

NEOMED RESEARCH POLICY	Policy No: 3349-R-610
RESEARCH POLICY TITLE: Biosafety and the Safe Use of Biohazards on the NEOMED Campus	EFFECTIVE DATE: May 2, 2018

(A) PURPOSE

The purpose of this policy is to provide appropriate guidance and oversight over potential or recognized biohazards in accordance and compliance with all local, State and Federal regulations.

(B) SCOPE

This policy applies to all personnel on the Northeast Ohio Medical University (University) Campus and related facilities and operations who are engaged in the use of biohazardous agents, carcinogens, rDNA or other agents that may be governed by the National Institutes of Health (NIH) Guidelines.

(C) DEFINITIONS

- (1) “Biohazardous Agent” refers to any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsia, protozoa or prions) or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing:
 - (a) Death, disease, or other biological malfunction in a human, animal, plant, or another living organism;
 - (b) Deterioration of food, water, equipment, supplies, or material of any kind; or
 - (c) Deleterious alteration of the environment

(D) POLICY STATEMENT

- (1) The University shall have an Institutional Biosafety Committee (IBC) which shall:
 - (a) Establish a Biological Safety Manual that provides information on work practices, procedures, and policies necessary to ensure the health and safety of individuals exposed to biohazardous agents in the laboratory setting.

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- (b) Review and approve all proposals, activities, and experiments for compliance with NIH guidelines and the principles and practices of risk assessment according to the Biosafety in Microbiological and Biomedical Laboratories (BMBL) which involve any of the following:
 - (i) an organism or product of an organism that presents a risk to humans. This includes, but is not limited to: work with potential pathogens and carcinogens;
 - (ii) work with human clinical samples and primary cell lines and work with DNA from pathogenic organisms;
 - (iii) rDNA; or
 - (iv) select agents or other biohazards.

- (2) The IBC shall be comprised, as follows, in accordance with Section IV-B-2 of the NIH guidelines:
 - (a) No fewer than five members, which collectively have experience and expertise in recombinant or synthetic nucleic acid molecule technology and the capability to assess the safety of recombinant or synthetic nucleic acid molecule;
 - (b) At least two members who are not affiliated with the institution (apart from their membership on the Institutional Biosafety Committee) and who represent the interest of the surrounding community with respect to health and protection of the environment;
 - (c) At least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments utilizing Appendix P, Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Plants, require prior approval by the Institutional Biosafety Committee;

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- (d) At least one scientist with expertise in animal containment principles;
 - (e) A Biological Safety Officer is mandatory and shall be a member of the Institutional Biosafety Committee when the institution conducts recombinant or synthetic nucleic acid molecule research at BL3, BL4, or Large Scale (greater than 10 liters),
 - (f) With persons having the following areas of expertise;
 - (i) Recombinant or synthetic nucleic acid molecule technology, biological safety, and physical containment experience;
 - (ii) Knowledge in institutional commitments and policies, applicable law, standards of professional conduct and practice, community attitudes, and the environment,
 - (iii) At least one member representing the laboratory technical staff.
- (3) The University’s current IBC roster structure is as follows, based upon current research needs.
- (a) Two laboratory technical staff member;
 - (b) Two Nonaffiliated Community members;
 - (c) Three Scientists, one which serves as Chair and one which serves as Vice-Chair;
 - (d) One Animal Containment Expert;
 - (e) One Safety Expert.