- **Animal Pathogens.** All projects that make use of infectious agents of animals, whether zoonotic pathogens or not, must be registered and approved by the IBC. Importation or interstate movement of livestock animal pathogens requires a permit from the United State Department of Agriculture (USDA) under the authority of 9 CFR 122. Some animal pathogens are select agents and may not be used at OSU at this time.
- **Plant Pathogens.** Plant pathogens are plant disease-producing organisms or biotic agents that include insects, nematodes, bacteria, fungi, oomycetes, viruses, viroids

and phytoplasmas. The USDA requires a permit for importation or interstate movement of many plant pathogens under the authority established in the regulations CFR Title 7 (Agriculture) Chapter III (APHIS) part 330 (FEDERAL PLANT PEST REGULATIONS). Some plant pathogens are select agents and may not be used at OSU at this time (contact BSO).

Research projects that make use of plant pathogens that are subject to approval by the IBC include:

1. All non-exempt recombinant plant pathogen work, as defined by the current *NIH Guidelines for Research Involving Recombinant or Synthetic Acid Molecules*.
2. All research involving plant pathogens that require an APHIS permit for possession and use, where the pathogen is in active use for research. Curation (e.g., maintaining archived isolates in long-term storage without propagation, experimentation, or distribution) is not considered active use. When registration is required, a copy of the permit must be supplied to the IBC along with approved standard operating procedures.
3. Any organism whose movement is restricted by either state or national quarantine.

Exemptions from IBC Registration for Plant Pathogens

Excluded from review by the IBC are research projects involving plant pathogens unregulated by APHIS or the state of Oregon (i.e., common indigenous isolates) and conducted under categorical exclusion 3407.6 under CFR Title 7 (Agriculture) Chapter XXXIV (NIFA) part 3407 Implementation of the National Environmental Policy Act ([Electronic code of Federal Regulations](#)).

Plant pests exempted from APHIS permit requirements by amendment to 7 CFR Parts 318, 319, 330 and 352 as described in Federal Register Vol. 84, No. 122, June 25, 2019.

Additional Requirements for Biohazard Research

Pathogen Biosecurity. All pathogens must be stored and used in a safe and secure manner that minimizes the possibility of accidental release, acts of vandalism, or the acquisition of pathogens by unauthorized persons. All pathogen laboratories and storage areas must limit access to trained research personnel and be locked when unoccupied. Doors to laboratories are to remain closed while experiments are in progress.

Inspections. The BSO, IBC, or EHS staff may inspect laboratories and other facilities where any of the activities described above are conducted. Inspections are intended to ensure proper safety equipment, work practices are in place, and that research is being conducted according to the containment and safety requirements established by the IBC and/or federal recommendations and regulations. Investigators must make areas where

research is conducted accessible to inspection. Inspection reports will document any identified deficiencies that must be corrected prior to a follow-up inspection.

Dual Use Research of Concern (DURC) and Gain of Function (GOF) Research.

OSU will comply with current federal policies governing Dual Use Research of Concern and Gain of Function research. These policies require institutions to identify research that may be reasonably anticipated to provide knowledge, technologies or products that could be directly misapplied to pose a significant threat to public health, agriculture, animals, the environment or national security. Screening for DURC and GOF potential will be incorporated into IBC registration review and annual updates.

OSU will implement these responsibilities in accordance with current U.S. Government policies on Dual Use Research of Concern and Enhanced Potential Pandemic Pathogen (ePPP) / Gain-of-Function research. When required, an institutional review entity (IRE), which may be the IBC or a designated subcommittee, will be convened to conduct the formal DURC or GOF risk assessment and to develop, review, and monitor risk mitigation plans.

When proposed research meets the criteria for DURC or GOF review, the IBC will ensure that an institutional risk assessment is completed and that appropriate risk mitigation measures are implemented. The IBC will also ensure that relevant federal guidance and oversight requirements are followed, including reporting to federal agencies as required. OSU will support federal efforts to strengthen DURC and GOF oversight and will participate in audits or assessments required under current federal policy.

Safety Violations. When routine deficiencies are noted during laboratory inspections, the BSO will suggest corrective action to the investigators. The BSO will serve as a resource to the principal investigator to provide him/her with whatever guidance and assistance is necessary to restore safe operating procedures to the research program. Follow-up inspections will be required after a reasonable length of time to implement corrective actions. If the principal investigator is unable or unwilling to implement corrective actions, the IBC may be asked to review the situation and suggest a remedy. In the case of investigators with repeated violations or failures to comply with corrective actions, the IBC may make recommendations for actions to department or college leadership and / or to the OSU Division of Research and Innovation.

In the case of serious violations of IBC requirements or applicable guidelines that pose a danger to personnel or the community, the BSO may order that the lab be secured and activities halt for a period of 48 hours. During this time, an emergency meeting of the IBC will be called to determine a satisfactory resolution of the issue.

Failure to Register. Principal investigators who conduct biohazard research at OSU must register their non-exempt projects in accordance to the policies established in this document. Principal investigators with active IBC registrations will be required to respond to an annual update and renew their registrations every three years; the IBC or BSO will contact registered principal investigators to request annual updates and

renewals. If there is no response to these requests, several reminders will be sent before an escalation to department or college leadership occurs. Continued unresponsiveness will result in escalation to leadership in the Division of Research and Innovation.

Registration of Projects and Programs

All research involving r/sNA, biological pathogens, biological toxins, human source materials, or any other biohazardous materials requiring institutional review must be registered with the IBC. As of January 2026, all IBC registrations, renewals, amendments, and annual updates must be submitted through the SciShield Biosafety Module.

Project vs. Program Registrations: Researchers may submit either a Project Registration or a Program Registration, depending on the scope of the work. Both registration types use the same SciShield form, but the level of detail must match the breadth of the registration.

- **Project Registration**
 - Narrow in scope
 - Typically corresponds to a single funded project or defined research effort
 - Appropriate when research activities differ substantially across projects
- **Program Registration**
 - Broader, comprehensive registration covering multiple related projects
 - Describes expected work over the three-year approval period
 - Allows new projects within the approved scope to be automatically “pre-approved”
 - Requires more detail at initial submission but reduces repeated filings over time

Required Training Documentation: All IBC registrations must include information confirming that project personnel have completed the training necessary for the safe and compliant conduct of the proposed work. This includes, as applicable:

- *NIH Guidelines* training for all researchers working with non-exempt r/sNA
- Laboratory Biosafety training for individuals working in BSL-2 or higher containment
- Bloodborne Pathogen training for researchers working with human source materials
- Any agent-specific or procedure-specific training required for pathogens, viral vectors, select biological toxins, or specialized high-risk work.

SciShield automatically pulls training completion data for many courses; however, investigators must ensure that all required training is current prior to registration submission. In cases where personnel have completed specialized or laboratory-specific training not documented in institutional systems, the PI must provide a written description of that training within the SciShield registration.

Standard Operating Procedures: Registrations must include Standard Operating Procedures (SOPs) when required by OSU policy or when necessary for the IBC to complete a biosafety review. SOPs are required for, but not limited to:

1. Work involving RG-2 or higher human pathogens
2. Work involving high-consequence agricultural, plant, or animal pathogens
3. Viral vector production or concentration procedures
4. High-risk laboratory manipulations identified during the risk assessment

SOPs should:

- Describe all manipulation steps involving the biological agent(s)
- Identify engineering controls (e.g., biosafety cabinets, aerosol-tight rotors)
- Specify PPE requirements
- Include spill response, waste disposal, and decontamination procedures

Where SOPs exist for common laboratory practices, investigators may reference them within SciShield rather than repeating the full text. However, any project-specific deviations, unique hazards, or non-standard procedures must be fully described within the registration to allow a complete biosafety risk assessment.

SciShield provides upload fields for SOPs and other supporting documents during the registration workflow.

SciShield Submission Process:

All registrations must be submitted through the SciShield Biosafety Module. Researchers should follow the current online process:

1. Log in to SciShield: <https://oregonstate.scishield.com>
 - Log in using ONID credentials
 - Open Biological Summary → Projects → Add a Project or Edit an existing one
2. Enter required project information
 - Project title, funding sources, plain-language summary
3. Identify all biological materials used.
Selecting items such as pathogens, viral vectors, or toxins automatically displays additional required forms.
4. Describe experimental procedures and safety controls, add in training and experience for personnel. Include any missing work locations not listed in SciShield.
5. Complete the biological risk assessment, if applicable
6. Specify required containment levels
7. List applicable authorizations or permits
8. Identify all rooms and spaces used for work or storage
9. Add all project personnel
10. Submit for review
 - If submitting as a researcher → send to PI for certification
 - PI certifies → SciShield automatically routes to BSO, then BSO routes to IBC for review

Incomplete or unclear submissions will be returned for revision.

Supplemental Agent-Specific Forms: If pathogens, viral vectors, select agents, or other regulated microorganisms are identified in the registration, SciShield automatically generates supplemental forms that must be completed before review can begin. These include:

- Pathogen Registration Form (one per pathogen)
- Viral Vector Registration Form (one per vector system)

Forms request detailed agent information, hazard assessment, trainings, personnel qualifications, and safety practices.

Approval, Duration, Annual Updates, and Amendments

Approval Notification

Upon approval, SciShield issues an electronic memorandum of approval to the PI.

Registration Duration

Registrations are valid for three years from the date of approval.

Annual Updates

All active registrations must be updated annually to confirm that ongoing activities remain within the approved scope. Annual updates are completed in SciShield.

Principal Investigators are responsible for ensuring that their SciShield registrations remain accurate and up to date at all times. Changes in scope, agents, personnel, or locations must be reflected via an amendment before the modified work begins.

Amendments

Amendments are required when:

- Project goals or scope change
- New biological agents are added
- New experimental methods, procedures, or technologies are introduced
- Personnel changes occur
- New rooms or facilities will be used

Amendments are submitted within the existing SciShield registration and routed through the same review pathway.

Types of Research and Review Procedures

The following section describes the categories of research reviewed by the IBC at OSU. These categories correspond to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (April 2024). Each category defines the level of oversight required before research may begin.

1. Research Described in Sections III-A and III-B – NIH & OSP Approval

Sections III-A and III-B describe the highest risk categories of recombinant or synthetic nucleic acid research. These projects require review and approval by both the IBC and the NIH Office of Science Policy. Because of the level of risk involved, no activities in these categories may begin until NIH OSP issues formal written approval.

Section III-A includes major actions such as the deliberate transfer of drug resistance traits to microorganisms when that trait could compromise the ability to treat disease.

Section III-B includes restricted experiments such as the cloning of toxin genes that encode molecules with an LD50 below 100 ng per kg body weight.

2. Research Described in Sections III-C and III-D – IBC approval

All studies that fall under Section III-C or Section III-D must be reviewed and approved by the IBC before any work begins. The BSO visit the laboratory, perform a risk assessment, and prepare an evaluation for the committee. When needed, the IBC may bring in outside scientific expertise to support the review.

Section III-C: Research Involving r/sNA in Human Participants

Section III-C applies to studies in which recombinant or synthetic nucleic acids are intentionally introduced into human participants. These studies require review by both the IBC and the Institutional Review Board. The IBC evaluates biosafety and containment considerations, while the IRB evaluates human subject protections. Both committees must issue approval before the work can begin.

Section III-D: Research That Requires Full IBC Review Prior to Initiation

Section III-D includes a broad range of studies that involve moderate or significant biosafety considerations. These projects cannot begin until the IBC issues formal approval.

Examples of Section III-D research include the use of Risk Group 2 or 3 host vector systems, the introduction of DNA from RG 2, RG 3, or RG 4 organisms into nonpathogenic hosts, the replication of recombinant animal viruses, and the introduction of r/sNA into animals including germline manipulations or testing engineered microorganisms in animals. Section III-D also includes the introduction of r/sNA into plants when the work involves exotic plant pathogens, agents of significant agricultural concern, or genes encoding vertebrate toxins with an LD50 above 100 ng per kg. Large scale cultures that exceed 10 liters and recombinant methods used to generate influenza viruses are also included in this category. Gene drive modified organisms are addressed in Section III-D and must be contained at a minimum of BL2, BL2 N, or BL2 P and undergo an ecological and genetic risk assessment during IBC review.

Institution-Specific Review Requirement (not NIH-mandated)

Any research involving RG2 or RG3 pathogens requires full IBC review and approval before activities may begin. This requirement applies whether or not recombinant or synthetic nucleic acid methods are used and applies to pathogens of humans, animals, plants, and environmental origin.

The Biological Safety Officer (BSO) conducts an initial review to verify that the proposed containment level, required training, laboratory practices, and facility readiness align with institutional expectations. The BSO will also confirm that any agent-specific requirements outlined in OSU biosafety guidance documents have been addressed, including:

- Requirements for handling and concentrating untreated or partially treated wastewater samples, including mandatory BSL-2 containment with inward airflow and use of a certified Class II biosafety cabinet or respiratory protection for aerosol-generating steps.
- Additional precautions and procedural requirements for research involving avian influenza viruses, including the prohibition on highly pathogenic avian influenza (HPAI) research at OSU due to lack of BSL-3 facilities, and the requirement that all low pathogenic avian influenza (LPAI) work be conducted under BSL-2 containment with appropriate PPE, disinfection procedures, and biosecurity measures for associated field or agricultural environments.

After BSO review, the registration is forwarded to the full IBC for committee evaluation. The IBC may request additional information, require modifications, or obtain subject-matter expertise when necessary to complete the risk assessment. No work involving RG2 or RG3 pathogens, including work with concentrated wastewater samples, avian influenza viruses, or other regulated human, animal, or plant pathogens, may begin until the IBC has issued written approval.

3. Research Described in Section III-E – IBC Notification

Section III-E includes studies that pose low biosafety risk but still require notification to the IBC at the time the work is initiated. After receiving the notification, the IBC reviews the activity and votes to approve the work. These studies are generally appropriate for BL1 or equivalent containment.

Examples include cloning r/sNA in nonpathogenic prokaryotic or eukaryotic hosts, use of animal viruses that contain less than two thirds of the viral genome when replication defective status is demonstrated, and recombinant plant systems or plant associated organisms that do not pose a realistic risk of spread or ecological harm.

4. Experiments Described in Section III-F and Appendix C: Exempt Experiments

Section III-F of the *NIH Guidelines* describes categories of r/sNA research that are exempt from the requirements of the Guidelines because they present minimal or no biosafety risk. Appendix C provides the detailed criteria for each exemption.

Although NIH does not require oversight for these activities, OSU requires that the IBC Administrator, IBC Chair, or another qualified IBC member verify that proposed work meets the exemption criteria before it is initiated.

Exempt experiments include activities in which r/sNA molecules are not used to transform, transfect, or infect living cells or organisms. Examples include PCR amplification, sequencing, or electrophoresis when the resulting material is not introduced into a biological system.

Several additional categories of r/sNA work are exempt under Appendix C, including:

- Experiments in which all r/sNA molecules consist entirely of sequences from a single source, when the resulting nucleic acids are not expected to increase the organism's biosafety risk.
- Experiments involving nucleic acids from a single prokaryotic species, propagated only in that species or transferred using natural physiological processes.
- Experiments involving organisms that naturally exchange genetic material, as defined in Appendix A. DNA exchanges occurring through recognized physiological mechanisms (e.g., specific bacterial mating groups) are exempt.

Appendix C also identifies other types of low-risk experiments that NIH has determined meet criteria for exemption, such as certain cloning activities, work using well-characterized strains with no pathogenic potential, and other r/sNA manipulations that do not alter host range, pathogenicity, or environmental risk.

See *Appendix 1: NIH Guidelines & OSU Quick Reference Table* for a summary of research activities and review requirements.

Procedures for IBC Meetings and Documents

Meetings

The IBC meets regularly to review registrations, amendments, incidents, and other biosafety matters. Meetings are generally held monthly. Scheduled meetings may be cancelled or additional meetings convened as needed at the discretion of the Chair.

The IBC Chair, or a designated alternate, presides over meetings and conducts business in accordance with modified Robert's Rules of Order. A quorum consisting of at least half of the members listed on the IBC roster filed with the NIH is required for regular

meetings. Emergency meetings may proceed with a reduced quorum as described in the *Contingency Procedures for Emergency Meetings* in the Incidents and Complaints section of this manual.

Confidentiality

IBC deliberations may involve sensitive, proprietary, or confidential information. Committee members are expected to maintain the confidentiality of all discussions designated as confidential by the Chair, the Principal Investigator, University Administration, or any member of the committee. Discussions not documented in the official minutes are considered confidential. Members may not disclose confidential information outside the meeting except as required by law or policy

IBC Documents and Recordkeeping

All official IBC documents are maintained by the IBC Administrator. Registration documents are retained for the full duration of the project registration period (three years), including all annual updates, amendments, and related correspondence. Minutes of IBC meetings are retained for at least ten years.

In accordance with *NIH Guidelines* and federal transparency requirements, OSU will publicly post the current IBC roster and approved meeting minutes. Posting will continue on an ongoing basis. Proprietary, personal, or otherwise sensitive information will be redacted before public release. OSU will also continue to provide IBC minutes and responses to public comments to NIH OSP as required.

In addition to registration documents and minutes, the IBC will retain:

- Incident and exposure investigation reports for a minimum of ten years after closure.
- DURC and GOF risk assessments and associated risk mitigation plans for a minimum of ten years after the completion of the covered research.
- IBC member training records and rosters for at least ten years after the end of membership.

Project registration records will be retained for at least three years after the registration expires or is formally closed, whichever is later, unless longer retention is required by sponsor or regulatory requirements.

Preparation and Distribution of Meeting Materials

The IBC Administrator prepares meeting agendas and distributes proposals, amendments, and other review materials to committee members in advance of scheduled meetings. Materials must be provided with sufficient time for committee members to review them thoroughly.

Minutes of each meeting are recorded by the IBC Administrator or another designated individual. Draft minutes are circulated to committee members for review before the next

meeting. Adoption of minutes occurs by vote at the subsequent meeting. Once adopted, minutes become the official public record of committee proceedings.

Documentation of Proposal Reviews

Within the official minutes, each registration or amendment review must be referenced by tracking number, proposal title, and Principal Investigator. For proposals involving r/sNA, the minutes must identify the relevant section(s) of the *NIH Guidelines* under which the research falls.

As applicable, the minutes must document the following elements of each review:

- Relevant characteristics of the biological agent(s), such as virulence, pathogenicity, and environmental stability
- The types of manipulations and experimental procedures proposed
- The sources and nature of inserted DNA sequences
- The host(s) and vector(s) to be used
- Any additional safety considerations or containment recommendations raised during the discussion
- The final motion, including any required conditions of approval

This level of documentation ensures regulatory compliance and provides a transparent record of committee deliberations.

Biosafety Review of Non-OSU Research Conducted in OSU Facilities

Federal rules and university policy require that all projects involving r/sNA or pathogens of humans, animals, or plants be reviewed for safety. Off-campus entities periodically conduct animal studies or other types of research involving biological hazards and/or r/sNA utilizing university resources or facilities on a contract basis. Often, some of the personnel involved in these projects are affiliated with the university as graduate students, animal care personnel, laboratory technicians, or senior investigators. An “off-campus entity” is defined as an organization or company that does not receive its funding from Oregon State University (OSU) or from a third party through the OSU Office of Sponsored Programs. The USDA / Agricultural Research Service units located on the OSU main campus are no longer considered off-campus entities and utilize the OSU IBC under a contractual agreement.

To ensure (i) that all biohazard and r/sNA research conducted at OSU conforms to current safety standards, (ii) that risks to personnel, the community, or the environment associated with these activities are mitigated by application of best practices, and (iii) that all such work has been reviewed in compliance with federal rules, the OSU IBC adopts the following policies and procedures for projects conducted by off-campus entities:

- 1) The OSU IBC will **not** serve as the compliance committee of record for the review of projects involving r/sNA being conducted at OSU by off-campus entities in the absence of a formal agreement between the OSU Division of

Research and Innovation and the non-OSU entities. The off-campus entity conducting the research must either form their own IBC or arrange to use a third party's IBC to meet the compliance requirements set forth in Section IV of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*. Review by an external IBC must be documented, and that documentation shall be provided to the OSU IBC upon request.

2) The OSU IBC requires and reviews a standard IBC Project Registration form and appropriate supporting documents to verify that the work meets the safety requirements imposed on OSU investigators for similar projects. All projects will require a research description addressing the goals of the project, hazardous materials or agents to be used, potential sources of risk to personnel or the environment, and procedures that will be used to minimize those risks during the conduct of the project. The registration must also indicate in which facility or facilities the work will be conducted and the appropriate biosafety level to be used for the project. For projects which will be conducted at BSL-2 / ABSL-2 equivalent or higher containment, supporting documents may also include at the discretion of the IBC (i) safety SOPs for conducting hazardous tasks, (ii) documentation of appropriate training for personnel.

3) Upon completion of a review of supporting documents for a proposed project involving an off-campus entity, the OSU IBC will forward a memorandum stating that clearance for the project to be conducted in OSU facilities is either obtained or denied. If the study involves vertebrate animal use, notice of approval will be provided to the IACUC; the OSU Attending Veterinarian serves as a member of the IBC.

Procedures for Incidents or Complaints about Biohazard Use

Receipt of Complaints

Concerns related to misuse, unsafe use, or suspected non-compliance involving biological materials may be submitted through multiple reporting pathways. Complaints may be made:

- Directly to the IBC Chair
- Directly to the Biological Safety Officer (BSO)
- Through the university's incident or safety reporting system (e.g., RiskONNECT)
- Through EHS
- Through confidential or anonymous university reporting mechanisms
- Verbally or in writing to any IBC member, who must forward the information to the Chair or BSO

Complaints may be submitted anonymously. When individuals choose to identify themselves, the IBC Chair (or designee) will acknowledge receipt of the complaint in writing.

All complaints will be treated as confidential to the extent possible and consistent with institutional and regulatory requirements.

IBC Chair Responsibilities

Upon receiving a complaint, the IBC Chair is responsible for:

- Ensuring prompt initial review of the concern
- Assigning the preliminary assessment to the BSO
- Determining whether a situation warrants immediate action
- Coordinating communications with other institutional offices as appropriate (e.g., Attending Veterinarian, IACUC, EHS, or Research Office)
- Ensuring that all investigation procedures follow institutional policies and uphold fairness and transparency
- Presenting the investigation findings to the full IBC for review and action

If the Chair is unavailable, these responsibilities are delegated to the BSO.

Preliminary Assessment

The BSO will conduct an initial assessment to determine whether:

- There is an immediate threat to personnel, the environment, animals, or property
- Immediate intervention or temporary suspension of activities is necessary
- Additional institutional offices must be notified

If the concern involves research animals, the University Attending Veterinarian will be notified and may participate in the preliminary assessment.

If an imminent hazard is identified, the BSO may take immediate action to halt work, secure biohazardous materials, or restrict access until further evaluation is completed.

Investigation and Reporting

If a formal investigation is warranted, the IBC Chair may appoint an investigation team or subcommittee to conduct a thorough review of the concern. The investigation may involve inspecting laboratories or research facilities, reviewing relevant protocols, training records, standard operating procedures, or other documentation, interviewing personnel involved in or knowledgeable about the situation, evaluating equipment, containment practices, and facility conditions, and collecting supporting evidence such as photographs or written statements.

Following the investigation, the BSO will prepare a written report summarizing the nature of the complaint, the investigative methods used, the findings, conclusions regarding the validity of the allegation, and any required or recommended corrective actions. The final investigation report will be provided to the full IBC, the Principal Investigator, the relevant Department Head and/or Dean, and other institutional officials as appropriate.

Procedures for Suspending Research

If the preliminary or full investigation determine that unsafe practices, non-compliance, or willful violations of safety practices have occurred which pose a threat to personnel, animals, the environment, or the community, the BSO has the authority to suspend the unsafe research activity, and to take control of any biohazardous materials present in the facility or laboratory. Following suspension, an emergency meeting of the IBC will be convened as soon as possible. In this meeting, the IBC will review the available evidence and possible consequences, interview the principal investigator responsible for the research program or other relevant personnel, and determine the appropriate corrective or administrative actions.

If an ongoing serious hazard is posed by resumption of research, the committee may not allow research to continue until the hazard(s) have been mitigated. The committee's action may include any or all of the following requirements to be implemented before any biohazard work may continue:

- Changes in procedures used in research to make the work safer.
- Additional / different personal protective equipment to be used during tasks.
- The use of biological safety cabinets or other safety equipment.
- Training or re-training of individuals conducting research.
- Registration or review of hazardous activities not previously reviewed.

In addition, the IBC may require the principal investigator to supply documents for a full review of all research activities under their direction.

In severe or repeated cases, the committee may decide that the risks posed by the activities are such that the work is indefinitely suspended, vote to revoke a biological use authorization, or subsequently refer the matter to the Research Office for resolution.

Contingency procedures for Emergency Meetings:

Emergency meetings of the IBC will follow standard quorum requirements whenever possible. If immediate action is required and a full quorum cannot be achieved, a minimum of three voting IBC members may convene to address the hazard.

If fewer than three members are available, the meeting will be postponed until the minimum threshold is met. Any actions taken under reduced quorum must be reviewed and ratified by the full IBC at the next scheduled meeting.

Outcomes and Follow-Up

After reviewing the investigation and determining any required actions, the IBC may conclude that:

1. No evidence of unsafe practices or non-compliance exists, and the complaint is closed.

2. A potential exposure or release occurred, requiring adherence to the institution's accident, illness, and exposure reporting procedures.
3. Improvements or corrective actions are needed, and the BSO may be directed to conduct post-monitoring of the research program through audits or unannounced inspections, with reports made to the IBC.

All follow-up actions will be documented and reported to the IBC.

Procedures for Accidents, Illnesses and Recognized Exposures

Accidents, illnesses related to biohazard activities, spills, or exposures to infectious or recombinant materials must be reported to the BSO as outlined in this policy. Different types of incidents require different responses and reporting pathways. Exposures or illnesses resulting from research activities may require any of the following:

- Medical evaluation by qualified health care professionals. When an exposure is confirmed, the provider may recommend treatment or prophylaxis consistent with current CDC guidance.
- Medical monitoring of any subsequent illness that develops following a research-related exposure to a biohazard.
- Reporting to regulatory authorities, as required by federal, state, and local regulations, including:
 - **NIH OSP Reporting:** In accordance with the *NIH Guidelines*, exposures or accidents involving r/sNA that occur in BL2 or BL3 laboratories must be reported to NIH OSP immediately. Other significant problems, violations, or research-related illnesses involving r/sNA must be reported within 30 days.
 - **Additional Federal Reporting:** Exposures or releases involving recombinant infectious agents in BL2 or BL3 labs require immediate reporting to the IBC and NIH OSP. The PI reports the event to the BSO, who submits the institutional report to NIH OSP; if the BSO is unavailable, the PI must report directly. BL1 r/sNA incidents must be reported within 30 days. Releases involving materials regulated by USDA/APHIS must be reported immediately to APHIS as required by permit conditions.
 - **Public Health Reporting:** Any laboratory-associated infection or suspected research-related infection must be reported to the local County Health Department, consistent with Oregon communicable disease reporting laws.

All accidents, exposures, or illnesses involving biohazardous materials, infectious agents, or r/sNA materials must be thoroughly documented and maintained by the BSO. Documentation ensures institutional compliance, supports required federal and state reporting, and provides a clear record for internal review and incident follow-up.

The documentation maintained by the BSO should include, as applicable:

- A description of the incident, including date, time, location, personnel involved, and materials or agents in use at the time of the event.
- A summary of immediate response actions, including spill cleanup, first aid, containment steps, and notifications made at the time of the incident.
- Assessment of exposure risk, including whether an overt exposure occurred (e.g., sharps injury, splash, animal bite), consistent with NIH definitions.
 - Overt exposures are considered reportable incidents under the *NIH Guidelines*.
- Medical follow-up and student or occupational health documentation if evaluation or monitoring was conducted.
- Copies of reports submitted to regulatory bodies, including:
 - NIH Office of Science Policy (OSP) (immediate or 30-day reports as required under the *NIH Guidelines*).
 - Local public health authority for reportable communicable diseases (Benton County Public Health serves as the LPHA for OSU).
 - USDA/APHIS, if the incident involves permit-regulated biological materials.
- Corrective actions or mitigation steps implemented to prevent recurrence.

All incident records must be retained by the BSO in accordance with institutional policy, applicable federal requirements, and expectations outlined in the *NIH Guidelines* for institutional oversight.

See *Appendix 2: Quick Reference – Reporting Requirements* for a summary of reporting pathways and timelines.

IACUC – IBC Coordination

The following procedure is intended to ensure appropriate review by both committees of biological research proposals involving non-exempt r/sNA and / or pathogens or toxins in animal studies. The IACUC and IBC may conduct their reviews in parallel; however, animal work involving pathogens or r/sNA may not begin until the IBC has determined that the project is exempt or has granted final IBC approval. The IACUC may withhold final activation of the animal use protocol contingent upon IBC notification of approval.

1) Investigators preparing animal use research proposals that involve any of the following must register their projects with the IBC:

- a) R/sNA in animals, including construction or breeding of transgenic animals (the purchase, creation or breeding of transgenic / knockout **rodents** is exempt if it meets the criteria described in Appendix C of the *NIH Guidelines*).
 - b) R/sNA in microorganisms or viral vectors which are subsequently introduced into animals.
 - c) Animal studies using bacteria, viruses, fungi, protozoa, helminthes, or other microbes or prions that are known or suspected pathogens of humans or animals.
 - d) The introduction of toxins of biological origin into animals.
- 2) For projects that involve pathogens or potentially infectious r/sNA, investigators are also required to fill out the “*Biohazard Warning and Safety Precautions for Animal Rooms*” Form issued by EHS. This form provides essential information on the infectious agent, required personal protective equipment, and the assigned Animal Biosafety Level (ABSL), and any special handling or husbandry considerations.

This completed form must be posted by the PI or designee on the door or other entrance to the animal room or area in which the biological agent will be used. Appropriate biohazard warning signage must also be affixed to individual cages or enclosures, including the universal biohazard symbol, when animals are actively infected or exposed to hazardous biological materials. EHS continues to provide this required posting form as part of its biological safety resources for animal facilities. This form is available as a download from the EHS website at <https://ehs.oregonstate.edu/bio/>.

The PI or designee is responsible for notifying and coordinating with animal care personnel before biological agents are introduced into animals. This includes ensuring animal care staff are aware of the planned work, understand associated hazards, and have access to required personal protective equipment and safety instructions. Posting must remain in place for the duration of the hazardous agent’s use or active infection period and removed promptly when the hazard no longer exists.

- 3) Once a registration has been received, reviewed and approved by the IBC, the IACUC administrator is notified that the project has been approved. Documents relating to the project will be supplied to the IACUC upon request.
- 4) The BSO serves on the IACUC and provides biosafety input into animal studies as appropriate.
- 5) Prior to initiation of infection studies involving animals, a meeting is held with research staff, animal care staff and the BSO to discuss procedures, hazards, and address any questions relating to the safety of the study.

IRB – IBC Coordination

The Institutional Review Board (IRB) and Human Research Protections Program (HRPP) review research with human subjects. Its oversight focuses on consent, privacy,

confidentiality, and minimizing risks to participants. The IBC reviews biological risks, including recombinant or synthetic nucleic acids, human source biological materials, human pathogens, biological toxins, and laboratory procedures that require containment.

When both IRB and IBC review are required

IBC review is required for human subjects research that involves:

- Collection or laboratory use of human blood, body fluids, tissues, or other human source biological materials
- Isolation, culture, amplification, or manipulation of human pathogens
- Any use of recombinant or synthetic nucleic acids in human research
- Laboratory work with human source materials that requires OSHA Bloodborne Pathogen Standard compliance

IRB and IBC reviews may occur in parallel. Human subjects research cannot begin until IRB approval or exemption is issued. Laboratory work involving biohazards cannot begin until IBC approval or exemption is issued.

Coordination of review responsibilities

When human subjects research involves human source biological materials, the HRPP refers it to the BSO to confirm compliance with the OSU Exposure Control Plan and OSHA Bloodborne Pathogen Standard. The BSO notifies the HRPP office when biosafety requirements are satisfied.

If IBC registration is required, the investigator must submit a biosafety registration through standard OSU processes. The IBC evaluates biological risks, containment, training, and compliance with the *NIH Guidelines*.

Information accuracy across submissions

To avoid delays, investigators must ensure that information in their IRB submission matches the information in their IBC registration. Submissions may be returned by the IRB or IBC when they contain inconsistent descriptions of materials, missing documents, or incomplete explanations of external collaborations or laboratory procedures. The IRB also requires that study personnel complete required human subjects training.

Communication between committees

The HRPP and IBC coordinate as needed to resolve questions about human source materials, specimen handling, confidentiality of labeled samples, and storage or disposal requirements. Investigators are responsible for meeting all requirements of both committees before beginning any work covered by their approvals or exemptions.

USDA ARS – IBC Coordination

Oregon State University and the USDA Agricultural Research Service (ARS) at the Corvallis location maintain a cooperative relationship for biosafety oversight. Under the cooperative agreement, ARS uses the Oregon State University IBC as its IBC of record for research conducted by ARS personnel or in ARS facilities that involves r/sNA, biohazardous materials, biological toxins, non-exempt rDNA, and plant or agricultural pathogens.

ARS designates one voting member to serve on the OSU IBC as its representative. The term of service follows OSU IBC membership practices and may be renewed or replaced according to ARS internal procedures.

ARS personnel conducting covered research submit registrations, amendments, and annual updates through OSU IBC processes and follow all OSU biosafety requirements, in addition to ARS Policies and Procedures 602.0. ARS ensures that required training and facility inspections occur as described in the *NIH Guidelines* and internal ARS policy.

Both institutions support reciprocal access to facilities, personnel, and records as needed to meet their regulatory or oversight obligations. The full details of responsibilities are maintained in the current cooperative agreement between OSU and ARS.

Appendix 1: NIH Guidelines & OSU Quick Reference Table

Guidelines / Category	Type of Work	Required Approvals / Notifications
III-A	<ul style="list-style-type: none"> Extremely high-risk r/sNA experiments Creation of agents with enhanced transmissibility, host range, or unusual hazards 	<ul style="list-style-type: none"> NIH Director (via OSP) before any IBC action Full IBC approval
III-B	<ul style="list-style-type: none"> r/sNA involving RG3, RG4, or restricted agents Constructs expected to increase virulence, pathogenicity, or environmental risk beyond normal III-D scope 	<ul style="list-style-type: none"> NIH OSP approval before work starts Full IBC approval
III-C	<ul style="list-style-type: none"> Human gene transfer trials Delivery of viral vectors, GMOs, or other r/sNA constructs to people 	<ul style="list-style-type: none"> IBC approval IRB approval
III-D	<ul style="list-style-type: none"> r/sNA work in RG2 or RG3 host-vector systems Cloning nucleic acid from RG2/3/4 organisms into nonpathogenic hosts Recombinant or host-range-altered animal viruses Introduction of r/sNA into: <ul style="list-style-type: none"> Vertebrate animals Plants under elevated-risk conditions Gene drive modified organisms 10 L large-scale cultures Influenza reverse-genetics systems 	<ul style="list-style-type: none"> Full IBC committee review and approval
OSU Institutional Requirement	<p>All work involving RG2 or RG3 pathogens, even without r/sNA. Examples:</p> <ul style="list-style-type: none"> Wild-type RG2 bacterial cultures Propagation of RG2 viruses Zoonotic agents handled at ABSL-2/3 Work with human-source materials Work with wastewater materials 	<ul style="list-style-type: none"> BSO review Full IBC review and approval
III-E	<ul style="list-style-type: none"> r/sNA introduced into RG1 organisms using defined, stable, non-mobilizable vectors Typical cloning in <i>E. coli</i> K-12, <i>B. subtilis</i>, <i>S. cerevisiae</i> under RG1 containment 	<ul style="list-style-type: none"> IBC notification Work may begin after administrative confirmation
III-F	<ul style="list-style-type: none"> r/sNA not introduced into living cells (PCR, sequencing, gel work) DNA from a single source propagated in that same species DNA exchange through natural physiological processes (Appendix A organisms) Other low-risk categories explicitly listed in Appendix C 	<ul style="list-style-type: none"> No NIH oversight OSU requires exemption verification (IBC Admin/Chair/designee)

Appendix 2: Quick Reference – Reporting Requirements

<p>Biohazard Incidents and r/sNA Exposures: Immediately notify the BSO for any biohazard incident, spill, or suspected exposure.</p> <ul style="list-style-type: none"> • r/sNA at BL2 or BL3: <ul style="list-style-type: none"> ○ Report immediately to BSO; ○ BSO (or PI if BSO is unavailable) reports to NIH OSP immediately as required by the <i>NIH Guidelines</i>. • r/sNA at BL1: <ul style="list-style-type: none"> ○ Report to BSO; ○ BSO or PI reports to NIH OSP within 30 days as required.
<p>USDA/APHIS-Regulated Agents</p> <ul style="list-style-type: none"> • The PI must report any release or loss immediately to USDA/APHIS in accordance with permit conditions.
<p>Workplace Injuries, Illnesses, and Claims: All workplace injuries, illnesses, or near misses must be reported through the OSU Riskconnect Incident Portal:</p> <ul style="list-style-type: none"> • https://risk.oregonstate.edu/ <ul style="list-style-type: none"> ○ Supervisors must complete required workers’ compensation forms (e.g., SAIF 801 within 24 hours when medical care is sought). • Property damage, auto incidents, and general liability claims must also be reported through the portal as required by OSU Insurance and Risk Management Services.
<p>Additional Reporting Expectations</p> <ul style="list-style-type: none"> • Medical evaluation and follow-up may be required for any confirmed exposure. • Exposures, spills, or illnesses involving r/sNA that occur in BL2 or BL3 laboratories must be reported immediately to NIH OSP; BL1 incidents must be reported within 30 days. • Any research-related infection or suspected laboratory-acquired infection must be reported to the local County Health Department, consistent with public health requirements.

Revisions

March 2026

Section	Change Made	Summary of Revision
Scope and Purpose	Updated and expanded	Modernized introduction; clarified purpose; aligned with federal and institutional requirements.
Summary of Roles and Responsibilities	New section created	Added high level summaries for IBC, Chair, BSO, and PI roles.
Detailed Roles and Responsibilities	Rewritten and consolidated	Merged duplicate content; added GDMO oversight; clarified duties and reporting expectations.
IBC Membership, Authority, and Composition	New section created	Added appointing authority (President for Research Integrity), clarified composition requirements, added quorum language, removed individual names.
ARS Coordination	Condensed and modernized	Replaced detailed agreement text with a brief summary describing ARS representation, scope of oversight, and reference to external agreement.
Training Requirements	Updated terminology and content	Added GDMO related training; aligned with 2024 <i>NIH Guidelines</i> ; standardized formatting and EHS terminology.
Registration of Projects and Programs	Completely rewritten	Updated for SciShield only workflow; added training documentation, SOP requirements, supplemental forms, annual updates, and amendment requirements.
IRB and IBC Coordination	Rewritten and streamlined	Clarified when dual review is required, aligned with HRPP guidance, simplified responsibilities, and removed outdated language.
Complaints, Incidents, and Suspension Procedures	Fully revised	Added anonymous reporting, clarified Chair and BSO responsibilities, added stepwise investigation workflow, and emergency quorum policy.
Animal Room Biohazard Posting	Modernized and clarified	Updated expectations for posting forms, required signage, and coordination with animal care personnel.
IBC Meetings and Documents	Rewritten for clarity	Updated quorum description, confidentiality standards, document retention requirements, and public posting expectations.
Terminology Clarifications	New clarifying statements	Added explanation of BL and BSL equivalence for labs, animals, and plants.
General Cleanup	Removed duplication; corrected terminology	Eliminated outdated paragraphs, removed inconsistent formatting, standardized terms, and aligned structure across sections.

References

NIH Office of Science Policy (NIH OSP).

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024).

https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf

NIH OSP Incident Reporting Guidance (reportable r/sNA incidents and timelines).

<https://osp.od.nih.gov/policies/incident-reporting-december-2023/>

CDC / NIH.

Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th Edition (2025).

<https://www.cdc.gov/labs/BMBL.html>

USDA Animal and Plant Health Inspection Service (APHIS).

Biological Materials Permitting (plant, animal, and select-agent regulated materials).

<https://www.aphis.usda.gov/aphis/ourfocus/permits>

Oregon Administrative Rules (OAR) 333-018 – Disease Reporting Requirements.

https://oregon.public.law/rules/oar_chapter_333_division_18

Oregon Health Authority – Communicable Disease Reporting.

<https://www.oregon.gov/oha/PH/DISEASES/CONDITIONS/COMMUNICABLEDISEASE/REPORTINGCOMMUNICABLEDISEASE/Pages/index.aspx>

Oregon Health Authority – How & Where to Report (Online Morbidity Report portal).

<https://www.oregon.gov/oha/PH/DiseasesConditions/CommunicableDisease/ReportingCommunicableDisease/Pages/counties.aspx>

Benton County Public Health – Communicable Disease Program.

<https://health.bentoncountyor.gov/communicable-diseases/>

Phone: 541-766-6835

Address: 530 NW 27th St, Corvallis, OR 97330

Oregon Occupational Safety and Health (Oregon OSHA).

<https://osha.oregon.gov/>

Oregon OSHA – Bloodborne Pathogens Topic Page.

<https://osha.oregon.gov/Pages/topics/bloodborne-pathogens.aspx>

Oregon OSHA – Bloodborne Pathogens Rule (OAR 437-004-9650).

https://oregon.public.law/rules/oar_437-004-9650

Oregon OSHA – Injury/Illness Recordkeeping & Reporting Requirements.

<https://osha.oregon.gov/Pages/topics/recordkeeping-and-reporting.aspx>

Reporting line for 8-hr / 24-hr required OSHA events: 1-800-922-2689

Oregon State University – Insurance & Risk Management.

OSU Incident Portal (Riskconnect): <https://riskconnectogsu.my.site.com/IncidentPortal/s/>

OSU Workers' Compensation – SAIF 801 Reporting.

<https://risk.oregonstate.edu/workerscomp/forms>

Oregon State University – Environmental Health & Safety (EHS).

Biosafety Program and Resources: <https://ehs.oregonstate.edu/bio/>

OSU SciShield Biosafety Module (for all IBC registrations).

<https://oregonstate.scishield.com/>