I. **INTRODUCTION** (Purpose and Intent)

The University of South Florida (USF) is committed to incorporating health and safety practices in research and/or teaching activities using biohazardous materials at a USF facility and/or by USF or USF-affiliated faculty, staff, and students. USF has established a systematic and comprehensive Biosafety Program designed to reduce the risk of potential exposure to infectious agents, biological toxins, select agents and toxins, and recombinant or synthetic nucleic acid molecules (rDNA) in research and teaching environments.

The Biosafety Program is managed in accordance with the following documents: National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules; the Centers for Disease Control and Prevention (CDC), Biosafety in Microbiological and Biomedical Laboratories, 6th Edition, and the following federal regulations governing select biological agents and toxins, high consequence livestock pathogens, and restricted plant pathogens as identified in 42 C.F.R. 73, Select Agents and Toxins; 9 C.F.R. 121, USDA Animal and Plant Health Inspection Service (APHIS): Possession, Use, and Transfer of Select Agents and Toxins; and 7 C.F.R. 331, USDA APHIS: Possession, Use, and Transfer of Select Agents and Toxins.

II. **STATEMENT OF POLICY**

The Biosafety Program provides administrative support to the Institutional Biosafety Committee (IBC). All research and teaching activities performed by USF or USF affiliated faculty, staff, and students using infectious agents, biological toxins, select agents and toxins, or rDNA materials must receive IBC review and approval prior to initiation of such activities and must be performed in accordance the Biosafety Program policies and procedures, available at the following website: https://www.usf.edu/research-innovation/research-integrity-compliance/ric-programs/biosafety-program/index.aspx.
III. INSTITUTIONAL OFFICIAL AND RESPONSIBLE OFFICIAL

The USF President has delegated authority and responsibility of the Biosafety Program to the Senior Vice President for Research, Innovation & Knowledge Enterprise. The Senior Vice President for Research, Innovation & Knowledge Enterprise serves as the Institutional Official for the Office of Biotechnology Activities, U.S. Department of Health and Human Services, and is responsible for oversight and compliant operation of the Biosafety Program with regard to rDNA research and teaching activities.

The Senior Vice President for Research, Innovation & Knowledge Enterprise has appointed an Institutional Biosafety Committee that is responsible for the oversight and evaluation of the use of biohazardous agents in research and teaching (i.e., the Biosafety Program).

The Senior Vice President for Research, Innovation & Knowledge Enterprise has delegated authority and responsibility of the Biological Select Agents and Toxins (BSAT) Program, a specialized and highly regulated subunit of the Biosafety Program, to the Institutional Biosafety Officer, who serves as the Responsible Official for the CDC and the U.S. Department of Agriculture and is responsible for the oversight and compliant operation of the BSAT Program.

IV. INSTITUTIONAL BIOSAFETY COMMITTEE

All infectious agents, biological toxins, select agents and toxins, and rDNA materials used in research or teaching supervised or performed by USF faculty, staff, or students must be reviewed and approved by the IBC pursuant to IBC processes, regardless of whether these activities are performed on USF premises, performed in a location administered by or under the control of USF, or supported by funds provided by or through USF.

The IBC has authority to:

A. Review, approve, require modification, or withhold approval of proposed research or teaching activities using infectious agents, biological toxins, select agents and toxins, and rDNA materials.

B. Inspect laboratories where these agents are used or stored.

C. Review and, if warranted, investigate concerns involving the care and use of biohazardous agents.

D. Prepare written reports of its evaluations.

E. Make recommendations to the Senior Vice President for Research, Innovation & Knowledge Enterprise and the Senior Associate Vice President for Research & Innovation concerning any aspect of the Biosafety Program.
F. Suspend any activity involving infectious agents, biological toxins, select agents and toxins, and rDNA materials that does not conform to IBC procedures, state laws, and federal regulations.

V. **RESEARCH INTEGRITY & COMPLIANCE**

Research Integrity & Compliance assists the IBC in its oversight and evaluation functions through provision of administrative support services via its Biosafety Program.

VI. **SANCTIONS**

Failure to comply with the policies and procedures of the Biosafety Program, Florida law, or federal regulations regarding the use of infectious agents, biological toxins, select agents and toxins, or rDNA materials in research or teaching activities within USF or by agents or affiliates of USF may result in suspension of such research or teaching activities. In addition, the Institutional Official has the authority to terminate current awards of the investigator. Further, as a result of such non-compliance, the investigator may be ineligible to receive future awards or to perform research within USF.

VII. **REFERENCES**

- National Institutes of Health, *Guidelines for Research Involving rDNA Molecules*.
- Centers for Disease Control, *Biosafety in Microbiological and Biomedical Laboratories, 6th Edition*.
- 42 C.F.R. 73, *Select Agents and Toxins*.
- Chapter 64E-16, Florida Administrative Code: *Biomedical Waste*.

*Current Responsible Office: Research & Innovation*

*Refer to the appropriate Responsible Office website for a current name of the Vice President or other Responsible Officer.*

*History: New 8-13-09, Amended 8-24-16 (technical), 10-1-21 (technical).*

*Consolidation Amendments Effective: 7-1-20.*