

Marshall University Institutional Biosafety Committee Charter (IBC approved January 28 2021)

Background

The Institutional Biosafety Committee (IBC) was established by the Marshall University Vice President for Research to ensure a safe working environment for the conduct of biological and biomedical research.

Guidance

This IBC is guided by and ensures compliance with the following regulations:

- the NIH Guidelines for Recombinant or Synthetic Nucleic Acid Molecules (“NIH Guidelines”) which specifies practices for the construction, handling, and disposal of recombinant DNA (rDNA) and synthetic DNA (sDNA),
- Biosafety in Microbiological and Biomedical Laboratories (BMBL) manual (DHHS/CDC).
- the Federal Select Agent Program (42 CFR Part 73) which governs the possession, use, and transfer of select infectious agents and toxins,
- the Joan C. Edwards School of Medicine (JCESOM) Bloodborne Pathogen Exposure Control Plan which addresses:
 - (1) risk classification for each research position in the School of Medicine,
 - (2) implementation of methods of compliance with regulations and policies,
 - (3) Hepatitis B vaccination (or waivers) and post-exposure follow-up,
 - (4) communication of hazards to employees through training, signs and labels,
 - (5) procedures for evaluating circumstances surrounding exposure incidents and
 - (6) special rules for HIV/HBV research or production facilities.
- The Infectious Waste Management Plans for the Byrd Biotech Center, the Weisberg Applied Engineering Building (WAEC), the Translational Genomics Research Institute (TGRI), Steven J. Kopp Hall, and the Coon Education Building (CEB)

The objectives of the Waste Management Plans are to provide (1) a safe and controlled environment for visitors, students, faculty and staff and (2) proper management of infectious waste in accordance with the West Virginia Infectious Waste Rule 64-CSR-56 and the Occupational Safety and Health Administration health regulations on exposure to Bloodborne Pathogens.

Institutional Biosafety Committee Charge

The IBC is charged with overseeing all research and educational activities which pose a biological or biomedical hazard. These activities include, but are not limited to, the handling and disposal of pathogenic organisms, rDNA, sDNA, biological toxins, Select Agents and infectious (biohazardous) waste. The Vice President for Research has granted the IBC the authority to investigate potential violations or compliance problems.

The IBC provides annual training in the safe handling of rDNA, human bloodborne pathogens, and infectious waste; all researchers (faculty, staff and students) working with rDNA and infectious agents are required to complete this training.

The IBC maintains a university website (<https://jcesom.marshall.edu/research/office-of-research-and-graduate-education/resources/institutional-biosafety-committee/>) that includes (1) contact information for safety personnel, (2) Committee Membership, (3) rDNA research application

forms, (4) biohazardous spill occurrence forms, (5) MU Biosafety Guidelines, (6) Human Gene Transfer policies (7) Federal Biosafety Guidelines and Resources, (8) Useful Biosafety Links including links to the NIH Office of Science Policy and Dual Use Research, (9) the Federal Select Agent Program and (10) Access to the Marshall University Online Biosafety Training Course.

The IBC is responsible for assessment of new or remodeled facilities where research will be conducted. The IBC's review of construction plans can help ensure that new facilities are compliant with the conditions and containment measures described in the NIH Guidelines.

rDNA Biosafety Policy

The NIH Guidelines section on compliance that under Section I-D-2 states that "All NIH-funded projects involving recombinant DNA techniques must comply with the *NIH Guidelines*. Non-compliance may result in: (i) suspension, limitation, or termination of financial assistance for the noncompliant NIH-funded research project and of NIH funds for other recombinant DNA research at the institution, or (ii) a requirement for prior NIH approval of any or all recombinant DNA projects at the institution."

The NIH Guidelines further state under Section I-D-2 that "All non-NIH funded projects involving recombinant DNA techniques conducted at or sponsored by an institution that receives NIH funds for projects involving such techniques must comply with the *NIH Guidelines*. Noncompliance may result in: (i) suspension, limitation, or termination of NIH funds for recombinant DNA research at the institution, or (ii) a requirement for prior NIH approval of any or all recombinant DNA projects at the institution.

Therefore, since Marshall University is a recipient of NIH funds, all researchers working with any rDNA protocol must submit an rDNA application even if the research has been determined to be in the exempt category. The IBC is responsible for the review and approval of all activities involving rDNA sDNA, infectious agents, biological toxins, and Select Agents.

IBC meetings: The IBC will meet at least six times per year to review rDNA applications and biosafety policies and protocols.

Safety Committee Communication: IACUC - IBC harmonization: Animal protocols that require use of rDNA or infectious agents require IBC approval prior to review and approval by the IACUC. After IACUC approval, the PI, lab staff, and the Animal Care Staff must meet to finalize the animal maintenance protocols and provide training in biosafety to all parties as needed. IRB - IBC harmonization: Human Gene Transfer protocols (introduction of rDNA into human subjects) require IBC approval prior to review and approval by the IACUC. The IBC has permanent representatives from the MU IRB and IACUC committees; these representatives notify their committees of protocols which will require IRB or IACUC review.