

**NEW MEXICO STATE UNIVERSITY (NMSU)
INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) OPERATING CHARTER**

GENERAL CHARGE

The New Mexico State University (NMSU) Institutional Biosafety Committee (IBC) reviews all institutional activities involving the use of **Biohazardous Agents** and **Recombinant DNA Molecules** that require approval for “biosafety activities” as described by current governmental agencies. These regulatory agencies include but are not limited to:

- Health & Human Services (HHS) Center for Disease Control (CDC)
<http://www.cdc.gov/od/ohs/biosfty/biosfty.htm>
- United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS)
<http://www.aphis.usda.gov/>
- United States Department of Agriculture (USDA) Occupational Safety and Health Administration (OSHA) regulations and compliance directives as adopted and adhered to by the New Mexico Occupational Health and Safety Bureau (NMOSHB).
http://www.nmenv.state.nm.us/OHSB_website/ohsb_home.htm
- National Institutes of Health (NIH) Recombinant DNA Guidelines (Guidelines)
[NIH Guidelines April 2002](#)

In recognition of the large amount of information on biohazardous agents, recombinant DNA technologies and changing regulatory environment, the IBC requires the support of the Biosafety Officer and may need additional specialists for technical consultation. As health risks, new technologies and new regulations emerge, the NMSU IBC Operating Charter will be revised accordingly.

DEFINITIONS

Biohazardous Agents:

- Any microorganism (including but not limited to bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance that is capable of causing: **1.** death, disease or other biological malfunction in a human, an animal, a plant or another living organism; **2.** deterioration of food, water, equipment, supplies, or materials of any kind; or **3.** a deleterious alteration of the environment.
- Any toxic material or product of plants, animals, microorganisms (including but not limited to bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule (whatever the origin and method of production), which includes any poisonous substance or biological product that: **1.** may be engineered as a result of biotechnology; **2.** produced by a living organism; or **3.** is an isomer or biological product, homologue, or derivative of such a substance.
- Infectious or pathogenic biological agent defined by: **1.** CDC as biosafety level (BSL) 2-4 ([BMBL 4th Edition](#)), or **2.** NIH as risk group (RG) 2-4 agent ([NIH Guidelines April 2002](#)) (also see Additional Definitions on page 5 of this Charter document).
- Regulated biological agent or toxin as identified by **1.** HHS 42 Code of Federal Regulations (CFR) Part 73 ([Select Agents Program](#)); **2.** USDA-APHIS lists of Biological Agents and Toxins that pose a severe threat to “animal health or animal products” (9 CFR Part 121); or to “plants health or plant products” (7 CFR Part 331) ([Federal Register 9CFR 121 7CFR 331](#)). Also see the [NACUA Agent and Toxin List](#) as compiled by the National Association of College and University Attorneys (NACUA), as a summary of all of the lists.

Recombinant DNA Molecules:

- Nucleic acid molecules constructed outside of living cells by joining natural or synthetic DNA segments to DNA molecules that can be replicated in a living cell.
- DNA molecules that result from the replication of those molecules described above.

NMSU IBC OPERATING CHARTER

IBC RESPONSIBILITIES AND SCOPE

- The IBC is responsible for reviewing all NMSU-IBC application forms submitted by research investigators and their laboratory staff members, teaching faculty, and visiting scientists (collectively defined as PI for Principal Investigator) whose activities involve:
 1. any biohazardous agent as defined above which can cause disease in humans
 2. any biohazardous agent which will be introduced into any animal
 3. any non-exempt recombinant DNA molecules (Exempt experiments are defined by NIH Guidelines Section III-F) ([NIH Guidelines April 2002](#))
 4. any large scale production of viable organisms containing recombinant DNA, or with the potential to produce toxic or hazardous substances (as defined by NIH Guidelines Section III-D-6 and Appendix K). ([NIH Guidelines April 2002](#))
 5. any possession, use, or transfer of HHS Select Agents and Toxins (42 CFR Part 73) ([Select Agents Program](#)), or USDA Biological Agents & Toxins (9 CFR Part 121) or listed Plant Pathogens (7 CFR Part 331) ([Federal Register 9CFR 121 7CFR 331](#))
- The IBC will ensure that to the fullest extent practical, that all risks to the health, safety, and well being of laboratory employees, the public, and the environment regarding the use of biohazardous agents, non-exempt recombinant DNA molecules, and large-scale production of recombinant DNA molecules, will be minimized.
- The IBC recommends policies to guide PIs, the University Biosafety Officer (BSO) and Environmental Health & Safety (EH&S) in the administration of NMSU's Biosafety Program with regard to the acquisition, use, transfer, storage, disinfection, disposal of agents, and emergency response procedures for all biosafety activities. The IBC shall ensure that such activities meet standards of good practice consistent with safety of personnel, the general public, and the environment in ways that best facilitate relevant research or teaching activities at NMSU.
- The IBC is vested with the authority to comprehensively review, and approve research applications with or without modifications, or withhold approval of all or any part of an application with regard to biological aspects of the research or activity. The IBC may make recommendations for corrective action on protocols.
- If a BSO review of a suspected or alleged violation of any University policy or external regulation that involves "biosafety activities" indicates that the violation is of a serious or continuing nature, the BSO will report such to the IBC. The IBC holds the authority to suspend any project in which serious or continuing violations have been reported. The IBC will notify the affected PI(s) and will proactively interact with the PI to rectify the situation. If further action is needed, the IBC will inform the Vice Provost for Research.
- Upon request, the IBC shall review and comment on proposed biosafety regulations, including but not limited to federal, state, and local policies. When appropriate, the IBC will formulate draft policies and procedures for approval by the Vice Provost for Research and other institutional officials as needed.
- The IBC shall periodically review the effectiveness of the Biosafety Program and make recommendations for improvements.
- The IBC shall ensure that "Biosafety activities that fall within the responsibility and scope of the IBC" which are official NMSU business conducted by an NMSU employee at a non-NMSU facility have been approved by the non-NMSU facility and adhere to the NMSU biosafety requirements.

NMSU IBC OPERATING CHARTER

IBC APPOINTMENTS and COMPOSITION

- The IBC is appointed by the Vice Provost for Research upon recommendation from but not limited to the Director of EH&S and the IBC Chair.
- The IBC Chair is appointed by the Vice Provost for Research and serves as the link between the Office of the Vice Provost and the IBC.
- A Vice Chair should be appointed to conduct business in the absence of the Chair, or in place of the Chair if and when the Chair has an application before the committee.
- The composition of the IBC should include at least 8 NMSU members and 2 community members that are not affiliated with NMSU.
 1. Individuals, either associated with NMSU or extra -institutional, with the following expertise and/or job duties may be appointed to the IBC:
 - o recombinant DNA technology
 - o molecular biology
 - o biological safety
 - o public health and epidemiology
 - o virology
 - o microbiology
 - o infectious diseases
 - o animal scientist
 - o plant pathogen or plant pest containment principles
 - o laboratory technician/non-doctoral
 - o facilities management
 2. The community members should represent the interests of the surrounding community with respect to health and protection of the environment and should be knowledgeable in the basic principals of microbiology and recombinant DNA technology, or capable of assimilating these principles within the context of their applicability to the surrounding community and the general public. Individuals with the following expertise and/or job descriptions should be considered:
 - o officials of state or local public health or environmental protection agencies
 - o persons involved in medical, occupational health or environmental concerns in the community
- The IBC may also include ex-officio non-voting members who may be invited to serve when their expertise is required and can supplement the deliberations of the IBC. These members shall include but not be limited to additional representatives, usually administrative, of the following departments: Environmental Health & Safety, Employee Health Services, Research Administration, University Council, Office of Facilities and Services and/or Planning Design and Construction, and biosafety expert consultants external to NMSU. All other members of the IBC appointed by the Vice Provost for Research will be voting members.

TERMS OF SERVICE

- The term of membership on the IBC is a 12 month renewable period. In general, members will serve 2-3 years. The IBC Chair and the Director of EH&S will make a recommendation for renewal of membership on the committee to the Vice Provost for Research.
- The IBC Chair is a continuous appointment by the Vice Provost for Research, with an annual confirmation from the committee to the Vice Provost for Research.
- The BSO is a continuous position appointment. The BSO is a professional position which reports to the EH&S Director.

NMSU IBC OPERATING CHARTER

IBC GUIDELINES AND PROTOCOL REVIEW PROCEDURES

- The IBC shall meet quarterly or as needed to ensure timely review of applications.
- All biosafety application/registration forms shall be available for review by any member of the IBC. The BSO shall maintain records of research application reviews, minutes of IBC meetings, including records of attendance and IBC deliberations.
- If requested, the minutes of meetings are available to the public under the open records law.
- Applications submitted by PIs for work that falls within the IBC responsibility and scope must be reviewed and approved by the IBC prior to the initiation of that work.
- Approval for biosafety activities is granted for three years after the **initial review** by the IBC, and is contingent upon the **affirmative** vote of the majority of a quorum. (The quorum for the NMSU IBC is defined under Additional Definitions on page 5 of this Charter document).
- An activity modification report must be submitted by the PI to the IBC if and when the project changes significantly in terms of experimental activities, facilities; or for any personnel change, during the approval period. If the PI on a project changes, a new application form must be submitted to the IBC.
- The BSO will conduct annual inspections of facilities of approved projects, and initial inspections of facilities of new projects, and report to the IBC.
- The following guidelines are established to aid the IBC in the exercise of its responsibilities:

1. Biohazardous Agents

- Research applications involving RG 1 and/or BSL 1 materials that do not involve recombinant DNA, **do not** require review by the IBC.
- Dictated by the lack of facilities at NMSU, research using any RG 4 agents or any materials that require BSL 4 containment will not be considered by the IBC for work at any NMSU location or facility.

2. Toxins

- The routine use of most toxins will not require IBC review and approval. However, the possession, use, or transfer of any toxin which is included in 1. HHS Select Agents and Toxins (42 CFR Part 73) ([Select Agents Program](#)), 2. the USDA-APHIS Biological Agents and Toxins - severe threat to animal health or animal products list (9 CFR Part 121), or 3. USDA-APHIS Biological Agents and Toxins -severe threat to plants health or plant products list (7 CFR Part 331) ([Federal Register 9CFR 121 7CFR 331](#)), will require IBC review and approval prior to initiation of the project. The BSO will notify the IBC if any experiments involve the isolation and production of toxins included in the aforementioned CFRs.

3. Recombinant DNA

- Projects using recombinant DNA (that are not exempt) require IBC review and approval before initiation.
- Experiments described as “Exempt” in Section III-F of the NIH Guidelines ([NIH Guidelines April 2002](#)) do not require IBC review and approval – but will require registration via the IBC application/ registration form for tracking and review by the BSO.
- Planned release of any organism (e.g. transgenic plants, animals, bacteria) outside of the approved laboratory environment requires registration with the appropriate Federal regulatory agency and must be filed with the IBC.

REPORTING LINE AND ADMINISTRATIVE SUPPORT

- The IBC reports to the Vice Provost for Research at New Mexico State University. The BSO is the administrator of the IBC and is also responsible for the day-to-day operation of the Biosafety Program. The BSO reports to the Director of EH&S and provides the necessary administrative support for the functions and business of the IBC.

ADDITIONAL DEFINITIONS

- **Biosafety Level (BSL).** A description of the degree of physical containment to be employed for managing infectious materials in the laboratory environment where they are being handled or maintained. The purpose of containment is to reduce or eliminate exposure of laboratory workers, other persons, and the outside environment to potentially hazardous agents. The levels are designated in ascending order, by degree of protection provided to personnel, the environment, and the community. The essential elements of the four biosafety levels defined by the CDC for activities involving infectious microorganisms and laboratory animals are summarized in **Sections III and IV** of the **Biosafety in Microbiological and Biomedical Laboratories (BMBL) 4th Edition.** ([BMBL 4th Edition](#))
- **Risk Groups (RG).** Agents are classified into four Risk Groups (RGs) according to their relative pathogenicity for healthy adult humans by the following criteria: (1) Risk Group 1 (RG1) agents are not associated with disease in healthy adult humans, (2) Risk Group 2 (RG2) agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available, (3) Risk Group 3 (RG3) agents are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available, (4) Risk Group 4 (RG4) agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available. **NIH recombinant DNA Guidelines Section II-I-A, and Appendix B.** ([NIH Guidelines April 2002](#))
- **Quorum for the NMSU IBC.** A quorum is defined as the number of members required to be present for business to be legally transacted. For the purpose of the NMSU IBC, a minimum quorum shall consist of the IBC Chair, the Biosafety Officer (BSO), a committee member representing the department or the research area of the proposed “biosafety activity”, a committee member whose expertise is necessary to address all safety issues of the proposed “biosafety activity”, and a committee member or members to meet the criteria of specific guidelines (such as the NIH Recombinant DNA Guidelines) when relevant.