Policy on
Institutional Biosafety Committee (IBC)

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Responsible University Official: | **Vice President for Research**

1.0 INTRODUCTION

Saint Louis University ("the University") endeavors to provide for the safe and secure use of biological materials used in research. Key objectives of safeguards for research activities utilizing biological materials are to prevent occupational exposures and accidental releases of biological agents that could harm employees, patients, students, the public, or the environment. To meet these important safety and security objectives, the Saint Louis University Institutional Biosafety Committee ("the IBC") exists to facilitate comprehensive oversight, including review and approval, of the use of biological materials at Saint Louis University.

2.0 POLICY

This policy establishes the Saint Louis University Institutional Biosafety Committee (IBC) which is empowered with the responsibility for the oversight, review and approval of all biological research conducted at Saint Louis University and institutional compliance with federal, state and local requirements governing the use of biological materials, including select agents and toxins, and life sciences dual use research of concern (DURC). All University faculty, staff, students, and others, including visiting scientists, companies and external scientists, engaged in biological research are responsible for the proper, safe and secure conduct of research at Saint Louis University facilities, in accordance with all applicable elements of this policy, IBC procedures, and the requirements of federal, state and local authorities, including those of funding agencies, governing the use of biological materials.

3.0 APPLICABILITY & SCOPE

3.1 Applicability: This policy, including the companion procedures, is applicable to all University faculty, staff, students and others engaged in the conduct of biological research at Saint Louis University facilities. Research conducted by SLU faculty, staff and students at non-SLU facilities is subject to this policy and the companion procedures if the research is funded by NIH or other funding agencies through Saint Louis University. This policy and the companion procedures are also applicable to all non-University faculty, staff, students and others (e.g. employees of start-up companies) engaged in the conduct of

biological research at Saint Louis University facilities.

Refer to the companion document to this policy: "Procedures for Institutional Biosafety Committee (IBC) Oversight and Principal Investigator Responsibilities", hereby incorporated by reference into this policy.

Exemption: Laboratories engaged in only clinical diagnosis and evaluation of patients are exempt from IBC review requirements of this policy if they operate under an infection control plan that meets the requirements of the Occupational Safety and Health Administration (OSHA) Blood-borne Pathogens Standard (29 CFR Part 1910.1030). However, these laboratories are required to be compliant with any applicable regulations related to the following:

A. Select Agents
B. Packaging and Shipment
C. Import and Export of Infectious Materials
D. Distribution of Imported Biological Agents within the United States.
E. Dual Use Research of Concern (DURC)

3.2 Scope: Biological agents coming under this policy include bacteria, viruses, rickettsia, parasites, prions, fungi, biological toxins, and other sources of biological materials, known to be, or suspected of being, hazardous to humans, plants or animals if released into the environment. All select agents and toxins (including Tier 1), as well as Life Sciences Dual Use Research of Concern (DURC) fall under the scope of this policy. Also included are ALL human-derived and primate-derived biological materials used in research. For purposes of this policy and IBC oversight, biological agents also include Risk Group 1 biological agents, as identified in the NIH guidelines, which are not known to be or suspected of being hazardous to humans.

Included within the scope of this policy is research involving the construction and/or handling of (1) recombinant nucleic acid molecules, (2) synthetic nucleic acid molecules, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, and (3) cells, organisms, and viruses containing such molecules. This includes human gene transfer in which recombinant or synthetic nucleic acid molecules are put into humans (with or without genome integration). These experiments are regulated by the NIH Office of Biotechnology Activities (OBA) under the "NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules", and require approval of the research by the IBC and/or by OBA's Recombinant DNA Advisory Committee (RAC), prior to initiation.

In summary, the scope of this policy includes any biohazards, recombinant or synthetic nucleic acid molecules, including human gene transfer experiments, and ALL human and primate derived biological materials used in research. Any animal cells or other biological materials that may have the potential for zoonotic disease are also included.

4.0 DEFINITIONS

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

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

Service.

4.3 Biological Agent: Any bacteria, viruses, rickettsia, parasites, prions, fungi, toxins, deoxyribonucleic acid (DNA), and ribonucleic acid (RNA), known to be, or suspected of being, hazardous to humans, 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.

4.4 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 full-time position within the Saint Louis University Office of Environmental Health and Safety, is a member of the IBC and serves as the Executive Secretary of the IBC.

4.5 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).

4.6 BMBL: Common abbreviation for CDC/NIH publication*: Biosafety in Microbiological and Biomedical Laboratories, 5th Edition, December 2009.*

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

4.8 CDC-DSAT: The CDC's **D**ivision of **S**elect **A**gents and **T**oxins.

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

4.10 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 directly misapplied 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 6.8)*

In essence, "DURC is life sciences research that is intended to benefit, but which might easily be misapplied to do harm." *(World Health Organization (WHO) – 2016.)*

4.11 Institutional Biosafety Committee (IBC): The University committee created consistent

with the requirements of the NIH Guidelines to review research involving recombinant or synthetic nucleic acid molecules, including Human Gene Transfer experiments, as well as other research that entails biohazard risks, including DURC. The IBC reports to the Vice President for Research through the IBC Chairperson.

4.12 Institutional Contact for Dual Use Research (ICDUR): An individual designated by the University to serve as an institutional point of contact for questions regarding compliance with and implementation of the requirements for the oversight of DURC as well as the liaison (as necessary) between the University and the relevant U.S. Government funding agencies. The Saint Louis University Biological Safety Officer is designated to serve as the ICDUR. *(Reference: See Section 6.8)*

4.13 Institutional Review Entity (IRE): A committee established by the University to review Dual Use Research of Concern, as required by the "United States Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern". The Saint Louis University IBC is designated to be the "Institutional Review Entity".

4.14 NIH: National Institutes of Health. 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).

4.15 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.

4.16 Office of Biotechnology Activities (OBA): 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. The conduct of clinical trials using recombinant and synthetic nucleic acids,
B. Biosafety for NIH supported research,
C. Biosecurity, including oversight and dual use research, and
D. Registration of new stem cells lines for NIH funded research.

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

4.18 Recombinant DNA Advisory Committee (RAC): An NIH advisory committee whose principal role is to provide advice and recommendations to the NIH Director on (1) the

conduct and oversight of research involving recombinant DNA, including the content and implementation of the NIH Guidelines, and (2) other NIH activities pertinent to recombinant DNA technology. A major element of this role is to examine the science, safety and ethics of clinical trials that involve the transfer of recombinant DNA to humans.

4.19 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 nuclei 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.

4.20 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-DSAT, 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.

4.21 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.

4.22 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-DSAT (or AgSAS as applicable) in advance, through the University's RO. Approval from the CDC-DSAT must be received through the RO before those activities can commence.

4.23 Select Agent Regulations: Regulations defining biological organisms and toxins that are of potential use to terrorists, and which must be registered with the CDC-DSAT 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).

Noncompliance with the Select Agent Regulations can result in sanctions that include the loss of NIH funding, as well as civil penalties. ***IMPORTANT! See the following WEB link for important details:*** 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.]

4.24 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.

5.0 INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) RESPONSIBILITIES

5.1 Authority and Administration of Policy: The Provost of the University has conferred upon the Vice President for Research the authority to appoint an Institutional Biosafety Committee (IBC) for Saint Louis University. The IBC reports to the Vice President for Research through the IBC Chairperson. The authority to review and approve or disapprove the biological safety aspects of any research or clinical protocol, including DURC, is vested in the IBC. The IBC also serves as a technical resource for the biological safety program, including but not limited to:

A. The drafting, review, approval and/or implementation of specific biological safety procedures, policies, manuals, and other documents intended to serve as tools in implementing the biological safety program.

B. The implementation and enforcement of the biological safety program by the Biological Safety Officer (BSO), working under the authority of and reporting through the Director of the Office of Environmental Health and Safety to the Vice President for Research.

C. When reviewing DURC, the IBC functions as the University's IRE. *(See Section 4.0 definitions.) Also refer to the companion document for this policy: "Procedures for Institutional Biosafety Committee (IBC) Oversight and Principal Investigator Responsibilities" for details.*

5.2 IBC Membership: Appointments made to the Institutional Biosafety Committee shall be

made in accordance with applicable federal requirements. *Refer to the companion document to this policy: "Procedures for Institutional Biosafety Committee (IBC) Oversight and Principal Investigator Responsibilities" for details.*

6.0 REFERENCES

6.1 **Saint Louis University *Procedures* for Institutional Biosafety Committee (IBC) Oversight and Principal Investigator Responsibilities**. This document can be downloaded at the following link: IBC Procedures and PI Responsibilities

6.2 ***Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*** dated November 2013. A copy of this document can be downloaded at the following link: http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines

6.3 ***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: SLU Exposure Control Plan for Bloodborne Pathogens. A hardcopy may be requested from the Saint Louis University Office of Environmental Health and Safety.

6.4 ***Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th Edition, December 2009.*** 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: http://www.cdc.gov/biosafety/publications/bmbl5/index.htm

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

6.6 ***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: 9 CFR Part 121

6.7 ***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

6.8 ***United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*** (Release Date: September 24, 2014; Effective Date: September 24, 2015). Available at following link: http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf

7.0 RECISSION

Policy on Institutional Biosafety Committee (IBC) dated April 1, 2002.

8.0 REVIEW DATE

This policy will be reviewed regularly as-needed to assure that it remains current with applicable federal, state and other requirements.

APPROVAL SIGNATURES

This policy has been approved by:

(Signed Copy on File) Date: 04/18/2016

Raymond C. Tait, Ph.D.
Vice President for Research

DOCUMENT HISTORY		
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April 1, 2002	2.0	Revision
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