POLICY STATEMENT

The University of North Dakota (UND) endeavors to minimize the risk of faculty, staff, and student exposure to biohazardous agents in research and instructional activities. All researchers working with biohazardous agents must follow documented procedures to ensure activities of a potentially biohazardous nature are conducted safely to protect employees, students, the public, the environment, and the public service interests of the University. Individuals intending to conduct research or instructional activities involving biohazardous material on campus or in a University sponsored, funded, or sanctioned activity must comply with all applicable government regulations, laws, and guidelines, as well as UND policies, including registering with UND’s Institutional Biosafety Committee (IBC).

REASON FOR POLICY

All researchers working with biohazardous agents are responsible for the proper use of agents and the safety of employees, students, the public, the environment, and the public service interests of the University. Furthermore, all researchers working with biohazardous agents must be in compliance with National Institutes of Health Guidelines for Research involving Recombinant or Synthetic Nucleic Acid Molecules, and other federal, state, and local rules and regulations.

SCOPE OF POLICY

This policy applies to:

- President
- Vice Presidents
- Deans, Directors & Department Heads
- Area Managers & Supervisors
- Faculty
- Staff
- Students
- Others: Visitors and Affiliates

WEB SITE REFERENCES

This policy: [http://UND.edu/finance-operations/_files/docs/6-26-institutional-biological-safety.pdf](http://UND.edu/finance-operations/_files/docs/6-26-institutional-biological-safety.pdf)
Vice President for Finance & Operations: [http://UND.edu/finance-operations/](http://UND.edu/finance-operations/)
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<td>15 CFR 730-774 – Commerce and Foreign Trade: Export Administration Regulations</td>
<td><a href="http://www.ecfr.gov/cgi-bin/text-idx?rgn=div5&amp;node=15:2.1.3.4.20">http://www.ecfr.gov/cgi-bin/text-idx?rgn=div5&amp;node=15:2.1.3.4.20</a></td>
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<td>42 CFR Part 73 – Public Health: Select Agents and Toxins</td>
<td><a href="http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&amp;SID=8a4be60456973b5ec6bef5dfeaffd49a&amp;r=PART&amp;n=42y1.0.1.6.61">http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&amp;SID=8a4be60456973b5ec6bef5dfeaffd49a&amp;r=PART&amp;n=42y1.0.1.6.61</a></td>
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<td>49 CFR § 171-180 – Transportation: Hazardous Materials Regulations</td>
<td><a href="http://www.ecfr.gov/cgi-bin/text-idx?SID=ad0266c92ec58e177723db148a8e0ace&amp;mc=true&amp;tpl=/ecfrbrowse/Title49/49C1subchapC.tpl">http://www.ecfr.gov/cgi-bin/text-idx?SID=ad0266c92ec58e177723db148a8e0ace&amp;mc=true&amp;tpl=/ecfrbrowse/Title49/49C1subchapC.tpl</a></td>
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<td>7 CFR Part 331 – Agricultural: Possession, Use and Transfer of Select Agents and Toxins</td>
<td><a href="http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&amp;SID=b9126e9fba23e3e7933354a1d2630d72&amp;ty=HTML&amp;h=L&amp;n=7y5.1.1.1.9&amp;r=PART">http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&amp;SID=b9126e9fba23e3e7933354a1d2630d72&amp;ty=HTML&amp;h=L&amp;n=7y5.1.1.1.9&amp;r=PART</a></td>
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<td>9 CFR Part 121 – Animals and Animal Products: Possession, Use and Transfer of Select Agents and Toxins</td>
<td><a href="http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&amp;SID=b9126e9fba23e3e7933354a1d2630d72&amp;ty=HTML&amp;h=L&amp;n=9y1.0.1.5.58&amp;r=PART">http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&amp;SID=b9126e9fba23e3e7933354a1d2630d72&amp;ty=HTML&amp;h=L&amp;n=9y1.0.1.5.58&amp;r=PART</a></td>
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<td>CDC Biosafety in Microbiological and Biomedical Laboratories</td>
<td><a href="http://www.cdc.gov/biosafety/publications/bmbl5/">http://www.cdc.gov/biosafety/publications/bmbl5/</a></td>
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<td>NIH Office of Science Policy</td>
<td><a href="http://osp.od.nih.gov/">http://osp.od.nih.gov/</a></td>
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<tr>
<td>Pipeline and Hazardous Materials Safety Administration (PHMSA)</td>
<td><a href="http://phmsa.dot.gov/hazmat">http://phmsa.dot.gov/hazmat</a></td>
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<tr>
<td>UND Institutional Biosafety Committee</td>
<td><a href="https://UND.edu/research/resources/institutional-biosafety-committee.cfm">https://UND.edu/research/resources/institutional-biosafety-committee.cfm</a></td>
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### CONTACTS

Specific questions should be directed to the following:

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<th>Subject</th>
<th>Contact</th>
<th>Telephone</th>
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### DEFINITIONS

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<th>Term</th>
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<tr>
<td><strong>Biohazardous Material</strong></td>
<td>All viable infectious, pathogenic, or toxin-producing agents, prions, biologically-derived toxins, or nucleic acid constructs that have the potential to affect the health of humans, animals, plants, or the environment. This includes vectors known to carry and transmit infectious agents, infected or potentially infected animals, infectious material, and recombinant or synthetic nucleic acid molecules capable of producing deleterious effects in humans, animals, plants, or ecosystems either directly through infection or indirectly through damage to the environment.</td>
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<td><strong>Biological Material</strong></td>
<td>All prokaryotic and eukaryotic organisms (and their components), viruses, subviral agents, recombinant DNA, and biologically-derived toxins used in research and instructional laboratories. For biosafety purposes biological material is characterized as biohazardous or non-biohazardous.</td>
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<tr>
<td><strong>Biological Safety Officer (BSO)</strong></td>
<td>The individual appointed by an institution to oversee management of biosafety risks.</td>
</tr>
<tr>
<td><strong>Biologically-Derived Toxins</strong></td>
<td>All naturally occurring molecules produced by animals, plants, microorganisms or other biohazardous agents that have a median lethal dose (LD$_{50}$) value of less than 50 mg/kg (as determined for rats). This includes the synthetic or recombinant production of naturally occurring biologically-derived toxins. Examples are bacterial exotoxins, some plant lectins such as ricin, and certain mycotoxins (aflatoxins, sterigmatocystin, rugulosin, patulin, etc.).</td>
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<tr>
<td><strong>Biosafety Level (BSL)</strong></td>
<td>A description of the degree of physical containment being employed to confine biohazardous material such as organisms containing recombinant or synthetic nucleic acid molecules and to reduce the potential for exposure of laboratory workers, persons outside of the laboratory, and the environment. In Appendix G of the NIH Guidelines, these are graded from BSL-1 (the least stringent) to BSL-4 (the most stringent).</td>
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<tr>
<td><strong>Centers for Disease Control and Prevention (CDC)</strong></td>
<td>A major operating component of the U.S. Department of Health and Human Services that works to protect America from health, safety and security threats.</td>
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<td><strong>CFR</strong></td>
<td>Code of Federal Regulations</td>
</tr>
<tr>
<td><strong>The United States Department of Health and Human Services (HHS)</strong></td>
<td>The HHS, also known as the Health Department, is a cabinet-level department of the U.S. federal government with the goal of protecting the health of all Americans and providing essential human services.</td>
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<tr>
<td><strong>Infectious Agents</strong></td>
<td>Human, animal, and plant pathogens (bacteria, parasites, fungi, viruses, prions).</td>
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<tr>
<td><strong>Infectious Material</strong></td>
<td>All biohazardous material that contains or has the potential to contain infectious agents. Examples of potentially infectious material include human blood and blood components, human tissues and body fluids, cultured cells (from humans and non-human primates), infected animals and animal tissues, non-human primates and any tissues from non-human primates and environmental samples likely to contain infectious agents.</td>
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<tr>
<td><strong>Institution</strong></td>
<td>NIH Guidelines defines institution as any public or private entity, including federal, state, and local government.</td>
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<tr>
<td><strong>Institutional Biosafety Committee (IBC)</strong></td>
<td>An institutional committee created under the NIH Guidelines to review research involving recombinant or synthetic nucleic acid molecules. The role of IBCs has evolved and UND’s committee also reviews other forms of research, as well as instructional activity that entail biohazardous risks as part of their institutionally assigned responsibilities.</td>
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<tr>
<td><strong>National Institutes of Health (NIH)</strong></td>
<td>A part of the U.S. Department of Health and Human Services that serves as the nation’s medical research agency.</td>
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<tr>
<td><strong>Non-Biohazardous Materials</strong></td>
<td>Biological materials that are not normally infectious and are therefore considered non-biohazardous. This includes non-pathogenic microorganisms, viruses, and subviral agents, biological material not likely to contain infectious agents, recombinant or synthetic nucleic acid molecules exempt from NIH Guidelines, environmental samples not likely to contain infectious agents, and biologically-derived non-toxic molecules.</td>
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<tr>
<td><strong>Recombinant Nucleic Acid Molecules</strong></td>
<td>Molecules constructed outside of living cells by joining natural or synthetic nucleic acid segments to nucleic acid molecules that can replicate in a living cell, or molecules that result from their replication. Recombinant nucleic acid molecules are considered biohazardous if they are not exempt from the NIH Guidelines. Examples include recombinant nucleic acid that is formed by the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally (if that transfer could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture); is designed for use in human gene transfer experiments; contains genes for the biosynthesis of toxic molecules lethal for vertebrates at a median lethal dose (LD₅₀) of less than 100 ng/kg body weight (e.g., microbial toxins such as the botulinum toxins, tetanus toxin, diphtheria toxin etc.; is designed for the generation of transgenic plants or animals; or contains infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus (NIH Guidelines).</td>
</tr>
<tr>
<td><strong>Risk Group Classification</strong></td>
<td>Classification system defined by the NIH Guidelines and World Health Organization that identifies four risk groups based upon hazardous agent characteristics. These agent characteristics include the ability to cause disease in a susceptible human or animal host, virulence, route of transmission, and availability to prevent or treat the disease the agent causes. The Biosafety in Microbiological and Biomedical Laboratories (BMBL) classifies agents based upon their potential hazard to laboratory personnel and the environment.</td>
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<tr>
<td><strong>Risk Group(s)</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Select Agents and Toxins</strong></td>
<td>Biological agents and toxins that: 1. The United States Department of Agriculture (USDA) identifies as having the potential to “pose a severe threat to animal or plant health, or to animal or plant products;” and/or.</td>
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2. The United States Department of Health and Human Services (HHS) identifies as having the potential “to pose a severe threat to public health and safety.” These biological agents and toxins are listed in Title 7 Code of Federal Regulations Part 331, and Title 9 Code of Federal Regulations Part 121 (7 CFR 331 and 9 CFR 121 Agricultural Bioterrorism Protection Act of 2002; Biennial Review and Republication of the Select Agents and Toxins List; Amendments to the Select Agent and Toxin Regulations; Final Rule), Title 42 Code of Federal Regulations Part 73 (42 CFR 73 “Possession, Use, and Transfer of Select Agents and Toxins; Biennial Review; Final Rule), or the HHS and USDA select agents and toxins list.

| United States Department of Agriculture (USDA) | A department of the United States government that manages various programs related to food, agriculture, natural resources, rural development and nutrition. |
| Wild Animal | An animal which lives in nature (is not provided shelter by a human), is responsible for getting its own food and water (is not provided food or water by humans), and is not cared for by humans. A number of zoonotic diseases can be passed between wild animals and humans. |

**PRINCIPLES**

**OVERVIEW** – UND acknowledges its responsibility to ensure the safety of employees, students, the community, and the environment from activities that are capable of producing deleterious effects upon humans, animals, plants, or the environment.

UND endeavors to minimize the risk of faculty, staff, and student exposure to biohazardous agents in research and instructional activities by requiring that all researchers working with biohazardous agents must be trained and follow documented procedures to ensure activities of a potentially biohazardous nature are conducted safely to protect employees, students, the public, the environment, and the public service interests of the University. Individuals intending to conduct research or instructional activities involving biohazardous material on campus or in a University sponsored, funded, or sanctioned activity must comply with all applicable government regulations, laws, and guidelines, as well as UND policies, including registering with UND’s Institutional Biosafety Committee (IBC).

All researchers working with biohazardous agents are responsible for the proper use of agents and the safety of employees, students, the public, the environment, and the public service interests of the University. Furthermore, all researchers working with biohazardous agents must be in compliance with National Institutes of Health Guidelines for Research involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines).

**PROCEDURES**

The University requires IBC to review and approve all research and instructional activities involving biohazardous material prior to initiating the activity. This includes research, instructional, clinical/diagnostic activities involving recombinant or synthetic nucleic acid molecules that qualify for exemption from the NIH Guidelines. Faculty, staff, and students of UND may only self-exempt for activities involving synthetic nucleic acid molecules that cannot replicate or generate nucleic acids that cannot subsequently replicate in any living cell (e.g., oligonucleotides). Examples of synthetic nucleic acid molecules that researchers cannot self-exempt include those designed for use in human gene transfer experiments, those that contain genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD₅₀ of less than 100 ng/kg body weight (e.g., microbial toxins such as the botulinum toxins, tetanus toxin, diphtheria toxin etc.), and those that are designed for generation of transgenic plants or animals. All other activities involving recombinant or synthetic nucleic acids, biohazardous agents, and/or biologically-derived toxins require IBC approval prior to initiation. For these activities, principal
investigators must conduct risk assessments and submit information to IBC in the form prescribed by the committee. IBC approval will be in writing to the principal investigator (PI) once the application has been reviewed. All registration documents are approved for a period of three years. Continued activity past three years will require a new registration document to be submitted to the IBC. However, the annual review form needs to be submitted every year.

Policy Scope and Applicability

This policy governs the review and conduct of all research and instructional activities involving biohazardous material (as defined in this policy) performed at the University of North Dakota including:

1. All research and instructional activities involving biohazardous material conducted completely or in part at UND or sponsored by UND faculty, researchers, staff, students, and employees.
2. Research, teaching, and clinical/diagnostic, activities involving any of the following:
   a) Recombinant and synthetic nucleic acids molecules that are constructed by joining nucleic acid molecules and that can replicate in a living cell;
   b) Nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or
   c) Molecules that result from the replication of those described in (a) or (b) above.
IBC has oversight over these activities. Moreover, the UND biosafety guidelines apply to these activities.
3. Activities performed in or on UND property and facilities; and/or research supported by government funding, industry sponsors, non-profit entities, or by UND resources and/or facilities regardless of funding source (if any).
4. Clinical and diagnostic activities normally and appropriately conducted at BSL-2 or higher containment.
5. Any work requiring USDA, CDC, or other federal permits.
6. Field collection or sampling of wild animals. The following activities involving the field collection or sampling of wild animals requires submission of an IBC registration document and approval by the IBC prior to initiation of work activities due to the risk of zoonotic diseases:
   a) Trapping and handling of wild animals for surveillance of agents infectious to humans and/or animals designated at BSL-2 or higher.
   b) Trapping and handling of wild animals that may transmit significant or life threatening zoonotic diseases (e.g., rabies, hantavirus pulmonary syndrome) as determined by risk assessment of the target species and proposed procedures.
   c) Laboratory processing of diagnostic samples collected from these studies. If a select agent or toxin is identified in a diagnostic lab, proper notification must be made and appropriate paperwork filed with the CDC.

University Responsibilities

UND is responsible for ensuring that any activity involving biohazardous agents/recombinant or synthetic nucleic acid molecules conducted at or sponsored by the institution is performed in compliance with the NIH Guidelines. Any research involving select agents or toxins conducted at or sponsored by the institution must adhere to the Select Agent Final Rule regulations. The vice president for research and economic development at UND is responsible for:

1. Establishing and implementing policies and procedures that provide for the safe conduct of activities involving biohazardous material that ensure compliance with the NIH Guidelines;
2. Ensuring compliance with the NIH Guidelines by principal investigators performing activities as specified in Section IV-B-7 of the NIH Guidelines;
3. Establishing an IBC that meets the requirements of the NIH Guidelines set forth in Section IV-B-2-a and carries out the functions detailed in Section IV-B-2-b;
4. Ensuring that the IBC has adequate expertise and training (using ad hoc consultants as necessary);
5. Appointing a biological safety officer (who serves as a member of the IBC) if the institution:
   a) Conducts recombinant or synthetic nucleic acid molecule research at BSL-3 or BSL-4 or
   b) Engages in large-scale (greater than 10 liters) research.
The biological safety officer carries out the duties specified in section IV-B-3 of NIH Guidelines.
6. Providing training for the IBC chair and members and biological safety officer based on specific needs (e.g., BSL-2 and BSL-3 practices);
7. Determining the necessity for health surveillance of individuals involved in activities involving biohazardous material, most particularly the activities delineated in Section IV-B-1-i of the NIH Guidelines;
8. Filing an annual report with the NIH Office of Biotechnology Activities that includes:
   a) A roster of IBC members clearly indicating the chair, contact person and, as applicable, the biological safety officer, plant expert, animal expert, and human gene transfer expert or ad hoc consultant; and
   b) Biographical sketches (e.g., curriculum vitae or résumé) of all IBC members;
9. Establishing procedures that the IBC must follow in its initial and continuing review and approval of applications, proposals, and activities; and making available to the public, upon request, all IBC meeting minutes and any documents submitted to or received from funding agencies that those agencies must make available to the public, in accordance with the NIH Guidelines and North Dakota Century Code.

Institutional Biosafety Committee (IBC)

The University is ultimately responsible for the effectiveness of its IBC. Therefore, the University may establish procedures that the IBC must follow in its initial and continuing review and approval of applications, proposals, and activities.

**IBC MEMBERSHIP** – The IBC is comprised of at least five members with collective experience and expertise in recombinant and synthetic nucleic acid technology and biohazards and the capability to assess the safety of such research and identify any potential risk to public health or the environment. The vice president for research & economic development appoints committee members for UND. Members serve a renewable three-year term. The members are so selected that the IBC is composed of:

- At least two members who are not affiliated with UND (apart from their membership on the IBC) and who represent the interest of the surrounding community with respect to health and protection of the environment, such as officials of state or local public health or environmental protection agencies, members of other local government bodies, or persons active in medical, occupational health, or environmental policy and practice in the community;
- At least one member representing the laboratory technical staff;
- At least one member with expertise in recombinant or synthetic nucleic acid technology, biological safety, and physical containment;
- The biological safety officer;
- At least one individual with expertise in containment principles of plants, plant pathogen, or plant pests when experiments involve plants and require IBC approval (See NIH Guidelines, Appendix P);
- At least one scientist with expertise in animal containment principles when experiments involve animals and require IBC approval (See NIH Guidelines, Appendix Q);
- At least one member who has expertise in and is familiar with clinical practices related to infection control in the hospital and clinical laboratories.

The chairperson and the vice chairperson must be members of the UND faculty. All appointments to the committee must be for a three-year term, unless they are appointed to complete the term of a member who will no longer serve. A member who cannot serve a complete term (e.g., sabbatical or separation) may be replaced by a new member who will be expected to serve the remainder of the initial member’s term, unless the initial member plans to return and complete his/her term. Members may be re-appointed at the end of each three-year term. The IBC may use non-voting, *ad hoc* consultants when necessary to provide special expertise during review of proposed research and instructional activities. The IBC may not allow any member to participate in the review and approval of any project in which the member has a conflicting interest, except to provide information requested by the IBC.

The Institutional Biosafety Committee is specifically responsible for:

1. Establishing campus specific policies and procedures governing all research, clinical/diagnostic, and instructional activities involving biohazardous material conducted by UND faculty, researchers, staff, and students;
2. Reviewing and approving all instructional, clinical/diagnostic, and research activities before any work begins in or on UND property and facilities; and/or research supported by government funding, industry sponsors, non-profit entities, or by UND resources and/or facilities regardless of funding source (if any);
3. Reviewing all instructional, clinical/diagnostic, and research activities within a month that involve recombinant or synthetic nucleic acid molecules conducted at or sponsored by the University for adherence with the NIH Guidelines, regardless of source of funding, unless the activity involves synthetic nucleic acid molecules that cannot replicate or generate nucleic acids that cannot subsequently replicate in a living cell (e.g., oligonucleotides);

4. Approving those instructional and research activities that conform to NIH Guidelines, including work involving recombinant or synthetic nucleic acid molecules unless the activity involves synthetic nucleic acid molecules that cannot replicate or generate nucleic acids that cannot subsequently replicate in a living cell (e.g., oligonucleotides);

5. Reviewing all instructional and research activities within a month that involve other biohazardous material conducted at or sponsored by the University, regardless of source of funding, for adherence with the guidelines in the latest edition of the PHS/CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL);

6. Approving those activities that conform to the BMBL guidelines;

7. Reviewing all instructional and research activities that involve select agents and toxins conducted at or sponsored by the University, regardless of source of funding, for compliance with the Select Agent Final Rule;

8. Approving those activities that conform to the pertinent regulations;

9. Determine appropriate containment levels required by all applicable regulations and/or guidelines;

10. Performing periodic reviews of all research and instructional activities that fall within the purview of an IBC to ensure compliance with all applicable guidelines, laws, regulations, and policies at the federal, state, and university level;

11. Notifying principal investigators in writing of the outcomes of IBC review of initial and renewal applications/protocols;

12. Receiving and reviewing adverse event reports regarding:
   a) Exposures of individuals to biological agents or recombinant or synthetic nucleic acid molecules,
   b) Loss or theft of biohazardous material, and
   c) Any incident that warrants an emergency response.

13. Reporting any problems with or violations of the NIH Guidelines and any instructional or research related incidents or illnesses involving recombinant or synthetic nucleic acid molecules to the campus’ vice president for research & economic development and the NIH Office of Biotechnology Activities within 30 days, unless it is confirmed that a report was already filed by the principal investigator or personnel of the campus research compliance office;

14. Reporting any noncompliance with IBC requirements and determinations and noncompliance with pertinent regulations, laws, guidelines, and University policies to the vice president for research & economic development;

15. Performing periodic reviews of this policy and recommending changes, as needed, to the vice president for research & economic development. Approximately every three years, this policy will be reviewed and updated as appropriate.

All research involving select agents on UND campus, requires submission of an application to the CDC or the USDA (see Federal Select Agent Program in Related Information) and submitting materials to the Federal Bureau of Investigation (FBI) (see FBI Bioterrorism Security Risk Assessment Form Instructions in Related Information) for a background check, all of which must be approved before any activity involving a select agent or toxin can begin.

The IBC will open its meetings to the public, in accordance with the NIH Guidelines and North Dakota Century Code Chapter 44-04, when possible and consistent with protection of privacy, security, and proprietary interests.

RESEARCH AND INSTRUCTIONAL APPROVALS – The IBC will approve research and instructional activities according to biosafety containment levels as follows:

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<th>BIOSAFETY CONTAINMENT LEVEL</th>
<th>APPROVAL TERM</th>
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Continued approval for terms noted above will be contingent on annual completion of the Annual Protocol Review form.

One component of the IBC approval process is satisfactory completion of an inspection of laboratories, facilities, and farms that are classified as biosafety containment level 1, 2 or 3. Inspections are tailored to the type of laboratory or facility (e.g., research laboratory, teaching laboratory, greenhouse, animal containment facility, or isolation area). The Safety Audits/Inspections of laboratories will be done by the IBC and Office of Safety.

The IBC may:
1. Seek appropriate resources in order to conduct thorough reviews of activities involving biohazardous material that fall within IBC purview;
2. Seek appropriate resources in order to inspect laboratories and facilities where proposed biohazardous activities may be conducted;
3. Suspend or terminate IBC approval;
4. Conduct inquiries pertaining to incidents of non-compliance prior to taking action;
5. Place restrictions on any activity that falls within IBC purview.

A decision by the IBC to disapprove an application/protocol may not be overruled, or reversed by the University, its officials, or other institutional compliance committees. Research covered by this policy that has been approved by the IBC is subject to additional review and approval or disapproval by officials of the University (e.g., president, vice president for research & economic development, deans, and department heads) who should consult with the IBC and other involved parties including the principal investigator.

Responsibilities of the Biological Safety Officer (BSO)

The responsibilities of the biological safety officer (BSO) include:
1. Advising IBC, administration, faculty, and staff on any concern regarding biohazards and their control;
2. Performing routine inspections of all facilities and laboratories in which potentially biohazardous activities are to be conducted;
3. Reporting any significant problems, violations, accidents or illnesses related to biohazardous activities to the appropriate University administration, the IBC, and appropriate federal agencies;
4. Serving as a permanent voting member on the IBC and assisting with risk assessments, which will be reviewed by the committee;
5. Serving as a first responder to biosafety incidents;
6. Providing UND personnel with information about current regulations, laws, guidelines, and safety pertinent to work with biohazardous materials;
7. Coordinating and delivering biosafety and biosecurity training programs to individuals who work with biohazardous material;
8. Developing and maintaining the incidence response plan related to biosafety and biosecurity; and
9. Serving as a liaison between the University and regulatory agencies.

All incidents involving biohazardous material must be reported to the BSO. All incident reports must be referred to the campus’ IBC for review, and, if appropriate, inquiry. Administrative heads of colleges, departments, and other units are responsible for employee safety within their units. No activity of a potentially biohazardous nature is to be permitted unless there is a commitment of effort and resources appropriate to ensure that the work can be conducted safely.
Responsibilities of Principal Investigators, Instructors, and Other Individuals

PRINCIPAL INVESTIGATORS, INSTRUCTORS, AND PERSONNEL IN CHARGE – Principal investigators (PI), instructors, and other personnel in charge of potentially biologically hazardous work are responsible for the activities conducted within their respective laboratories. PIs are responsible for carrying out activities in accordance with the IBC approved registration document (i.e., protocol), and in a laboratory approved for the proposed work. PIs must promptly report biohazard incidents to the IBC using the IBC Adverse Event Reporting form. The BSO needs to be also notified for biohazard incidents to assist with post incident evaluation. PIs are ultimately responsible for the instruction and training provided to all staff and students engaged in the potentially biohazardous activity under their supervision.

When the University plans to possess, use, and/or transfer select agents and toxins, a responsible official (RO) must be appointed to have oversight responsibility for the institution’s select agent program, per the Select Agent Final Rule. Alternate responsible officials (ARO) may be appointed to act for the RO when he/she is unavailable. AROs have the authority and responsibility to ensure compliance with the select agent regulations. If an activity that involves biohazardous material is funded by a sponsoring agency, an application/protocol must be submitted to the IBC for review and approval prior to initiating the work.

ADMINISTRATION – The vice president for research & economic development (IBC) or his/her designee and the vice president for finance & operations (Office of Safety) or his/her designee have independent authority to terminate any UND campus activities or operations related to the use of biohazardous material where health and safety appear to be compromised. Consequently, the vice president for research & economic development or his/her designee and the vice president for finance & operations or his/her designee have the vested authority to act immediately by terminating any UND campus activities related to the use of biohazardous material for the purpose of assuring individual well-being and the integrity of the University without consulting the IBC. A report of such action will be made to the IBC by the vice president for research & economic development or his/her designee or the vice president for finance & operations or his/her designee for further evaluation. This will allow two levels of oversight of this highly regulated area.

EMPLOYEES – Employees must be familiar with all University and departmental safety instructions, whether written or oral, and comply with such instructions when performing assigned duties. Employees must report all incidents involving biohazardous materials to their immediate supervisor, IBC, and the Office of Safety within 24 hrs. Supervisors must ensure that employees who have not received appropriate training and specific hazard information, or who cannot be adequately supervised, cannot use or handle biohazardous materials.

STUDENTS – Students must follow all of the instructions provided on the laboratory door signs and wear the required protective equipment. They must also report, without delay, all accidents and incidents to their immediate supervisor. Students who have not received appropriate training and specific hazard information, or who cannot be adequately supervised, cannot use or handle biohazardous materials.

VISITORS – Visitors are not permitted unsupervised entry into areas where biohazardous materials are used or stored unless they have received University-specific training and information and appropriate supervision is provided. PI’s should ensure that visitors to their laboratories must follow all of the instructions provided on the laboratory door signs and to wear the required protective equipment.

RESPONSIBILITIES

| Biological Safety Officer | ▪ Advise the IBC, administration, faculty, and staff on any concern regarding biohazards and their control, and serve as a permanent voting member on the IBC.  
| ▪ Perform routine inspections of facilities in which biohazardous activities are conducted, and report significant problems, violations, accidents or illnesses related to biohazardous activities. |
Provide UND personnel with information about current regulations, laws, guidelines, and safety pertinent to work with biohazardous materials, and coordinate/deliver training programs.

- Develop and maintain the incidence response plan related to biosafety and biosecurity, and serve as a first responder to biosafety incidents.
- Serve as a liaison between the University and regulatory agencies.
- Oversee shipping of biohazardous materials as necessary.

### Institutional Biosafety Committee

- Establish campus specific policies and procedures governing all research, clinical/diagnostic, and instructional activities involving biohazardous material conducted by UND faculty, researchers, staff, and students.
- Review and approve all instructional, clinical/diagnostic, and research activities that involve biohazardous material.
- Perform risk assessments and periodic reviews of all research and instructional activities that fall within the purview of an IBC to ensure compliance with all applicable guidelines, laws, regulations, and policies at the federal, state, and university level, and assess facilities, procedures, practices, and the training and expertise of personnel involved in the proposed activities.
- Notify principal investigators in writing of the outcomes of IBC review of initial and renewal applications/protocols.
- Receive and review incident reports, and report problems and violations.
- Review policy and recommend changes, as needed.

### Principal Investigators/Supervisors

- Submit an IBC registration form for all activities (research and teaching) that involve the use of biohazardous agents.
- Carry out activities in accordance with the IBC approved registration document.
- Submit an adverse event reporting form to IBC within 24 hours of an incident.

### Vice President for Research & Economic Development

- Oversee the activities of IBC.

### Vice President for Finance & Operations

- Oversee activities involving biohazardous materials.

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### FORMS

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<thead>
<tr>
<th>FORM</th>
<th>Link</th>
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<tbody>
<tr>
<td>IBC Research Registration Document</td>
<td><a href="https://UND.edu/research/resources/institutional-biosafety-committee.cfm">https://UND.edu/research/resources/institutional-biosafety-committee.cfm</a></td>
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<td>IBC Teaching Registration Document</td>
<td><a href="https://UND.edu/research/resources/institutional-biosafety-committee.cfm">https://UND.edu/research/resources/institutional-biosafety-committee.cfm</a></td>
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<td>Annual Review Form/Change in Protocol</td>
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### APPENDICES

There are no appendices associated with this policy.
## REVISION RECORD

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<thead>
<tr>
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<tr>
<td>01/11/2016</td>
<td>Policy Implementation</td>
<td>Signed by President Robert O. Kelley</td>
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