USF Biosafety Program
Frequently Asked Questions (FAQs)
By Topic Area

Institutional Biosafety Committee Review

Q: What types of agents and materials need to be registered with the Institutional BioSafety Committee?
A: Faculty and staff who use, possess, store, and or transport infectious agent(s) (e.g. bacteria, viruses, parasites, fungi, protozoa, prions etc), biological toxin(s), recombinant DNA (rDNA) and/or Select Agent(s)/Toxin(s) regulated by the CDC and/or the USDA, must register their use with the USF Institutional Biosafety Committee (IBC).

Q: Who must apply for IBC review and approval?
A: All University of South Florida faculty and staff engaged in research or teaching activities involving biohazardous materials or rDNA conducted on USF premises, or in a building or location administered by or under the control of USF are required to obtain IBC review and approval for allwork (regardless of the funding source).

Q: What is an IBC registration?
A: It is an electronic protocol completed by the principal investigator to describe research and/or teaching activities involving **biohazardous materials** or **recombinant DNA**.

• A biohazardous material is any infectious agent, and or any biological toxin molecule that is capable of causing death, disease/malfunction, in a human, an animal, or a plant. Use of such an agent the must be registered with and approved by the IBC.

• Recombinant DNA molecules are defined as either: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above. Use of rDNA must be registered with and approved by the IBC.

Q: What if I will only be storing infectious agents and not doing any manipulation/research with them?
A: The storage of infectious agents/biological toxins/recombinant DNA at this university must be registered with and approved by the Institutional Biosafety Committee (IBC) prior to acquisition of the agents. Storage applications are limited to storage (short or long term) of agents that are not actively being manipulated, used in research or teaching endeavors, but that are being stored for future use. If you wish to store infectious agents/biological toxins/rDNA please complete and submit for expedited review by IBC.

Q: How do I register my research with the IBC?
A: Protocols are created in our electronic system, BiosafetyNet. **BiosafetyNet** can be accessed in the ARC system.

Q: What if I need assistance in completing the IBC protocol in BiosafetyNet?

A: The Biosafety Program staff is available to assist you in completing your application. If you need help completing a BiosafetyNet application, or assistance in incorporating suggested revisions to your draft BiosafetyNet application, contact the Biosafety Office (biosafety@usf.edu) or contact us individually:

- Debra Howeth- Telephone: (813) 974-5091
- Marianna Sansone- Telephone: (813) 974-9343

If you need technical assistance with logging in or locating the submission form, you may contact the ARC Help Desk by email or call (813) 974-2880.

There are Help Texts (represented by question marks) throughout the common BiosafetyNet protocol to provide guidance, suggestions, and template responses that will assist you with your input.

The following guidance/training documents are available to familiarize yourself and assist in the BiosafetyNet process:

- **USF BiosafetyNet Beginners Guide** (PDF)
- **Guidance document for PIs to assist in filling out protocol** (PDF)

These resources and others can be found on our BiosafetyNet webpage. In addition, the staff pre-reviews the application prior to placing it on the agenda for the IBC meeting.

Q: What are the possible determinations made by the IBC of the application?

A: After reviewing the application, the IBC will notify the principal investigator (PI) of one of the following determinations:

• Full approval - granted by the IBC if there are no outstanding biosafety issues. An approval is valid for three years from the date of review.

• Requires Modifications to Secure Approval - The IBC clearly states what modifications the PI must make. The PI must respond in writing to each of the modifications requested by the Committee and receive final approval prior to initiating the research.

• Tabled/Deferred – The application is deferred for consideration at a subsequent meeting because the IBC has determined that a complete risk assessment of the hazards cannot be made based upon the information submitted. The PI must submit the information requested by the Committee and receive final approval prior to initiating the research.

• Disapprove the Registration - The IBC has determined that the research proposal has substantive biosafety issues. The PI must correct the identified issues and submit a revised registration application for review by the full IBC and receive final approval prior to initiating the research.

Q: When do I reapply for IBC registered studies?

A: Research studies and teaching/training laboratory courses are approved either for a 3-year approval with annual Continuing (CRs) Reviews or for the life of the study with a five-year CR.

Reminder notifications will be sent out by the ARC system the PI prior to each annual review date. Three months prior to the end of the three-year cycle, you will need to submit a new IBC protocol for review and approval in order to continue the project. More information on CRs can be found on our webpage.

Q: How do I modify an existing Biosafety protocol?
A: The PI must inform the IBC of any proposed changes in research. This should be done by submitting an amendment in BiosafetyNet. This must be completed for ***all*** proposed modifications. Changes must not be initiated until written IBC approval is received. More information can be found on our webpage.

Q: How and when do I terminate an IBC protocol?
A: When the research study has been completed or is no longer active, please request closure of your protocol by submitting a Closure Request in BiosafetyNet.

Please be aware that the approval for the possession, use and storage of biohazardous material terminates when an IBC protocol is closed. All biohazardous materials must be appropriately disposed of prior to terminating the registered study. However, if you intend to store the biohazardous material and not dispose of them, please be aware that a IBC storage protocol must be submitted. Please contact the Biosafety Program staff for further assistance.

Q: Where can I find University of South Florida Biosafety guidelines and policies?
A: The Institutional Biosafety Manual and the IBC Committee policy can be found our Policies and Procedures page.

• The USF Biosafety Manual provides guidelines for laboratories using biohazardous materials. It offers guidance to PIs to develop their own laboratory-specific Biosafety manuals.
• The USF IBC Committee Policy contains all of the policies related to the IBC.

Q: I receive no funding from NIH. Do I have to register?
A: Yes. Regardless of funding source, if your research involves infectious agents, biological toxins, Select Agents/Toxins and/or rDNA, you must register with USF's IBC. Because the University receives funding from NIH grants, **all** research conducted at the University must comply with the NIH Guidelines and University policy.

Q: Do I have to register for PCR work?
A: If you are cloning the PCR product first, prior to sequencing, you will need to register the work with the IBC. However, the direct sequencing of PCR products does not need to be registered with the IBC as long as there is no cloning involved.

Q: How do I determine the appropriate Risk Group (RG) and/or Biosafety Level (BSL) for my protocol application?
A: Risk groups are a classification system for etiological agents; the lower the risk – the lower the risk group class. Biosafety level refers to the physical and procedural barriers used to contain an etiological agent. Risk groups and biosafety containment levels are not proportional determinations. The IBC registration document appendices provide definitions regarding risk groups and biosafety levels. The IBC uses recommendations in:
• CDC/NIH BMBL (*Biosafety in Microbiological and Biomedical Laboratories*, 6th Edition)
• Classification of human etiologic agents on the basis of hazard in Appendix B of the NIH

Guidelines.
• American Biological Safety Associations (ABSA) Classification in their Risk Group database
• American Type Culture Collection (ATCC) http://www.atcc.org/)
• Health Canada Pathogen Safety Data Sheets (https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment.html)
• Or other comparable sources for risk groups and biosafety levels.
If you are unsure of the proper determinations after reviewing this information, please contact the Biosafety Program staff.

Q: How do I know when IBC meetings are scheduled, and when do I need to submit a registration document for review by the IBC?
A: The IBC meets once a month, with a submission deadline 8 days prior to the meeting. Th schedule and submission deadlines are posted on the Biosafety Committees & Meetings Schedules Web Page.

Q: What is a human gene transfer research?
A: Human gene transfer or HGT is research involving the transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules into human subjects. It is also sometimes referred to as "Gene Therapy." This refers to the delivery of genes to counteract genetic diseases, such as cystic fibrosis and cancer or for the treatment of rare genetic disorders. In addition, all of this research in the U.S. is limited to "somatic" gene transfer, meaning transfer of genes to the non-reproductive cells of the body. HGT research requires review and approval by USF Institutional Biosafety Committee in addition to review and approval by the Institutional Review Board (IRB).

Q: What documents do I need to include with my IBC protocol?
A: You will need to upload a copy of the Clinical Protocol and the Investigators Brochure. On a case by case basis the IBC may require other documents as a part of the protocol submission.

Biosafety Training

Q: How do I access the USF Biosafety training information and registration Web Pages?
A: This link will take you to the USF Biosafety training information Web Page and the links to the training courses available: https://www.usf.edu/research-innovation/research-integrity-compliance/ric-programs/biosafety-program/education.aspx

Q: Am I required to attend the USF Biosafety training Core Course?
A: Biosafety Training is required for all Principal Investigators, staff, and/or graduate/undergraduate students who use and/or store recombinant DNA, infectious agents, Select Agents/Toxins, and biological toxins or who work in a laboratory where these materials are used and/or stored.

This core Biosafety Training Course is a one-time requirement for those who have not completed it previously. However, it can be repeated in subsequent years to meet the annual requirement for continuing education. It can be registered of on our Education webpage **Biosafety Course Registration Page**.

Q: Can I take the Web-based (on-line) continuing education courses?
A: A Web-based continuing education course can be taken by those individuals who have completed the core course in a previous year. This meets the triennial biosafety continuing education requirement. These courses

are located on YouTube and can be accessed worldwide from the Internet. Each takes about 45 minutes to complete.

To complete the quiz, click on "Show More" in the description box and you should see the link for the quiz. You must complete the quiz to receive credit for the course. For information on the individual courses and to register for triennial CE courses complete the **Continuing Education registration form**.

Q: How long does it take to process my Web-based Biosafety Training quiz to receive my certificate?
A: Approximately 2 business days. Biosafety training certificates are now available online for all Biosafety trainings (Core Course and Triennial CEs). **Find and Print your Biosafety Training Certificates**

Q: Do I need training to ship biohazardous materials?
A: Those personnel who ship and/or receive potentially infectious biological agents are required to complete this course biannually. This is computer-based training that takes about 3 hours to complete. **Register for the Shipping Training Course**.