Effective January 2026. All registrations must be completed in SciShield.

Overview: Project vs. Program Registrations

Researchers may register either Project or Program protocols.

Project Registrations
- Narrow in scope; typically represent one grant or distinct study
- Best when research activities vary significantly across projects

Program Registrations
- Broad, comprehensive descriptions covering multiple related projects
- Newly initiated work within scope is automatically "pre approved"
- Require more detail up front, but reduce repeated submissions over the 3 year approval period

Both use the same SciShield form. The level of detail should match the scope. All submissions must provide enough detail for a complete IBC biosafety risk assessment.

SciShield Biosafety Module (Current Process)

Starting January 2026, all IBC activities must be submitted in SciShield:
- New registrations
- Renewals
- Amendments
- Word documents and paper forms are no longer accepted

How to Register an IBC Project or Program in SciShield

1. Log in to SciShield
    - Go to https://oregonstate.scishield.com
    - Log in with ONID
    - From the dashboard, select: Biological Summary > Projects > Add a Project (or Edit for existing registrations)

2. Enter Project Information
    - **Project Title** Provide a clear and descriptive title.
    - **Funding Sources** Examples include NIH R01, NSF, startup funds, or internal OSU grants.
    - **Brief Project Summary** Provide a plain language description including:
        - Purpose
        - Objectives or aims
        - Biological context or relevance
        - Spelled out acronyms

3. Select All Biological Materials Used
   SciShield will display additional required forms based on your selections.

- Human or non-human primate materials
- Non-primate animals and derived materials
- Microorganisms
- Recombinant or synthetic nucleic acids
- Viral vectors
- Biological toxins or infectious proteins
- Other hazards (physical hazards, mixed waste, etc.)

4. Describe Experimental and Procedural Details
   Provide a narrative explaining:
   - What is being done with the biological materials
   - Key manipulations
   - Engineering controls such as biosafety cabinet use and aerosol mitigations
   - PPE
   - Decontamination and exposure prevention strategies
   - Trainings & experience of all workers, including how competency is determined (only needed if not captured in pathogen or viral vector forms, see below)
   - Additional spaces used for work, if not shown/associated with your lab (i.e. meaning they are not available for selection when indicating rooms)

   Do not paste full SOPs. Any SOPs can be uploaded as part of the registration, however. See SOPs, below.

5. Complete the Biological Safety Risk Assessment
   - Rate each item assuming no controls in place:
   - Human risk: likelihood, severity, spread
   - Animal risk: likelihood of spread

   Scale: 1 (Very Low) to 4 (High). The BSO may adjust ratings.

6. Specify Required Safety Levels
   - **BSL 1:** Basic biological safety; work with well-characterized agents not known to cause disease in healthy adults.
   - **BSL 2:** Work with agents that pose moderate hazards to personnel or the environment; requires additional training, biosafety cabinets, and exposure-control practices.
   - **BSL 3:** Work with agents that can cause serious or potentially lethal disease via inhalation; requires controlled access, respiratory protection, and specialized facility design.
   - **ABSL 1:** Animal research equivalent of BSL 1; work with animals exposed to agents not known to cause disease in healthy adults.
   - **ABSL 2**: Animal research equivalent of BSL 2; work with animals exposed to moderate-risk agents requiring more stringent containment.
   - **BSL LS**: Large-scale biological production; applies when cultures exceed 10 liters or involve equipment/processes that increase risk.
   - **BSL P**: Plant biosafety level; containment for genetically modified plants, plant pathogens, and agricultural pests.

7. List Authorizations and Permits
   Any project involving animals, humans or their data/materials, or regulated biological agents must include the appropriate oversight protocol numbers and federal permits. This information allows the IBC to verify that all required institutional and regulatory approvals are in place before work begins. Required items may include:
   - **IACUC protocol**: For any work involving live vertebrate animals or animal-derived procedures requiring IACUC approval.
   - **IRB protocol**: For any research involving human subjects, human data, or identifiable biospecimens.
   - **USDA, APHIS, or PPQ permits**: Required for regulated plant pests, plant pathogens, restricted agricultural materials, or interstate transport of certain biological agents.
   - **CDC import or export permit**s: Required for importing or exporting infectious materials, regulated pathogens, or certain biological toxins.

   Document Upload: All applicable protocols and permits may be uploaded under *Biological Summary → Biological Registration Documents* in SciShield.

8. Identify Rooms and Spaces
   For each OSU location specify:
   - Work areas
   - Storage areas
   - Project specific rooms

   If the room option is not available for the work area, especially if it is a shared facility or space, please indicate which rooms will be used in the *Project Information* text box.

9. Add Project Team Members
   - Include all individuals who will work on the project:
   - Lab personnel
   - OSU collaborators
   - External collaborators

   The PI must be listed and will certify the protocol.

10. Submit for Review
    - Researcher submits to PI
    - PI certifies
    - SciShield routes to BSO review, then IBC review

Incomplete or unclear submissions will be returned for revision.

Standard Operating Procedures (SOPs)

SOPs are required for:
- Work with RG 2 or higher human pathogens
- Work with high consequence animal or plant pathogens

Researchers should:

- Provide detailed SOPs covering manipulation steps
- Reference SOPs in the registration narrative to avoid duplication
- Upload SOP documents to *Bio > Biological Summary > Biological Registration Documents*

Approvals, Duration, and Amendments

Approval
The PI receives a formal approval memorandum after IBC approval.

Duration
Registrations are valid for 3 years.

Amendments Required For:

- New biological agents
- Changes in goals or scope
- New methods or procedures
- New personnel
- New rooms or facilities

Annual Updates
Required for all active registrations.

Supplemental Agent Specific Forms
If you select pathogens, viral vectors, or regulated agents, SciShield will automatically display the required supplemental forms. These must be completed before submission.

Pathogen Registration Form
One form is required for each pathogen. Include details regarding:
Step I: Pathogen Information

- Name, strain, type
- Source and transport method
- Genetic modifications
- Rooms for storage or use

Step II: Project Details

- Host or target
- Use in recombinant DNA experiments
- Duration of work
- Project objectives

Step III: Safety

- Health restrictions
- Vaccines or treatments
- Medical surveillance
- Sharps use
- Engineering controls
- Disinfection and spill cleanup
- PPE

Step IV: Risk Assessment
Description of hazards, transmission routes, containment, and mitigation.
Step V: Personnel
List personnel, roles, training, and experience.

Viral Vector Registration Form
One form is required for each viral vector system. Include the following details:
Step 1: Vector Information
- Vector system name and type
- Supplier
- Helper viruses
- Host range
- Replication competent testing

Step 2: Vector Production
- Production in lab or vendor
- Methods, cell lines, titer
- Rooms involved
- Collaborating labs

Step 3: Insert Information
- Gene or sequence name
- Type of insert
- Gene function
- Whether toxic, secreted, growth altering, or gene drive related

Step 4: Viral Use
- Experimental use
- Storage and use locations
- Use in animals
- Transgenic animal generation
- Environmental release considerations
- Human administration if any

Step 5: Safety
- Exposure risks
- Sharps considerations
- Disinfection
- Spill response
- Use of biosafety cabinet
- PPE

Step 6: Personnel
List personnel, roles, trainings, and experience.

If you indicate the use of any pathogen or viral vector in your Biological Materials section, you must complete the corresponding supplemental form(s) before submitting your IBC registration. Incomplete forms will delay the review process.

Missing the Bio tab in SciShield? Email biosafety@oregonstate.edu to bioenable your lab.