Institutional Biosafety Committee (IBC) Procedures and Principal Investigator Responsibilities

Companion document to Institutional Biosafety Committee (IBC) Policy

Table of Contents

1.0 Introduction

These procedures are a companion document to the Saint Louis University Institutional Biosafety Committee (IBC) Policy. The IBC Policy should be reviewed prior to review and use of these procedures. These procedures, and subsequent revisions, are incorporated by reference into the IBC Policy. Compliance with both the policy and the current edition of these companion procedures is expected. Refer to Section 12.0 for Sanctions for Non-Compliance.

2.0 Definitions

[Note: Most of these terms, arranged alphabetically, are also listed in the Policy on Institutional Biosafety Committee, Section 8.0. This list is slightly more comprehensive.]

2.1 AgSAS: APHIS's **Ag**riculture **S**elect **A**gent **S**ervices.

2.2 Alternate Responsible Official (ARO): The Alternate Responsible Official (ARO) is the individual designated by the University and approved by the U.S. Department of Health and Human Services with the authority and control to ensure compliance with the select agent regulations (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331), in the absence of the Responsible Official (RO). See Responsible Official (RO) definition.

2.3 Animal Biosafety Level (ABSL): Biosafety Level assigned to a laboratory or other support space where animals containing biological agents are present.

2.4 APHIS: The U.S. Department of Agriculture's **A**nimal and **P**lant **H**ealth **I**nspection **S**ervice.

2.5 Assistant or Associate Biological Safety Officer (ABSO): The ABSO is a position within Saint Louis University's Environmental Health and Safety office, and serves as the principal back-up for the BSO when unavailable. The ABSO is appointed to the IBC as an alternate for the BSO, with voting privileges when the BSO is unable to attend. The ABSO is the primary Alternate Responsible Official (ARO) for the select agent program.

2.6 Authorized Organization Representative (AOR): The designated individual(s) within an organization legally authorized to sign and submit grant applications, signifying that the organization accepts responsibility for the proposed project and agrees to comply with all grant terms and conditions if awarded.

2.7 Biological Agent: Any bacteria, viruses, parasites, prions, fungi, toxins, deoxyribonucleic acid (DNA), and ribonucleic acid (RNA), known to be, or suspected of being, hazardous to human, plants, and animals, ALL human-derived and primate-derived biological materials used in research, and any recombinant or synthetic nucleic acid molecules, and cells, organisms, and viruses containing such molecules.

For purposes of this policy and IBC oversight, biological agents also include Risk Group 1 (RG1) biological agents listed below.

A. RG1 biological agents that could be opportunistic pathogens that may cause infection in the young, the aged, and/or immunodeficient or immunosuppressed individuals.

B. RG1 biological agents that are known or suspected of being hazardous to animal populations or plants.

2.8 Biological Safety Officer (BSO): An individual appointed by the University to oversee management and implementation of all aspects of the biosafety program, minimizing biosafety and biosecurity risks. The Biological Safety Officer, a position within Saint Louis University's Environmental Health and Safety office, is a member of the IBC, serves as the Executive Secretary of the IBC, and serves as the University's Institutional Contact for Dual Use Research (ICDUR).

2.9 Biosafety Level (BSL): A description of the level of physical containment and specific work practices (this includes combinations of laboratory work practices and techniques, safety equipment, and laboratory facilities) required to be employed to contain biological agents and to reduce the potential for exposure of laboratory workers, persons outside of the laboratory, and the environment. Each combination is specifically appropriate for the operations performed, the documented or suspected routes of transmission of the infectious agents, and the laboratory function or activity. Biosafety levels are graded from BSL-1 (lowest containment) to BSL-4 (highest containment).

2.10 BMBL: Common abbreviation for CDC/NIH publication: *Biosafety in Microbiological and Biomedical Laboratories*, *6th Edition, June 2020.*

2.11 Category 1 Research: Research which fits the following 3 criteria: 1) It involves one or more biological agents and toxins described in the USG Policy (all select agents and most risk group 3 agents), 2) it involves one of the experimental outcomes described in the USG Policy, and 3) based on current understanding, the research can be reasonably anticipated to provide, or does provide, knowledge, information, products, or technologies that could be misapplied to do harm with no — or only minor — modification to pose a significant threat with potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

2.12 Category 2 Research: Research which fits the following 3 criteria: 1) It involves, or is reasonably anticipated to result in, a Pathogen with Pandemic Potential, 2) It involves one or more of the 4 experimental outcomes defined in the USG Policy, and 3) The research can be reasonably anticipated to result in the development, use, or transfer of a PEPP or an eradicated or extinct PPP that may pose a significant threat to public health, the capacity of health systems to function, or national security.

2.13 CDC: The Department of Health and Humans Services' **C**enters for **D**isease **C**ontrol and Prevention.

2.14 CDC-DRSC: The CDC's **D**ivision of **R**egulatory **S**cience and **C**ompliance.

2.15 Department of Health and Human Services (HHS): U.S. Department of **H**ealth and **H**uman **S**ervices.

2.16 Dual Use Research: Research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that can be utilized for benevolent or harmful purposes.

2.17 Dual Use Research of Concern (DURC): "Life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be misapplied to do harm with no, or only minor, modification to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals and the environment, materiel, or national security." *(Reference: See Section 13.8)*

2.18 Environmental Health and Safety (EHS): Operational unit of the Office of Vice President for Research (OVPR) responsible for environmental safety, including biological safety, chemical safety, radiation safety and related compliance.

2.19 Gene Drive: A technology whereby a particular heritable element biases inheritance in its favor, resulting in the heritable element becoming more prevalent than predicted by Mendelian laws of inheritance in a population over successive generations.

2.20 IBC Manager (or Coordinator): Reporting to the Biological Safety Officer (and the EHS Executive Director when BSO is absent), this University position is responsible for the conduct of routine IBC business functions, including screening IBC protocols for completeness and thoroughness, advising Principal Investigators, performing biosafety inspections, drafting meeting minutes and providing other IBC support functions. This position is the primary contact for updating the IBC roster, and related functions, with NIH. The IBC Manager is the operational/technical point of contact with IBC software vendor. The IBC Manager serves as an Alternate Responsible Official (ARO) for the Select Agent Program.

2.21 Institutional Biosafety Committee (IBC): The University committee created consistent with the requirements of the NIH Guidelines to review research conducted in University owned or leased facilities involving recombinant or synthetic nucleic acid molecules, including Human Gene Transfer experiments, as well as other research that entails biohazard risks, including DURC and PEPP. The IBC reports to the Vice President for Research through the IBC Chairperson.

A. **SLU IBC:** For purposes of the *"Institutional Biosafety Committee (IBC) Policy"* and the companion *"Institutional Biosafety Committee (IBC) Procedures and Principal Investigator Responsibilities"* document, the term "Institutional Biosafety Committee" or "IBC" always means the Saint Louis University (SLU) IBC.

B. **SSM Health Saint Louis University Hospital IBC:** The SSM Health Saint Louis University Hospital IBC reviews research conducted by SLU Principal Investigators in SSM Health Saint Louis University Hospital facilities when it involves recombinant or synthetic nucleic acid molecules, including Human Gene Transfer experiments, as required by the NIH Guidelines.

C. **SSM Health Cardinal Glennon Children's Hospital IBC:** The SSM Health Cardinal Glennon Children's Hospital IBC reviews research conducted by SLU Principal Investigators in SSM Health Cardinal Glennon Children's Hospital facilities when it involves recombinant or synthetic nucleic acid molecules, including Human Gene Transfer experiments, as required by the NIH Guidelines.

2.22 Institutional Contact for Dual Use Research (ICDUR): The official designated by the research institution to serve as an internal resource for application of the *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential* as well as the liaison (as necessary) between the institution and the relevant federal funding agency. The ICDUR at Saint Louis University is the Biological Safety Officer (BSO). *(Reference: See Section 13.8)*

2.23 Institutional Review Entity (IRE): The entity established by the research institution to execute the institutional oversight responsibilities described in the USG Policy. The Saint Louis University IBC is designated to be the IRE.

2.24 NIH: **N**ational **I**nstitutes of **H**ealth. The NIH is one of several health agencies within the Public Health Service, which is an agency within the U.S. Department of Health and Human Services (DHHS).

2.25 NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines): The NIH Guidelines detail safety practices and containment procedures for basic and clinical research involving recombinant or synthetic nucleic acid molecules, including the creation and use of organisms and viruses containing recombinant or synthetic nucleic acid molecules.

Important Note: ***Although not regulatory by definition, compliance with the NIH Guidelines is mandatory.*** The NIH Guidelines (in Section I-D) state that, as a condition for NIH funding of recombinant or synthetic nucleic acid molecule research, institutions shall ensure that all such research conducted at or sponsored by the institution, irrespective of the source of funding, shall comply with the *NIH Guidelines*. Failure by one PI at Saint Louis University to follow the NIH Guidelines (whether or not NIH funded) can lead to suspension or termination of NIH funding for all NIH sponsored programs at Saint Louis University.

2.26 Non-hazardous Biological Material: A biological material that does not meet the definition of "Biological Agent", as defined in Section 2.3 of these procedures.

2.27 Office of Science Policy (OSP): The NIH office responsible for promoting sciences, safety and ethics in the development of public policies in the areas of Biomedical Technology Assessment, Biosafety, and Biosecurity. By monitoring research and through consultation, coordination, and analysis, the office develops policies related to:

A. Biosafety for NIH supported research,
B. Biosecurity, including oversight and dual use research, and
C. Registration of new stem cells lines for NIH funded research.

2.28 Pathogen with enhanced pandemic potential (PEPP): A type of pathogen with pandemic potential (PPP) resulting from experiments that enhance a pathogen's transmissibility or virulence, or disrupt the effectiveness of pre-existing immunity, regardless of its progenitor agent, such that it may pose a significant threat to public health, the capacity of health systems to function, or national security. Wild-type pathogens that are circulating in or have been recovered from nature are not PEPPs but may be considered PPPs because of their pandemic potential.

2.29 Pathogen with pandemic potential (PPP): A pathogen that is likely capable of wide and uncontrollable spread in a human population and would likely cause moderate to severe disease and/or mortality in humans.

2.30 Principal Investigator (PI): Faculty or other lead researcher who is primarily responsible for the conduct of the research requiring IBC approval.

2.31 Reasonably anticipated: An assessment of an outcome such that, generally, individuals with scientific expertise relevant to the research in question would expect this outcome to occur with a non-trivial likelihood. It does not require high confidence that the outcome will definitely occur but excludes experiments in which experts would anticipate the outcome to be technically possible, but highly unlikely.

2.32 Recombinant and Synthetic Nucleic Acid Molecules: Under the current NIH Guidelines, these are:

A. Molecules that (1) are constructed by joining nucleic acid molecules and (2) that can replicate in a living cell, i.e., recombinant nucleic acids;
B. Nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or
C. Molecules that result from the replication of those described in A. or B. above.

2.33 Registered Entity: Any government agency (Federal, State or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity that has submitted the information requested in APHIS/CDC Form 1 (registration application packet) to CDC and has been issued a certificate of registration (approval) issued by the HSS Secretary. (Saint Louis University is a registered entity.)

2.34 Registered Individual: Any person who has successfully completed a Security Risk Assessment (SRA) by the FBI, is enrolled in the Federal Select Agent Program Management (FSAP) Management System by the RO and obtains an "Approved" (unrestricted access) status in the FSAP system. Approvals are valid for 3 years unless terminated sooner by Saint Louis University.

2.35 Responsible Official (RO): The Responsible Official (RO) is the individual designated by the University and approved by the U.S. Department of Health and Human Services with the authority and control to ensure compliance with the select agent regulations (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331). The RO has been designated as the primary contact for compliance with the select agent regulations, including the registration of select agents with the CDC-DRSC, or AgSAS when applicable. The RO is also the person responsible and authorized to transfer and receive select agents on behalf of University researchers. The Saint Louis University Biological Safety Officer is designated as the RO at Saint Louis University.

2.36 Risk Groups (RGs): Categories of biological agents based on their relative pathogenicity for healthy adult humans, as defined in the NIH Guidelines, that are used in making risk assessments, according to the following criteria:

- **Risk Group 1 (RG1)** agents are not associated with disease in healthy adult humans.
- **Risk Group 2 (RG2)** agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are *often* available.
- **Risk Group 3 (RG3)** agents are associated with serious or lethal human disease for which preventive or therapeutic interventions *may* be available.
- **Risk Group 4 (RG4)** agents are likely to cause serious lethal human disease for which preventive or therapeutic interventions are *not usually* available.

Refer to the NIH Guidelines, available at the following WEB site, for additional details: NIH Guidelines.

Risk groups are the result of a classification of microbiological agents based on their

association with, and resulting severity of, disease in humans. The risk group of an agent is one factor considered in association with mode of transmission, procedural protocols, experience of staff, and other factors in determining the BSL in which the work will be conducted.

2.37 Security Risk Assessment: A required element of the HHS approval for select agent and/or toxin access. In order to become a registered individual, a person must first undergo a Security Risk Assessment (SRA) completed by the FBI, Criminal Justice Information Services Division (CJIS). This process is initiated through Saint Louis University's RO and requires that the individual complete form FD-961 and be fingerprinted. Upon completion of the SRA by CJIS, the information is communicated to HHS, where the final determination and approval for select and/or toxin access is made.

2.38 Select Agents and Toxins: Any one of a number of microorganisms or toxins listed by CDC at Select Agents and Toxins List. (Click on the hyperlinks for details.) The term "select agent" also includes nucleic acids that can produce infectious forms of any of the select agent viruses and recombinant nucleic acids that encode for the functional form(s) of any of the select agent toxins. Anticipated use of any select agents involving importation to Saint Louis University, or exportation from Saint Louis University, requires registration with the CDC-DRSC (or AgSAS as applicable) in advance, through the University's RO. Approval from the CDC-DRSC must be received through the RO before those activities can commence.

2.39 Select Agent Regulations: Regulations defining biological organisms and toxins that are of potential use to terrorists, and which must be registered with the CDC prior to importation to the University or exportation from the University, and for which there must be an established compliance program in place. ***These rules are codified at*** 42 CFR Part 73 - Select Agents and Toxins. (Click on hyperlink for details).

Non-compliance with the Select Agent Regulations can result in loss of NIH funding, as well as civil penalties. ***IMPORTANT! See the following WEB link for important details that may be applicable to your research:*** http://www.selectagents.gov/.

[Note: Select Agent regulations are also codified specific to Animals and Animal Products at 9 CFR Part 121 and specific to Agriculture at 7 CFR Part 331.]

2.40 Tier 1 Select Agents and Toxins: A subcategory of select agents and toxins that are subject to additional regulatory requirements, including increased security and personnel suitability assessments. Refer to the CDC Select Agents and Toxins list. Contact the Biological Safety Officer (and Responsible Official) for additional information.

3.0 IBC Membership

3.1 **IBC Membership:** Appointments made to the Institutional Biosafety Committee by the Vice President for Research shall include at least five members so selected that they collectively have experience and expertise in biohazard control and recombinant or synthetic nucleic acid molecule technology and the capability to assess the safety of research involving biohazardous agents (inclusive of all select agents), as well as recombinant or synthetic nucleic acid molecule research, including human gene transfer trials, and to identify any potential risk to public health or the environment. The Committee membership shall include:

A. Animal Containment Expertise: At least one individual with expertise in animal containment principles.

B. Assistant or Associate Biological Safety Officer (ABSO): The ABSO is an individual trained and experienced in microbiological techniques, and related safety procedures. The ABSO is appointed to the IBC as an alternate for the BSO, attends all IBC meetings as a non-voting member when the BSO is present. When the BSO is absent, the ABSO is a voting member and serves as Executive Secretary of the IBC. The ABSO also serves as the primary Alternate Responsible Official (ARO) for the CDC Select Agent Program.

C. Biological Safety Officer: The University's Biological Safety Officer, who is an individual trained and experienced in microbiological techniques, and related safety procedures. The BSO serves as the Executive Secretary of the IBC. The BSO also serves as the CDC Select Agent Program Responsible Official (RO) and the Institutional Contact for Dual Use Research (ICDUR). In the BSO's absence, or when there is a conflict of interest, the ABSO will serve as both a voting member and the Executive Secretary of the IBC.

D. Community Representatives: At least two members not otherwise affiliated with the University who represent the interests of the surrounding community with respect to health and protection of the environment. The extra-University members should be knowledgeable in the basic principles of microbiology and of recombinant or synthetic nucleic acid molecule technology or capable of assimilating these principles within the context of their applicability to the surrounding community and the general public.

E. Occupational Health Program Manager: The University's Occupational Health Program Manager, who is responsible for managing the Occupational Health Program, including vaccinations, respiratory protection program, as well as other important occupational health and compliance program elements and related compliance.

F. Director of Environmental Health and Safety: The University's Director of Environmental Health and Safety, who is responsible for overall implementation of University safety programs as related to protection of workers and the surrounding community from environmental risks.

G. IBC Manager: The IBC Manager is responsible for the conduct of routine IBC business functions, including screening IBC protocols for completeness and thoroughness, advising Principal Investigators, drafting meeting minutes and providing

other IBC support functions including administrative reviews and administrative approvals of simple personnel amendments and annual Continuing Reviews not involving substantive protocol changes (e.g., only involving simple personnel updates). The IBC Manager serves as a non-voting member of the IBC. The IBC Manager also serves as an Alternate Responsible Official (ARO) for the CDC Select Agent Program.

H. Plant Expertise: At least one individual with expertise in plant, plant pathogen, or plant containment principles, if research is to be conducted involving recombinant or synthetic nucleic acid molecules in plants.

I. Research Scientists: There shall be three or more research scientists with expertise in recombinant or synthetic nucleic acid molecule technology, biological safety, and physical containment in order to ensure the competence necessary to review and approve recombinant or synthetic nucleic acid molecule research activities.

J. Research Technical Staff: There shall be at least one member representing the laboratory technical staff.

K. Other ad hoc Members/Consultants: Additional individuals knowledgeable in institutional commitments and policies, applicable law, standards of professional conduct and practice, community attitudes, and the environment will be utilized as consultants or ad hoc members of the committee on an as-needed basis. When the institution conducts research involving gene drive modified organisms the institution must ensure that the IBC has adequate expertise (e.g., specific species containment, ecological or environmental risk assessment) using ad hoc consultants if necessary.

L. Alternate IBC Members: Alternate members may be appointed for certain IBC members who are unable to attend each meeting but for which their particular position or area of expertise is important for review and informed IBC approval of eIBC protocols. Alternate members may attend any IBC meeting, but only have voting privileges when fulfilling the role of Alternate IBC member for the primary member for which they are the appointed alternate member.

3.2 Chairperson and Vice Chairperson: The Vice President for Research shall appoint a Committee Chairperson and a Vice Chairperson. The Vice Chairperson shall be selected from among the members to fulfill the role of Acting Chairperson if the Chairperson is not available.

3.3 IBC Membership Terms: Appointment to the Institutional Biosafety Committee is for three years from date of appointment and is automatically extended until reappointed or until a successor is named and duly appointed.

3.4 Conflict of Interest: No member of the IBC or IRE may be involved (except to provide information requested by the IBC or IRE, respectively) in the review or approval of a project in which he/she has been or expects to be engaged or has a direct financial interest.

4.0 IBC Meetings

4.1 IBC Meeting Frequency:

A. Regular Meetings: In order to facilitate expeditious review of research investigator protocol applications, and to conduct other committee business, the IBC shall have regularly scheduled meetings, at least monthly.

B. Ad hoc Meetings: To enhance expeditious review of research protocol application submissions or resubmissions between regularly scheduled meetings, ad hoc meetings will be scheduled as practical, taking into consideration IBC membership availability.

C. Cancellation of Regular Meetings: In the event there is no committee business to discuss, the regularly scheduled IBC meeting may be cancelled prior to the meeting without notice to the University community. Notwithstanding cancellation of a regularly scheduled meeting, ad hoc meetings will be scheduled if needed.

4.2 IBC Meeting Quorum: A quorum is required to conduct routine committee business. To establish a quorum:

A. The number of committee members present must equal one more than half of the total number of voting members;

B. The Committee Chairperson or Vice Chairperson must be present;

C. The BSO (or his/her alternate) or the Director of Environmental Health and Safety must be present.

[Note: The BSO or ABSO MUST be present if the meeting agenda includes research at BSL-3, or large scale (greater than 10 liters).]

D. At least one community representative must be present.

E. Three (3) research scientist members.

F. If research involving animals is to be considered, at least one individual with expertise in animal containment principles is required to be present (this requirement may be met by one or more of the research scientist members if so qualified).

G. If research involving recombinant or synthetic nucleic acid molecules in plants is to be considered, at least one individual with expertise in plant, plant pathogen, or plant containment principles is required to be present.

H. If research involving gene drive modified organisms is to be considered, the IBC must have adequate expertise (e.g., specific species containment, ecological or environmental risk assessment) to thoroughly review the research, using one or more of the research scientist members if qualified, or ad hoc consultants if necessary.

5.0 IBC Functions

5.1 **IBC Review Functions:** The IBC functions to review research involving biological agents and toxins, including select agents, DURC and PEPP, serving as the University's IRE. The IBC also reviews recombinant or synthetic nucleic acid molecule research conducted at or sponsored by Saint Louis University for compliance with the NIH Guidelines and approves those research projects that are found to conform to the NIH Guidelines. The review shall include:

A. Independent assessment of the biosafety containment levels required by the BMBL and/or NIH Guidelines, as applicable.

B. Assessment of the facilities, procedures, practices, and training and expertise of personnel involved in research involving biological agents and/or recombinant or synthetic nucleic acid molecule research.

C. Notifying the PI of the results of the IBC's review and approval.

D. Periodically reviewing biohazard and recombinant or synthetic nucleic acid molecule research conducted at the University to ensure compliance with OSHA requirements, select agent regulations, the NIH Guidelines, and all other applicable safety standards and guidelines. These are commonly referred to as the annual Continuing Review (CR) and are supplemented with a recent laboratory biosafety inspection performed by the IBC Manager, ABSO and/or the BSO, depending on risk group and containment level.

E. Adopting emergency plans covering accidental spills and personnel contamination resulting from biohazards and recombinant or synthetic nucleic acid molecule research.

F. 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/OSP within 30 days, unless the IBC determines that a report has already been filed by the PI.

G. Referring PIs to the Chemical Hygiene Officer for oversight of hazardous chemicals, the Radiation Safety Officer for oversight of radioactive materials, and to the IACUC Manager and Veterinarian for issues related to animal science.

5.2 **IBC Review Decisions:** The IBC can make four types of decisions regarding a submitted protocol: 1) full approval, 2) contingent approval, 3) tabled, and 4) disapproval. In rare circumstances the IBC may, in consultation with the SLU Vice President for Research, request the PI to withdraw an IBC application or protocol. The committee will return protocols to the PI when they are either contingently approved or tabled, along with IBC review comments and/or requests to incorporate additional information or safeguards. (See Section 8.15 of these procedures for additional details regarding IBC approvals and other actions following review of IBC research application protocols.) If returned for revision, the PI may request in their response a review of points with which he/she disagrees, and a meeting between the PI and the IBC may be scheduled.

5.3 **Institutional Review Entity (IRE) DURC and PEPP Review Functions:** In its role as the "Institutional Review Entity" (IRE), the IBC reviews applicable research, consistent

with the expectations delineated in the *"United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential*". In as much as practical, the IRE meetings and discussions will occur separate from the IBC meetings and discussions, though both meetings may be held sequentially. IRE meeting minutes will be recorded separate from the IBC meeting minutes. *(See Section 11.0 for details.)*

6.0 Biological Safety Officer Functions

6.1 Biological Safety Officer: The Saint Louis University Biological Safety Officer, employed in the Environmental Health and Safety office, oversees the management of biosafety risks. The Biological Safety Officer is responsible for and/or oversees:

A. Inspections: Periodic inspection to ensure that laboratory biological safety standards are rigorously followed.

B. Reporting: Reporting to the IBC and the Director of Environmental Health and Safety any significant problems, violations of the NIH guidelines, and any significant research-related accidents or illnesses of which the Biological Safety Officer becomes aware unless the Biological Safety Officer determines that a report has already been filed by the PI.

C. Emergency Plans: Developing emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving biohazard agents, including select agents, and any recombinant or synthetic nucleic acid molecule research. The Biological Safety Officer will review at least annually the Select Agent Incident Response Plan and update as necessary.

D. Security Planning: Providing advice on laboratory security, as well as reviewing at least annually and updating as necessary the Select Agent Security Plan.

E. Technical Resources: Providing technical advice to PIs and the IBC on research safety procedures, protocol development, and best practices.

F. Responsible Official: Serving as the "Responsible Official" in assuring PI and University compliance with the select agent Regulations (42 CFR Part 73, 9 CFR part 121, 7 CFR Part 331).

G. IBC Membership Roster: Preparation and filing of the annual IBC membership report to NIH/OSP.

H. Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP) Oversight: Serving as the **I**nstitutional **C**ontact for **D**ual **U**se **R**esearch (ICDUR).

6.2 Annual Report to NIH/OSP: The IBC Manager, under the direction of the Biological Safety Officer and on behalf of Saint Louis University and the IBC, shall file an annual report with NIH/OSP which includes:

A. IBC Roster: A roster of all IBC members clearly indicating the Chairperson, contact person, Biological Safety Officer, plant expert (if applicable), animal expert, human gene therapy expert or ad hoc consultant (if applicable).

B. Biographical Sketches: Biographical sketches of all IBC members, including community members. The biographical sketch is a brief statement based on the IBC member's curriculum vitae. (Each IBC member is required to submit a current curriculum vitae at the time of appointment and at 3 year intervals, coinciding with reappointment.)

(Reference: NIH Guidelines, Section IV-B-2-a-(3).)

7.0 Principal Investigator Responsibilities & Resources

7.1 Principal Investigator Responsibilities – IBC Research Protocol Application: The cornerstone of the IBC review and approval process relies on the accuracy, thoroughness and completeness of the Principal Investigator in completing the IBC research protocol application, including the protocol summary portion, and other requested documents. It is expected that the PI will complete the application with the same level of quality, completeness, attention to details and diligence (including timely submission) that they expect their research deserves. Doing so will facilitate a more efficient review and approval of the PI's IBC application. The information and procedures which are provided below and in Section 8.0 which follows are intended to help guide the PI through an understanding of the process and how to be successful at submitting quality and timely applications.

7.2 PI Responsibilities –Limitations on Acquiring New Biological Agents: A PI may not acquire, take possession of, or introduce into any SLU laboratory a new biological agent until required IBC approval for use and/or storage of the new biological agent is attained. *(Refer to Section 2.6 for definition of biological agent.)*

7.3 PI Responsibilities – Commitment to Safe Practices: Each PI is required to commit to general biological safety practices listed in this section as well as in the IBC application, including biosafety practices that may be uniquely tailored to their specific research as detailed in their approved IBC research protocol application.

A. Laboratory Signage: The universal biohazard sign shall be posted by EHS on all doors accessing laboratories listed in the application.

B. Work Surfaces Decontamination: All work surfaces on which the biological agents are used, or which could possibly have become contaminated by the agent, shall be cleaned thoroughly, immediately after use and at the end of each day, with a disinfectant known to be effective against the biological agent or toxin.

C. Personal Protective Equipment (PPE):

(1) **Wearing of PPE:** Personal protective equipment prescribed by the Principal Investigator must be worn by anyone handling or working with the approved biological agent(s).

(2) **Laundering of Reusable PPE:** At no time shall protective clothing that has been used in the laboratory or contaminated street clothing be removed from a laboratory to be laundered in a private home. Reusable clothing that becomes contaminated shall be autoclaved or disinfected with an agent appropriate for the contaminating biological agent before it is laundered. On-site laundering or an appropriate commercial launder must be used. *(Contact Environmental Health and Safety for vendors.)*

(3) **Disposal of Single Use (Disposable) PPE:** Disposal of contaminated, disposable clothing shall be discarded only in approved waste receptacles.

(4) **PPE Safety Etiquette and Zone Control:**

(a) Protective laboratory wear, including gloves, shall not be worn outside of the laboratory into a corridor or any facility in which the biological agent is not being used.

(b) Gloved hands should be presumed to be contaminated and must not touch clean surfaces such as doorknobs, telephones, elevator buttons or computer keyboards.

(c) Gloves shall be removed and discarded any time that a tear, hole or other discontinuity in the glove material is observed.

D. Hand Washing: A hand washing sink shall be provided in each laboratory approved for working with biological agents. Hands will be thoroughly washed with antiseptic soap solution upon removing gloves. Hands shall be washed before exiting the laboratory.

E. House Vacuum Line Protection: House vacuum lines shall be protected from contamination by a trap of liquid disinfectant and a high-efficiency particulate air (HEPA) filter, as appropriate for the task. This is an inline filter that is placed between the house vacuum lines and the trap for liquid disinfectant. Hypochlorite-based disinfectants must be prepared fresh each day to maintain adequate potency to kill and/or inactivate biological agents. Manufacturers' instructions shall be followed on all other types of disinfectants for killing and/or inactivation of biological agents or toxins.

F. Biological Safety Cabinet Certification: The proper functioning of all biological safety cabinets shall be certified at least annually and any time the cabinet is relocated by a person qualified to certify such devices.

G. Design Procedures to Eliminate or Minimize Creation of Aerosols and/or Splash Droplets and Utilize Appropriate Containment:

(1) **Use of Biosafety Cabinet:** When procedures with a potential for creating infectious aerosols or splashes involving pathogens are conducted *(e.g. pipetting, centrifuging, grinding, blending, shaking, mixing, sonicating, opening containers of infectious materials, inoculating animals intranasally, and harvesting infected tissues from animals or eggs, etc.)*, properly maintained biological safety cabinets must be used. Procedures that can cause aerosolization of a pathogen (e.g. use of syringes with hypodermic needles, or other devices, etc.) shall not be used unless no other alternative exists. *[**Note:** High concentrations or large volumes of infectious agents may be centrifuged in the open laboratory only if using sealed rotor heads or centrifuge safety cups.]*

(2) **Alternative Proposals:** If procedures with a potential for creating infectious aerosols or splashes cannot be performed in a biological safety cabinet, another appropriate physical containment device and/or use of appropriate personal protective equipment (e.g. suitable masks, face shield, etc.) may be proposed, subject to an appropriate risk assessment and IBC approval. During such procedures, laboratory traffic through the area should be minimized, and laboratory doors should remain closed throughout the procedure.

H. Limited Use and Disposal of Sharps Devices:

(1) **Limitation of Use:** The use of sharps devices, such as needles or scalpels shall be limited to procedures for which no other alternative exists.

(2) **Acceptable Types of Needles and Syringes:** Where hypodermic needles and syringes **must** be used to inject or aspirate potentially infective material (such as into or from animals or diaphragm bottles), only needle-locking syringes or one-piece syringe/needle units shall be used.

(3) **Removal of Reusable Needles:** Where there is no satisfactory alternative to using a reusable needle, removal of the needle from the syringe body must be performed by grasping the hub of the needle with a needle holder, hemostat, or other clamping device which will not reasonably permit the fingers of the operator to contact the sharp point of the needle.

(4) **Recapping of Needles:** Recapping of needles is not recommended. However, if absolutely necessary, a needle removal/recapping device (preferred method) or the single-handed scoop method must be used.

(5) **Sharps Disposal:** Any sharp object must be disposed of in a clearly marked, puncture-resistant container (either of red color or bearing a biohazard sign) as near the location of use as possible. Contaminated disposable needles shall not be sheared, bent, or removed from the syringe before being placed in the sharps container.

I. Inventory of Biological Agents and Cold Storage Units:

(1) **Inventory Tracking System:** Each investigator will devise and implement an inventory tracking system for biological agents or toxins specified in this application such that the investigator and/or his/her staff have the capability to readily assess the loss or theft of these biological agents or toxins.

(2) **Reporting Loss or Theft:** The investigator and/or his/her staff will report the loss or theft of these biological agents or toxins to the Environmental Health and Safety office within one business day of the investigator's determination that a loss or theft has occurred.

(3) **Cold Storage Units:** Cold storage units shall be inspected and reviewed at least annually by the PI to assure that biological agent inventory records are accurate and that any containers with unidentified contents are promptly evaluated, and their disposition decided. Certification of the annual cold storage unit(s) review shall be provided to the IBC during the annual update to approved IBC research protocol applications.

J. Basic Laboratory Safety Hygiene: Eating, drinking, smoking, application of cosmetics, and the insertion or removal of contact lenses are **SPECIFICALLY PROHIBITED** in any laboratory in which biological agents or toxins are in use or in which biological agents or toxins have recently been used or stored. **No storage of food or beverages shall be permitted in any room in which the Universal Biohazard symbol is displayed on the door.**

K. Security: The PI and his/her staff shall adhere to all security requirements and procedures as detailed elsewhere in these Biosafety Procedures and in applicable

approved IBC research protocol applications and in Select Agent and Toxin security plans if applicable.

L. Training: The PI shall assure that the PI and his/her laboratory staff remain current and up-to-date on all required safety training, including PI provided lab procedure specific safety training, as well as Environmental Health and Safety provided training, and on-line training (including annual Bloodborne Pathogens training if applicable) as described in sections 8.12 and 8.13.

7.4 PI Resources: In addition to EHS staff, specifically, the BSO, ABSO, and the IBC Manager, there are a number of resources available to PIs that provide relevant details of PI responsibilities, depending on the type of research to be conducted.

A. Research Involving Recombinant or Synthetic Nucleic Acid Molecules:

(1) PIs submitting IBC Applications for research involving recombinant or synthetic nucleic acid molecules must comply with Section 8.0 and Section 9.0 of these procedures, and all applicable elements of the NIH Guidelines (https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf).

B. Research Involving Select Agents and Toxins:

(1) PIs submitting IBC Applications for Research involving select agents or toxins must comply with Section 8.0 and Section 10.0 of these procedures, and all applicable elements of select agents and toxins regulations.

(2) Federal Select Agent Program Website: https://www.selectagents.gov/

(3) Saint Louis University Select Agent Program Specific Requirements: Contact the University's Biological Safety Officer and Responsible Official.

C. Research Involving Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP):

(1) PIs submitting IBC Applications for Research involving DURC or PEPP must comply with Section 8.0 and Section 11.0 of these procedures, and all applicable elements of the U*nited States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential*. This includes performing an assessment for Category 1 and Category 2 research as outlined in the US Government Policy.

(2) Saint Louis University DURC and PEPP Review Program Specific Requirements: Contact the University's Biological Safety Officer and Institutional Contact for Dual Use Research.

(3) All IBC Applications for research involving DURC or PEPP will be reviewed in accordance with the *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential.*

D. Environmental Health and Safety (EHS) Staff:

(1) **IBC Manager:** The IBC Manager is available to answer questions and guide the PI through the application process. The IBC Manager can be emailed directly at: eIBC@slu.edu.

(2) **Biological Safety Officer (BSO):** The BSO contact information is available on the EHS website staff directory.

(3) **Assistant (or Associate) Biological Safety Officer (ABSO):** The ABSO contact information is available on the EHS website staff directory.

EHS Staff Directory: https://www.slu.edu/research/faculty-resources/research-integrity-safety/environmental-health-safety/ehs-staff.php

E. EHS Website: Several important resources are available on the IBC Related Downloads page of the EHS Website (https://www.slu.edu/research/faculty-resources/research-integrity-safety/environmental-health-safety/index.php). These include:

(1) **Exposure Control Plan for Bloodborne Pathogens**

(2) **Policy on the Use of Human Cell Lines**

(3) **Policy on Supplied Natural Gas in Recirculating Biological Safety Cabinets**

F. Additional References: See also Section 13.0 of these procedures for additional references.

8.0 Principal Investigator Procedures IBC Application

8.1 Grant Applications or Contracts Requiring Prior IBC Notification or Approval Before Submitting to Granting Agency:

A. Select Agents and Toxins – Prior Notification of the BSO/RO Required: Any grant application or contract involving select agents or toxins requires prior notification to the Biological Safety Officer (also designated as the Responsible Official) of the intent of the principal investigator to submit a protocol for use of that biological agent in research. *(See Section 10.0 of these procedures for further details.)*

B. Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP) – Prior Approval of IBC (IRE) Required:

(1) Any grant application or contract that involves potential life sciences dual use research of concern (DURC) or Pathogens of Enhanced Pandemic Potential (PEPP) requires prior submission of an IBC Research Protocol Application to the IBC (IRE) and full approval by the IBC (IRE) before submission of the grant application or contract to the funding agency. *(See Section 11.0 of these procedures for further details.)*

(2) The BSO (also appointed as the Institutional Contact for Dual use Research (ICDUR)) must be consulted early in the process to facilitate expedient IBC (IRE) review of the IBC application involving DURC and PEPP.

(3) Only the BSO, also designated as the ICDUR, may provide IRE documents to funding agencies. *(See Section 11.4. J. of these procedures for additional details.)*

8.2 Electronic IBC (eIBC) Research Protocol Application: Effective April 1, 2016, only eIBC research protocol applications are accepted (Link: https://eibc.slu.edu). Please contact the IBC Manager (eibc@slu.edu) for instructions for logging in to eIBC, creating an eIBC protocol, and other information

8.3 Types of IBC Research Protocol Application Submissions: It is the PI's responsibility to assure that the appropriate application is timely submitted, in accordance with established timelines, and that none of the research for which IBC approval is required is initiated until final IBC approval is received. It is also the PI's responsibility to assure that their approved IBC research protocol applications do not expire before they submit their renewal application and it is approved by the IBC.

A. New IBC Research Protocol Application: IBC Research Protocol Applications by new faculty, or for new projects by existing faculty, must be submitted using the electronic IBC Research Protocol Application. In accordance with procedures elsewhere in this policy, the research may not be initiated until full approval is received from the IBC. Full approval is valid for 5 years from the approval date and expires at the end of 5 years unless an IBC research protocol renewal application is submitted and approved prior to the expiration date.

(1) **Timeline for Submission:** New IBC research protocol applications must be submitted *at least 3 weeks prior to the next regularly scheduled IBC meeting* in

order to be considered at that meeting if it is prepared in accordance with Section 7.0 of these procedures. Consideration of a new IBC research protocol application at an IBC meeting is not a guarantee of approval at that IBC meeting. *Research shall not be conducted until full IBC approval is received.*

(2) **Full IBC Approval:** New IBC research protocol applications require full IBC review in order to be approved.

B. Amendment to Approved IBC Research Protocol Application: Requests to amend an approved IBC research protocol application must be submitted to the IBC and be approved prior to initiating a new line of investigation. All amendments to previously approved IBC research protocol applications are made through the eIBC software.

(1) **Timeline for Submission:** Amendment applications must be submitted well in advance of *the next regularly scheduled IBC meeting* in order to be considered at that meeting.

(2) **Administrative Approval by the IBC Manager, Biological Safety Officer, or Assistant/Associate Biological Safety Officer:**

(a) Add/delete lab personnel (Note BSO must approve all BSL-3 users).

(b) Updated study documents when no new methods/agents used.

(3) **Administrative Approval by the Biological Safety Officer – Simple Amendments:** Simple amendments are those that are requesting amendment of an existing approved protocol for one or more of the reasons listed below.

(a) Add/delete lab A/BSL3 personnel.

(b) Add new cell lines from sources not known to be infectious from a category of equal or lower risk than already approved by the IBC.

(c) Add laboratory in contiguous space (non-contiguous space may need to be approved by the full committee).

(d) Delete laboratory.

(e) Delete use of animals.

(f) Delete research involving recombinant or synthetic nucleic acid molecules.

(g) Delete use of select agents or toxins, or other biohazardous agents.

(h) Termination of research/closing of an IBC protocol (other than DURC/PEPP).

Simple amendments are reviewed by the IBC Manager and approved administratively by the BSO. This permits new faculty or staff to immediately begin work with already approved biological materials under an approved PI, or an additional location to be used, immediately after approval by the Biological Safety Officer. Similarly, decommissioning of a laboratory (if applicable) may begin immediately following the Biological Safety Officer's approval of the amendment terminating research.

(4) **Interim Approval by the Biological Safety Officer:** The BSO in consultation with the IBC Chairperson or Vice Chairperson, may approve research under the

circumstances specified below.

(a) Add a new risk group 1 agent or additional risk group 2 specific strain to an already approved biological agent category (e.g., adding a new H3N2 risk group 2 influenza strain to an IBC protocol with other H3N2 strains already listed and approved) provided that no new procedures are added.

(b) Adding a new disinfectant and/or disinfection process provided that documentation of efficacy against the specific agent(s) is submitted.

(c) Making minor changes to previously approved research with biological agents and recombinant or synthetic nucleic acids which do not pose increased risks.

(d) Receiving a new biological agent for storage only.

Amendments granted interim approval by the BSO will be reviewed and approved by the IBC at the next scheduled meeting.

(5) **Full IBC Approval – All Other IBC Research Protocol Amendments:** All other amendments to existing approved IBC research protocol applications, including those listed below, require full IBC review and approval before the research may commence.

(a) Add research involving additional recombinant or synthetic nucleic acid molecules, or other biological agents or toxins (other than those specified above under "(4) Interim Approval by the Biological Safety Officer".

(b) Add/delete the use of human subjects in conjunction with recombinant or synthetic nucleic acid molecules or biohazardous agents.

(c) Add use of CDC select agents and/or toxins, including DURC and PEPP.

(d) Add use of animals.

(e) Add use of radioactive materials.

(f) Add use of chemo-therapy agents.

C. <u>Renewal</u> IBC Research Protocol Application: Approved IBC research protocol applications will be valid for a period of 5 years from the date of approval without requiring renewal. Renewal IBC research protocol applications require submission of the full electronic IBC Research Protocol Application, inclusive of updates made through past amendments and any other new information. Tools are available in eIBC to facilitate the renewal application. Each renewal application shall also include a statement certifying that the PI's cold storage units have been inspected and reviewed within the past year, that inventory records are accurate, that any containers with unidentified contents were promptly evaluated, and their disposition determined. (See Section 7.3 I. (3) above.)

(1) **Timeline for Submission:** Renewal IBC research protocol applications should be submitted <u>*at least 90 days prior to the 5 year expiration date*</u> of the original IBC approval of the original new application or previous renewal application. IBC research protocol renewal applications received under 90 days in advance of the expiration date are at increased risk of not being approved before the expiration

date. *Previously approved research shall not be conducted under an expired approval*.

(2) **Automated eIBC Generated Email Reminders:** Automated reminders generated by eIBC will be emailed to the PI in advance of the pending expiration date.

(3) **Full IBC Approval:** Renewal IBC research protocol applications require full IBC review and approval prior to the expiration date. Failure to obtain the necessary approval by the expiration date requires termination of previously approved research. No new research requiring IBC approval may be conducted until a new IBC research protocol application is submitted and approved. In extenuating circumstances, the IBC Manager in consultation with the BSO and IBC Chairperson may administratively provide a short extension of an approved IBC protocol provided that a 5 year renewal has been submitted by the PI and is under review by the IBC.

D. Annual Continuing Review to Approved IBC Research Protocol Application:

(1) eIBC: Automated annual update reminders generated by eIBC will be emailed to the PI in advance of each anniversary date of the approval. Any needed IBC research protocol application updates will be required to be submitted through eIBC, specifying in an amendment any changes in procedures, laboratory staff, or other relevant information updates that are needed. Updated training records for all laboratory personnel are required for all Annual Continuing Reviews. If no changes are needed, the PI will need to submit an amendment stating that there are no changes. Each annual update shall also include a statement certifying that the PI's cold storage units have been inspected and reviewed within the past year, that inventory records are accurate, that any containers with unidentified contents were promptly evaluated, and their disposition determined. (See Section 7.3 I. (3) above.)

(2) Timeline for Submission: Substantive annual IBC research protocol application updates must comply with the submission timeline for the application type being submitted (amendment or new application) and be submitted prior to the original approval anniversary date each year. Non-substantive annual IBC research protocol application updates (stating that no changes are necessary) must be received *prior to the approval anniversary date each year*.

(3) Approvals: Continuing Reviews with minor changes to personnel and training records will be administratively reviewed and approved by the IBC Manager. Continuing Reviews considered as simple amendments as outlined in section 8.3.B.(2) and 8.3.B.(3) may be approved administratively, or on an interim basis by the BSO pending IBC review and approval at the next full IBC meeting [8.3.B.(4)]. All other Continuing Reviews will be reviewed by the full committee at the next scheduled IBC meeting.

8.4 Registration of Work with Potentially Non-Hazardous Biological Materials: Work with non-hazardous biological materials *(as determined by the Biological Safety Officer in consultation with other subject matter experts)*, including research involving recombinant

or synthetic nucleic acid molecules that are exempted under Section III-F of the NIH Guidelines, can be filed with the IBC simultaneous with beginning that work by submitting a "Work with Non-Hazardous Biological Materials IBC Registration". Submission of this registration document via email to eIBC@slu.edu permits faculty or staff to immediately begin work with the biological materials after the Biological Safety Officer provides documented approval of the registration. The registration document is presented to the IBC during the next regularly scheduled IBC meeting.

8.5 Principal Investigator Review Guidance: Prior to undertaking research with a biological agent *(as defined in Section 2.5)* the investigator must evaluate the hazards of the agent(s) that will be used. Specific categories and guidance documents are listed below.

A. Determining Risk Group Assignment of Biological Agents: In evaluating the hazards of the biological agents, the PI must determine the risk group assignment of each biological agent. See Section 2.0 Definitions, paragraph 2.28. A useful reference is the American Biological Safety Association (ABSA) Risk Group Database: https://my.absa.org/tiki-index.php?page=Riskgroups.

B. Organisms Pathogenic to Humans: A primary reference for organisms that are pathogenic to humans is the most recent edition of the Center for Disease Control-National Institutes of Health publication: *Biosafety in Microbiological and Biomedical Laboratories*.

If the experiment involves the use of an organism pathogenic to humans, the principal investigator must obtain a copy of the *Saint Louis University Pathogen Exposure Control Plan* to use as a guide for training employees and for writing the protocol to be submitted to the committee.

C. Organisms Potentially Pathogenic to Warm-Blooded Nonhuman Species: For organisms that might be pathogenic to warm-blooded, nonhuman species the investigator is advised to consult with the veterinary pathologist of the Department of Comparative Medicine and the Biological Safety Officer.

D. Vectors to Be Used to Incorporate Foreign Genomic Material: See paragraph 8.5 E. below (Research Involving Recombinant or Synthetic Nucleic Acid Molecule Research).

E. Research Involving Recombinant or Synthetic Nucleic Acid Molecule Research: Before using a vector to incorporate foreign genomic material, Section 9 must be reviewed and followed and the latest *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* must be consulted. *(See Section 7.4 for references.) See Section 9 for details on completing applications involving Select Agents and Toxins.*

F. Select Agents and Toxins: Before obtaining or using select agents or toxins, the planned research must be provided preliminary review by consulting with the University's Biological Safety Officer and Responsible Official. *(See Section 7.4 for additional references.) See Section 10 for details on completing applications involving Select Agents and Toxins.*

G. Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP): *See Section 7.4 for additional references. See Section 11 for details on completing IBC applications involving DURC and PEPP.*

8.6 Risk Groups: The PI must identify the Risk Group (RG 1, 2 or 3) of each biological agent in the IBC Research Protocol Application. Risk groups are the result of a classification of microbiological agents based on their association with, and resulting severity of, disease in humans. The risk group of an agent is one factor considered in association with mode of transmission, procedural protocols, experience of staff, and other factors in determining the BSL in which the work will be conducted. Refer to Section 2.0 Definitions for details.

8.7 Containment Levels: The PI must specify the proposed containment level (BSL-1, 2 or 3) of each biological agent in the IBC Research Protocol Application.

A. BSL-1 or BSL-2 Containment: Experiments requiring BSL-1 or BSL-2 containment will be expected to be carried out only in laboratories in which the requirements for the respective level of containment are carefully observed. Refer to the BMBL for further details at: Biosafety in Microbiological and Biomedical Laboratories

B. BSL-3 Containment: Organisms requiring BSL-3 containment will be approved for use at Saint Louis University only in facilities that have the IBC's approval as meeting BSL-3 standards. Refer to the BMBL for further details at Biosafety in Microbiological and Biomedical Laboratories

C. BSL-4 Containment: Organisms classified as requiring CDC Biosafety Level 4 (BSL-4) conditions can be carried out only within a few specialized laboratories in the United States and *will not be conducted at Saint Louis University*.

8.8 Security of Biological Agents:

A. Physical Facility Security Overview: All biological agents, including recombinant or synthetic nucleic acids and all select agents, must be secured against unauthorized access or unauthorized removal at all times. To this extent, the elements of physical facility security listed in the following table shall be in place for the particular agents as specified.

Physical Facility Security Overview		
Element of Physical Facility Security	**Select Agents**	**Other Biological Agents**
Building Security: Building will be a "controlled access" building 24 hours per day, 7 days per week	Mandatory	Strongly Recommended
Laboratory Security: All laboratory entrances secured 24 hours per day, 7 days per week when laboratory staff are not physically present in the laboratory. [1]	Mandatory	Mandatory
Biological Agent Security: All agents physically locked within their storage unit, e.g. refrigerator, freezer, cabinet, etc. when not in use.	Mandatory	Strongly Recommended

Physical Facility Security Overview		
Element of Physical Facility Security	**Select Agents**	**Other Biological Agents**
[1] *Routine housekeeping, maintenance and other services must be performed during daytime hours when a laboratory staff member is likely to be present in the laboratory and EHS and other personnel capable of responding to incidents are likely to be onsite*		

B. PIs Using or Contemplating Use of Select Agents and/or Toxins:

(1) **Saint Louis University Select Agent & Toxins Security Plan:** Please contact the Biological Safety Officer and Responsible Official for the Select Agent Program to obtain an up-to-date copy of the Saint Louis University Select Agent & Toxins Security Plan. Refer to the Saint Louis University Select Agent & Toxin Security Plan for details.

(2) **BMBL:** In addition, Appendix F to the BMBL provides security recommendations specific to Select Agents. For further details, refer to Section VI of the BMBL, available at the following link: Biosafety in Microbiological and Biomedical Laboratories

C. Data Security Overview: All data pertinent to select agents, DURC and PEPP inventory, access and security systems shall be securely stored. *See Section 10 and 11 for additional information on data security for research involving select agents and toxins and/or DURC/PEPP, respectively.*

8.9 Transport of Biological Agents or Toxins Within or Between SLU Buildings:

A. Internal Transportation (Ambulatory/Hand Carried or Cart):

(1) PIs are required to specify whether any biological agents, including biohazard waste, are to be transported via a corridor or other thoroughfare which is used by person not directly working with the agent.

(2) PIs are required to describe in detail the precautions that will be employed to minimize breakage of containers and release of biological agents or toxins during transport within these areas and describe in detail the primary and secondary containment to be used. In general, both the primary and secondary containment vessels must be secured with a lid, and be puncture resistant and leak-proof and labelled with a biohazard sticker.

B. External Transportation (Ambulatory/Hand Carried or Cart): Any intent to transport biological agents between campus buildings must also be addressed in the IBC application.

8.10 Packaging, Shipment, Export, Receipt & Importation of Biological Agents

A. Packaging, Shipment, and Training (Domestic or International):

(1) **DOT and IATA Compliance:** No person shall handle, offer for transport, or transport biological agents unless they are trained in accordance with Department of Transportation (DOT) and International Air Transport Association (IATA) Dangerous Goods Regulations.

(2) **Function Specific Training:** Function specific training is required for packaging, labeling, manifesting, and/or transport of biological agents, including clinical specimens.

(3) **Two to Four Week Advanced Notice:** To arrange for the necessary training, contact the Biological Safety Officer at least two weeks in advance of anticipated need to ship a biological agent (and at least four weeks in advance if shipping internationally).

(4) **Export of Biological Agents Internationally:** The export of a biological agent internationally may require a license or permit from the Department of Commerce and registration with the CDC.

B. Importation of Biological Agents from a Foreign Country: Prior to initiating importation of a biological agent from any foreign country, the PI must notify the BSO well in advance of the need to receive the agent. In order to legally import many biological agents, compliance with the following may be required:

(1) An import permit issued by the Director of the CDC must be obtained by the importer.

(2) The importer (PI) is legally responsible for assuring that the foreign personnel package, label, and ship the infectious materials in accordance with the following federal regulations:

(a) U.S. Public Health Service regulations (42 CFR Part 72 – Interstate Shipment of Etiologic Agents)

(b) U.S. Department of Transportation (DOT) regulations (DOT 49 CFR Part 173 – Transportation of Etiologic Agents)

(c) International Air Transport Association (IATA) Dangerous Goods Regulations.

(3) A United States Department of Agriculture (USDA) permit and/or a United States Department of Fish and Wildlife Service (USFWS) permit may be required.

(4) If transported in a private vehicle, the "SLU Quick Reference: MOT Exception for Transporting Category B Biological Agents" document should be referenced, attached and followed.

C. Distribution of Imported Biological Agents within the United States:

(1) **Four Week Notice:** The BSO shall be contacted by the PI <u>at least four weeks in advance</u> of the anticipated need to ship a biological agent internationally or to distribute an imported biological agent domestically.

(2) **Distribution Permits:** The distribution of an imported biological agent within the United States may require a permit issued by the CDC Director and registration with the CDC and/or APHIS.

D. Receipt: Prior to initiating an action resulting in receipt of a biological agent from any external or internal supplier (i.e., includes other Saint Louis University faculty, staff or students) approval of the IBC is required, as delineated below:

(1) If IBC approval is required prior to working with the biological agent, and such approval has not been obtained.

(2) If IBC approval has already been granted to work with the biological agent, further approval of the IBC is not required; however if the agent is being obtained from a foreign supplier, the requirements delineated in Section 8.10.B. and/or Section 8.10.C. above shall be met specific to the agent and supplier in question.

8.11 Personnel Protective Equipment (PPE) and Splash/Spill/Exposure Procedures:

(1) PIs must specify in the IBC Research Protocol Application the appropriate personnel protective equipment (PPE) to be worn by personnel working with the biological agents or toxins

(2) PIs must commit to following established splash and exposure control procedures.

(3) In addition, the PI must be cognizant of and include in the IBC Research Protocol Application the signs and symptoms of infection with, or exposure to the biological material or other specified hazard.

8.12 Required Training: It is the responsibility of the PI to assure that all required training has been completed and appropriately documented for each individual named in the IBC Research Application or IBC Amendment. Regulatory agencies require that all training be documented in writing with date, names of participants and their signatures, and a list of topics covered.

A. PI Provided "eIBC Protocol-Specific Training": Anyone performing experiments with recombinant or synthetic nucleic acid molecules, or other biological agents (including select agents and toxins) hazardous to man or the environment, must be well trained in proper microbiological technique to ensure minimization of risks. The assurance of proper training is the obligation and responsibility of the PI and laboratory supervisor of the facility in which the biological agents are used. This training includes reading all eIBC protocols on which the personnel are listed. Training shall be documented on the **Lab Specific Biosafety Training Form:** (https://www.slu.edu/research/faculty-resources/research-integrity-safety/documents/biosafety-lab-specific-training-outline.pdf).

B. Environmental Health and Safety (EHS) Provided Training: EHS provides certain types of generalized safety training. A listing of training offered is available on the EHS website training page (click on link): https://www.slu.edu/research/faculty-resources/research-integrity-safety/environmental-health-safety/training.php

C. All required training must be completed and up-to-date prior to filing of a New, Amendment, Renewal IBC Research Protocol Application, as well as during annual Continuing Reviews. Failure to do so will result in delays in full approval of the application and/or prevent submission of an eIBC application.

8.13 PI Certification and Agreement for All IBC Research Protocol Application Submissions: The PI shall certify upon submission of each IBC research protocol application the following.

A. **Accuracy and Completeness of Submission:** The PI certifies that the application is accurate and complete.

B. **Compliance with Federal, State and University Requirements:** The PI agrees to comply with federal, state and university requirements pertaining to the handling, shipment and transfer of biological materials.

C. **Training of All Workers Involved in the Project:** The PI agrees to accept responsibility for the training of all workers, students and volunteers involved in the project.

8.14 Additional Certification by PI and All Lab Personnel: Following Full IBC approval, the approved protocol must be read by the PI and each person listed as personnel on the protocol. The PI certification of the approved IBC research protocol application affirms that:

A. **Awareness:** The personnel are aware of the biological agents in the clinic or laboratory environment in which they work.

B. **Follow Precautions:** The personnel will abide by the precautions stipulated and agreed to by the PI and approved by the IBC to minimize the probability of release of the biological agent and/or any exposure to the biological agent.

C. **Informed of Symptoms of Infection or Exposure:** The personnel have been informed of the symptoms that would occur if they became infected with or were exposed to any biological agent or other hazard specified within the approved IBC Research Protocol Application.

D. **Report Spills and Exposures:** The personnel will promptly report any spill, release, and potential or known occupational exposures to their supervisor and the Environmental Health and Safety office, in accordance with the Emergency Spill Procedures specified within the approved IBC research protocol application.

E. **If the approved eIBC protocol includes Select Agents, ABSL-3 or BSL-3 work,** the IBC Manager will email a pdf of the approved eIBC protocol and special acknowledgment form to each person listed on the protocol. The PI is responsible for ensuring that all individuals listed on the eIBC Protocol review the protocol and sign the special acknowledgement form.

8.15 IBC Approvals and Other Actions: Experiments involving recombinant or synthetic nucleic acid molecules, including gene transfer, select agents or other potentially hazardous agents covered by the Policy on Institutional Biosafety Committee (IBC) and these companion procedures and for which IBC approval is required before experiments are initiated will be reviewed by the IBC at a meeting at which a quorum is present. No experiments requiring IBC approval may be initiated until full approval is attained. Following IBC review, the following actions may be taken:

A. **Full Approval:** Full approval will be granted by the IBC if there are no outstanding issues. Research is approved to begin.

B. **Contingent Approval:** Contingent approvals may be given by the IBC for protocols that require minor revision. Minor revisions involve changes to the protocol that can be

prescribed by the IBC or additional information that is specified by the IBC. Full IBC approval is dependent upon the contingencies being met by the PI in an updated resubmitted protocol. Responses to contingently approved IBC Research Protocol Applications are reviewed by the IBC Manager and the Biological Safety Officer to verify that the contingencies have been met. Upon such verification, the protocol is considered fully approved, and research can begin. If it is determined that the contingencies have not been met, the IBC Manager may communicate directly with the applicant or, in some cases, may redirect the protocol to the IBC Chairperson or the full IBC for final review and approval. No research may commence until the IBC research protocol application receives full IBC approval upon satisfaction of the contingencies and communication of same from the IBC Manager. Previously approved research must terminate if full IBC approval has not been received by the expiration date, unless an extension has been granted administratively by the IBC Manager in consultation with the BSO and IBC Chair for extenuating circumstances.

C. Tabled: When an IBC application requires substantive revisions, significant additional information, and/or major clarifications, decisions regarding the IBC application will be tabled pending resubmittal with responses to requests for substantial modifications. A tabled IBC application will require full IBC review (i.e., the modified protocol must be returned to the Committee for further review). PIs must submit the revised IBC application with the requested information. No research may commence until the IBC application receives full IBC approval. Previously approved research must terminate if full IBC approval has not been received by the expiration date, unless an extension has been granted administratively by the IBC Manager in consultation with the BSO and IBC Chair for extenuating circumstances.

D. Disapproval: In some instances, the IBC may disapprove an IBC Research Protocol Application or other document with finality. This may involve a poorly constructed application with risks that clearly outweigh possible benefits of research findings. It could also involve an IBC decision in its capacity as the IRE in reviewing DURC/PEPP, or other high risk – high hazard research. (See Section 11.0)

E. External Approval Pending: In the case of experiments requiring external review by an outside agency, full IBC approval may be contingent upon approval being granted by the outside agency.

F. Withdrawal: In rare circumstances the IBC may, through coordination with the SLU Vice President for Research, request the PI to withdraw an IBC application or protocol.

G. Suspension: When significant issues related to safety and research compliance arise, the IBC may suspend a specific IBC protocol. Because of the potential time-sensitive nature of such issues, suspension of an IBC protocol can be undertaken by the BSO, the IBC Chairperson, or the IBC Vice-Chairperson. The purpose of a protocol suspension would be to temporarily halt research with a biological agent (or agents) until the PI adequately addresses and remedies the cited concerns.

8.16 Laboratory Inspections and Post-Approval Monitoring: The IBC has an obligation to ascertain that experiments with infectious or recombinant organisms are safely managed.

A. The Biological Safety Officer or other Environmental Health and Safety staff conduct annual safety audits of facilities in which these types of experiments are performed at any time with or without prior notice. Such inspections will include an assessment that commitments made by the PI and staff in the approved IBC application protocol are being met.

B. A subset of IBC Protocols will be evaluated using Post Approval Monitoring visits during which the Biological Safety Officer and/or other Environmental Health and Safety staff will meet with the PI to determine compliance with the targeted IBC Protocol. Areas of non-compliance (i.e., deficiencies) identified during these inspections must immediately be addressed by the PI. Failure to address items of non-compliance in a timely manner may result in suspension of the IBC Protocol.

C. The IBC encourages semi-annual self-inspections to be conducted using the inspection forms available from the IBC Manager (eibc@slu.edu) as best practice to ensure safety and compliance between annual inspections.

9.0 Recombinant or Synthetic Nucleic Acid Molecule Research

9.1 Research Involving Recombinant or Synthetic Nucleic Acid Molecules Requiring IBC Review: Types of recombinant DNA experiments that require approval by the IBC prior to initiation include, but are not necessarily limited to, the following:

A. Experiments Involving the Deliberate Transfer of a Drug Resistance Trait to Microorganisms that Are Not Known to Acquire the Trait Naturally, if Such Acquisition Could Compromise the Use of the Drug to Control Disease Agents In Humans, Veterinary Medicine, Or Agriculture: Experiments involving the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture require IBC approval and NIH Director approval before initiating the experiments. *(See NIH Guidelines, Section III-A-1-a.)*

B. Experiments Involving the Cloning of Toxin Molecules with An LD_{50} of Less than 100 Nanograms per Kilogram Body Weight: Experiments Involving the Cloning of Toxin Molecules with An LD_{50} of Less than 100 Nanograms per Kilogram Body Weight require IBC approval. Specific experiments already approved under this section may be obtained from the Office of Science Policy, National Institutes of Health, preferably by submitting a request for this information to: NIHGuidelines@od.nih.gov; additional contact information is also available here and on the OSP website (www.osp.od.nih.gov). *(See NIH Guidelines, Section III-B-1.)*

C. Experiments Involving the Deliberate Transfer of Recombinant or Synthetic Nucleic Acid Molecules, or DNA or RNA Derived from Recombinant or Synthetic Nucleic Acid Molecules, into One or More Human Research Participants: Experiments involving the deliberate transfer of recombinant or synthetic nucleic acid molecules, DNA or RNA derived from recombinant or synthetic Nucleic Acid Molecules, or specific types of synthetic nucleic acids into one or more human research participants require IBC approval and all other applicable institutional and regulatory authorization(s) and approvals have been obtained. *(See NIH Guidelines, Section III-C-1.)*

D. Experiments using Risk Group 2, Risk Group 3, Risk Group 4, Restricted Agents or Select Agents as Host-Vector Systems: Experiments using Risk Group 2, Risk Group 3, Risk Group 4, Restricted Agents (as listed in the NIH Guidelines or BMBL) or Select Agents as host vector systems require IBC approval before initiating the experiments. Furthermore, containment conditions for experiments involving the introduction of recombinant or synthetic nucleic acid molecules into restricted agents shall be set on a case-by-case basis following NIH OSP review. A U.S. Department of Agriculture - Animal and Plant Health Inspection Service (USDA/APHIS) permit is required for work with plant or animal pathogens (see Section V-G and V-M, Footnotes and References of Sections I-IV).. *(See NIH Guidelines, Section III-D-1.)*

E. Experiments in which DNA From Risk Group 2, Risk Group 3, Risk Group 4, Restricted Agents or Select Agents is Cloned Into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems: Experiments in which DNA from Risk

Group 2, Risk Group 3, Risk Group 4, Restricted Agents (as listed in the NIH Guidelines or the BMBL) or Select Agents is cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems require IBC approval before initiating the experiments. *(See NIH Guidelines, Section III-D-2.)*

F. Experiments Involving the Use of Infectious DNA or RNA Viruses Or Defective DNA or RNA Viruses in the Presence Of Helper Virus in Tissue Culture Systems: Experiments involving the use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems require IBC approval before initiating the experiments. *(See NIH Guidelines, Section III-D-3.)*

G. Experiments Involving Whole Animals:

(1) Experiments involving whole animals in which the animal's genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules, or nucleic acids derived therefrom, into the germ-line (***transgenic animals***) and experiments involving viable recombinant or synthetic nucleic acid molecule-modified microorganisms tested on whole animals require IBC approval before initiating the experiments. *(See NIH Guidelines, Section III-D-4.)*

(2) ***Experiments Involving Transgenic Rodents at BSL-1 Containment:*** Experiments involving the generation of rodents in which the animal's genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules, or nucleic acids derived therefrom, into the germ-line (transgenic rodents), whether ABSL-1, ABSL-2, or ABSL-3 containment, require IBC approval before initiating the experiments.

(SLU Note: NIH Guidelines require notice simultaneous with initiation of the experiment and permits IBC review and approval after initiation of the experiment in the case of such experiments that require only ABSL-1 containment. SLU's policy and procedures are more restrictive to assure that the proper containment level has been assigned to the research. This averts the potential for noncompliance that would occur if a PI or their staff incorrectly assigns ABSL-1 containment to an agent that should be handled at ABSL-2 or higher containment.)

H. Experiments Involving Whole Plants:

(1) Experiments to genetically engineer plants by recombinant or synthetic nucleic acid molecule methods, to use such plants for other experimental purposes (e.g., response to stress), to propagate such plants, or to use plants together with microorganisms or insects containing recombinant or synthetic nucleic acid molecules require IBC approval before initiating the experiments. *(See NIH Guidelines, Section III-D-5.)*

(2) Experiments involving nucleic acid molecule-modified whole plants, and/or experiments involving recombinant or synthetic nucleic acid molecule-modified organisms associated with whole plants require IBC approval before initiating the experiments.

(SLU Note: NIH Guidelines require notice simultaneous with initiation of the experiment and permits IBC review and approval after initiation of the experiment.

SLU's policy and procedures are more restrictive to assure that the proper containment level has been assigned to the research. This averts the potential for noncompliance that would occur if a PI or their staff incorrectly assigns BSL-1 containment to an agent that should be handled at BSL-2 or higher containment.)

I. Experiments Involving More Than 10 Liters of Culture: Experiments involving more than 10 liters of culture require IBC approval before initiating the experiments. *(See NIH Guidelines, Section III-D-6.)*

J. Experiments Involving Influenza Viruses: Experiments involving certain influenza viruses may require BSL-3 enhanced containment. *(See NIH Guidelines, Section III-D-7 for detailed NIH requirements.)*

K. Experiments involving Gene Drive Modified Organisms: Experiments involving gene drive modified organisms generated by recombinant or synthetic nucleic acid molecules shall be conducted at a minimum of BSL-2 or ABSL-2 and require IBC approval before initiating experiments. *(See NIH Guidelines, Section III-D-8.)*

L. Experiments Involving the Formation of Recombinant or Synthetic Nucleic Acid Molecules Containing Any Portion of the Genome of Any Eukaryotic Virus: Experiments involving the formation of recombinant DNA molecules containing any portion of the genome of any eukaryotic virus require IBC approval before initiating the experiments.

(SLU Note: NIH Guidelines require notice simultaneous with initiation of the experiment and permits IBC review and approval after initiation of the experiment if the experiments involve the formation of recombinant or synthetic nucleic acid molecules containing no more than two-thirds of the genome of any eukaryotic virus. SLU's policy and procedures are more restrictive to assure that the proper categorization and risk assessment has been performed and the appropriate containment level has been assigned to the research.)

9.2 Research that is Exempt from NIH Guidelines and IBC Registration: The following recombinant or synthetic nucleic acid molecules are exempt from the NIH Guidelines and registration with the IBC. *(However, other federal and state standards of biosafety may still apply to such research. The PI must check the BMBL for details specific to the research being contemplated.)*

A. Those synthetic nucleic acids that:

(1) Can neither replicate nor generate nucleic acids that can replicate in any living cell (e.g., oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase), and

(2) Are not designed to integrate into DNA, and

(3) Do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight.

If a synthetic nucleic acid is deliberately transferred into one or more human research participants and meets the criteria of Section 8.4 C. above (Section III-C of the NIH

Guidelines), it is not exempt. *(Reference: NIH Guidelines, Section III-F-1.)*

B. Those recombinant or synthetic nucleic acids that are not in organisms, cells, or viruses and that have not been modified or manipulated (e.g., encapsulated into synthetic or natural vehicles) to render them capable of penetrating cellular membranes. *(Reference: NIH Guidelines, Section III-F-2.)*

C. Those recombinant or synthetic nucleic acids that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature. *(Reference: NIH Guidelines, Section III-F-3.)*

D. Those recombinant or synthetic nucleic acids that consist entirely of nucleic acids 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. *(Reference: NIH Guidelines, Section III-F-4.)*

E. Those recombinant or synthetic nucleic acids that consist entirely of nucleic acids 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). *(Reference: NIH Guidelines, Section III-F-5.)*

F. Those recombinant or synthetic nucleic acids 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 exchanges has been prepared and is periodically revised by the NIH Director after appropriate notice and opportunity for public comment. See NIH Guidelines, Appendices A-I through A-VI, Exemptions under Section III-F-6—Sublists of Natural Exchangers, for a list of natural exchangers that are exempt from the NIH Guidelines. *(Reference: NIH Guidelines, Section III-F-6.)*

G. Those genomic DNA molecules that have acquired a transposable element, provided the transposable element does not contain any recombinant and/or synthetic DNA. *(Reference: NIH Guidelines, Section III-F-7.)*

H. Those recombinant or synthetic nucleic acids that do not present a significant risk to health or the environment, as determined by the NIH Director and following appropriate notice and opportunity for public comment. See NIH Guidelines, Appendix C, Exemption under Section III-F-8 for other classes of experiments which are exempt from the NIH Guidelines. *(Reference: NIH Guidelines, Section III-F-8.)*

10.0 Select Agents and Toxins Use in Research

10.1 Select Agent Registration & Access: PIs Contemplating Use of select agents and/or toxins or already approved to use select agents and/or toxins in research must follow the procedures below. Certain security requirements required by CDC for use of Tier 1 select agents are embedded below and in the Saint Louis University "Select Agent & Toxins Security Plan", and unless otherwise noted, are applicable for use of any select agents and toxins at Saint Louis University.

A. Select Agent Registration: Select agents are required to be registered with CDC prior to importation into Saint Louis University, as well as prior to exportation from Saint Louis University. The Biological Safety Officer, who is also the designated "Responsible Official", shall be contacted by any Saint Louis University PI who anticipates the need to procure or transfer a select agent well in advance of the need to do so.

Non-compliance with the select agent regulations can result in loss of the University's NIH funding, as well as civil penalties.

Important! See the following web link for important details that may be applicable to your research: http://www.cdc.gov/od/sap//

B. Select Agent Access (Reference 42 CFR 73.10)**:** The select agent regulations have very specific requirements for restricting access to select agents. These requirements include the following.

(1) **Restricting Access, Security Risk Assessment, and Registering Individuals:** No individual may be provided access to a select agent or toxin, or select agent – registered space, and no individual may access a select agent or toxin, unless the individual is approved by the HHS Secretary or Administrator, following a security risk assessment by the U.S. Attorney General. (Application documents are sent to FBI-CJIS under the oversight of the University's Responsible Official.) Knowingly providing access to select agents and toxins to an unregistered individual subjects the provider to fines and/or imprisonment for up to 10 years.

(2) **Application for Access to Select Agents or Toxins:** Application for access to select agents or toxins is made through the University's Biological Safety Officer and Responsible Official by submitting the information necessary to conduct a security risk assessment which will be forwarded to the U.S. Attorney General.

(3) **Access Defined:** Access is defined to be possession of a select agent or toxin (e.g. ability to carry, use or manipulate) or the ability to gain possession of a select agent or toxin.

(4) **Training:** Each individual with access to select agents or toxins must have the appropriate education, training, and/or experience to handle or use such agents or toxins.

(5) **Access Approval Denial, Limitations, or Revocation:** An individual's access approval may be denied, limited, or revoked as follows:

(a) An individual's access approval will be denied or revoked if the individual is

within any of the categories described in 18 U.S.C. 175b, i.e. the individual is a "Restricted Person".

(b) An individual's access will be denied, limited, or revoked if:

i. The individual is reasonably suspected by any Federal law enforcement or intelligence agency of committing a crime specified in 18 U.S.C. 2332b(g)(5), having knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence, or being an agent of a foreign power (as described in 50 U.S.C. 1801), or

ii. It is determined such action is necessary to protect public health and safety.

(6) **Access Approval:** Access approval is valid for a maximum of three years.

(7) **Notification to CDC of Termination of Access:** The Biological Safety Officer and Responsible Official shall immediately notify CDC (or APHIS if applicable) when an individual's access to select agents or toxins is terminated by the University and the reasons for termination of access.

(8) **Suitability Assessment:** Consistent with select agent and toxin regulations, individuals who are successfully registered for select agent and toxin access may also be subject to initial and annual thereafter suitability assessments conducted by the Biological Safety Officer and Responsible Official in conjunction with the University's Suitability Panel, as required by the CDC regulations and University policy. Suitability Assessments are currently required by the CDC and University policy for individuals with access to any Tier 1 select agents and toxins.

C. PI and Department Responsibilities:

(1) **Access to Select Agents and Toxins:** No unregistered persons or restricted persons shall have access to any select agent in Saint Louis University laboratories.

(2) **Access to Select Agent and Toxins Laboratories:** No unregistered persons shall have unescorted access to laboratories where select agents are used in experiments.

(3) **PI Responsibility and Personal Liability:** It is the responsibility of the principal investigator to diligently enforce this policy within their research laboratories, subject to the full force of the federal regulations and penal code.

(4) **Department Chairperson Responsibility and Personal Liability:** It is the responsibility of each department chairperson to implement and enforce this policy within his or her department.

10.2 Physical Security: A written security plan sufficient to safeguard select agents and toxins against unauthorized access, theft, loss or release is required. It must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the select agent or toxin, given its intended use. Drills or exercises testing and evaluating the effectiveness of the security plan must be conducted at least annually. The security plan must be reviewed and revised as necessary at least annually, and after any drill or exercise and after any incident. The security plan is required to be made available to the CDC.

A. Key Required Elements of the Select Agent and Toxins Security Plan:

(1) Procedures for physical security, inventory control, and information systems control.

(2) Provision for the control of access to select agents and toxins including the safeguarding of animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent, against unauthorized access, theft, loss or release.

(3) Provisions for routine cleaning, maintenance, and repairs.

(4) Procedures for removing unauthorized or suspicious persons.

(5) Procedures for addressing loss or compromise of keys, passwords, combinations, etc. and protocols for changing access numbers or locks following staff changes.

(6) Procedures for reporting unauthorized or suspicious persons or activities, loss or theft of select agents or toxins, or alteration of inventory records.

(7) Provisions for ensuring that all individuals with access approval from the HHS Secretary or Administrator understand and comply with the security procedures.

(8) Procedures for how the Responsible official will be informed of suspicious activity that may be criminal in nature and related to the entity, its personnel, or its select agents or toxins; and procedures for how the University will notify the appropriate Federal, State or local law enforcement agencies of such activity.

(9) Provisions for information security. (See Section 10.3 below for details).

(10) Provisions and policies for shipping, receiving, and storage of select agents and toxins, including documented procedures for receiving, monitoring and shipping of all select agents and toxins. These provisions must provide that the University will properly secure containers on site and have a written contingency plan for unexpected shipments.

B. Saint Louis University Select Agent & Toxins Security Plan: For security reasons, the Saint Louis University Select Agent & Toxins Security Plan has limited distribution and is available only through the Biological Safety Officer and Responsible Official on a need-to-know basis. The PI should contact the Biological Safety Officer and Responsible Official if they have a need to obtain an up-to-date copy of the Saint Louis University Select Agent & Toxins Security Plan. The security plan may be shared by the PI with the PI's staff on a limited need-to-know basis. Under no circumstances should the plan be shared outside of the University.

C. BMBL: In addition, Appendix F to the BMBL provides security recommendations specific to select agents. For further details, refer to Section VI of the BMBL, available at the following link: Biosafety in Microbiological and Biomedical Laboratories.

10.3 Information Security: All information pertinent to select agents and toxins, DURC and PEPP inventory, access and security systems shall be securely stored. Information security specific to Saint Louis University is addressed in detail within the Saint Louis University

Select Agent & Toxins Security Plan.

A. Key Elements of Information Security

(1) Provisions that ensure that all external connections to systems which manage security for the registered space are isolated or have controls that permit only authorized and authenticated users.

(2) Provisions that ensure that authorized and authenticated users are only granted access to select agent and toxin related information, files, equipment (e.g., servers or mass storage devices) and applications as necessary to fulfill their roles and responsibilities, and that access is modified when the user's roles or responsibilities change or when their access to select agents and toxins is suspended or revoked.

(3) Controls that are designed to prevent malicious code (such as, but not limited to, computer virus, worms, spyware) from compromising the confidentiality, integrity, or availability of information systems which manage access to select agent and toxin spaces or various records, including inventory, acquisition, transfer and destruction records, as well as the list of registered individuals authorized to access select agents and toxins.

(4) A robust configuration management practice for information systems to include regular patching and updates made to operating systems and individual applications.

(5) Backup security measures in the event that access control systems, surveillance devices, and/or systems that manage the required select agent and toxin record keeping are rendered inoperable.

B. Isolated Computer: An isolated computer that is not connected to any network may be used for storage of select agent or DURC and PEPP data. Isolated computers shall not be used to access the internet in any way. Isolated computers shall be stored in secured locations meeting the elements of "Building Security" and "Laboratory Security" delineated in the table in Section 8.8 A. and in all other ways compliant with the Saint Louis University Select Agent & Toxin Security Plan. ***Refer to the Saint Louis University Select Agent & Toxin Security Plan for additional details.***

C. Networked Computer: The use and storage of any select agent and toxin information on a computer connected to a network by any means (Ethernet, wireless, landline, etc.) requires a highly secure computer and network. The security of such computer and network must be evaluated by Saint Louis University Information Technology information security and network security experts prior to use of a networked computer for storage or communication of select agent or toxin data. ***Refer to the Saint Louis University Select Agent & Toxin Security Plan for details.***

10.4 Facility Biosafety Plan: A written facility biosafety plan is required that contains sufficient information and documentation to describe the biosafety and containment procedures for each select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent. The biosafety and containment procedures must be sufficient to contain the select agent or toxin. The facility biosafety plan is commensurate with the risk of the select agent or toxin, given its intended used. Drills or exercises testing and evaluating the effectiveness of the

facility biosafety plan must be conducted at least annually. The facility biosafety plan must be reviewed and revised as necessary at least annually, and after any drill or exercise and after any incident. For individuals with access to Tier 1 select agents and toxins, the biosafety plan requires enrollment in the occupational health program, consistent with CDC requirements.

The Saint Louis University ABSL-3 Facility Biosafety Plan details all of the required biosafety plan elements for any animal research requiring ABSL-3 containment, including but not limited to animal work involving select agents and toxins. For security reasons, this document has limited distribution and is available only through the Biological Safety Officer and Responsible Official on a need-to-know basis. The PI should contact the Biological Safety Officer and Responsible Official if they have a need to obtain an up-to-date copy of the Saint Louis University ABSL-3 Facility Biosafety Plan. The ABSL-3 Facility Biosafety Plan may be shared by the PI with the PI's staff on a limited need-to-know basis. Under no circumstances should the plan be shared outside of the University.

10.5 Select Agent Incident Response Plan: A select agent and toxin incident response plan based upon a site-specific risk assessment is required. The incident response plan must be coordinated with any University-wide plans, kept in the workplace, and available to employees for review.

A. Key Elements of the Incident Response Plan: The incident response plan must fully describe the University's response procedures for the theft, loss, or release of a select agent or toxin; inventory discrepancies, security breaches (including information systems), severe weather and other natural disasters, workplace violence, bomb threats and suspicious packages, and emergencies such as fire, gas leak, explosion, power outage, and other natural and man- made events. The response procedures must account for hazards associated with the select agent or toxin and appropriate actions to contain such select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent. Additional key required elements of the incident response plan are detailed in 42CFR73.14. (See: 42 CFR 73.14 Incident Response Plan Requirements.)

B. Additional Incident Response Plan Key Elements for Tier 1 Select Agents and Toxins: With regard to Tier 1 select agents and toxins, the incident response plan must fully describe the University's response procedures for failure of intrusion detection or alarm systems. Storage or use of Tier 1 select agents and toxins also requires that the incident response plan describes how the University will notify the appropriate Federal, State, or local law enforcement agencies of suspicious activity that may be criminal in nature and related the University, its personnel or its select agents and toxins.

The Select Agent Incident Response Plan must be reviewed and revised as necessary at least annually, and after any drill or exercise and after any incident. Drills or exercises to test the incident response plan are required at least annually. The incident response plan may be shared by the PI with the PI's staff on a limited need-to-know basis. Under no circumstances should the plan be shared outside of the University.

Refer to the Saint Louis University Select Agent Incident Response Plan for details.

11.0 Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP)

11.1 DURC and PEPP – Scope of Research Requiring Oversight: Consistent with *The United States Government Policy for Oversight of Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP)*, subsequently referred to as *USG Policy* in this section, all federally funded research must undergo assessment for Category 1 (DURC) and Category 2 (PEPP). For purposes of this policy, the following applies to all research at SLU, regardless of funding source.

Category 1 Research meets the definitions of 11.1A-C, and Category 2 Research meets the definitions of 11.1D-F, as defined below.

A. Category 1 (DURC): Biological Agents or Toxins within Scope of Category 1 (DURC) Research:

(1) All Select Agents and Toxins listed in 9 CFR 121.3–121.4, 42 CFR 73.3–73.4, and 7 CFR 331.3 and regulated by USDA and/or HHS. (https://www.selectagents.gov/sat/list.htm)

(2) All Risk Group 4 pathogens listed in Appendix B of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines).

(3) A subset of Risk Group 3 pathogens listed in Appendix B of the NIH Guidelines - Classification of Human Etiologic Agents on the Basis of Hazard.

(4) For biological agents affecting humans that have not been assigned a Risk Group in the NIH Guidelines, refer to the current edition of Biosafety in Microbiological and Biomedical Laboratories (BMBL). In such cases, agents affecting humans that are recommended to be handled at Biosafety Level 3 (BSL-3) or Biosafety Level 4 (BSL-4) per the BMBL guidance are subject to the *USG Policy*.

(5) Biological agents added during future updates to the *Implementation Guidance for the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential,* subsequently referred to as *USG Policy Implementation Guidance* in this section, as specified in the *USG Policy* Sections 7 and 8.

B. Category 1 (DURC) Research Experimental Outcomes:

(1) Increase transmissibility of a pathogen within or between host species

(2) Increase the virulence of a pathogen or convey virulence to a non-pathogen

(3) Increase the toxicity of a known toxin or produce a novel toxin

(4) Increase the stability of a pathogen or toxin in the environment, or increase the ability to disseminate a pathogen or toxin

(5) Alter the host range or tropism of a pathogen or toxin

(6) Decrease the ability for a human or veterinary pathogen or toxin to be detected

using standard diagnostic or analytical methods

(7) Increase resistance of a pathogen or toxin to clinical and/or veterinary prophylactic or therapeutic interventions

(8) Alter a human or veterinary pathogen or toxin to disrupt the effectiveness of preexisting immunity, via immunization or natural infection, against the pathogen or toxin

(9) Enhance the susceptibility of a host population to a pathogen or toxin

C. Category 1 (DURC) Risk Assessment:

(1) Based on current understanding, the research can be reasonably anticipated to provide, or does provide, knowledge, information, products, or technologies that could be misapplied to do harm with no — or only minor — modification to pose a significant threat with potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

D. Category 2 (PEPP) Biological Agents within Scope of Category 2 (PEPP) Research:

(1) A Pathogen with Pandemic Potential (PPP), or any pathogen that will be modified in such a way that is reasonably anticipated to result in a PPP.

E. Category 2 (PEPP) Research Experimental Outcomes or Actions:

(1) Enhance transmissibility of the pathogen in humans

(2) Enhance the virulence of the pathogen in humans

(3) Enhance the immune evasion of the pathogen in humans such as by modifying the pathogen to disrupt the effectiveness of pre-existing immunity via immunization or natural infection

(4) Generate, use, reconstitute, or transfer an eradicated or extinct PPP, or a previously identified PEPP

F. Category 2 (PEPP) Risk Assessment:

(1) The research can be reasonably anticipated to result in the development, use, or transfer of a PEPP or an eradicated or extinct PPP that may pose a significant threat to public health, the capacity of health systems to function, or national security. See the *USG Policy Implementation Guidance* for additional guidance, including illustrative examples.

11.2 Responsibilities of Principal Investigators Regarding DURC and PEPP:

A. PI Must Provide Completed Assessment of Research for DURC and PEPP to IBC/IRE.

(1) **DURC**: The PI's research with one or more of the agents listed in Section 11.1.A. (USG Policy Section 4.1.1), is reasonable anticipated to result in, or does result in,

one or more of the experimental outcomes listed in Section 11.1.B. above (*USG Policy* Section 4.1.2), and based on current understanding, meets the definition described in Section 11.1.C above (*USG Policy* Section 4.1.3).

(2) **PEPP**: The PI's research involves, or is reasonably anticipated to result in a Pathogen with Pandemic Potential (PPP) as in Section 11.1.D. (*USG Policy* Section 4.2.1), is reasonable anticipated to result in, or does result in, one or more of the experimental outcomes or actions listed in Section 11.1.E. above (*USG Policy* Section 4.2.2), and based on current understanding, meets the definition described in Section 11.1.F above (*USG Policy* Section 4.2.3).

B. IBC Notification Requires PI Assessment: The PI's IBC notification must include the PI's assessment of whether any research meets the definitions of DURC or PEPP described above.

C. PI Required Commitments:

(1) **Training:** The PI must undergo training on the *USG Policy.* The PI must also ensure that laboratory personnel (i.e., those under the supervision of laboratory leadership, including graduate students, postdoctoral fellows, research technicians, laboratory staff, and visiting scientists) conducting life sciences research within scope of the *USG Policy* have received education and training on DURC and PEPP.

(2) **Assessment:** The PI must assess their research at the proposal stage, and continuously throughout the research lifecycle, to identify whether there is research reasonably anticipated to be within scope of Category 1 or Category 2. This type of research must be approved by the IBC (IRE) prior to proposal submission to a federal funding agency.

(3) **Notify Federal Funding Agency:** If the proposed research is within scope of the *USG Policy*, the PI shall notify the federal funding agency at the time of proposal submission

(4) **Work with the IBC:** The PI shall work with the IBC (IRE) to develop a risk-benefit assessment and draft risk mitigation plan to the federal funding agency for review and approval.

(5) **Know and Comply with All Policies and Procedures:** PIs should conduct Category 1 and Category 2 research in accordance with the provisions identified in the risk mitigation plan approved by the federal funding agency. They shall also provide annual progress reports for Category 1 research and semiannual progress reports for Category 2 research, and as requested by the federal funding agency (e.g., as part of terms and conditions of award or risk mitigation plans), for review, evaluation, assessment, and, where necessary, clarification or confirmation.

(6) **Communicate DURC/PEPP in a Responsible Manner:** All PIs shall communicate Category 1 and Category 2 research in a responsible manner. Communication of research and research findings is an essential activity for all researchers and occurs throughout the research process, not only at the point of publication. When researchers are planning to communicate Category 1 and Category 2 research results, it is their duty to ensure that it is done in a responsible

manner, and follows any measures outlined in the risk mitigation plan approved by the IBC (IRE) and federal funding agency.

11.3 IBC Review of DURC and Role as Institutional Review Entity (IRE): The Saint Louis University IBC serves the role of the Institutional Review Entity (IRE) for purposes of DURC and PEPP. The IBC is empowered through the Saint Louis University Policy on Institutional Biosafety Committee (IBC) to ensure it can execute the requirements of the *USG Policy*. This includes but is not limited to the following:

A. IBC (IRE) Membership:

(1) **Number of Members:** Consistent with the IBC policy and procedures, as well as *USG Policy,* when functioning as the IRE, the IBC is composed of at least five members,

(2) **IBC (IRE) Breadth of Experience:** The IBC (IRE) includes persons with sufficient breadth of expertise, to include biosafety and biocontainment expertise, to assess the applicability of Section 11.1 above to the range of relevant life sciences research conducted at a given research institution and understand biosafety and biosecurity implications of such research. The membership shall have knowledge of PPPs, PEPPs, dual use concerns, and related institutional and U.S. government policies and understand risk assessment and risk management considerations,

(3) **Conflict of Interest:** On a case-by-case basis, the IBC (IRE) will recuse any member of the IBC (IRE) who is involved in the research project in question or has a direct financial interest, except to provide specific information requested by the IBC (IRE).

B. IBC (IRE) Meetings on DURC/PEPP: IBC (IRE) meetings engaged in the review of DURC and PEPP shall be conducted separate from the regular IBC meetings.

C. Dialogue with PI: The IBC (IRE) will engage in an ongoing dialogue with the PI of the research in question when conducting a risk-benefit assessment and developing a risk mitigation plan.

D. IBC (IRE) Review Process: The IRE review process will be undertaken using as a guide the *USG Policy Implementation Guidance.* The Review steps include the following.

(1) **Assess for Category 2 Research**

Step 1: Confirm that the research involves, or is reasonably anticipated to result, in, a PPP. To determine whether research should be designated as Category 2, the IRE should assess and confirm the PI's assessment that the research involves, or is reasonably anticipated to result in, a PPP.

If the research involves or is reasonably expected to result in a PPP (including an eradicated, extinct, or existing PPP), proceed to **Step 2** below; If not, proceed to **Step 4**.

Step 2: Confirm that the research is reasonably anticipated to result in, or does result in, one or more of a listed experimental outcomes or actions in scope of Category 2 research. To determine whether research should be designated as

Category 2, the IRE should assess and confirm the PI's assessment that the research is reasonably anticipated to result in, or does result in, one or more of a listed experimental outcomes or actions, listed in the *USG Policy*.

If the research is reasonably anticipated to result in, or does result in, one or more of the listed experimental outcomes or actions above, proceed to **Step 3**; If not, proceed to **Step 4**.

Step 3: Assess risks of potential Category 2 research and determine whether research should be designated as Category 2. To determine if research should be designated as Category 2, the IRE should assess the research for biosafety and biosecurity risks. In performing the risk assessment, the IRE should examine descriptions of the research in question, the PI's assessment of the applicability of the pathogen (Step 1) and categories of experimental outcome or action (Step 2), and other relevant information. In designating research as Category 2, the IRE is required to determine whether the research can be reasonably anticipated to result in the development, use, or transfer of a PEPP, or an eradicated or extinct PPP that may pose a significant threat to public health, the capacity of health systems to function, or national security. Key to this Category 2 determination is an assessment of whether the research involves a pathogen that, through one or more of the listed experimental outcomes, *may pose a significant threat to public health, the capacity of health systems to function, or national security*. More information on how to assess this is included in Section B.2 of the *USG Policy Implementation Guidance.*

There are two potential outcomes following the risk assessment.

If the research can be reasonably anticipated to result in the development, use, or transfer of a PEPP or an eradicated or extinct PPP that poses a significant threat to public health, the capacity of health systems to function, or national security, the IRE shall designate the research as Category 2 research. The IRE should proceed to **Step 6a** to assess the Category 2 research for potential DURC risks, and then notify the funding agency of the Category 2 designation (**Step 7**).

If the research is NOT reasonably anticipated to result in the development, use, or transfer of a PEPP or an eradicated or extinct PPP that poses a significant threat to public health, the capacity of health systems to function, or national security, the research does not meet the scope of Category 2 research and the IRE does not need to proceed with Category 2 assessment and risk mitigation. The IRE should proceed to **Step 4** to evaluate the research for Category 1 designation. However, the PI should be informed that if at any time the reviewed research may meet the scope of Category 1 or Category 2 research, the PI should halt further work, refer the research again to the IRE for review, and notify the funding agency.

(2) <u>Assess for Category 1 Research</u>

Step 4: Confirm that the research involves one or more of the listed biological agents or toxins. To determine whether research should be designated as Category 1, the IRE should assess and confirm that the PI's assessment that the research directly involves one or more of the biological agents or toxins listed in section 4.1.1 the *USG*

Policy.

If the research involves one or more of the biological agents or toxins listed in Section 4.1.1 of the Policy, the IRE should proceed to **Step 5**. If not, the research should not be designated as Category 1 research and the IRE does not need to continue with the Category 1 assessment and risk mitigation. However, the IRE must still proceed to **Step 7** to notify the appropriate federal funding agency of its findings. The PI should be informed that if at any time the reviewed research may meet the definition of Category 1 or Category 2 research, the PI should halt further work,

Step 5: Confirm that the research is reasonably anticipated to result, or does result, in one or more of the listed experimental outcomes in scope of Category 1 research.

To determine whether research should be designated as Category 1, the IREs should assess and verify the PI's assessment of whether the research is reasonably anticipated to result, or does result, in one or more of the listed experimental outcomes listed in item 11.1B above.

If the research is reasonably anticipated to result, or does result, in one or more of the listed experimental outcomes on a designated biological agent or toxin identified in Step 4, proceed to **Step 6**. If NONE of the listed experimental outcomes applies, the research should not be designated as Category 1 research and the IRE does not need to continue with the Category 1 assessment and risk mitigation. However, the IRE must proceed to **Step 7** to notify the appropriate federal funding agency of its findings. The PI should be informed that if at any time in the future if the reviewed research may meet the definition of Category 1 or Category 2 research, the PI should halt further work, and refers the research again to the IRE for review, and notify the federal funding agency.

Step 6: Assess the dual use risk associated with the research and determine whether research should be designated Category 1 (if applicable).

Step 6a: Assess the dual use risk associated with the research.

Research already designated as Category 2, or research being assessed as potential Category 1, should next be assessed for risks associated with DURC. When considering whether the research in question meets the definition of DURC, the IRE should identify the risks associated with the potential misuse of the information, technologies, or products that may be generated. The *USG Policy Implementation Guidance* offers additional details on this step.

Step 6b: Determine whether research should be designated Category 1.

To determine whether research should be designated as Category 1, IREs should assess whether the research, based on current understanding, constitutes DURC, as specified in Section 4.1.3 of the *USG Policy*. Careful consideration of the dual use risks associated with the research should underpin the determination of whether the research in question meets the definition of DURC.

(3) Risk-Benefit Assessments, Risk Mitigation Plan, and Oversight of Category 1 or Category 2 Research

Step 7: Notify federal funding agency of Category determination.

If the IRE determines that the research meets Category 1 or Category 2 designation, the IRE should inform the PI and funding agency of its findings and proceed with the review process, which includes drafting of risk-benefit assessments (proceed to **Step 8** and **Step 9**) and a risk mitigation plan (**Step 10**).

If the IRE determines that the research does NOT meet Category 1 or Category 2 designation, the IRE must still inform the PI and the federal funding agency of these findings. However, no further actions are needed.

Step 8: Assess the potential benefit.

In order to determine the acceptable level of risk associated with Category 1 and Category 2 research and the best mitigation strategies, the research should be assessed for its potential benefits. There are many benefits inherent to scientific research, but it must be performed safely and securely. Such benefits may impact various sectors of society and be realized over different time frames. See the *USG Policy Implementation Guidance* for additional details.

Step 9: Develop risk-benefit assessments.

The IRE shall produce a risk-benefit assessment that assesses the potential benefits and the potential risks of the proposed research in a clear and thorough manner. See the *USG Policy Implementation Guidance* for additional details.

Step 10: Develop a draft risk mitigation plan.

The risk-benefit assessments will be used by the PI and IRE to develop a draft risk mitigation plan. Both the risk-benefit assessments and the draft mitigation plan will be provided to the federal funding agency for review and approval within 90 calendar days from the IRE determination.

The IRE, along with the PI, should draft a risk mitigation plan and determine if additional measures are needed to mitigate risks associated with Category 1 or Category 2 research. Guidance for developing this risk mitigation plan is provided in Part F of the *USG Policy Implementation Guidance.*

Step 11: Oversee the research.

Following approval of risk-benefit assessments and the risk mitigation plan by the federal funding agency, the IRE will assist with and oversee the implementation of the risk mitigation plan. This includes ensuring that the research is conducted in accordance with the approved risk mitigation plan and is periodically reviewed by the research institution to determine if additional modifications to the risk mitigation plan are appropriate.

The IRE will also evaluate the risk mitigation plan at least annually and, working with the funding agency as appropriate, modify the plan as necessary for the duration of the research.

11.4 University Responsibilities:

A. Establishing Internal Policies and Practices for the Identification and Effective Oversight of DURC and PEPP: The University has established policies and procedures for identification of DURC and PEPP through its Policy on IBC, IBC Procedures and the IBC application process. The IBC procedures establish a mechanism for the PI to immediately refer a project to the IBC (IRE).

B. Establishing IRE: The IBC is empowered to serve as the IRE and to fulfill all of its functions. An IBC (IRE) review and oversight process is defined in Section 11.3 above.

C. Provide IRE Reviews: The IRE will conduct an institutional oversight process when a PI makes an initial assessment that research may constitute Category 1 or Category 2. Also, the University ensures that internal policies establish a mechanism for the PI to refer an existing project to the IBC (IRE) if, at any time, the research is potentially defined as Category 1 or 2.

D. Designation of an Institutional Contact for Dual Use Research (ICDUR): The Biological Safety Officer is designated to serve as the ICDUR, a University point of contact for questions regarding compliance with and implementation of the requirements for the oversight of research that falls within the scope of Section 11.1 above. If questions arise regarding compliance, implementation of University policies governing DURC or PEPP, or when guidance is needed about identifying DURC or PEPP or developing risk mitigation plans, the ICDUR serves as the liaison (as necessary) between the University and the relevant program officers at the U.S. Government funding agencies, or for non-U.S. Government funded research, between the University and NIH (or the U.S. Government agency to which NIH refers the University).

E. Provide Education and Training on DURC and PEPP: The Environmental Health and Safety office's Biological Safety Officer, or his designee, provides training on DURC and PEPP for individuals conducting life sciences research. The Biological Safety Officer maintains records of such education and training for the term of the research grant or contract (or for the duration of the research project if not externally funded) plus three years after its completion.

F. Maintaining Records: Records of IRE reviews and completed risk mitigation plans shall be maintained for the term of the research grant or contract (or for the duration of the research project if not externally funded) plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation. These records may be maintained independent of IBC records.

G. Inventory: The IRE shall ensure that the resulting biological agent or toxin from Category 1 and Category 2 research are properly accounted for and destroyed when no longer needed if not already required to do so by existing law and regulation.

H. Ensuring Compliance with the DURC Requirements and Approved Risk Mitigation Plans and Immediate Reporting of Non-Compliance:

(1) **Immediate Reporting of Non-Compliance to Biological Safety Officer:** Any

non-compliance with DURC requirements and/or risk mitigation plans identified by University personnel, including grants administrators, PIs and their staff, must be reported immediately to the Biological Safety Officer for review, investigation, and follow-up internal and external reporting by the Biological Safety Officer.

(2) **30 Day Reporting to Funding Agency:** Instances of non-compliance with the *USG Policy* and non-compliance with approved risk mitigation plans, as well as the mitigation measures undertaken by the University to prevent recurrences of similar non-compliance, will be reported within 30 calendar days of institutional awareness or receipt of notification of a failure to the U.S. Government funding agency by the Biological Safety Officer (designated ICDUR). In the case of non-U.S. Government funded research, reports will be made to the U.S. Government agency designated by the NIH.

I. Assisting PIs: As necessary, the University will assist PIs conducting life sciences research when questions arise about whether their research may require further review or oversight.

J. Appeal Mechanism: PIs may appeal IBC (IRE) decisions regarding research that is determined by the IBC (IRE) to meet the definition of DURC and PEPP directly to the Vice President for Research. If the Vice President for Research determines that the IBC (IRE) should reopen the DURC and PEPP review, a special meeting of the IBC (IRE) will be convened as soon as possible. The application materials previously submitted and any new information from the PI will be reviewed by the IBC (IRE). The PI may be invited to be present during the IBC (IRE) meeting to present information and/or answer questions. The final decision of the IRB (IRE) following the appeal review will be communicated in writing to the PI and the Vice President for Research.

K. Review Processes: Information about the process for review of research subject to the *USG Policy* is available upon request, consistent with applicable law.

L. Certification by University:

(1) When applying for or accepting U.S. Government funds for life sciences research, as applicable, the University will certify that it is in compliance with all aspects of the *USG Policy* on DURC and PEPP.

(2) All potential DURC and PEPP (see Section 11.1 above) must be reviewed and approved by the IBC (IRE) before submitting grant applications or contracts. *(See Section 8.1. B. of these procedures for details.)*

12.0 Non Compliance and Sanctions

12.1 Impact of Violations: Failure to timely summit IBC Research Protocol Applications and to receive IBC approval of these applications before initiating research with a hazardous biological agent, or failure to register certain types of experiments utilizing recombinant organisms, can have far-reaching effects, including citation of the University and the PI for possible violations of Federal Code and/or denial of federal funds for research to the PI or the University.

12.2 Reporting of Violations: Non-compliance with the Policy on Institutional Biosafety Committee and the companion Procedures for Institutional Biosafety Committee (IBC) Compliance, including IBC Procedures for timely submission of IBC Research Protocol Applications, amendments, failure to complete required training, and other violations of IBC policy or IBC procedures must be reported to the Saint Louis University Biological Safety Officer, the Institutional Biosafety Committee, the Environmental Health and Safety office, or the Vice President for Research.

12.3 Sanctions: Gross or repeated violations of the IBC policy and/or IBC procedures may result in disciplinary actions. Disciplinary actions for non-compliance can result in suspension or termination of research by the BSO, IBC or the Vice President for Research, including withholding of funding, a report of suspected misconduct, and/or a reporting to the applicable government regulatory and/or funding agencies. Individuals who fail to comply with this policy and the procedures associated with it may also be subject to disciplinary actions guided by the University's Staff Performance Management Policy, SLU Faculty Manual (St. Louis Campus), or Student Handbook. Non-compliance with this policy may result in disciplinary action, up to and including separation from the University. Refer to the Institutional Biosafety Committee (IBC) Policy for additional details.

13.0 References

13.1 **Saint Louis University** ***Institutional Biosafety Committee (IBC) Policy dated February 7, 2024. It can be downloaded at this link:*** *IBC Policy*.

13.2 ***Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*** dated April 2024. A copy of this document can be downloaded at the following link: https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf

13.3 ***Saint Louis University Exposure Control Plan for Bloodborne Pathogens***. A copy of this document should be available in any laboratory in which work with pathogenic organisms is performed or used. It can be downloaded at the following link: https://www.slu.edu/research/faculty-resources/research-integrity-safety/environmental-health-safety/-pdf/exposure-control-plan.pdf. A hardcopy may be requested from the Saint Louis University Environmental Health and Safety office.

13.4 ***Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th Edition, June 2020.*** A copy of this document, jointly produced by the CDC and NIH, is available to PIs contemplating work with pathogenic organisms. It can be downloaded at the following link: https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf

13.5 ***Code of Federal Regulations (CFR), Title 42: Public Health, Part 73 – Select Agents and Toxins.*** Available at the following link: 42 CFR Part 73

13.6 ***Code of Federal Regulations (CFR), Title 9: Animals and Animal Products, Part 121 – Possession, Use, and Transfer of Select Agents and Toxins.*** Available at the following link: https://www.ecfr.gov/current/title-9/part-121

13.7 ***Code of Federal Regulations (CFR), Title 7: Agriculture, Part 331 – Possession, Use, and Transfer of Select Agents and Toxins.*** Available at the following link: 7 CFR Part 331

13.8 ***United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential*** (Release date May 2024, Effective Date May 6, 2025). Available at the following link: https://aspr.hhs.gov/S3/Documents/USG-Policy-for-Oversight-of-DURC-and-PEPP-May2024-508.pdf

13.9 ***Implementation Guidance for the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential.*** Available at the following link: https://aspr.hhs.gov/S3/Documents/USG-DURC-PEPP-Implementation-Guidance-May2024-508.pdf

13.10 ***NIH Policy for Research with Human Stem Cells.*** A copy of this document can be downloaded at the following link: https://stemcells.nih.gov/research-policy/guidelines-for-human-stem-cell-research

13.11 ***NIH Policy for Research involving Human Embryos.*** A copy of this policy can be downloaded at the following link: NIH Policy for Research Involving Human Embryos

Approval Signatures

These "Institutional Biosafety Committee (IBC) Procedures and Principal Investigator (PI) Responsibilities" have been approved by:

_____ Date: _____

Ellen K. Barnidge, Ph.D.
Vice President for Research

Document History

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