

POLICY ON THE USE OF BIOHAZARDOUS AGENTS AND RECOMBINANT DNA IN RESEARCH AND TEACHING LABORATORIES AT THE UNIVERSITY OF NORTH CAROLINA AT GREENSBORO

(Approved by the Chancellor, September 24, 2008)

I. Background and definitions

The University of North Carolina at Greensboro (UNCG) is committed to the protection of the general environment, as well as planning and implementation of control practices for the prevention of laboratory-acquired infections or harmful exposure to biohazards in all research and teaching activities involving biohazardous agents.

Laboratories working with microorganisms and/or recombinant DNA technologies are special, often unique, work environments. The materials being used may pose risks to persons working in or near the laboratory or to the environment, should the material escape the laboratory. The University has therefore established this policy in order to ensure the safe handling of biohazardous agents and recombinant DNA, to ensure the appropriate assessment of potential risks, and to reduce the opportunity of personnel exposure or accidental environmental release.

Prior to stating the UNCG policy on the management and handling of biohazards and and/or recombinant DNA, it will be helpful to review some relevant definitions.

Recombinant DNA (rDNA) refers to novel “unnatural” DNA molecules that are engineered by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell. As by definition rDNA is chimeric, the possibility for novel life forms of unknown toxicity or environmental hazard has been a concern since rDNA technology was invented in 1973. Thus, rDNA is considered a potential biohazard, and NIH has mandated that research institutions monitor and regulate its use.

Biohazardous Agents in laboratory settings are organisms, or substances derived from organisms, that pose a threat to (primarily) human health, but also to certain animals and plants. In addition to some rDNAs, biohazards, as broadly defined, include the following categories.

1. **Infectious/pathogenic organisms**, including certain bacterial, fungal, parasitic, viral, rickettsial or chlamydial agents, or other infectious/pathogenic agents having the potential for causing disease in healthy individuals, animals, or plants. (A list of infectious agents and their assigned biosafety level can be found in the CDC/NIH Guidelines).
2. **Biological toxins** including metabolites of living organisms and materials rendered toxic by the metabolic activities of microorganisms (living or dead).
3. **Blood** - Human blood, human blood components, and products made from human blood.
4. **Other Potentially Infectious Materials** - (1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; and (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead).
5. **Biological Select Agents and Toxins** are highly controlled biological agents or toxins with potential as biowarfare agents, as listed by the Centers for Disease Control (CDC) and/or the USDA Animal Plant Health Inspection Service (APHIS). This is referred to as the “Select Agents List”, and investigators working with these agents require an FBI background check.

Biosafety Levels (BSL) are categories for biocontainment precautions, based on levels of hazard, *Level 1* being minimum risk and *Level 4* being extreme risk. Various organisms and biohazardous materials are referred to as “BSL_n agents”, or sometimes as *Class 1* through *Class 4* agents. *These BSL-based categories are not to be confused with the “Risk Group” classification used by NIH.*

1. *Biosafety Level 1 (BSL1):* Work involving minimal or no known hazard to laboratory personnel and the environment. Standard microbiological procedures are adequate and a biosafety cabinet is not required for personal protection (but may be used to protect the biological sample from contamination).
2. *Biosafety Level 2 (BSL2):* Work involving agents of moderate potential hazard to personnel and the environment, requiring a type II biosafety cabinet for containment. Also applies to standard recommendations for handling human blood or body fluid specimens, as covered in the OSHA Bloodborne Pathogen Program standard.
3. *Biosafety Level 3 (BSL3):* Work involving indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route. Requires additional containment practices and protective equipment beyond that used for BSL2.
4. *Biosafety Level 4 (BSL4):* Exclusively applies to viruses that cause severe to fatal disease in humans, that are easily transmissible by aerosols or contact entry, and for which vaccines or other treatments are *not* available. Requires the highest level of containment, unlikely to be attained in an academic research environment.

II. Policy

A. It is UNCG policy that all Principal Investigators (PI) or Laboratory Directors (for both teaching and research laboratories) must assume primary responsibility for the proper use, response to exposure or release incidents, handling and disposal of all biohazardous agents and rDNA molecules associated with their research. UNCG principal investigators and teaching/research personnel must comply with applicable Federal, State, local regulatory standards, and university safety and health policies and procedures as well as any administrative requirements established by UNCG.

B. UNCG’s laboratory biosafety policy shall be implemented through an Institutional Biosafety Committee (IBC), which will establish and make available a Laboratory Biosafety Manual that will be part of the UNCG Safety and Health Policy and Procedure Manual. The Laboratory Biosafety Manual provides specific procedures and recommended practices for the handling of biohazardous agents and rDNA in laboratories.

C. To ensure that UNCG operates its laboratories in compliance with all applicable biosafety regulations and good laboratory practices, all researchers and lab directors who plan to use biohazardous agents and rDNA must have a protocol approved by the IBC before the work can be initiated. Guidelines for the preparation of this protocol will be established by the IBC and can be found under “Guidelines for Use of Biohazardous Agents and rDNA” posted on the ORC website. Researchers or lab directors who plan to use biohazardous agents or rDNA are responsible for knowledge of the University’s procedures.

D. Some rDNA projects and all BSL1 agents are exempt from IBC review. Currently, BSL3 and BSL4 agents are not approved for use at UNCG. Furthermore, the procurement and use of any agent designated by the Federal Government as a Select Agent is currently prohibited at UNCG. Any UNCG investigator desiring to initiate work with BSL3 or Select Agents must discuss this with the Associate Provost for Research and Public / Private Sector Partnerships. Registration of Select Agents with the Federal Government must be done through the

university's Responsible Official (RO), the Assistant Vice Chancellor for Environmental Safety or his designee.

E. Failure to comply with this policy in its entirety may result in an administrative review and a possible suspension of approval by the IBC for work with biohazardous agents and/or non-exempt rDNA molecules.

III. Biosafety organization and responsibilities

A. Institutional responsibility and authority

The Associate Provost for Research and Public/ Private Sector Partnerships oversees the Institutional Biosafety Committee (IBC) and the implementation of this policy. The Associate Provost has designated the Director for the Office of Research Compliance responsible for ensuring that government regulations regarding rDNA and Biohazardous Agents in research laboratories are met through the IBC.

B. The Office of Research Compliance (ORC)

The ORC provides administrative support to the IBC, maintains the most current version of the Guidelines for Use of Biohazardous Agents and rDNA, manages all IBC registration and reporting processes, maintains appropriate records, and serves as liaison with the NIH in the ongoing implementation of the IBC program.

C. Institutional Biosafety Committee (IBC)

The IBC is appointed by and reports to the Chancellor of the University through the Office of Research and Public/Private Sector Partnerships. The existence of the IBC, and its composition (e.g. the requirement for community members from outside the university), is mandated by NIH as a requirement for NIH funding.

The IBC has the following responsibilities:

1. As a basis for the review process, the IBC establishes guidelines, procedures and application forms for the registration, use and containment of rDNA and BSL2 agents and/or procedures.
2. The IBC is responsible for the review, approval, and oversight of rDNA research conducted at or sponsored by the University in accordance with the NIH Guidelines, regardless of the source of funding.
3. The IBC is responsible for the review of any experiments that introduce or expose biohazardous agents to plants, animals, or human participants. If necessary, for an application involving an unusual biohazard, the Director for the Office of Research Compliance will appoint additional members or consult with appropriate professionals as necessary to ensure that the membership is constituted in accordance with NIH Guidelines.
4. The IBC assembles and approves the Laboratory Biosafety Manual which contains biosafety standards from the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), and other applicable regulations. It also includes information about the specific hazards of each class of biohazardous agents. The Laboratory Biosafety Manual is maintained by the Office of Safety and must be posted online, and thereby be available to every relevant laboratory on campus.

5. The IBC works with the Office of Safety to ensure appropriate compliance with IBC-approved policies and procedures, e.g. via laboratory inspections, provision of biosafety instruction, biohazardous waste disposal and response to exposure or release incidents.

D. Office of Safety

The Office of Safety is assigned the responsibility for monitoring and providing services in conformity with the policy and standards set forth in the Laboratory Biosafety Manual such as described in C.5 above. A member of the Office of Safety will serve as an ex-officio member of the IBC.

The Office of Safety provides technical support to the IBC and maintains the most current version of the Laboratory Biosafety Manual. It will review and approve the Laboratory Biosafety Manual developed by the IBC in order to insure compliance with applicable regulations, best practices in biological safety, and inclusion in the UNCG Safety and Health Policy and Procedure Manual.

E. Biosafety Officer

Most large research universities have a Biosafety Officer (BSO), whose duties typically involve facilitating the operation of the biosafety program, assuring that the use of biohazardous agents conforms to the University policy and applicable governmental regulations, conducting periodic inspections of biological laboratories, and providing biosafety training as needed.

At its current level of biological research activity, UNCG is not required by NIH to appoint a Biosafety Officer (BSO). Various functions recognized as typical BSO responsibilities which can not easily be met by the IBC will be delegated to the Assistant Vice Chancellor for Environmental Safety and the Office of Safety. These include activities such as:

Assisting investigators in developing lab safety plans, coordinating biosafety training, lab safety inspections, incident response for exposures or spills/environmental release, and informing the IBC, unit heads, PIs, and others of legally mandated biosafety requirements, governmental guidelines and regulations.

The responsibilities of this role are defined in the NIH Guidelines section IV-B-3a-c.

F. Principal Investigator or Laboratory Director Responsibility

The Principal Investigator (PI) or Laboratory Director (for both teaching and research laboratories) has the following responsibilities:

1. Instructing and training laboratory staff in the practices and techniques required to ensure safety and proper emergency response and notification procedures in the event of an accident or injury, including providing emergency contact information and being available to respond to emergencies as needed;
2. Familiarizing his/her staff with the symptoms of exposure and other pertinent information about the biohazardous agent used in the experiment before allowing lab personnel to work with the agent;
3. Supervising the laboratory staff's safety performance to ensure that the required safety practices and techniques are employed;
4. Informing the staff of the reasons and provisions for any precautionary medical practices advised or requested, such as immunization or serum collection;

5. Selecting and providing personal protective equipment to all laboratory staff members based on the experimental procedures used in the lab and documenting this as required by OSHA and the UNCG Safety and Health Policy and Procedure for Personal Protective Equipment;
6. Making available a copy of the UNCG Laboratory Biosafety Manual to all laboratory staff members;
7. Maintaining written documentation for all training activities, which includes instruction in laboratory safety procedures, for all laboratory staff personnel;
8. Investigating and reporting in writing to the IBC and the Office of Safety any significant problems or incidents pertaining to the operation and implementation of containment practices and procedures;
9. Correcting conditions that may potentially result in the release of biohazardous agents;
10. Having biosafety cabinets certified by an approved contractor on an annual basis, or when moved; and
11. Ensuring compliance with the other procedures established by the IBC and other university entities governing the use of biohazardous agents.

Investigators shall not possess nor permit the University to possess on their behalf any biological agents, toxins, or delivery systems not reasonably justified by prophylactic, protective, bona fide research, or other peaceful purposes.