

# Institutional Biosafety Committee Policies

## Policy/Procedure

### I. INTRODUCTION

Dickinson College recognizes the importance of conducting a broad spectrum of investigative research as well as classroom and laboratory educational activities that require the use of recombinant or synthetic nucleic acid molecules technology or infectious agents, and/or involve human tissue or body fluids, or involve animals that may carry zoonotic disease. Cognizant that these activities may be accompanied by some risks, the College requires that these activities be reviewed and approved by an Institutional Biosafety Committee (IBC) to ensure that they are conducted in a safe and appropriate manner, and in accordance with the current editions of the [NIH Guidelines For Research Involving Recombinant or Synthetic Nucleic Acid Molecules](#), the [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories](#), and the [Occupational Safety & Health Administration \(OSHA\) Standards for Bloodborne Pathogens](#). Adherence to this policy shall not exempt investigators employing recombinant or synthetic nucleic acid molecules or infectious agents in their research from compliance with other applicable laws, regulations or policies (e.g. research with human subjects, vertebrate animals, or radioactive materials). The appropriate paperwork must also be filed with the Institutional Review Board for the Protection of Human Subjects (IRB), the Institutional Animal Care and Use Committee (IACUC), and the Radiation Safety Officer.

### II. DEFINITIONS

- Recombinant or synthetic nucleic acid molecules are defined as either (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate inside a living cell, or (ii) DNA molecules that result from the replication of those described in (i). Synthetic DNA segments likely to yield a potentially harmful polynucleotide or polypeptide (e.g. a toxin or pharmacologically active agent) shall be considered as equivalent to their natural DNA counterpart. If the synthetic DNA segment is not expressed *in vivo* as a biologically active polynucleotide or polypeptide product, it is exempt from this policy.
- Infectious agents are defined as those biological agents, both pathogenic and non-pathogenic, known to infect human as well as selected animal agents that may pose theoretical risks if inoculated into humans.

### III. APPLICABILITY

This policy is applicable to all research, teaching, and outreach activities involving recombinant or synthetic nucleic acid molecules or infectious agents that are conducted at or sponsored by (or under the aegis of) Dickinson College. No activity involving the construction or handling of recombinant or synthetic nucleic acid molecules or the use of infectious agents shall be initiated without the review and approval of the appropriate registration documents by the Dickinson College Institutional Biosafety Committee.

#### **IV. INSTITUTIONAL BIOSAFETY COMMITTEE**

An Institutional Biosafety Committee (IBC) comprised of College faculty and staff appointed by the Provost and at least two outside community members shall fulfill the responsibilities described in this policy and in the *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, Biosafety in Microbiological and Biomedical Laboratories*, and *OSHA Standards for Bloodborne Pathogens*.

##### ***A. Committee Membership***

The IBC members shall be selected so that they collectively have experience and expertise in recombinant or synthetic nucleic acid molecules and technology, infectious organisms and the capability to assess the safety of such activities and any potential risk to public health or the environment. At least two members shall not be affiliated with Dickinson College (apart from membership on the IBC) and shall represent the interest of the community area with respect to the health and protection of the environment. The Director of Compliance & Enterprise Risk Management shall also be a member, and the Administrative Liaison/IBC Administrator, under the direction of the Provost of the College shall be a member with non-voting status.

##### ***B. Meetings***

The IBC shall meet as needed, but at least once per year. A schedule of meetings shall be publicly posted when feasible. Meetings will be open to the public consistent with protection of privacy and proprietary interests. A quorum for conducting business shall consist of 2/3 of the current members except that at least one member not affiliated with Dickinson College (apart from serving the IBC) must be present. The meetings will follow recognized parliamentary procedure.

##### ***C. Reports***

The IBC will report publicly to the College community concerning the performance of its assigned functions by making available a copy of the approved minutes of each IBC meeting. Copies may be obtained from the Provost's Office or from the Chair of the IBC.

The IBC may redact proprietary or private information captured in the minutes and other publicly accessible documents, but will strive to do so judiciously and consistently for all documents requested by the public. The definition of "public" shall be interpreted in its broadest sense – as referring to all peoples and entities. The criteria used in determining which information will be redacted include, but are not limited to:

- Trade secret information and other confidential commercial information
- Home telephone numbers and home addresses of IBC members
- Specific information whose disclosure would directly compromise institutional or national security.

In addition to any redacted report, minutes or other documents made necessary to protect the information set forth above, the IBC shall also maintain a full report without redactions that shall not be publicly available.

Minutes may be recorded electronically via video or audio imaging for the sole purpose of assisting the memory of the person taking minutes. Such recordings will be destroyed immediately upon production of the formal written minutes.

#### ***D. Conflicts of Interest***

Members of the IBC shall not participate in the review and approval of applications under consideration by the IBC when a conflict of interest exists. Conflicts of interest include, but are not limited to, the following:

- The IBC member is currently engaged, or expects to be engaged, in the research project under review, as defined in the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*.
- The IBC member has a direct financial interest in the PI or the entity funding the research proposed by the PI, as defined by the college and/or *NIH Guidelines*.
- The IBC member and the PI of the application under consideration share a familial relationship.
- The IBC member has other reasons to feel that they cannot render an independent assessment of an application.

The IBC member shall disclose the conflict of interest at the following time:

- When the IBC member is contacted to participate in the review of a project with which the IBC member has a conflict of interest.
- Prior to discussion at a convened meeting of a project for which the IBC member has a conflict of interest.
- Immediately upon discovery of the conflict of interest if at other than the foregoing times.

An IBC Vice-Chair will be selected to manage committee business when the Chair has a conflict of interest.

Although an IBC member shall be recused from voting on the final disposition of projects for which they have a conflict of interest, the IBC member shall nevertheless remain eligible to answer questions related to the review of the proposal to the IBC.

### **V. FORMS AND PROCEDURES**

- A. Each investigator/instructor using recombinant DNA molecules or infectious organisms is required to submit the registration document (protocol)\* as described below. \*These registration documents are currently combined into a single form.
- *Registration Document for Research/Teaching Involving Recombinant or Synthetic Nucleic Acid Molecules*: for those investigators/instructors employing recombinant or synthetic nucleic acid molecules and technology, including the construction and use of transgenic animals, and transfection of mammalian cell lines. Investigators conducting "exempt experiments" must still submit a registration from to the IBC. However, investigators completing this registration document need not complete an additional registration document for infectious agents for the same project.
  - *Registration Document for Research/Teaching Involving Infectious Agents*: for those

investigators/instructors employing infectious agents in their research and teaching, but not involving recombinant or synthetic nucleic acid molecule technology

- *Registration Document for Research/Teaching Involving Human Tissue or Body Fluids*: for those investigators/instructors employing human tissue or body fluids, including saliva, urine, blood, or primary human cell cultures.
- *Registration Document for Research/Teaching Involving Wild-Caught or Random Source Animals or Animal Tissues*: for those investigators/instructors employing animals that may carry zoonotic disease.

In addition, any substantive changes in procedures or type of recombinant DNA molecules/infectious agents should be reported to the IBC. At the very least, an annual report/continuing review must be submitted each year for each approved registration. A new registration document must be completed every three years (every five years for classroom projects).

The IBC Administrator may administratively approve continuing reviews only if there are no changes, or minor amendments if the only changes consist of student researchers or teaching assistants. All other changes to protocol are forwarded to the Committee for review and approval.

#### B. Review Procedures

When a protocol is submitted, a notification will be sent to all committee members via electronic mail.

1. The committee chair, on behalf of the committee, will ask the Principal Investigator to respond to questions and requests for revisions or clarifications. The chair will arrange a meeting of the committee to review, and then vote on the protocol.
2. Once the committee is satisfied that the protocol is in compliance with the policies and guidelines noted in Section VI, A (below), they should recommend approval of the protocol to the committee chair. The chair, on behalf of the committee, sends the Principal Investigator official notification that they may begin the research described in the protocol and reports the protocol's approval at the next full committee meeting.

## **VI. FUNCTIONS AND RESPONSIBILITIES OF THE IBC**

- A. On behalf of Dickinson College, the IBC shall review all protocols to assure compliance with this policy and the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, the *CDC Biosafety in Microbiological and Biomedical Laboratories*, and the *OSHA Standards for Bloodborne Pathogens*.
- B. On behalf of Dickinson College, the IBC shall conduct periodic self-studies of the effectiveness of College policy on biosafety and the implementation procedures, reporting the results to the Provost and recommending any needed revisions. This will involve responsibility for:
  1. Reviewing the registration submission for the appropriateness of biosafety

procedures and assignment to the proper biosafety containment levels of experiments;

2. Reporting within 30 days to the Director of Compliance & Enterprise Risk Management and the Administrative Liaison identified problems with or violations of the guidelines and research-related accidents or illnesses; the IBC along with the Administrative Liaison, under the direction of the Provost, has responsibility for communication with external sponsoring and monitoring agencies;
  3. Participating with the Director of Compliance & Enterprise Risk Management in the development of emergency plans to deal with accidental spills and personnel contamination resulting from research;
  4. Insuring through periodic inspections that laboratory standards are rigorously followed.
- C. On behalf of Dickinson College, the IBC may investigate issues and reports of unanticipated problems or serious or continuing non-compliance, and undertake a range of possible actions in response. These include but are not limited to: suspension of protocol; termination of protocol; IBC consultation with institutional officials, including Human Resource Services and the Faculty Personnel Committee.

## **VII. INVESTIGATOR'S RESPONSIBILITIES**

The Principal Investigator is responsible for reviewing this policy and complying with its requirements. Specifically, they will:

- A. Determine whether the research is subject to Section III-A, III-B, III-C, III-D, III-E of the *NIH Guidelines*, or is exempt research. The IBC Chair or Biosafety Officer (BSO) is available to assist the Principal Investigator in making this determination.
- B. File the appropriate Registration Document and an Annual Renewal form for each project for review and approval, and meet all the requirements of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, the *CDC Biosafety in Microbiological and Biomedical Laboratories*, and the *OSHA Standards for Blood borne Pathogens* prior to initiating research subject to the *NIH Guidelines*. This registration (see Section IV, above) includes:
  - a. Proposing physical and biological containment levels in accordance with the *NIH Guidelines* when registering research with the IBC.
  - b. Proposing appropriate microbiological practices and laboratory techniques to be used for the research.
- C. Under certain unusual circumstances:
  - a. Seeking OBA's determination of containment for experiments that require case-by-case review.
  - b. Petitioning OBA, with notice to the IBC, for proposed exemptions from the *NIH Guidelines*.
  - c. Seeking NIH approval, in addition to IBC approval, to conduct experiments specified in Sections III-A and III-B of the *NIH Guidelines*.

- D. Make available to laboratory staff and students copies of the registration documents and other protocols that describe potential biohazards and the specific precautions to be taken;
- E. Provide appropriate instruction and training in practices and techniques necessary to ensure laboratory safety;
- F. Supervise the laboratory staff to ensure that appropriate safety techniques and procedures are employed;
- G. Report in writing to the IBC any significant problems pertaining to the operation and implementation of containment practices and procedures.

<b>Related Information</b>
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<b>History/Revision Information</b>
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<b>Responsible Division/Office:</b>	Provost and Dean of the College, Institutional Biosafety Committee
<b>Effective Date:</b>	2/20/2012
<b>Last Amended Date:</b>	9/20/2022
<b>Next Review Date:</b>	9/20/2025
<b>Also Found In:</b>	<a href="#">IBC Website</a>
	IBC Mentor On-line Protocol Management System