



Institutional Biosafety Committee Policy

**Division of
Research Integrity & Compliance**

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Purpose

The University of South Florida (USF) Biosafety Program and the USF Institutional Biosafety Committee (IBC) is committed to incorporating health and safety practices governing all USF personnel working with biohazardous materials in research and/or teaching activities at USF. The USF Biosafety Program is established to reduce the risk of potential occupational exposure to infectious agents, biological toxins, Select Agents/Toxins, and Recombinant Deoxyribonucleic Acid (rDNA) in a research and/or teaching environment.

It is the policy of the USF Biosafety Program that all research and/or teaching involving infectious agents, biological toxins, Select Agents/Toxins, and rDNA must be conducted in a safe manner. Biosafety containment practices protect the faculty, staff, students, volunteers, and visitors from exposure to infectious agents, biological toxins, Select Agents/Toxins, and Recombinant Deoxyribonucleic Acid (rDNA) and prevent the release of biological hazards into the environment. To ensure the safe handling of infectious agents, biological toxins, Select Agents/Toxins, and rDNA, USF requires compliance with the National Institute of Health ([NIH Guidelines For Research Involving rDNA Molecules](#)), Centers for Disease Control and Prevention ([Biosafety in Microbiological and Biomedical Laboratories, 5th Edition](#)), US Department of Health and Human Services, Office of Biotechnology Activities, Office of Health and Safety-Biosafety, [USF Biosafety Program Institutional Biosafety Manual](#), and other applicable federal, state, and local regulations.

SECTION 1.0 IBC Policy Regarding Use of Biohazardous Agents

Section 1.1 Overview

- 1.1.1 A USF Biosafety registration is required for all (research and/or teaching) laboratory activities which involve the use or manipulation of infectious agents (including but not limited to bacteria, viruses, fungi, rickettsia, protozoa, or parasites), biological toxins, Select Agents/Toxins, and/or recombinant deoxyribonucleic acid (rDNA) which are:
 - a. supervised or conducted by USF faculty or staff;
 - b. conducted on USF premises, or in a building or location administered by or under the control of USF; and/or
 - c. supported by funds provided by or through USF.
- 1.1.2 Principal Investigators (PI) at USF who possess or plan to possess, store, work with, or transport infectious agent(s), biological toxin(s), Select Agent(s)/Toxin(s), and/or rDNA must register the infectious agent(s), biological toxin(s), Select Agent(s)/Toxin(s), and/or rDNA with the USF Institutional Biosafety Committee (IBC).
- 1.1.3 It is the policy of the IBC that the Principal Investigator (PI) is responsible for the proper acquisition, use, handling, storage, transportation, and disposal of biohazardous material (i.e., infectious agent(s), biological toxin(s), Select

Agent(s)/Toxin(s), and/or rDNA materials) in research and/or teaching. In addition, all individuals working with these materials must adhere to IBC policy, procedures, and rules.

- 1.1.4 It is the policy of the IBC that Biosafety Containment Level 4 (BSL-4) agents may not be used or stored at the University of South Florida. See [Appendix B-IV](#) of the NIH [Guidelines for Research Involving Recombinant DNA Molecules](#) (NIH *Guidelines*) for a list of these agents.
- 1.1.5 All work with infectious agents, biological toxins, Select Agents/Toxins, and/or rDNA will be conducted in compliance with USF IBC policy, the publications [Biosafety in Microbiological and Biomedical Laboratories \(BMBL\) 5th edition](#), and the [NIH Guidelines](#) published by the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH), and [42 CFR 73](#), [9 CFR 121](#), and [7 CFR 331](#) for Select Agents.

Section 1.2 Scope of IBC Policy

- 1.2.1 This policy applies to USF faculty, staff, students, volunteers, and visitors who engage in any university activity within all divisions and departments of USF and/or conducted on university premises ([refer to section 1.1.2](#)).
- 1.2.2 USF faculty, staff, students, volunteers, and visitors use infectious agents, biological toxins, Select Agents/Toxins, and rDNA (as defined per item 2.1) for research and/or teaching.

Section 2.0 Biohazardous Materials

Section 2.1 Types of Biohazardous Materials that Require Registration with the IBC

- 2.1.1 USF IBC review and approval is required prior to using the following biohazardous agents:
 - a. The use of recombinant DNA (rDNA) as defined by the [NIH Guidelines](#) (see section [8.2](#));
 - b. Any microorganism (including but not limited to bacteria, viruses, fungi, rickettsia, protozoa, or parasites), or infectious substance, or naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance that is capable of causing death, disease, or other biological malfunction in a human, an animal, or a plant;
 - c. Select Biological Agents and Toxins, High Consequence Livestock Pathogens, and Restricted Plant Pathogens as identified by [42 CFR 73](#), [9 CFR 121](#), and [7 CFR 331](#);
 - d. Any biological toxin: A toxic material or product of plants, animals, microorganisms (including but not limited to bacteria, viruses, fungi,

- rickettsia, or protozoa), or infectious substances, or a recombinant or synthesized molecule (whatever the origin and method of production);
- e. Any clinical materials that may contain wild poliovirus;
 - f. The definition also includes projects that involve known biohazards that do not appear to fall into one of the above criteria (e.g., prions or cells lines known to be infected with viruses). If in doubt as to whether a material constitutes a potential biohazard; the USF Institutional Biosafety Officer (IBO) should be consulted.

Exceptions: Research using any materials that require BSL-4 containment will not be considered by the IBC for work at any USF location or facility (dictated by the lack of qualifying facilities at USF).

- 2.1.2 All use of infectious agents, biological toxins, Select Agents/Toxins, and/or rDNA as indicated above must be proposed to, and approved by the IBC on the appropriate application form(s):
 - [*Registration Document for the Use of Infectious Agents and Biological Toxins*](#)
 - [*Registration Document for the Use of Non-Exempt Recombinant DNA*](#)
 - [*Registration Document for the Use of Exempt Recombinant DNA*](#)
 - [*Registration Document for the Use of Infectious Agents, Biological Toxins, and/or rDNA in a Teaching/Training Laboratory*](#)

Section 3.0 Assessment and Selection of Appropriate Safeguards

- 3.1 It is the responsibility of the PI to conduct a preliminary risk assessment to determine the appropriate level of perceived risk and biological and physical containment level prior to possessing or using biohazardous material(s). Evaluating the risk allows the PI to choose the appropriate containment level for the organism.
- 3.2 The PI is encouraged to consult with the USF Institutional Biosafety Officer (IBO) regarding the risk assessment. However, the IBC will make the final decision as to the level of risk and appropriate biological and physical containment levels for infectious agents, biological toxins, Select Agents/Toxins, and/or rDNA that are subject to its review and approval.

Section 4.0 Regulations and Guidelines

- 4.1 The IBC Policy is drafted in accordance with the following regulations and guidelines:
 - a. [*NIH Guidelines for Research Involving Recombinant DNA Molecules \(NIH Guidelines\)*](#). The NIH *Guidelines* publication is available at www4.od.nih.gov/oba/rdna.htm.
 - b. [*Biosafety in Microbiological and Biomedical Laboratories \(BMBL\) 5th edition*](#), published by the Centers for Disease Control and Prevention (CDC)

and NIH. The BMBL is generally considered the standard for biosafety and is available at [BMBL 5th Edition - Table of Contents](#).

- c. Code of Federal Regulations (CFR): [42 CFR 73](#),
- d. [Agricultural Bioterrorism Protection Act of 2002](#), [7 CFR 331](#), and [9 CFR 121](#),
- e. [USA Patriot Act \(October 2001\)](#),
- f. [Public Health Security and Bioterrorism Preparedness Response Act of 2002](#).

Section 5.0 Institutional Official

- 5.1 The Vice President for Research is the Institutional Official responsible for the Biosafety Program.
- 5.2 The Vice President for Research is responsible for an Institutional Biosafety Committee (IBC)-.
- 5.3 The Vice President for Research is responsible for the appointment of IBC members, alternates, ex-officio, ad hoc, and consultants.
- 5.4 The Vice President for Research shall appoint the members of the IBC and may add, reappoint, or remove members. Qualified successors shall be nominated as required, based on the recommendation of the Institutional Biosafety Officer, the IBC Chairperson, and/or the Director of the Division of Research Integrity & Compliance. Procedures for appointment of alternate members, terms of appointment, length of service, and duties are the same as for regular IBC members.
- 5.5 The Vice President is responsible for notifying the NIH/OBA (Office of Biotechnology Activities) and/or CDC of incidents of serious or continuing noncompliance with IBC policy or applicable federal regulations.

Section 6.0 Institutional Biosafety Committee (IBC)

- 6.0.1 An IBC is an appropriately constituted group that has been formally designated to review and monitor research involving infectious agents, biological toxins, Select Agents/Toxins, and/or rDNA. In accordance with the NIH guidelines and the CDC BMBL requirements, the IBC is responsible for approving, requiring modification to secure approval, deferring, or disapproving research involving infectious agents, biological toxins, Select Agents/Toxins, and/or rDNA.
- 6.0.2 The IBC is empowered with the authority to suspend or terminate activities involving infectious agents, biological toxins, Select Agents/Toxins, and/or rDNA for activities/practices that jeopardizes the health and safety of any USF faculty, staff, students, volunteers, and visitors at USF, repeated safety violations, and/or continued noncompliance with IBC regulations and policy.

- 6.0.3 The University of South Florida (USF) Division of Research Integrity & Compliance provides professional and administrative support to the IBC.

Section 6.1 Charge of the Committee

- 6.1.1 The Institutional Biosafety Committee (IBC) is responsible for advising the Vice President for Research on all matters pertaining to the safe use of infectious agents, biological toxins, Select Agents/Toxins, and/or rDNA in research at USF.
- a. The IBC establishes guidelines for USF faculty, staff, students, volunteers, and visitors conducting research and/or teaching programs involving biological agents which are potentially harmful to the environment and/or potentially pathogenic to humans, animals, and/or plants, as well as projects involving recombinant DNA.
 - b. The IBC guides and supports the work of the university's researchers in conducting research and/or teaching programs involving infectious agents, biological toxins, Select Agents/Toxins, and/or rDNA which are potentially harmful to the environment and/or potentially pathogenic to humans, animals, and/or plants, as well as projects involving recombinant DNA.
 - c. The IBC assures compliance with appropriate federal/state/local regulations and IBC Policy by reviewing applications and conducting laboratory audits for the use of infectious agents, biological toxins, Select Agents/Toxins, and/or rDNA.
- 6.1.2 The IBC establishes policy, practices, and/or procedures for review of all projects involving the use of infectious agents, biological toxins, Select Agents/Toxins, and/or rDNA to assure compliance with federal, state, and local regulations and guidelines.
- 6.1.3 It is the IBC's responsibility to establish, monitor, and enforce policy and procedures for the use of infectious agents, biological toxins, Select Agents/Toxins, and/or rDNA.
- 6.1.4 All use of infectious agents, biological toxins, Select Agents/Toxins, and/or rDNA must be reviewed and approved by the IBC before the possession of and/or the use of the agent.
- 6.1.5 The IBC shall maintain diverse membership representing the community and a variety of University interests.
- 6.1.6 Non-committee faculty/ad hoc experts may be asked to advise the IBC when necessary.

Section 6.2 IBC Membership

- 6.2.1 IBC members and their alternates are selected so that they have collective experience and expertise to fully evaluate the biosafety risks associated with the wide variety of research and/or teaching agents which come under its review.
- 6.2.2 The IBC is composed of scientists and clinical investigators from USF and its affiliate institutions and representative(s) from the community.
 - a. The IBC consists of at least five members that have experience and expertise in biosafety and are able to assess the safety of research involving infectious agents, biological toxins, Select Agents/Toxins, and/or rDNA, including human gene transfer trials, to identify any potential risk to USF faculty, staff, students, volunteers, and visitors, the environment, or public health.
 - b. These appointments may come from the Colleges of Medicine, Arts and Sciences, Engineering, Public Health, or other appropriate colleges.
 - c. At least two members shall not be affiliated with the University but should represent the interests of the surrounding community with respect to health and protection of the community and the environment.
 - d. The Institutional Biosafety Officer (IBO) serves as a voting member of the IBC.
 - e. A representative from the USF Office of Environmental Health and Safety, with expertise in biomedical waste disposal shall serve as a voting member of the IBC.
- 6.2.3 The IBC shall include at least one individual with expertise in plant, plant pathogen, and/or plant pest containment principles when research involving recombinant plants is reviewed by the IBC (Refer to [Appendix P](#), Physical and Biological Containment for Recombinant DNA Research Involving Plants, of the [NIH Guidelines](#)).
- 6.2.4 The IBC shall include at least one individual with expertise in animal containment principles when research involving animals and infectious agents, biological toxins, Select Agents/Toxins, and/or rDNA materials is reviewed by the IBC.
- 6.2.5 The IBC shall include at least one individual with expertise in human gene transfer principles and safety issues when research involving human subjects and rDNA materials is conducted by the university.
- 6.2.6 IBC members are appointed by the Vice President for Research for a term of three years.
- 6.2.7 The Vice-President for Research and the Director of the Division of Research Integrity & Compliance shall serve on the IBC in an ex-officio capacity.
- 6.2.8 No member of the IBC may be involved (except to provide information requested by the IBC) in the review or approval of a project in which he or she has been or expects to be engaged in and has a direct financial interest, or any other type of *conflict of interest*.

- 6.2.9 IBC meetings are held on the third Tuesday of every month. The IBC will not meet on days that USF is “closed for business”. The IBC meeting schedule is available at <http://www.research.usf.edu/cs/biosafetyschedule.htm>.
- 6.2.10 IBC alternates are appointed to ensure that the committee is properly constituted at all times. The following apply for alternate members:
- Alternate members will have voting rights, except that they may not vote at meetings attended by their respective regular members.
 - Alternate members will be included in determining or establishing quorum at meetings when their respective regular members are absent.
 - Alternate members must be listed on the IBC’s official membership roster, which must specify which member is represented by the alternate.
- 6.2.11 All members and alternates of the IBC are provided information on an ongoing basis regarding current biosafety news, topics, and regulations.
- 6.2.12 IBC members must attend each regular monthly scheduled meeting or send their alternate. IBC members must notify the IBC administrative staff of planned absences prior to protocol review assignments.
- 6.2.13 Visitors and guests that are non-members of the IBC that attend IBC meetings are not allowed to participate in the discussions unless acknowledged by the IBC Chairperson.
- 6.2.14 The IBC, at its discretion, may recruit ad hoc consultants whose input to the deliberations at meetings has unique importance. These recruited ad hoc consultants may be University or non-University affiliated scientists, clinical investigators, or community representatives.

Section 6.3 Operational Procedures and Guidelines

- 6.3.1 The IBC shall adopt and adhere to the operating procedures and principles as described in the National Institutes of Health (NIH) [Guidelines for Research Involving Recombinant DNA Molecules](#) and the Centers for Disease Control and Prevention (CDC/NIH) [Biosafety in Microbiological and Biomedical Laboratories, 5th edition](#) (BMBL).

Section 6.4 Institutional Biosafety Committee (IBC) Responsibilities

- 6.4.1 The committee develops recommendations, operating policy, and procedures regarding the use of infectious agents, biological toxins, Select Agents/Toxins, and/or rDNA, as needed to supplement the federal, state, and local regulations and guidelines.

- 6.4.2 The IBC reviews the use of infectious agents, biological toxins, Select Agents/Toxins, and/or rDNA research conducted at or sponsored by the USF for compliance with the applicable guidelines and regulations. The review will include:
- a. Assessment of potential risks to health and the environment for the proposed research.
 - b. Assessment of the containment levels of the proposed research.
 - c. Assessment of the facilities, procedures, practices, and training and expertise of personnel involved in use of infectious agents, biological toxins, Select Agents/Toxins, and/or rDNA;
 - d. Providing for the adjustment of containment levels based on risk for experiments as specified in the [*NIH Guidelines*](#), CDC/NIH) [*Biosafety in Microbiological and Biomedical Laboratories, 5th edition*](#) (BMBL), [*USF Biosafety Program Institutional Biosafety Manual*](#), or IBC policy;
 - e. Providing a forum for the discussion of biosafety concerns and assisting in the resolution of any biosafety issues brought before the IBC.
 - f. Notifying the PI of the results of the IBC review.

Section 6.5 Quorum

- 6.5.1 A quorum is required in order to conduct routine IBC business. In order to establish a quorum the number of committee members present must equal one more than half of the total committee membership. A passing vote will be a simple majority of members present; minority views will be recorded in the minutes.

Section 6.6 Chairperson/Vice Chairperson

- 6.6.1 Initially, and thereafter (renewal time, unexpected vacancy, etc.), the Vice President for Research shall appoint the Chairperson of the IBC and may reappoint or remove the Chairperson. A qualified Chairperson shall be nominated as required, based on the recommendation of the Institutional Biosafety Officer, the IBC Chairperson, and/or the Director of the Division of Research Integrity & Compliance. Procedures for appointment of the Chairperson, terms of appointment, length of service, and duties are exactly as for regular IBC members.
- 6.6.2 The IBC Chairperson has the following duties:
- a. Conduct each meeting in an orderly manner.
 - b. The Chairperson is responsible for chairing the meeting, conducting business so that each registration application is fairly and completely reviewed, and that the committee reaches a decision on the disposition of each registration.
 - c. Sign correspondence on behalf of the IBC.
 - d. Appoint a Vice Chairperson following consultation with and agreement by a majority of the members of the IBC. The Vice Chairperson will be an

experienced faculty member of the IBC who will assume the responsibilities of the Chairperson during any period of absence.

Section 6.7 Institutional Biosafety Officer (IBO)

- 6.7.1 Responsibilities of the IBO include:
- a. Screening research protocols proposed by investigators for completeness and forwarding them to the IBC for review.
 - b. Reporting to the IBC significant problems related to accidents and illnesses, operations, or other activities involved with proposed or approved protocols.
 - c. Assisting laboratories in conforming to pertinent regulatory guidelines and IBC policy by providing training, facility inspection, and communication of program requirements.
 - d. Conducting audits and site inspections, to ensure adherence to federal, state, and University regulations and IBC policy for the use of infectious agents, biological toxins, Select Agents/Toxins, and/or rDNA at USF.
 - e. Monitor federal, state, and local regulatory trends and communicate such to the IBC and responsible institutional representatives.
 - f. Serve as a voting member of the IBC and conducting certain activities on behalf of the IBC in support of the program (e.g., review/inspect individual facilities, biosafety manuals) and confirm compliance with NIH and/or CDC guidelines and/or USF IBC policy, procedures, and requirements.
 - g. Provide recommendations to the IBC on biosafety matters.
 - h. Preparation and filing of annual IBC membership report to NIH/OBA.
 - i. Act as a liaison with University and Institutional Review Boards (IRBs), Institutional Animal Care and Use Committees (IACUC), Infection Control Units, and the Environmental Health and Safety (EHS) office.

Section 6.8 Biosafety Program Support Staff

- 6.8.1 The Division of Research Integrity & Compliance Biosafety Program personnel/staff (IBO, et al) will serve as support staff to the IBC.
- 6.8.2 IBC support staff supplements the function and operation of the IBC at the direction of and under the supervision of the Institutional Biosafety Officer.
- 6.8.3 Responsibilities of the Institutional Biosafety Program Staff:
- a. Maintain the official roster of IBC members;
 - b. Schedule IBC meetings;
 - c. Distribute meeting materials prior to the scheduled meeting;
 - d. Compile and maintain the minutes of IBC meetings in compliance with regulatory requirements;
 - e. Maintain all IBC documentation and records;
 - f. Facilitate communication between investigators and the IBC;
 - g. Track the progress of each research protocol submitted to the IBC;

- h. Maintain a computerized IBC database for tracking purposes and record incoming information into the database;
- i. Serve as a resource for investigators on regulatory information, biosafety procedures and practices, and provide guidance regarding submission procedures;
- j. Conduct laboratory inspections;
- k. Propose, review, and revise IBC documents;
- l. Draft reports and correspondence on behalf of the IBC or IBC Chairperson;
- m. Review IBC applications.

Section 6.9 Reporting to NIH—Recombinant DNA

- 6.9.1 The VP for Research shall report any significant problems with or violations of the [NIH Guidelines](#) and any significant research-related accidents or illnesses to the NIH/OBA within 30 days; unless the IBC determines that a report has already been filed by the Principal Investigator.
- 6.9.2 The Institutional Biosafety Officer, on behalf of USF and the IBC, shall file an annual report with NIH/OBA which includes:
 - a. A roster of all IBC members clearly indicating the Chairperson, contact person, Institutional Biosafety Officer, plant expert (if applicable), animal expert, human gene therapy expert, or ad hoc consultant (if applicable).
 - b. Biographical sketches of new IBC members, including community members.

Section 6.10 Director, Division of Research Integrity & Compliance

- 6.10.1 The Director of the USF Division of Research Integrity & Compliance (DDRIC) is designated as overall Administrator for the USF IBC and is responsible for ensuring that it functions and operates within USF in compliance with all federal, state, and local laws and regulations and USF IBC policy and procedures that govern the safe use of infectious agents, biological toxins, Select Agents/Toxins, and rDNA in the conduct of research and/or teaching activities.
- 6.10.2 The DDRIC may delegate operational authority to the USF System Institutional Biosafety Officer as appropriate.
- 6.10.3 The Director, Division of Research Integrity & Compliance (DDRIC) is responsible for immediate notification to the USF Vice President for Research regarding:
 - any serious injury/exposure to infectious agents, biological toxins, Select Agents/Toxins, and rDNA;
 - any serious adverse event related to gene therapy use;
 - major biohazardous material spills;
 - breach of Biosafety Level 3 agents;
 - unanticipated problems;
 - any theft of restricted agents;

- any biosecurity issues;
- serious or continuing non-compliance with IBC policy and requirements by research investigators; or
- suspension or termination of IBC approval.

SECTION 7.0 Responsibilities for Safe Use of Biohazardous Materials

Section 7.1 Principal Investigator

- 7.1.1 The Principal Investigator (PI) applicant is defined as a faculty member at USF and/or its affiliated institutions. The PI is ultimately responsible for the activities in their laboratory.
- 7.1.2 All uses, storage, and/or possession of infectious agents, biological toxins, Select Agents/Toxins, and/or rDNA must be registered with and approved by the IBC.
- 7.1.3 The PI should make an initial determination of the required levels of physical and biological containment in accordance with the requirements set in the [NIH Guidelines](#) and [CDC BMBL, 5th edition](#).
- 7.1.4 The PI must select appropriate microbiological practices and laboratory techniques to be used for the research intended.
- 7.1.5 The PI must complete and submit the appropriate registration application to the IBC for review and approval. Current applications can be downloaded at the following website <http://www.research.usf.edu/cs/biosafety.htm>
- 7.1.6 Prior to initiation, the PI must submit all proposed modifications to a previously approved IBC study for IBC review and approval. The proposed modifications must be reported to the IBC for review and approval using a Modification Request form accessed at http://www.research.usf.edu/cs/biosafety_forms/modification.doc.
- 7.1.7 Prior to Initiating Research the Principal Investigator shall:
- a. Make available to all laboratory staff and involved facilities staff the protocol that describes the potential biohazards and the precautions to be taken.
 - b. Instruct and train all research personnel in protocol specific procedures and:
 - i. The practices and techniques required to ensure safety;
 - ii. The procedures for dealing with accidents and spills; and
 - iii. The reasons and provisions for any precautionary practices advised or requested (e.g., vaccinations or personal protective equipment).
 - c. Ensure that transportation of any biohazardous material comply with all applicable packaging and shipping requirements.
- 7.1.8 During the Conduct of the Research the Principal Investigator shall:

- a. Supervise the safety performance of the laboratory staff to ensure that the required safety practices are employed.
- b. Report any significant problems pertaining to the operation and implementation of containment practices and procedures to the IBC.
- c. Immediately notify the IBO (813) 974-0954 (during normal working hours) or the University Police using 911 (after hours) of any biological spills, accidents, containment failure, or deviations of biosafety practice which result in the release of biohazardous material and/or the exposure of laboratory personnel or members of the public to [biohazardous materials](#).
- d. Restrict access to the laboratory when experiments are in progress to those who are aware of the risks associated with the use of biohazardous agents and are trained to safely handle the biohazardous agents.
- e. Be responsible for full compliance with the policy, practices, and procedures set forth in this policy manual and as described in the approved IBC registration application. Investigators are required to notify the IBC promptly of any noncompliance regarding applicable regulatory requirements (federal, state, and local) and IBC policy.

7.1.9 As part of the general responsibilities, the Principal Investigator shall:

- a. Complete the Biosafety Core Course requirement and annually thereafter a refresher biosafety training course.
- b. Develop and implement written laboratory-specific biosafety procedures and containment practices (for BSL-2 and higher) that are consistent with the nature of current and planned research activities. The PI shall ensure that all laboratory personnel, including other faculty members, understand and comply with these laboratory specific biosafety procedures.
- c. Ensure that all laboratory personnel (e.g., faculty, staff, students, volunteers, visitors), and maintenance personnel, who have the potential to be exposed to any [biohazardous materials](#) are informed in advance of their potential risk and of the safety procedures required to minimize that risk.
- d. Ensure that all maintenance work in, on, or around contaminated equipment is conducted only after that equipment is thoroughly decontaminated by the laboratory staff or PI.
- e. Ensure that research materials are properly decontaminated before disposal and that all employees are familiar with the different methods of waste disposal.
- f. Report any significant problems, violations of the policy, practices, and procedures set forth in this manual, or any significant research-related accidents and illnesses, to the [Institutional Biosafety Officer](#) (813) 974-0954.
- g. Refer to the directives set on the USF Environmental Health and Safety (EH&S) web page regarding “*What to Do If You Are Injured on-the-Job*”: [FAQ's: What to Do If Injured At USF](#)
- h. For all blood borne pathogen exposures notify the USF Health Medical Health Administration immediately (813) 974-5171, pager: (813) 216-0153, or Infectious Disease Physician (813)222-2763 during regular working hours (Monday-Friday 8 am-5 pm) and the on call Infectious Disease physician at (813)974-2201 during non-regular working hours.

- i. Comply with shipping requirements for infectious agents, biological toxins, Select Agents/Toxins, and/or rDNA.

Section 7.2 Laboratory Worker

- 7.2.1 Any person working with infectious agents, biological toxins, Select Agents/Toxins, and/or recombinant DNA or who works in a laboratory where these materials are used/stored is defined as a laboratory worker, whether the person is a faculty member, a student, an intern, a visiting scholar, or a volunteer.
- 7.2.2 It is the laboratory staff's responsibility to:
 - a. Complete the Biosafety Core Course requirements and annually thereafter a refresher biosafety training course.
 - b. Follow laboratory specific biosafety practices and procedures.
 - c. Inform the PI of any personal health requirements that may require implementation of safety precautions.
 - d. Report to the PI or the lab supervisor all problems, deviations in procedure, spills involving biohazardous materials and/or safety/security concerns (e.g., suspicious persons or activities).

Section 7.3 Authorized Maintenance and Janitorial Personnel

- 7.3.1 USF Physical Plant personnel (housekeeping and maintenance) that are required to enter laboratory facilities where biohazardous materials are being used, stored, and/or disposed of (e.g., BSL-2 labs) should be informed of the potential risks associated with biohazardous materials. If maintenance personnel have concerns regarding biosafety issues, these concerns should be discussed with their supervisor, the Principal Investigator, the Institutional Biosafety Officer, or the Institutional Biosafety Committee members.
- 7.3.2 USF Physical Plant personnel (housekeeping and maintenance) and other maintenance personnel do not have unrestricted access to Biological Safety Level 3 (BSL-3) laboratories. Housekeeping staff will not be provided access to BSL-3 areas unless approved by the BSL-3 facility director and the IBO. Any maintenance personnel who enter a BSL-3 facility must be supervised at all times by the BSL-3 lab director/lab manager or their designee. No work with biologic agents is allowed during a visit by maintenance personnel. All affected environmental surfaces in the BSL-3 facility need to be decontaminated prior to entry by maintenance personnel. The BSL-3 lab director/lab manager or their designee completes a *Safety Checklist for Maintenance Work in BSL-3 Laboratories* prior to maintenance work being accomplished. BSL-3 personal protection equipment (PPE) is provided to the maintenance personnel. A BSL-3 containment practices training is presented annually to USF Physical Plant personnel. The IBO ensures that USF maintenance personnel have attended BSL-3 training prior to them undertaking any task in a BSL-3 facility.

Section 8.0 Activities Involving Recombinant DNA Material

- 8.0.1 All research involving recombinant DNA (rDNA) materials at USF must comply with the "[Guidelines for Research Involving Recombinant DNA Molecules](#)," (NIH *Guidelines*) published by the National Institutes of Health (NIH).
- 8.0.2 Recombinant DNA as defined by the NIH *Guidelines*: “Nucleic acid molecules constructed outside of living cells by joining natural or synthetic DNA segments to DNA molecules that can be replicated in a living cell. DNA molecules that result from the replication of those molecules described above.”

Section 8.1 Non-Exempt rDNA Experiments

- 8.1.1 It is the policy of the USF IBC that research involving the use of rDNA as defined by the [NIH Guidelines](#) must be documented by a registration and be reviewed and approved by the IBC. All research and/or teaching activities involving the use of rDNA material, whether [Exempt](#) or [Non-Exempt](#) from [NIH Guidelines](#), must be registered with the IBC, using the appropriate registration forms.
- 8.1.2 Non-Exempt recombinant DNA registrations must be submitted for review using the [Registration Document for the Use of Non-Exempt Recombinant DNA](#)
- 8.1.3 Approval by the IBC is required prior to initiating the research or teaching activity involving Non-Exempt rDNA work (i.e., prior to handling the agent).
- 8.1.4 Non-Exempt registrations require full committee review. Non-Exempt rDNA registrations are approved for a one-year period at the end of which, an annual renewal form may be submitted for years two (2) and three (3) of the protocol. A new registration application must be submitted to and approved by the full committee every three (3) years.
- 8.1.5 All changes to an approved Non-Exempt rDNA registration must be reported using an IBC [Modification Request](#) application. No changes can be instituted to a previously approved Non-Exempt rDNA registration application until that proposed modification has been submitted to and approved by the IBC.

Section 8.2 Exempt rDNA Experiments

- 8.2.1 All exempt research involving rDNA shall be conducted in accordance with the current version of the [NIH Guidelines](#).
- 8.2.2 Exempt recombinant DNA registrations must be submitted for review using the [Registration Document for the Use of Exempt Recombinant DNA](#).

- 8.2.3 No annual renewals are required during the life of the Exempt rDNA study. However, any changes to the exempt rDNA registration must be reported using an IBC [Modification Request](#) application.
- 8.2.4 Exempt registrations are reviewed by an expedited process. The IBC Chairperson, the IBC Vice Chairperson, and/or the Institutional Biosafety Officer may review Exempt rDNA registrations. The IBC Chairperson, the IBC Vice Chairperson, and/or the Institutional Biosafety Officer may request a full committee review of the Exempt registration.
- 8.2.5 Types of recombinant DNA experiments that are exempt by NIH definitions but require IBC submission before initiation include, but are not necessarily limited to, the following: (for details see NIH *Guidelines*: [Section III-F](#); [Appendix A](#), [Appendix C](#))
- rDNA containing less than ½ of a eukaryotic viral genome propagated in cell culture (with the exception of DNA from Risk Group 3, 4, or Select Agents/Toxins).
 - rDNA work involving *E. coli* K12, *S. cerevisiae*, and *B. subtilis* hot-vector systems (with the exception of DNA from Risk Group 3, 4, or Select Agents/Toxins).
 - Those not contained in organisms or viruses.
 - Those that consist entirely of DNA segments from a single non-chromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent.
 - Those that do not present a significant risk to health or the environment (see NIH *Guidelines* [Section IV-C-1-b-\(1\)](#), Major Actions), as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment.
 - [Appendix C](#), Exemptions under [Section III-F-6](#) for other classes of experiments which are exempt from the NIH *Guidelines*.

Section 8.3 Recombinant DNA Studies Involving Human Research Participants

- 8.3.1 Principal investigators performing human gene transfer work must adhere to the responsibilities and reporting requirements that are detailed in [Appendix M](#) of the most current version of the [NIH Guidelines](#).
- 8.3.2 For experiments involving the deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA, into human research participants (human gene transfer), no research shall be initiated ([NIH Guidelines](#): see definition of enrollment in [Section I-E-7](#)) until the NIH Recombinant DNA Advisory Committee (RAC) review process has been completed ([NIH Guidelines](#): see [Appendix M-I-B](#), RAC Review Requirements), Institutional Biosafety Committee (IBC) approval (from the clinical trial site) has been obtained, Institutional Review Board (IRB) approval has been obtained, and all applicable regulatory authorization(s) have been obtained.

- 8.3.3 For human gene transfer protocols, the rDNA study is assigned to two IBC members (primary and secondary reviewer) for review, with copies of the protocol sent to all members.
- a. The primary reviewer assigned the human gene transfer protocol is to be a Clinician/Physician.
 - b. The primary and secondary reviewer's responsibilities are to provide a thorough review of the registration documents and provide their recommendations regarding approval of the study.
- 8.3.4 Human research protocols using rDNA materials are initially approved for a six month period that coincides with the IRB Continuing Review Process. This requires that a copy of the IRB continuing review application be submitted to the IBC at the time of the IRB continuing review submission.

Section 8.4 Documents Submitted for IBC Gene Transfer Review

- 8.4.1 The PI should consult with [Appendix M](#) of the [NIH Guidelines](#) for gene transfer protocol requirements. The following is a list of documents that are required to be submitted to the IBC for review of gene transfer protocols:
- a. IBC Application Form ([Registration Document for the Use of Non-Exempt Recombinant DNA](#))
 - b. Copy of the Letter of Review by NIH/OBA.
 - c. RAC review comments, if any.
 - d. Copy of Human Subjects IRB Application Form.
 - e. Copy of Human Subjects IRB Consent Form.
 - f. Study Sponsor's Clinical Protocol.
 - g. Investigational Brochure.
 - h. Based on a case by case review the IBC may require additional information.

Section 8.5 Reporting Requirements for Gene Transfer Protocols

- 8.5.1 Copies of all correspondence/documents that are submitted to the IRB relating to the gene transfer study or in support of gene transfer protocol must be submitted to the IBC for review. This includes:
- a. All SAEs reported to the IRB.
 - b. All Continuing Review Reports to the IRB.
 - c. All Change in Procedures reported to the IRB.
 - d. All Changes in Consent Form reported to the IRB.
 - e. All Protocol Deviations/Exceptions reported to the IRB.
 - f. All other items reported to the IRB.
 - g. Report(s) of significant problems, violations of the [NIH Guidelines](#), or any significant research-related accidents and illnesses.
 - h. A copy of the annual data report form submitted to the NIH/OBA.

Section 8.6 Reporting Adverse Events

- 8.6.1 All serious adverse events (SAE) involving enrolled study patients and the use of rDNA must be reported to the USF IBC regardless of whether or not the events are thought to be related to the gene transfer intervention.
- a. SAEs are to be reported within 48 hrs to the USF Institutional Biosafety Officer of the Division of Research Integrity & Compliance at (813-974-0954) or fax (813-974-7091).
 - b. Immediate written notification via e-mail as soon as possible (copied to IBC Chairperson & Institutional Biosafety Officer) to NIH/OBA (oba@od.nih.gov) using the designated Serious Adverse Event Reporting Form. Written notification is to be submitted to the Institutional Biosafety Committee (IBC), Institutional Review Board (IRB), Office of Human Research Protections (OHRP) (if applicable), NIH/OBA, and the Food and Drug Administration (FDA).

Section 8.7 Use of Recombinant Viral Vectors with Animals

- 8.7.1 Investigators planning to administer recombinant DNA (rDNA) to animals should refer to [Appendix Q](#) and [Section III-D-4](#) of the [NIH Guidelines](#) for information on biological and physical containment practices. Visit the USF Division of [Comparative Medicine Website](#) for additional guidance and to obtain applications to work with animals. Work involving laboratory animals requires USF Institution Animal Care and Use Committee (IACUC) approval and IBC approval before initiation of the study. IACUC applications can be obtained from the following website: <http://www.research.usf.edu/cm/applicationsc.htm>.
- 8.7.2 A pre-performance meeting must be conducted prior to using animals with potentially infectious rDNA materials requiring BSL-2 containment practices. The meeting is scheduled with the PI and his/her staff that represent the applicant's laboratory, Division of Comparative Medicine staff, and the Institutional Biosafety Officer or his/her designee.
- a. This pre-performance meeting is required in order to ensure that all involved personnel are aware of the precautions, containment practices, facilities, protective devices, disposal and decontamination procedures, and other necessary safety procedures that must be followed to protect personnel from accidental exposure to the biohazardous material and to prevent cross contamination to other animals.
 - b. Agent specific information must be provided to all animal husbandry personnel involved in handling animals exposed to potentially infectious rDNA materials. Information should cover: the hazards associated with the work; required containment practices and procedures; proper handling of bedding, food, and water; cage washing; and all other husbandry materials associated with the experiment.
- 8.7.3 Animals that are infected with adeno-associated viral vectors, must utilize an Animal BSL-2 (ABSL-2) containment area for the procedure(s). ABSL-2 housing is required due to the replication-defective virus may revert or recombine in vivo

thereby causing the vector to become replication competent. In turn this live virus may be shed from the animal and pose a potential exposure to those handling animals, animal bedding, feces, etc.

- a. Animals exposed to replication incompetent adeno-associated viral vector(s) as a part of the research protocol, must be housed under Animal BSL-2 (ABSL-2) containment practices for first the 72 hours following infection of the animal.
- b. Precautions must be taken to minimize aerosol creation (e.g., emptying animal waste material, washing down cages, cleaning the room with water hoses).

Section 8.8 Using rDNA to Create Genetically Engineered/Transgenic Animals

- 8.8.1 Investigators who create genetically engineered animals (either by pronuclear microinjection of DNA, or by blastocyst microinjection of embryonic stem cells that have been electroporated with DNA, or by other methods of genetic engineering involving recombinant DNA) must submit an IBC registration prior to initiation of the experiment. In addition, the appropriate IACUC documents must be completed and approved.
- 8.8.2 Experiments involving the purchase of, or the transfer of, transgenic rodents that require Biosafety Level 1(BSL-1) containment practices are exempt from the [NIH Guidelines](#) and IBC registration

Section 8.9 Using rDNA to Create Genetically Engineered /Transgenic Plants

- 8.9.1 Experiments to genetically engineer plants by recombinant DNA methods require IBC review and approval.
- 8.9.2 To prevent the release of transgenic plant materials into the environment, the [NIH Guidelines](#), [Section III-D-5](#) provides containment recommendations that must be implemented.

Section 8.10 Research Studies and Protocols Involving Oligonucleotides

- 8.10.1 All human oligonucleotide therapy protocols will be examined on a case by case basis by the IBC chairperson and/or Institutional Biosafety Officer to determine whether they pose any biosafety issues.

Section 9.0 Activities Involving Infectious Agents

Section 9.1 Infectious Agents

- 9.1.1 All research and teaching activities involving the use of infectious agents must be registered with and approved by the IBC ([Biosafety Registration Forms](#)), using the appropriate registration form(s).

- 9.1.2 The use of agents requiring BSL-4 containment is not permitted at the University of South Florida.
- 9.1.3 **Definition:** Infectious/Biological Agent refers to any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsia, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or other living organism.
- 9.1.4 The use of agents requiring BSL-3 containment will be restricted to laboratories designated as BSL-3 containment laboratories. Applications requesting the use of BSL-3 containment facility and practices will be reviewed by the IBC.

Section 9.2 Cell Lines

- 9.2.1 Cell cultures known to contain an infectious/pathogenic agent in the cell line can be classified at the same level as that recommended for the agent.
- 9.2.2 Cell lines which are non-primate in origin, which do not harbor a primate virus, which are not contaminated with bacteria, mycoplasma or fungi and which are well established are classified as Risk Group 1 cell lines and manipulated at Biosafety Level 1 containment practices.
- 9.2.3 All cell lines exposed to or transformed by a primate oncogenic virus, and all virus containing primate cell lines are classified as Risk Group 2 cell lines and manipulated at Biosafety Level 2 containment practices.

Section 9.3 Use of Potentially Infectious Pathogens with Animals

- 9.3.1 Animal Biosafety Level (ABSL) Criteria. ABSL criteria must be adhered to as specified in the [CDC BMBL](#) (5th edition) when using infectious agents in animals.
 - a. All work with animals involving the use of infectious agents must be submitted to the IBC for review and approval in addition to review and approval from the IACUC.
 - b. Studies involving the use of animals exposed to infectious agents require a pre-performance meeting involving the PI and his/her staff that represent the applicant's laboratory, Division of Comparative Medicine staff, and the Institutional Biosafety Officer or his/her designee.
- 9.3.2 Appropriate facilities and equipment must be used to provide containment for laboratory animals exposed to or harboring infectious agents which is appropriate to the risk level of the infectious agents involved.

- 9.3.3 Housing of animals infected with BSL-2 agents must be in accordance with the recommendations of the [CDC BMBL, 5th edition](#) for Animal Biosafety Levels.

(Please Note: There are no Animal Biosafety Level 3 or 4 facilities at USF.)

Section 9.4 Transplantation of Human Umbilical Cord Blood (HUCB) into Research Animals

- 9.4.1 The IBC in conjunction with the Division of Comparative Medicine has implemented specific practices to be followed to reduce the risk of exposure of research faculty and staff, animal care personnel, and animals to potentially infected human tissues and/or clinical samples.
- 9.4.2 Samples Characterized For Pathogens Prior To Transplantation
- a. Prior to injecting animals with HUCB a copy of the testing results from an accredited laboratory must be submitted to the Division of Comparative Medicine and the USF IBC for each different lot/sample control number.
 - i. If the testing results are positive for any pathogen and if the Principal Investigator chooses to transplant them into animals, these animals must be housed in accordance with Animal Biosafety Level 2 (ABSL-2) practices.
 - ii. If the testing results are positive for any pathogen the investigator must notify the Institutional Biosafety Officer and the pathogen must be registered with the Institutional Biosafety Committee.
- 9.4.3 Samples Not Screened For Pathogens Prior To Transplantation
- a. The usage of any unscreened sample(s) of HUCB in animals will require the animals to be housed under Animal Biosafety Level 2 (ABSL-2) containment in accordance with the OSHA Blood Borne Pathogen Standard using Standard Precautions (formerly known as Universal Precautions).
- 9.4.4 In handling any and all cord blood samples the IBC recommends that samples be handled with Standard Precautions (OSHA Blood Borne Pathogen Standard). At a minimum, that should include the use of gloves, lab coats, and protective eyewear.
- 9.4.5 During transport of HUCB, specimens should be doubly contained to prevent spills and/or leakage with adequate absorbent material between the primary and secondary container to absorb all spills and/or leakage.

Section 10.0 Work with Biological Toxins

- 10.1 **Definition:** Biological Toxin refers to the toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsia, or protozoa), or a recombinant or synthesized molecule.

- 10.2 All research and teaching activities involving the use of Biological Toxins must be registered with and approved by the IBC ([Biosafety Registration Forms](#)), using the appropriate registration form(s).
- 10.3 Researchers and students must follow requirements as specified in the [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories Manual, Appendix I Guidelines for Work with Toxins of Biological Origin](#), as the minimum containment required for this work. Containment requirements are subject to modification by the IBC.

Section 11.0 IBC Review and Approval Process

- 11.1 The IBC reviews all use of infectious agents, biological toxins, Select Agents/Toxins, and/or rDNA material. No research or teaching activities involving biohazardous materials may be initiated or continued at USF or by USF's employees without prospective review and approval by the IBC.
- 11.2 There are four types of registration documents:
 - [Registration Document For The Use of Exempt Recombinant DNA](#)
 - [Registration Document For The Use of Non-Exempt Recombinant DNA](#)
 - [Registration Document For The Use of Infectious Agents and Biological Toxins](#)
 - [Registration Document for the Use of Infectious Agents, Biological Toxins, and/or rDNA in a Teaching/Training Laboratory](#)
- 11.3 IBC meetings are held on the third Tuesday of every month. The IBC will not meet on days that USF is "closed for business". The IBC meeting schedule is available at <http://www.research.usf.edu/cs/biosafetyschedule.htm>. A complete application must be submitted by the submission deadline date which is 10 days prior to the meeting date. Applications received after this date will automatically be put on the next month's agenda for review.
- 11.4 Prior to the convened meeting, all IBC members are provided with all agenda items. IBC members are charged to review these materials for each protocol.
- 11.5 The IBC conducts full board initial review of all Non-Exempt rDNA and Infectious Agent/Biological Toxin research/teaching use at a convened meetings unless the research falls into one or more of the categories appropriate for expedited review.
- 11.6 A quorum of the IBC members (or their designated alternates) must be present in order to conduct a convened meeting. In order for research to be approved, it must receive the approval of a simple majority of those members present at the meeting.

- 11.7 The IBC reviews are conducted in accordance with applicable federal, state and local requirements (e.g., [NIH Guidelines](#) and the CDC/NIH [BMBL 5th edition](#)).
- 11.8 The IBC uses a primary reviewer system for the initial review of new registrations (except [Human Gene Transfer studies](#)) at a convened meeting. The primary reviewer for initial reviews is considered the lead reviewer for research proposals assigned to them. They are responsible for:
- conducting an in-depth review of the application and all supporting materials,
 - presenting a review of the research at the convened meeting,
 - proposing a motion of action (i.e., Final Full Approval, Requires Modifications to Secure Approval, Tabled/Deferred, or Disapprove the Registration).

The IBC uses a primary and secondary reviewer system to assist in the initial review of research involving Human Gene transfer studies. The primary and secondary reviewers for the initial review of research involving Human Gene transfer studies are considered the lead reviewers for research proposals assigned to them. Human Gene transfer studies are reviewed in accordance with [Appendix M](#) of the [NIH Guidelines](#).

- 11.9 IBC staff selects a primary reviewer based on the member's scientific or scholarly expertise. IBC staff ascertain that the reviewer chosen as a primary reviewer is not listed as personnel on the IBC registration application to prevent a *Conflict of Interest*. The IBC may rely on ad hoc consultant(s) to review the study in the absence of IBC expertise in a particular area. Consultants will have access to all documents submitted to the USF IBC relevant to the specific project under review. The Consultant may participate in the deliberations and make recommendations, but may not vote
- 11.10 The entire IBC file will be available to all IBC members, and all IBC members will be afforded the full opportunity to discuss each research proposal during the convened meeting. It is permissible for the primary reviewer to contact individual investigators for clarification on any point prior to the convened meeting.
- 11.11 The IBC may take one of the following actions:
- Final Full Approval** - Full approval will be granted by the IBC if there are no outstanding biosafety issues. The approval is only for materials, personnel, facility, and procedures specifically described and provided in the application. The PI may commence the research only *after* receiving written approval indicated by a signed approval letter from the IBC chairperson.
 - Requires Modifications to Secure Approval** - Such clarification(s) and/or additional information is clearly delineated by the IBC. The additional items of clarification are not a major biosafety concern. The PI must respond in writing to provisions requested by the Committee and receive final approval prior to initiating the research. The registration with the requested

- modifications is to be reviewed by a designated IBC member. The research may be approved by the designated reviewer or the chairperson.
- c. **Tabled/Deferred** - Deferred for consideration at a subsequent meeting. The IBC determines that a Tabled/Deferred study lacks sufficient information about the research procedures or safety practices and a complete risk assessment of the biohazards cannot be performed. The research may not proceed until the convened IBC has reviewed and approved a revised application that incorporates all necessary information as requested by the committee. Additional information may or may not secure approval.
 - d. **Disapprove the Registration** - The IBC has determined that the research proposal has substantive biosafety issues. Registrations that are disapproved require submission of a revised registration application for review by the full IBC. The research may not proceed until the convened IBC has reviewed and approved a revised application that incorporates all necessary information as requested by the committee. Additional information may or may not secure approval.
- 11.12 After committee review, the decision of the committee is communicated to the PI by memo.
 - 11.13 Infectious agents, biological toxins, Select Agents/Toxins, and/or rDNA material may not be used and/or handled until notification of approval is received by the PI from the IBC.
 - 11.14 If an application requires modifications to secure approval, the PI has 90 days to respond by submitting the modifications as requested by the committee. If the IBC does not receive a response within 90 days of the initial request, the application will be administratively closed and the PI must resubmit the application if he/she wishes to conduct the study.
 - 11.15 **Investigator Assurance for All Approvals:** The principal investigator, by placing his/her signature on the registration or modification request agrees to adhere to the practices, procedures, and information described in the registration or modification request as it was written when it was reviewed and approved by the IBC.
 - 11.16 The IBC reviews research through an expedited procedure if:
 - a. The research meets the NIH definition of an exempt rDNA registration;
 - b. The research constitutes a minor change in a previously approved research application during the period for which approval is authorized; or
 - c. The research requires BSL-1 containment.
 - 11.17 Under an expedited review procedure, the IBC Chairperson and/or the Institutional Biosafety Officer may review and approve the research on behalf of the IBC.

Section 12.0 Continuing Review of Approved Registrations

- 12.1 The IBC approves requests for the use of infectious agents, biological toxins, Select Agents/Toxins, and/or Non-Exempt rDNA for a period of twelve months. The PI may annually renew an IBC-approved study for up to a total of two additional one-year periods.
- 12.2 After three years all continuing studies must be completely re-described in a new registration application.
- 12.3 Researchers cannot continue to work with infectious agents, biological toxins, Select Agents/Toxins, and/or rDNA material under an expired registration. If a PI wishes to continue the research a new application must be submitted and approved by the IBC prior to the expiration of the previous registration.
- 12.4 Approximately 90 days before the end of the first and second year approval period, the Biosafety staff reminds the PI (by memorandum) to submit a request for continuing review or notice of termination to the Office of Research Integrity & Compliance prior to the end of the approval period. If changes have been made or if changes are proposed to be made to the approved protocol, the PI must also file a [Modification Request](#) form.
- 12.5 The Continuing Review forms are reviewed by the IBC chairperson and/or the Institutional Biosafety Officer (IBO) through an expedited process. The Continuing Review forms may be approved by the IBC chairperson and/or the Institutional Biosafety Officer (IBO). The chairperson and/or IBO have the discretion to request a full committee review.
- 12.6 Approximately 90 days before the end of the three year approval period, the IBC office staff reminds the PI (by Memorandum) to submit a new Registration Form or to close the existing study.
- 12.7 Exempt rDNA registrations are approved for the life of the study as described in the registration application. If a proposed modification changes the overall scope, intent of the study, or the risk (e.g., addition of an infectious agent from a higher Risk Group) a new research application must be submitted.

Section 13.0 Modifications to an IBC Approved Registration Application

- 13.1 All proposed modifications to an approved research study involving infectious agents, biological toxins, Select Agents/Toxins, and/or rDNA material must be submitted to the IBC for review and receive approval prior to the implementation of the proposed modifications.

- 13.2 If the proposed modification changes the overall scope, intent of the study, or the risk (e.g., addition of an infectious agent from a higher Risk Group) a new research application must be submitted.
- 13.3 The IBC reserves the right to determine whether the proposed modification(s) are substantive and to request further information or a new IBC registration application.
- 13.4 The IBC may utilize Expedited Review procedures to review a proposed modification to previously approved research. A modification request considered for Expedited Review does not change or alter:
- the Risk Group or Biosafety Level;
 - the research design or methodology;
 - the use of aerosol generating procedures;
 - the facilities available to support safe conduct of the research.
- 13.5 Modifications eligible for Expedited Review involve logistical, administrative, and/or editorial aspects of the research project. Examples of changes eligible for Expedited Review:
- Change in Biological Agent (must remain within the same family of agents previously approved-must not change overall BSL)
 - Change in Protocol Title;
 - Change in Protocol Sponsor;
 - Change in Lab Location;
 - Change in Lab Equipment;
 - Change in Procedure;
 - Change in Personnel; and
 - Other Information
 - contact information,
 - addresses,
 - typographical errors, and
 - changes that do not alter the overall risk of the study.
- 13.6 The Modification Request forms are reviewed by the IBC chairperson and/or Institutional Biosafety Officer through an expedited process. The Modification Request forms are approved by the IBC chairperson and/or the Institutional Biosafety Officer (IBO). The chairperson and/or Institutional Biosafety Officer have the discretion to request a full committee review.
- 13.7 When a Modification Request does not meet the criteria for Expedited Review (policy item 13.4 & 13.5) then the full IBC must review the proposed change(s) at a convened meeting. The IBC may require a new research application to be submitted.

Section 14.0 Biosafety Laboratory Audits

- 14.1 Required Laboratory Audits (to verify the status of safety compliance, evaluate the conditions, and document the review/audit):
 - a. if required by the granting agency (e.g., Department of Defense)
 - b. to establish an American Type Culture Collection (ATCC) account
 - c. laboratories registered with the USF IBC utilizing Biosafety Level 2 (BSL-2) and Biosafety Level 3 (BSL-3) containment
- 14.2 Prior to securing the Institutional Biosafety Officer's signature to establish an ATCC account the PI must schedule a laboratory audit with the Institutional Biosafety Officer (IBO) and/or the IBO's designee.
- 14.3 Biosafety laboratory audits will be conducted for materials requiring BSL-2 and/or BSL-3 containment as part of the IBC approval process of a research/teaching registration study and annually thereafter. Biosafety containment practices, facilities, and equipment are assessed as part of the registration approval process but prior to the initiation of the project. The biosafety audits will be scheduled in advance whenever possible. However, unannounced random and follow-up inspections may also be conducted.
- 14.4 All biosafety laboratory audits will be performed in accordance with requirements published by the CDC/NIH in the [Biosafety In Microbiological and Biomedical Laboratories, 5th edition](#) for the required biosafety containment level for the biohazardous materials utilized.

Section 15.0 Select Agents and Toxins

Section 15.1 Background

- 15.1.1 The United States Department of Health and Human Services (HHS) and the United States Department of Agriculture (USDA) have identified certain bacteria, viruses, toxins, rickettsia, and fungi that pose a potential threat to public health and welfare. These organisms are considered Select Biological Agents and Toxins (HHS), High Consequence Livestock Pathogens and Toxins (USDA), or HHS/USDA overlap agents.
- 15.1.2 A select agent may not be possessed or used in the United States, received from outside the United States, or transferred within the United States by any individual(s), academic institution, or other legal entity unless such activities are conducted for a lawful purpose and in accordance with the federal law.
- 15.1.3 The University of South Florida (USF), in order to comply with the USA PATRIOT Act of 2001, and the Public Health Security and Bioterrorism

Preparedness and Response Act of 2002, requires PIs to register the possession, use, and transfer of Select Biological Agents and Toxins with the IBC.

- 15.1.4 PI's who wish to possess, use, and or transfer Select Biological Agents and Toxins must be registered with the USF IBC. Registration with the Centers for Disease Control and Prevention (CDC) and/or the USDA/APHIS is also required.

Section 15.2 Registration with the USF IBC for Use of Select Agents

- 15.2.1 A PI planning to work with any Select Agent/Toxin material must also complete a USF Registration Document for the Use of Infectious Agents and Biological Toxins and submit it to the Institutional Biosafety Committee (IBC) for review and approval. This Registration Document is available on our Web Site at: http://www.research.usf.edu/cs/biosafety_forms/infectregistration.doc

Section 15.3 CDC/USDA Requirements for Use of Select Agents

- 15.3.1 Registration is valid only for the specific Select Biological Agents and Toxins, the particular activities and locations involved, and the specific individuals approved to handle or use the regulated materials listed on the application.
- 15.3.2 The PI must collaborate with the USF Institutional Biosafety Officer to develop and implement agent-specific plans for biosafety, site-specific plans for security (e.g., inventory control, access control, cyber security), and emergency response.
- 15.3.3 As part of the federal registration process the Responsible Officer, Alternate Responsible Officer, PI, and staff will undergo a security risk assessment that includes a background check and finger printing.
- 15.3.4 Only those individuals who have documented a legitimate need to handle or use Select Biological Agents and Toxins and who have appropriate training and skills to handle such agents will be granted access to the agents.
- 15.3.5 There are specific requirements for record keeping, notification of transfer, theft, loss, and/or destruction.
- 15.3.6 The laboratory will be inspected by the CDC or USDA before final federal approval is granted.
- 15.3.7 The Responsible Official or his/her alternate, must conduct regular inspections of the laboratory where select agents/toxins are used or stored.

Section 16.0. Coordination with other Compliance Committees/Divisions

Section 16.1 Animal Use

- 16.1.1 Review by the IBC is independent of review by the Institutional Animal Care and Use Committee (IACUC). However, there is representation on both committees that communicate and coordinate regarding Biosafety issues in animal studies.
- 16.1.2 Initiation of the animal component of the study is contingent upon the completion of and approval by the Institutional Animal Care and Use Committee (IACUC) process.

Section 16.2 Human Subjects

- 16.2.1 Review by the IBC is independent of review by the IRB. However, there is representation on both committees that communicate and coordinate regarding Biosafety issues in Human Gene transfer trials.
- 16.2.2 The IBC consults with the Office of Biotechnology Activities/Recombinant DNA Advisory Committee (OBA/RAC) for novel Human Gene Therapy experiments or ones not explicitly covered in the [NIH Guidelines](#).

Section 16.3 Office of Sponsored Research

- 16.3.1 Biosafety Program staff make available to the Office of Sponsored Research information regarding Approval, Closure, and Continuing Review letters of all studies approved by the IBC.

Section 17.0 Biosafety Education and Training

Section 17.1 Persons Required to Complete Training

- 17.1.1 Training and education in microbiological techniques is required for anyone working with infectious agent(s), biological toxin(s), Select Agents/Toxins, and/or rDNA or who works in a laboratory where these materials are used and/or stored.
 - a. The PI is responsible for providing training, conducting practical demonstrations, and assessments of competence in the laboratory regarding microbiological techniques.
 - b. The Biosafety Program requires education in biosafety principles and practices for all faculty, staff, students, volunteers, and visitors directly involved in the conduct of research with infectious agent(s), biological toxin(s), Select Agents/Toxins, and/or rDNA or who works in a laboratory where these materials are used and/or stored. The Division of Research Integrity and Compliance provides this education.

Section 17.2 Training Requirements

- 17.2.1 There are three types of Biosafety training requirements:
- a. **Core Course** – The Biosafety Principles and Practices course. All persons involved in the conduct of research with infectious agent(s), biological toxin(s), Select Agents/Toxins, and/or rDNA must complete the core course requirements before they directly handle the biological material.
 - b. **Continuing Education** – Annual (calendar year) completion of an IBC approved continuing education course by investigators and personnel involved in all IBC approved studies
 - c. **Special Topics** – Required for persons involved in certain types of work (e.g., BSL-3 training, shipping infectious substances, and diagnostic specimens).

Section 18.0 Non-Compliance

- 18.1 Information regarding non-compliance and/or deficiency (ies) with the [NIH Guidelines](#), [CDC/NIH BMBL 5th edition](#), and IBC policy may be brought to the attention of the USF Institutional Biosafety Committee and/or the USF Biosafety Program by any individual.
- 18.2 Information concerning non-compliance and deficiencies with the [NIH Guidelines](#), [CDC/NIH BMBL 5th edition](#), and IBC policy is presented in a manner that protects, to the limits possible, the identity of the complainant, investigator, study, or facility.
- 18.3 Reports regarding biosafety concerns, deficiency, and non-compliance with the [NIH Guidelines](#), [CDC/NIH BMBL 5th edition](#), and IBC policy are immediately forwarded to the IBC chairperson. The Institutional Biosafety Officer (IBO) in consultation with the IBC chairperson and Director, Division of Research Integrity & Compliance (DDRIC) shall have the authority to interrupt (e.g., temporarily suspend the project or practice) any activity involving research or teaching using infectious agents, biological toxin(s), Select Agents/Toxins, and/or rDNA that jeopardizes the health and safety of any individual or presents a threat to the safety of the environment. Further review following the above alleged non-compliant activity will occur. The IBC will meet within three (3) business days and make a recommendation on how to address the situation before work will be allowed to resume.
- 18.4 In cases of non-compliance with established safety rules that is discovered during a safety audit, but where there is no imminent danger to individuals or property, the IBO will notify the PI to correct the deficiency (cies). In instances where the noncompliance is not corrected, a two step process will be followed:

- Step 1:** The IBO will notify the PI (faculty member in charge of the lab) in writing describing the deficiency (ies) and personnel involved. A suggestion for how compliance with University procedures can be achieved will be included and the faculty member will be asked to notify the IBC of the status of his/her efforts to make the correction. The laboratory will be scheduled for a follow-up inspection by the IBO.
- Step 2:** If the IBO is not able to achieve compliance through efforts outlined in Step 1, the status of the situation will be brought to the attention of the IBC.

- 18.5 All reports of alleged biosafety concern(s), deficiency, or non-compliance are forwarded to the IBC for investigation and corrective action. The subject Principal Investigator is informed of the allegation in writing by the IBC Chairperson and may be invited to meet with the IBC to respond to questions regarding the alleged deficiency.
- 18.6 The VP for Research is responsible for reporting any significant problems with or violations of the [NIH Guidelines](#) and any significant research-related accidents or illnesses to the appropriate institutional official and NIH/OBA within 30 days; unless the Institutional Biosafety Committee determines that a report has already been filed by the Principal Investigator.

Section 19.0 Suspension or Termination of IBC Approval

- 19.1 The IBC may suspend an activity that it previously approved if it determines:
- failure to willfully comply with federal/state regulations and/or IBC policy;
 - any activities adversely affecting the health and safety of any individual involved in research or teaching using infectious agents, biological toxin(s), Select Agents/Toxins, and/or rDNA;
 - any serious adverse event related to gene therapy study; or
 - the activity does not match the description of the activity originally approved by the IBC.
- 19.2 The IBC deliberates regarding reports of alleged deficiencies at its next regularly scheduled monthly meeting, or the IBC Chairperson can call an emergency quorum to discuss the issue in advance of a regular meeting if deemed necessary. The IBC Chairperson can choose to invite involved personnel to the meeting to whom questions can be directed. The IBC reports the findings of its deliberations to the PI and the Vice President of Research.
- 19.3 If the IBC suspends an activity involving infectious agents, biological toxin(s), Select Agents/Toxins, and/or rDNA, the PI will be informed in writing of the suspension, its conditions, and the expectations of the IBC which need to be met before additional activities involving infectious agents, biological toxin(s), Select Agents/Toxins, and/or rDNA resume.

- 19.4 The IBC may vote, at a convened meeting, to suspend or terminate approval of research that has been associated with noncompliance regarding applicable regulatory requirements and/or IBC policy.

Section 20.0 Policy Review

- 20.1 This policy will be reviewed annually.
- 20.2 The policy changes (e.g., additions, deletions) must be approved by a quorum of IBC members at a convened IBC meeting.

APPENDIX I - HHS & USDA Regulated Select Agents and Toxins

HHS SELECT AGENTS AND TOXINS

Abrin
Cercopithecine herpesvirus 1 (Herpes B virus)
Coccidioides posadasii
Conotoxins
Crimean-Congo hemorrhagic fever virus
Diacetoxyscirpenol
Ebola virus
Lassa fever virus
Marburg virus
Monkeypox virus
(Reconstructed 1918 Influenza virus) Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments
Ricin
Rickettsia prowazekii
Rickettsia rickettsii
Saxitoxin
Shiga-like ribosome inactivating proteins
South American Hemorrhagic Fever viruses
 Flexal
 Guanarito
 Junin
 Machupo
 Sabia
Tetrodotoxin
Tick-borne encephalitis complex (flavi) viruses
 Central European Tick-borne encephalitis
 Far Eastern Tick-borne encephalitis
 Kyasanur Forest disease
 Omsk Hemorrhagic Fever
 Russian Spring and Summer encephalitis
Variola major virus (Smallpox virus) and
Variola minor virus (Alastrim)
Yersinia pestis

OVERLAP SELECT AGENTS AND TOXINS

Bacillus anthracis
Botulinum neurotoxins
Botulinum neurotoxin producing species of *Clostridium*
Brucella abortus
Brucella melitensis
Brucella suis
Burkholderia mallei (formerly *Pseudomonas mallei*)
Burkholderia pseudomallei (formerly *Pseudomonas pseudomallei*)
Clostridium perfringens epsilon toxin
Coccidioides immitis
Coxiella burnetii
Eastern Equine Encephalitis virus
Francisella tularensis
Hendra virus
Nipah virus
Rift Valley fever virus
Shigatoxin
Staphylococcal enterotoxins
T-2 toxin
Venezuelan Equine Encephalitis virus

USDA SELECT AGENTS AND TOXINS

African horse sickness virus
African swine fever virus
Akabane virus
Avian influenza virus (highly pathogenic)
Bluetongue virus (Exotic)
Bovine spongiform encephalopathy agent
Camel pox virus
Classical swine fever virus
Cowdria ruminantium (Heartwater)
Foot-and-mouth disease virus
Goat pox virus
Japanese encephalitis virus
Lumpy skin disease virus
Malignant catarrhal fever virus (Alcelaphine herpesvirus type 1)
Menangle virus
Mycoplasma capricolumi M. F38/M. *mycoides* Capri (contagious caprine pleuropneumonia)
Mycoplasma mycoides mycoides (contagious bovine pleuropneumonia)
Newcastle disease virus (velogenic)
Peste des petits ruminants virus
Rinderpest virus
Sheep pox virus
Swine vesicular disease virus
Vesicular stomatitis virus (Exotic)

USDA PLANT PROTECTION AND QUARANTINE (PPQ)

SELECT AGENTS AND TOXINS

Candidatus Liberobacter africanus
Candidatus Liberobacter asiaticus
Peronosclerospora philippinensis
Ralstonia solanacearum race 3, biovar 2
Schlerophthora rayssiae var *zeae*
Synchytrium endobioticum
Xanthomonas oryzae pv. *oryzicola*
Xylella fastidiosa (citrus variegated chlorosis strain)