

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 registration and review?

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 all work (regardless of the funding source).

Q: What is an IBC registration document?

A: It is an application form 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, using the [*Registration Document for the Use of Infectious Agents and Biological Toxins*](#)
- 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 using the [*Registration Document for the Use of Non-Exempt Recombinant DNA*](#) or [*Registration Document for the Use of Exempt Recombinant DNA*](#). Non-Exempt registrations require full committee review while Exempt registrations are reviewed by an expedited process. Click here to see definitions of types of recombinant DNA experiments that are classified as [Exempt](#) or [Non-exempt](#).

Q: Where do I find the Biosafety registration applications?

A: The Biosafety Registration applications and other pertinent information may be accessed by visiting the USF Biosafety Program Web Site at <http://www.research.usf.edu/cs/biosafety.htm>.

Q: What if I need assistance in completing the form?

A: The Biosafety Program staff are available to assist you in completing your application. In addition, the staff pre-reviews the application prior to placing it on the agenda for the IBC meeting. Should you have questions about completing the application, contact the Biosafety Program staff:

- Adrian Perez via telephone at (813) 974-5091 or e-mail at aperez@research.usf.edu

- Archie Ellwood via telephone at (813) 974-5110 or e-mail at aellwood@research.usf.edu.
- Farah Moulvi, Institutional Biosafety Officer (IBO), via telephone at (813) 974-0954 or e-mail at fmoulvi@research.usf.edu

Q: What are the possible determinations by the IBC as a result of the application review?

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 for a three-year period, but continuing review requests must be submitted annually before the second and third year of a project to continue the approval. The IBC will send reminder forms to 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 registration application for review and approval in order to continue the project.

Q: How do I modify an existing Biosafety registered study?

A: The PI must inform the IBC of any proposed changes in research. This should be done by completing and submitting a [Modification Request](#) form and any supporting documents for *all* proposed modifications. Changes must not be initiated until written IBC approval is received.

Q: How and when do I terminate an IBC registered study?

A: When the research study has been completed or is no longer active, please provide written notification to the IBC. The IBC will send the Principal Investigator (PI) a closure letter.

Please be aware that the approval for the possession, use and storage of biohazardous material terminates when an IBC registered study 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 for future use please be aware that a new IBC registration will be required prior to handling the biohazardous materials. In addition, all materials must be safely and securely stored. Please contact the Biosafety Program staff for further assistance.

Q: Where can I find University of South Florida Biosafety guidelines?

A: The Institutional Biosafety Manual provides guidelines for laboratories using biohazardous materials. It is available at the Biosafety Program Web Site: <http://www.research.usf.edu/cs/biosafety.htm>. It offers guidance to PIs to develop their own laboratory-specific Biosafety manuals.

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*, 4th Edition)
- Classification of human etiologic agents on the basis of hazard in [Appendix B of the NIH Guidelines](#).
- American Biological Safety Associations (ABSA) Classification at <http://www.absa.org/resriskgroup.html>.
- American Type Culture Collection (ATCC) <http://www.atcc.org/>)
- Health Canada (<http://www.hc-sc.gc.ca/pphb-dgsp/msds-ftss/index.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 meeting schedules and application submission deadlines are posted on the Biosafety Web Page at <http://www.research.usf.edu/cs/biosafetyschedule.htm>. The IBC meets once a month. Your application must be received at least two (2) weeks before the meeting date.

Q: What is a human gene transfer research?

A: Human gene transfer research is research that involves introducing recombinant DNA materials into the cells of one or more human research participants. Gene transfer experimental research efforts are focused on "gene therapy," meaning 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. Human gene transfer research requires review and approval by USF Institutional Biosafety Committee.

Q: Which application needs to be submitted for a human gene therapy study?

A: The correct IBC application is entitled “*Registration Document for the use of Non-Exempt recombinant DNA.*” Applications can be downloaded from the USF Biosafety Program Web Site at <http://www.research.usf.edu/cs/biosafety.htm>

Q: Do I need to submit any other documents in addition to the IBC Non-Exempt rDNA application?

A: Yes, you need to submit copies of the following documents:

- USF IBC rDNA/NE registration application
- Copy of review letter form NIH /OBA or, if selected for full RAC review, the RAC review comments
- Items that will be submitted to IRB-such as a copy of the USF IRB Application for Initial Review
- Copy of USF IRB Consent Form
- Clinical Protocol
- Investigational Brochure
- Based on case by case reviews the IBC may require other communication letters from other agencies such as the FDA with modifications of the protocol based on FDA requirements.

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: <http://www.research.usf.edu/cs/biosafetyeducation.htm>.

Q: Am I required to attend the USF Biosafety training Core Course?

A: Annual attendance in an approved Biosafety Training course 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.

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 annual biosafety continuing education requirement. To receive credit, you must pre-register on-line: <http://www.research.usf.edu/cs/biosafetyeducation.htm>

Q: How long does it take to process my Web-based Biosafety Training quiz to receive my certificate?

A: Approximately 1 business day.

Exempt Categories Of rDNA Experiments

--[NIH Guidelines](#) ([Section III-F](#); [Appendix A](#), [Appendix C](#))

1. rDNA containing less than 2/3 of an eukaryotic viral genome propagated in cell culture (with the exception of DNA from Risk Group 3, 4, or restricted agents).
2. rDNA work involving *E. coli* K12, *S. cerevisiae*, and *B. subtilis* host-vector systems (with the exception of DNA from Risk Group 3, 4, or restricted agents). Exempt registrations are reviewed by an expedited process.
3. Those that are not in organisms or viruses.
4. Those that consist entirely of DNA segments from a single nonchromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent.
5. Those that consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well established physiological means.
6. Those that consist entirely of DNA from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).
7. Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers can be found in [Section IV-C-1-b-\(1\)-\(c\)](#), [Major Actions](#). For a list of natural exchangers that are exempt from the NIH Guidelines, see [Appendices A-I through A-VI](#), Exemptions under [Section III-F-5](#)--Sub lists of Natural Exchangers.
8. Those that do not present a significant risk to health or the environment (see [Section IV-C-1-b-\(1\)-\(c\)](#), [Major Actions](#)), as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment. See [Appendix C, Exemptions under Section III-F-6](#) for other classes of experiments which are exempt from the NIH Guidelines.

Non-Exempt Categories Of rDNA Experiments:

--[NIH Guidelines](#) ([Section III-D](#))

1. Deliberate transfer of a drug trait to a microorganism not known to acquire it naturally (if it could compromise the use of the drug to control disease agents in humans, animal, or agriculture).
2. Human gene transfer experiments.
3. Cloning of DNA encoding molecules lethal to vertebrates at an LD 50 of <100ug/kg body weight.
4. Cloning using human or animal pathogens as host-vector systems.
5. Cloning of DNA from all Risk Group 3, 4 or restricted human or animal pathogens (including HIV and related viruses, and human tumor viruses).
6. Experiments using more than 2/3 of the genome of infectious animal or plant viruses or defective viruses grown in the presence of helper virus.
7. Recombinant DNA experiments involving:
 - a. animals in which the animal's genome has been altered by stable introduction of recombinant DNA or DNA derived there from, into the germ-line (transgenic animals).
 - b. viable recombinant DNA-modified microorganisms tested on animals.
8. Large scale DNA project (>10 liters of culture combined).
9. Plant recombinant DNA experiments.
10. Transgenic or knockout rodent experiments. (Note: The purchase or transfer of transgenic rodents for BSL-1 experiments is exempt from registration.)
11. All experiments not specified on this sheet. Non-Exempt registration requires full committee review.