

 <p>Institutional Biosafety Committee Guiding Principles and Procedures</p>	<p>Effective: 2011</p> <p>Revised: June 13, 2014, October 2016, August 2021, October 2022. February 2023</p>
<p>Title: Scope and Regulatory Authority</p>	<p>Page 1 of 2</p>

SCOPE

These NDSU Biosafety Guidelines apply to employees and students that conduct clinical, research, and/or teaching activities as described in Section 2.1. Outside organizations using NDSU facilities and/or equipment also must follow the NDSU Biosafety Guidelines, and submit protocol applications listing an NDSU contact person as responsible party.

REGULATORY AUTHORITY

The *NDSU Biosafety Guidelines* are based on several regulatory requirements, as well as nationally recognized consensus standards and guidelines. The following list is not inclusive of all regulations and/or requirements that may pertain to any given project. Other requirements may apply depending on other factors, such as, but not limited to, concurrent use of radioactive materials, live animals, and human subjects, or additional specific funding organization requirements. Principal Investigators (PIs) must familiarize themselves with all requirements pertaining to their particular projects.

The federal regulations and guidelines that follow are the basis for the NDSU biosafety program. This list is not all-inclusive. In cases where federal, state, and local regulations differ, NDSU will follow the most stringent regulations.

- **Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules** (herein referred to as “NIH Guidelines”), U.S. Department of Health and Human Services, National Institutes of Health. 59 FR 34496 (Final Rule) and subsequent amendments. <https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy#tab2/>
- **Biosafety in Microbiological and Biomedical Laboratories, 6th Ed.** (herein referred to as “BMBL” or “CDC Guidelines”), U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention. <https://www.cdc.gov/labs/BMBL.html>

- **49 CFR Parts 100 to 185. Hazardous Materials Regulations. U.S. Dept. of Transportation.** <http://www.phmsa.dot.gov/hazmat/standards-rulemaking/hmic>
- **42 CFR Part 73, Select Agents and Toxins.** <https://www.ecfr.gov/current/title-42/part-73>
- **Dangerous Goods Regulations (DGR). International Air Transport Association (IATA).** <http://www.iata.org/publications/dgr/Pages/index.aspx>
- **29 CFR 1910.1030, Blood-borne Pathogens. U.S. Department of Labor, Occupational Safety and Health Administration.**
https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051
- **42 CFR Parts 71 and 72, Control of Communicable Diseases. U.S. Dept. of Health and Human Services, Center for Disease Control and Prevention.**
<http://www.cdc.gov/quarantine/final-rules-control-communicable-diseases.html>
- **9 CFR Parts 92, 94, 95, 96, 122, and 130. Importation of Etiologic Agents of Livestock, Poultry, and Other Animal Diseases. US Dept. of Agriculture, Animal and Plant Health Inspection Service.** <http://www.aphis.usda.gov/wps/portal/aphis/home/>
- **7 CFR Part 330. Importation and Domestic Transfer of Plant Pests. US Dept. of Agriculture, Animal and Plant Health Inspection Service.**
<http://www.aphis.usda.gov/wps/portal/aphis/home/>
- **15 CFR Parts 730 to 799. Export of Etiologic Agents of Humans, Animals, Plants, and Related Materials. U.S. Dept. of Commerce, Bureau of Industry and Security.**
<http://www.bis.doc.gov//index.php/regulations/export-administration-regulations-ear>

See NDSU IBC [webpage](#) for current links

Annual report to NIH OBA

An annual report is submitted to NIH OBA detailing the IBC members as well as MOUs currently in place. The report is submitted by the IBC office.

Policy on Public Comments

Section IV-B-2-a-(7) of the NIH Guidelines states that if the public comments on IBC actions, the institution will forward both the comments and the IBC response to NIH. This shall be handled by the Research & Integrity Compliance office.