The University of Notre Dame Institutional Biosafety Committee Policy

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1.0 Purpose

It is the responsibility of the University of Notre Dame (ND) Institutional Biosafety Committee (IBC) to review, approve and oversee the use of recombinant DNA (rDNA), biohazardous agents, materials and toxins in all research or instructional activities conducted in ND facilities or by ND research personnel. Together, the *Institutional Biosafety Committee Policy* (IBC Policy) and the associated ND *Biosafety Manual* and the policies referenced therein, set forth the relevant regulatory and local requirements that govern biohazardous research activities and ND.

Because laboratory work can involve exposure not only to rDNA, biohazardous agents, materials, and toxins, but also to chemical and radiological hazards, the IBC Policy and the associated Biosafety Manual should be used in conjunction with any other pertinent ND policies and procedures.

1.1 Mission Statement

The IBC's mission is to ensure that ND safeguards human health and the environment by adhering to the *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)* and the *Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th ed.* and their successors. Through a balance of outreach and support for research personnel, the IBC will:

- Assure activities meet the ethical and legal requirements for the responsible use of rDNA, biohazardous agents, materials, and toxins.
- Establish policies and make recommendations to ND regarding such activities.

- Minimize risks to the research personnel, the broader community, and the environment by educating the ND community regarding the regulatory requirements for the use of rDNA, biohazardous agents, materials, and toxins.

1.2 Authority of the IBC

The ND IBC is responsible for the review, approval and oversight of research and instructional activities involving rDNA and biohazardous materials, agents, and toxins. IBC responsibilities include assessing facilities, procedures, practices, and training of research personnel to assure compliance with National Institutes of Health/Office of Biotechnology Activities (NIH/OBA) and other pertinent guidelines and regulations. To successfully fulfill these responsibilities, the IBC is appointed to achieve sufficient knowledge and expertise in biomedical research and biosafety. The IBC has the authority to approve, require modifications to secure approval, disapprove, suspend, or terminate research activities as required to assure adherence to the appropriate regulations and guidelines.

In collaboration with ND Risk Management and Safety (RMS), the ND IBC is responsible for the planning and implementation of the campus Biosafety program with a purpose to ensure the health and safety of all personnel working with rDNA and biohazardous materials, agents, and toxins. The IBC responsibilities include:

- Ensuring that research conducted at the Institution complies with the *NIH Guidelines*, *BMBL*, and United States Department of Agriculture (USDA) regulations;
- Collaborating with RMS to develop relevant campus policies and procedures; and
- Reviewing individual research proposals using rDNA and biohazardous materials, agents, and toxins.

To the extent that ND receives NIH funding for research involving rDNA molecules, all activities involving rDNA must follow the *NIH Guidelines*. Failure to adhere to these guidelines can result in suspension or termination of NIH funding, or to a requirement for prior NIH approval of any or all rDNA projects at the institution. The IBC is therefore responsible for cocreating and implementing policies that provide for the safe conduct of research involving rDNA and biohazardous materials, agents, and toxins to ensure adherence with *NIH Guidelines*, regardless of funding status or source.

IBC responsibilities with regards to activities involving rDNA and biohazardous materials, agents and toxins are specified in the *NIH Guidelines*. The IBC has the authority to oversee all research and teaching activities involving rDNA and biohazardous materials, agents and toxins including suspension or termination of research that does not comply with IBC Policy and the associated Biosafety Manual.

1.3 Committee Composition

The President of ND appoints IBC members, and alternates as needed. The Notre Dame Institutional Official appoints the IBC Chair. All members are voting members, and consist of faculty, research personnel, and the community. At least one member of the ND Institutional Animal Care and Use Committee (IACUC) shall be a member of the ND IBC.

The Chair shall have knowledge and experience with work involving rDNA, biohazardous materials, agents, and toxins.

The ND Director of Laboratory Safety, or designee, and the Director of Research Integrity shall be voting members *ex officio*. All other IBC membership terms are staggered for three years and are renewable upon mutual agreement. Members will be evaluated annually by NDR on the basis of satisfactory attendance, their preparation for each meeting by reviewing the submitted research, and if they have effectively contributed to the functions of the IBC.

Members will collectively have appropriate expertise and experience in the use of rDNA and biohazardous materials, agents, or toxins. They must have expertise in assessment of risk to environment and public health along with knowledge of institutional commitments and policies, applicable law, professional standards, community, and environment. The IBC will have no fewer than five members whose expertise will be in the following areas[1], as determined by the ND research agenda:

- At least one expert in rDNA technology.
- At least one member expertise in biological safety and physical containment.
- At least one expert in the use, storage, transfer, and disposal of select agents and toxins (at present, this requirement is waived because ND does not engage in this line of research).

[1] One person may fulfill more than one role.

- At least one member with expertise in animal containment principles.
- An individual representing laboratory technical staff.
- The Biological Safety Officer.
- At least two members from the surrounding community, and not affiliated with ND, to represent the interests of the community regarding the health and protection of the environment.

Consultants may be invited to meetings for their expert advice when necessary but will not be allowed to vote on any protocol.

At present, ND does not engage in research involving plant, plant pathogen, or plant pest containment principles. Should ND seek to engage in such work, a member with expertise in those areas would be appointed to the IBC.

1.4 Scope

The IBC Policy and the associated Biosafety Manual apply to all ND personnel engaged in instructional and/or research activities involving rDNA, biohazardous agents, materials and toxins that are:

- Sponsored by ND;
- Conducted by ND personnel;
- Conducted using ND's property or facilities;
- Received, stored, used, transferred, or disposed of at any of ND's facilities;
- Conducted on behalf of ND at other research institutions.

1.5 Federal Registrations

The ND IBC is registered with the Office of Biotechnology Activities[2] (OBA) for purposes of rDNA research. The ND IBC will renew its registration annually in February. Annual renewal takes the form of a report that the NDR files with OBA. This report includes an updated list of IBC members indicating the role of each member and biosketches for each member.

Additionally, NDR will notify OBA of any changes in IBC membership when they occur. Such notice shall include a revised list of members, contact information and a biosketch for each new member. These annual reports and periodic updates serve three primary purposes:

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[2] For more information visit http://www4.od.nih.gov/oba/.

- To assure OBA that local review of Biosafety risks takes place;
- To indicate the ND point of contact for Biosafety matters; and
- To provide a census of the field by informing OBA where rDNA research is being conducted.

1.6 Regulations and Guidelines

The IBC Policy and the associated Procedure Manual are based upon the following regulations and guidelines:

- ***NIH Guidelines*** This document specifies practices and provides guidelines for constructing and handling rDNA molecules and organisms containing rDNA molecules. Institutions conducting or sponsoring rDNA research covered by *NIH Guidelines* are responsible, through established policies and its IBC, for ensuring that such research is conducted in compliance with the *NIH Guidelines* are available online at http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm.

- **BMBL** is published by Centers for Disease Control and Prevention (CDC) and the NIH – This document contains guidelines for microbiological practices, safety equipment, and facilities that constitute the four established biosafety levels. The BMBL is considered the standard for biosafety. The BMBL is available online at http://www.cdc.gov/biosafety/publications/bmbl5/index.htm.

- **Select Agents and Select Agent Toxins** – The Department of Health and Human Services (HHS), Center for Disease Control and Prevention (CDC) regulations, 42 CFR Part 73, and the United States Department of Agriculture (USDA) regulations, 9 CFR Part 121, establish requirements regarding the possession, use, receipt, and transfer of listed select agents and select agent toxins. The regulations set forth the requirements for registration of listed select agents and select agent toxins, security risk assessments, safety plans, security plans, emergency response plans, training, transfers, record keeping, inspections, and notifications. For more information visit http://www.selectagents.gov/.

- **For Research Involving Animals and Plants -**The Animal and Plant Health Inspection Service (APHIS) regulates genetically engineered (GE) organisms and certain GE organisms that may pose a risk to plant or animal health. APHIS uses the term biotechnology to mean the use

of recombinant DNA technology, or genetic engineering to modify living organisms. Permits are required for the importation, transit, domestic movement, and environmental release of organisms that impact plants. For more information visit:

- **Biotechnology:** http://www.aphis.usda.gov/biotechnology/index.shtml
- **Permits:** http://www.aphis.usda.gov/plant_health/permits/index.shtml