Division of RESEARCH

POLICY ON INSTITUTIONAL BIOSAFETY COMMITTEE

Policy Number: 3.0.6 **Version Number:** 003
Classification: Research Compliance **Effective Date:** August 18, 2024
Responsible University Office: Office of Research Compliance

1.0 Purpose

Clemson 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, students, the public, or the environment. To meet these important safety and security objectives, the Clemson University Institutional Biosafety Committee ("the IBC") exists to facilitate comprehensive oversight, including review and approval, of the use of biological materials at Clemson University.

2.0 Applicability

This policy is applicable to all University faculty, staff, students and others engaged in the conduct of biological research at Clemson University facilities. Research conducted by CU faculty, staff and students at non-CU facilities is subject to this policy and the companion procedures if the research is funded by NIH or other funding agencies through Clemson University. This policy is also applicable to all non-University faculty, staff, students and others engaged in the conduct of biological research at Clemson University facilities.

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.
In summary, the scope of this policy includes any biohazards, recombinant or synthetic nucleic acid molecules, and ALL human and primate derived biological materials used in research. Any research that uses nanoparticles with any of the items listed are also included.

3.0 Government Rules and Regulations

The basis of compliance is determined by the Centers for Disease Control-NIH Biosafety in Microbiological and Biomedical Laboratories, The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, USDA Guidelines for Research Involving Planned Introductions into the Environment of Genetically Modified Organisms (December 3-4, 1991), and other applicable regulations.

4.0 Definitions

4.1 APHIS: The U.S. Depart of Agriculture's Animal and Plant Health Inspection Service.

4.2 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.

4.3 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 Clemson University Office of Research Safety, is a member of the IBC.

4.4 **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).

4.5 **BMBL:** Common abbreviation for CDC/NIH publication*: Biosafety in Microbiological and Biomedical Laboratories,*

4.6 **CDC:** The Department of Health and Humans Services' Centers for Disease Control and Prevention.

4.7 **CDC-DSAT:** The CDC's Division of Select Agents and Toxins.

4.8 **Department of Health and Human Services (HHS):** U.S. Department of Health and Human Services.

4.9 **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: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern)*

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.)*

4.10 **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 Assistant Vice President for Research through the IBC Chairperson.

4.11 **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 Clemson University IBC Chairperson is designated to serve as the ICDUR.

4.12 **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 Clemson University IBC is designated to be the "Institutional Review Entity".

4.13 **National Institutes of Health** (**NIH):** The NIH is one of several health agencieswithin the Public Health Service, which is an agency within the U.S. Department of Health and Human Services (DHHS).

4.14 **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 NIHGuidelines 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 complywith the *NIH Guidelines*. Failure by one PI at Clemson 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 Clemson University.

4.15 **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.

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

4.17 **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 activitiespertinent to recombinant DNA technology. A major element of this role is to examine the science, safety and ethics of clinical trials that involve the transferof recombinant DNA to humans.

4.18 **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.

4.19 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 Clemson University Biological Safety Officer is designated as the RO at Clemson University.

4.20 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 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.

4.21 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 Clemson University, or exportation fromClemson 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.

4.22 **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.

Noncompliance with the Select Agent Regulations can result in sanctions that include the loss of NIH funding, as well as civil penalties.

5.0 Policy

This policy establishes the Clemson University Institutional Biosafety Committee (IBC) which is empowered with the responsibility for the oversight, review and approval of all biological research conducted at Clemson 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 Clemson 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.

6.0 Responsibilities

Authority and Administration of Policy: The President of the University has the authority to appoint an Institutional Biosafety Committee (IBC) for Clemson University. The Office of Research Compliance is responsible for the administration of IBC functions.

The authority to review and approve or disapprove the biological safety aspects of any research, including DURC, is vested in the IBC. The IBC also serves as a technical resource for the biological safety program.

When reviewing DURC, the IBC functions as the University's IRE.

IBC Membership: Appointments made to the Institutional Biosafety Committee shall be made in accordance with applicable federal requirements.

7.0 Sanctions for Non-Compliance

The IBC has the authority to suspend or terminate research activities deemed not in compliance with governmental regulations and University Policy, as well as hold funding until compliance is achieved.

8.0 Approval Signatures

This policy has been approved by:

Tanju Karanfil
Vice President for Research

_12.4.2024_
Date

REVISION HISTORY		
EFFECTIVE DATE	**REVISION NUMBER**	**MODIFICATION**
February 5, 2019	01	Incorporated into VPR Policy Template
January 28, 2021	02	Clarification of Language; changed from 3.0.7 to 3.0.6
August 19, 2024	03	Removed use of hazardous chemicals in vertebrate animals from IBC scope, updated hyperlinks