

OFFICIAL DIVISIONAL POLICY Academic Affairs Division Division of Business Affairs

Biosafety Policy

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1.0 Introduction

The University of Charleston, South Carolina, a component of the College of Charleston (hereafter, "institution") recognizes its responsibility to protect the health and safety of the institution community, the community at large, and the environment from risks inherent in the conduct of research and teaching. Some of that research involves the use of biohazards and recombinant or synthetic nucleic acid (r/sNA) molecules. This policy establishes the Institutional Biosafety Committee (IBC) to ensure that all such research, teaching activities, and research facilities comply with applicable federal, state and local regulations, institutional policies, and the highest standards of ethics and practice.

2.0 Purpose and Applicability

- 2.1 This policy is designed to ensure employees, students, and visitors follow safe work practices when working with or near biologically hazardous materials (infectious agents, biohazards or recombinant or synthetic nucleic acid (r/sNA) molecules).
- 2.2 This policy applies to College of Charleston employees, students, and visitors who engage in College-sponsored activities at any facility under the purview of the College of Charleston including but not limited to the downtown campus, Grice Marine Laboratory, and Dixie Plantation.

3.0 Definitions and Scope

- 3.1 "Biosafety" or "biological safety" is a concept that promotes safe laboratory practices, procedures, and proper use of containment equipment and facilities by laboratory workers in the biomedical environment to prevent occupationally-acquired infections or release of organisms to the environment. Biosafety is the responsibility of all persons who manipulate pathogenic microorganisms and recombinant or synthetic nucleic acid (r/sNA) molecules.
- 3.2 "Biohazards" are infectious agents or biologically derived infectious materials that present a risk or potential risk to the health of humans or animals, either directly through infection or indirectly through damage to the environment. Infectious agents have the ability to replicate and give rise to the potential of large populations in nature when small numbers are released from a controlled situation.
- 3.3 "Infectious waste" or "biohazardous waste" is defined by the South Carolina Department of Health and Environmental Control and includes sharps; microbiological specimens such as vaccines, culture dishes, and other waste that has been exposed to human pathogenic agents; blood and blood products; pathological waste which includes body fluids and any part removed from a human body; contaminated animal waste including parts, bodies, and bedding of animals exposed to human pathogens; and other waste designated as infectious or that has come in contact with infectious waste.

4.0 Roles and Responsibility

- 4.1 The Institutional Biosafety Committee (IBC) is a College-wide committee charged with formulating policy and procedures related to the use of biohazardous agents, including: human pathogens, oncogenic viruses, other infectious agents, and r/sNA molecules. The IBC is responsible for review and approval of projects involving r/sNA molecules and biohazardous materials. The committee sets containment levels in accordance with National Institutes of Health (NIH) and Centers for Disease Control and Prevention (CDC) guidelines, and adopts emergency plans covering accidental spills and personnel contamination. The President appoints members of the IBC.
- 4.2 The Principal Investigator (PI) is responsible for full compliance with approved research protocols, the institution's biosafety policies and procedures, NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid, the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Standard (human-derived materials) and other local, state and federal regulations that apply to research.
- 4.3 The Office of Environmental Health and Safety (EHS) is the operational arm of the IBC. It oversees the daily implementation of the Biosafety Program. EHS is responsible for development and review of the biological safety manual, and other related documents, development of infectious waste disposal policies and procedures to comply with state regulations and plans for emergency response to accidental biohazard spills and personnel contamination. It provides instruction and training on safe work practices, conducts routine inspections of work areas,

investigates accidents and recommends preventive/corrective actions, reviews animal research protocols involving hazardous materials, reviews construction design for safety features and responds to emergencies.

- 4.4 The Office of Research and Grants Administration, Research Protections and Compliance (ORGA RPC) is responsible for administering the institutional compliance programs in the areas of human subjects (Institutional Review Board), the care and use of animals in research (Institutional Animal Care and Use Committee) and the Institutional Biosafety Committee.
- 4.5 Each Department is responsible for the removal, packaging, and shipment of all infectious waste in accordance with local, state, and federal regulations.

5.0 Policy Manager and Responsible Department or Office

Provost (or Provost's Designee) Executive Vice President for Business Affairs (or Designee)

6.0 Departments/Offices Affected by this Policy

Office of the Provost All Academic Deans, Departments, and Academic Programs Graduate School Office of Environmental Health and Safety Office of Research and Grants Administration

7.0 Procedures Related to this Policy

- 7.1 Registration Forms and Protocols PIs are responsible for initiating research proposals to be reviewed by the IBC and/or EHS for work with r/sNA molecules or biohazards. PIs are responsible for completing registration forms to be reviewed for work with r/sNA molecules or biohazards. Upon submission of the forms, in accordance with the IBC and NIH Guidelines, the IBC and/or EHS review the projects. The EHS staff performs an inspection of the facility and reviews work practices.
- 7.2 Procedures and Training The EHS staff conducts biosafety training in accordance with institutional policies and procedures and applicable local, state, and federal requirements.
- 7.3 Laboratory Audits As part of the EHS laboratory audit program, the EHS staff participates in laboratory inspections on an annual basis and audits laboratories that generate r/sNA molecules and newly approved BSL2 labs.
- 7.4 Recordkeeping IBC project approval records are maintained by ORGA RPC in accordance with federal standards. Laboratory inspection results and training attendance records are maintained by EHS. Principal Investigators are responsible for updating IBC-approved projects with the IBC and/or EHS, and providing current listings of personnel involved in IBC-approved

projects.

8.0 Related Policies, Documents or Forms

Faculty/Administration Manual
Institutional Biosafety Committee Charter
Institutional Biosafety Committee Review Procedures
Protocol Review Forms
Bloodborne Pathogens Exposure Control Plan
Chemical Hygiene Plan

9.0 Review Schedule

Approved: February 2017

Next Review Date: October 1, 2022

Signed	:
	Brian R. McGee
	Provost and Executive Vice President for Academic Affairs
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Signed	
	Stephen C. Osborne
	Executive Vice President for Business Affairs