

✓USF System USF USFSP USFSM

Number: 0-311
Title: Biosafety Program
Responsible Office: Research & Innovation

Date of Origin: 8-13-09

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I. INTRODUCTION (Purpose and Intent)

The University of South Florida system (USF System) is committed to incorporating health and safety practices in research and/or teaching activities using biohazardous materials at a USF System facility and/or by USF System or USF System affiliated faculty, staff, and students. The USF System 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 deoxyribonucleic acid (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 rDNA Molecules](#); the Centers for Disease Control and Prevention (CDC), [Biosafety in Microbiological and Biomedical Laboratories, 5th 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](#), *CDC Final Rule: Possession, Use, and Transfer of Select Agents and Toxins*; [9 C.F.R. 121](#), *USDA Animal and Plant Health Inspection Service (APHIS): Possession, Use, and Transfer of Biological Agents and Toxins*; and [7 C.F.R. 331](#), *USDA APHIS: Possession, Use, and Transfer of Biological Agents and Toxins*.

II. STATEMENT OF POLICY

The Biosafety Program provides administrative support to the USF System Institutional Biosafety Committee (IBC). All research and teaching activities performed by USF System or USF System 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: <http://www.research.usf.edu/dric/biosafety/docs/ibc-policy.pdf>.

III. INSTITUTIONAL OFFICIAL AND RESPONSIBLE OFFICIAL

The USF System President has delegated authority and responsibility of the Biosafety Program to the Senior Vice President for Research, Innovation & Economic Development. The Senior Vice President for Research, Innovation & Economic Development 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 & Economic Development 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 & Economic Development has delegated authority and responsibility of the Select Biological Agent and Toxin 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 Select Biological Agents and Toxins 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 system faculty, staff, or students must be reviewed and approved by Institutional Biosafety Committee pursuant to IBC processes, regardless of whether these activities are performed on USF System premises, performed in a location administered by or under the control of the USF System, or supported by funds provided by or through USF System.

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 & Economic Development 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 the USF System or by agents or affiliates of the USF System 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 the USF system.

VII. REFERENCES

- [National Institutes of Health](#), *Guidelines for Research Involving rDNA Molecules*.
- [Centers for Disease Control](#), *Biosafety in Microbiological and Biomedical Laboratories, 5th Edition*.
- [42 C.F.R. 73](#), *CDC Final Rule: Possession, Use, and Transfer of Select Agents*.
- [9 C.F.R. 121](#), *USDA Animal and Plant Health Inspection Service (APHIS): Possession, Use, and Transfer of Biological Agents and Toxins (livestock pathogens)*.
- [7 C.F.R. 331](#), *USDA-APHIS: Possession, Use, and Transfer of Biological Agents and Toxins (plant pathogens)*.
- [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.**

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