

 <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: Research Categories Requiring IBC Approval</p>	<p>Page 1 of 4</p>

Guiding Principle

There are three categories regulated under the NDSU Biosafety Guidelines involving biohazardous materials. All categories require approval from the IBC committee prior to work beginning on the NDSU campus.

- Recombinant or Synthetic Nucleic Acids (Section 1)
- Infectious Agents (Section 2)
- Human Blood, Bodily Fluids, Tissues or Cell Culture (Section 3)

1. Recombinant or synthetic nucleic acids

The NDSU Biosafety Guidelines are based on the NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES (NIH GUIDELINES) APRIL 2019 and NDSU policy 347. All projects involving recombinant or synthetic nucleic acids must be reviewed by the IBC. No work on any project may begin without IBC approval.

NIH guidelines are broken into two groups that require IBC review:

- EXEMPT Recombinant or synthetic nucleic acid projects (Section 1.1)
- NON-EXEMPT Recombinant or synthetic nucleic acid projects (Section 1.2)

1.1 NON-EXEMPT

There are five categories of experiments involving recombinant or synthetic nucleic acid molecules that are regulated by NIH Guidelines and require full board review by the NDSU Biosafety committee.

To access the full list of NIH Guidelines, click here:

<https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy#tab2/>

Common protocol examples at NDSU:

- **Section III-D-3** Experiments involving the use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper viruses/ packaging systems in tissue culture (example: lentiviral vector systems).
- **Section III-D-5** Experiments involving whole plants – BSL2 or higher
When growing or creating transgenic plants on NDSU campus, prior authorization is required from the Ag Experiment Station Director before obtaining or creating plants.
- **Section III-E-2** Experiments involving whole plants (requiring BL1-P and BL2-P containment)
- **Section III-E-3** experiments involving transgenic rodents that require BSL-1 containment

1.2 EXEMPT

All other experiments fall under the exempt category and will be reviewed by the Designated Member Review process (DMR)

2. Infectious Agents

NDSU regulates the following areas of research involving Infectious Agents, defined as any agent that can be infectious to humans, plants/environment, or animals.

NIH guidelines and WHO Risk Groups are used to determine Biosafety level for research on campus.

Helpful tool for the PI to determine Risk Group of Infectious Agents can be found here:

[ABSA Risk Group Database](#)

- Prions (Section 2.1)
- Select Agents/ Biological Toxins (Section 2.2)
- Dual Use Research of Concern (DURC) (Section 2.3)

For more information, please see:

[The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules Biosafety in Biomedical and Microbiological Laboratories](#)

The WHO Laboratory Biosafety Manual

OIE Terrestrial Manual 2012

[Canadian Pathogen Safety Data Sheets](#)

2.1 Prions

Any research involving animal or human prions must be reviewed by the IBC prior to work beginning. Classification and containment requirements will depend on the type of prion used. **If the prion requires BSL-3 containment, this research cannot be conducted on the NDSU campus at this time.**

For more information, please see:

[Biosafety in Microbiological and Biomedical Laboratories \(BMBL\) 6th Edition](#)

[Recommended Biosafety Practices for Handling Prions and Prion-Infected Tissues](#)

2.2 Select Agents / Biological Toxins

Research and teaching laboratory projects involving select agents/biological toxins do not fall under NDSU IBC purview. Investigators who plan to use select agents/biological toxins are advised to contact the NDSU Responsible Official (RO) through the IBC Office (701-231-8908).

Select agent information also may be found at <https://www.selectagents.gov/>

[Current list of select agents](#)

If the agent/toxin requires BSL-3 containment, this research cannot be conducted on the NDSU campus at this time. Additional information on requirements when working with toxins is available from the NDSU Laboratory and Chemical Safety Committee by contacting the UP&SO at 701-231-7759.

2.3 Dual Use Research of Concern (DURC)

Research that would fall under this category will be evaluated by the Institutional Review Entity (IRE), an ad hoc subcommittee of the IBC. The IRE will determine what requirements must be completed.

Biological research is considered 'dual-use' in nature if the methodologies, materials, or results could be used to cause harm. Dual Use Research of Concern (DURC) is a small subset of life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

The [United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern](#) is aimed at preserving the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research.

For further information, please visit the [NIH Office of Science Policy webpage on Dual Use Research of Concern](#). Additional resources on DURC are available on the HHS Science Safety and Security [website](#).

3. Human Blood, Bodily Fluids, Tissues or Cell Culture

Research and teaching laboratory projects involving the culture, production, concentration, experimentation, and manipulation of human blood, bodily fluids or tissues (including cell lines) are subject to review and approval by the IBC.

All work with Human samples will be performed under BSL-2 conditions.

The NDSU Blood borne Pathogen/Exposure Control Plan applies to projects of this nature. The Exposure Control Plan is located on the UP&SO website:

https://www.ndsu.edu/police_safety/environmental_health_and_safety/biological_safety/

Employees and students who have exposure to blood borne pathogens will be offered the Hepatitis B vaccine series at no cost to themselves.

Contact the UP&SO at 701-231-7759 for information on the Hepatitis B series.

For more information, please see:

[Biosafety in Microbiological and Biomedical Laboratories \(BMBL\) 6th Edition](#)

<https://www.osha.gov/bloodborne-pathogens/standards>