

Biohazard Project Registration

Description

The purpose of the Biohazard Project Registration process is to identify and assess risks associated with work handling certain biological materials and to set control measures and practices to avoid exposure. Upon approval, the Biosafety Office and/or Institutional Biosafety Committee (IBC) will communicate specific guidance and requirements for the appropriate containment, procedures, and practices needed to prevent accidental exposures or unintended releases of these materials.

Registrations are project specific.

The Biosafety Office **no longer accepts paper registration forms** (*apart from Select Agent projects*). All new project submissions, technical change amendments, and 5-year renewals are processed through the [Gator TRACS Biohazard Project Registration module](#).

[su_spoiler style="fancy" icon="chevron" title=" What Requires Registration? "] **Projects that involve:**

1. Culturing or propagating an unknown/uncharacterized pathogen.
2. Analysis of samples known or suspected to be contaminated with an infectious biological agent.
3. The use of infectious biological agents pathogenic to otherwise healthy humans.
4. Project will involve specimen collection (i.e. tissues, feces, saliva) from old world monkeys (i.e. macaques, baboons, etc.) which may be contaminated with herpes B virus.
5. The use of cells immortalized with a virus (e.g. EBV, SV40).
6. The use of **toxins of biological origin** that are either acute (LD50 < 100 µg/kg body weight) or [export-controlled](#)
7. Experiments using recombinant nucleic acids
8. Experiments using synthetic nucleic acids of any of the following: I) Designed to integrate in DNA; II) Replication competent; III) Encode a toxin with an LD50 < 100 ng/kg body weight.
9. The use of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from such molecules, in human research subjects
Specific Inclusion Criteria include:
 - I. Recombinant nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules, or
 - II. Synthetic nucleic acid molecules, or DNA or RNA derived from synthetic nucleic acid molecules, that meet any one of the following criteria:
 - a. Contain more than 100 nucleotides; or
 - b. Possess biological properties that enable integration into the genome (e.g., cis elements involved in integration); or
 - c. Have the potential to replicate in a cell; or
 - d. Can be translated or transcribed.
10. The requirement of federal or state permits (for possession, import, transport, or release)

[/su_spoiler] [su_spoiler style="fancy" icon="chevron" title=" How Do I Register My Project? "]

1. Login to [Gator TRACS](#) and complete the Biohazard Project Registration.
2. Please access the [User Guide](#) for more detailed instructions on how to fill out the form.

[/su_spoiler] [su_spoiler style="fancy" icon="chevron" title=" How Do I Register Work with Select Agents? "]

1. Visit the [Select Agent](#) webpage for more information.
2. Contact the [Biosafety Office](#) for further instructions.

[/su_spoiler] [su_spoiler style="fancy" icon="chevron" title=" How Do I Amend My Project in Gator TRACS? "]

If your project is currently approved in Gator TRACS, you may amend the project by clicking “New Amendment” and selecting the appropriate project.

- Please review the [PI User Guide](#) and [Quick Guide to Amendments](#) for further instructions.

[/su_spoiler] [su_spoiler style="fancy" icon="chevron" title=" How Do I Amend My Current Paper-Based Project? "] All amendments to all active projects registered on paper forms with project numbers that start with RD-, BA- or AT- will require submission of a new Biohazard Project Registration in GatorTRACS which must include all previously approved work still in progress as well as the new amendments to the project.

Paper-based project registrations that are no longer needed should be terminated by emailing the request to bsu@ehs.ufl.edu

[/su_spoiler] [su_spoiler style="fancy" icon="chevron" title=" How Do I Transfer My Project to Another Investigator? "] The transfer of projects from one investigator to another may only be done by the Biosafety Office. Please email BSO@ehs.ufl.edu to request this change.

[/su_spoiler] [su_spoiler style="fancy" icon="chevron" title=" What Projects Require Review by the Institutional Biosafety Committee (IBC) and When Does the Committee Meet? "]

1. Projects that include the use of rDNA/synthetic nucleic acid, projects that are non-exempt from [NIH Guidelines](#), those that use CRISPR/Cas9 technology, are BSL-3 projects, or [Select Agent](#) projects require full [Institutional Biosafety Committee](#) (IBC) review and approval.
2. The IBC meets monthly. [\[IBC Meeting schedule\]](#)

[/su_spoiler] [su_spoiler style="fancy" icon="chevron" title=" What Scope of Work Constitutes a Project? "] What constitutes a project is at the discretion of the PI. In general, a project covers a specific scope of work with specific aims. An “umbrella” registration for all the work done in the laboratory does not provide sufficient detail for a useful risk assessment, whereas registration of individual experiments requires too frequent upkeep of the registrations. Consult the Biosafety Office for guidance as needed.

[/su_spoiler] [su_spoiler style="fancy" icon="chevron" title=" How Long Does It Take to Get a Project Approved? "] Project approvals generally take anywhere from 2 weeks to several weeks (6+ weeks). This is dependent on the complexity of the project, the quality of the submission, and the lab’s response time to EH&S/IBC comments and inquiries. These steps will help expedite your project approval:

1. Submit a thorough application with sufficient detail to understand the methodology.
2. Promptly address reviewer comments/concerns noted in Gator TRACS. Please ensure that you are checking the status of your project in Gator TRACS on a regular basis.
3. Register immediate work and not future planned work. Amendments can be filed at any time.
4. Ensure information aligns with related IACUC and IRB protocols.

[/su_spoiler] [su_spoiler style="fancy" icon="chevron" title=" How Much Time Do I Have to Address

Reviewer Comments? “] In addition to system-generated notifications, the PI will receive at least two (2) email notifications from the reviewer in a 60-day period requesting a response to the comments in Gator TRACS. If a response is not received within the 60-day period, the Biosafety Officer will notify the PI that the application will be canceled.

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