Biological Agents and Materials Requiring Oversight

Oregon State University – Biological Safety Program
(Revised 2026)

Purpose

This document defines the categories of biological agents, materials, and research activities that require review, registration, and oversight by the Oregon State University Institutional Biosafety Committee (IBC).

These requirements support compliance with:

- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
- CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)
- OSHA Bloodborne Pathogens Standard
- Applicable federal, state, and institutional policies

All applicable work must be reviewed and approved prior to initiation.

IBC Oversight Framework

At Oregon State University, biological oversight is risk-based and applies broadly to:

- Recombinant or synthetic nucleic acid (r/sNA) research
- Infectious agents and pathogens
- Biological toxins
- Human source materials
- Other activities that may pose biological risk

The IBC has full authority to:

- Review and approve research
- Require modifications
- Establish containment levels
- Suspend non-compliant work

Registration Requirement (SciShield)

All research requiring IBC oversight must be registered through the SciShield Biosafety Module and approved prior to work initiation.

This includes:

- New projects
- Amendments
- Annual updates

- Renewals

Word documents and paper forms are no longer accepted.

Categories of Biological Materials Requiring Oversight

The following activities require IBC review and approval prior to initiation:

1. Recombinant or Synthetic Nucleic Acids (r/sNA)

All non-exempt r/sNA research must be registered and reviewed in accordance with the NIH Guidelines.

This includes:

- Genetic modification of organisms
- Cloning, expression, or manipulation of nucleic acids
- Viral vector systems (including commercial systems)
- Transgenic plants and animals (non-exempt)
- Gene drive modified organisms (GDMOs)

The IBC:

- Determines exemption status
- Assigns containment level
- Defines required controls

2. Infectious Agents and Pathogens

Work involving infectious agents that present a potential risk to human, animal, or plant health or require elevated containment must be reviewed and approved by the IBC prior to initiation.

This includes, but is not limited to:

- Risk Group 2 or higher organisms
- Work requiring BSL-2 or higher containment
- Environmental or field samples with credible pathogen risk
- Laboratory propagation of microorganisms

OSU requires IBC review for Risk Group 2 or higher pathogens regardless of recombinant status.

3. Human Source Materials

IBC oversight is required for work involving human-derived biological materials where there is potential for exposure to infectious agents, including:

- Blood and blood products
- Body fluids (excluding sweat, urine, saliva unless contaminated with blood)
- Unfixed tissues or organs

- Primary cells, cell strains, or cell lines
- Materials reasonably expected to contain human-derived biological agents (e.g., wastewater)

Such work must also comply with:

- OSHA Bloodborne Pathogens Standard
- OSU Exposure Control Plan

4. Biological Toxins

Research involving biological toxins must be registered with the IBC or, where appropriate, the Biological Safety Officer, in accordance with institutional review requirements.

This includes:

- Naturally derived toxins
- Synthetic or recombinant toxins
- Expression of toxin genes

Some toxins may also be regulated under federal Select Agent regulations.

5. Gene Drive Modified Organisms (GDMOs)

All research involving gene drive systems must be:

- Registered
- Reviewed by the IBC
- Conducted at minimum BSL-2 containment

Additional:

- Ecological risk assessment required
- Specialized training required

6. Plant and Animal Pathogens

Oversight is required for:

- Infectious agents of animals or plants
- Zoonotic pathogens
- Regulated agricultural pathogens
- Work requiring USDA/APHIS permits

7. Other Biohazardous Materials

IBC registration may also be required for:

- Prions or non-microbial infectious agents

- Novel or emerging biological hazards
- Work involving unknown or poorly characterized agents

Exemptions

Some activities may be exempt from IBC oversight if they meet criteria established in the NIH Guidelines (Appendix C).

Examples may include:

- Work not involving living systems (e.g., PCR, sequencing)
- Certain low-risk cloning activities

Exemption must be confirmed by the IBC or designee before work begins.

Training and Responsibilities

Personnel (including faculty, staff, students, and affiliates) conducting work requiring IBC oversight must:

- Complete required institutional training (assigned through SciShield)
- Receive task- and procedure-specific training
- Follow SOPs and containment requirements

Principal Investigators are responsible for:

- Ensuring registration prior to work
- Providing and documenting training
- Ensuring compliance with IBC requirements

Incident Reporting Requirements

All incidents involving biological materials must be reported through the OSU incident reporting system (Riskonnect).

This includes:

- Sharps injuries
- Exposures
- Spills or releases
- Near-misses

Reports submitted in Riskonnect serve as the official institutional record and are used by Environmental Health & Safety (EHS), including the Biological Safety Officer (BSO), for review, response, and regulatory reporting, as applicable.

Certain incidents must also be reported to federal agencies (e.g., NIH OSP).