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Owner	Michelle Bowles: Director of Research Assurance & Ethics
Area	Research & Economic Development
References	CDC, CFR, NIH + 1 more

Institutional Biosafety Committee Noncompliance

POLICY STATEMENT

All personnel involved in research overseen by the University of North Dakota (UND/University) Institutional Biosafety Committee (IBC) have an obligation to report concerns of noncompliance to the Office of Safety and/or the IBC for investigation and corrective action. All concerns are treated as suspected noncompliance when initially reported.

REASON FOR POLICY

The UND IBC is charged with ensuring adherence with the National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), OSHA Bloodborne Pathogen Standard (29 C.F.R. part 1910.1030), the Federal Select Agent Program (7 C.F.R. Part 331, 9 C.F.R. Part 21 and 42 C.F.R. part 73), the United States Government Policy for Oversight of Dual Use Research of Concern (DURC) and consistency with the guidance found in the Centers for Disease Control's (CDC) Biosafety in Microbiological and Biomedical Laboratories 6th Edition (BMBL).

IBC has developed this policy for evaluating issues of non-compliance with IBC protocols, policies and regulatory guidelines. Although uniform standards can serve as a guide, each individual case is unique and will be judged on its own merits.

SCOPE OF POLICY

- President
- Vice Presidents, Associate & Assistance Vice Presidents
- Deans, Directors & Department Heads
- Area Managers & Supervisors
- Faculty
- Staff
- Students

CONTACTS

Specific questions should be directed to the following:

Subject	Contact	Telephone	E-Mail / Website
Policy Clarification	Institutional Biosafety Committee	701.777.2492	Institutional Biosafety Committee Website UND.ibc@UND.edu
Reporting Allegations of Non-Compliance	Office of Safety	701.777.3341	Department of Public Safety Website UND.safety@UND.edu
	Institutional Biosafety Committee	701.777.2492	Institutional Biosfety Committee Website UND.ibc@UND.edu

DEFINITIONS

Allegation of Non-compliance	An unconfirmed report of non-compliance with applicable federal, state, or local laws or regulations, IBC SOPs, or with an approved IBC protocol.
Complainant	The individual who presents an allegation of non-compliance. Such an allegation of non-compliance must be made in good faith and with a reasonable basis for believing that the non-compliance occurred.
Continuing Non-compliance	Non-compliance that has been previously reported and that re-occurred after the non-compliance individual was provided with education on the non-compliance. Also, a pattern of non-compliance that suggests a lack of understanding of University policies.
Finding of Non-compliance	A determination of non-compliance pursuant to this SOP.
Institutional Official (IO)	The individual at an institution with the authority to speak for and legally commit the institution to adherence to the requirements of the federal regulations regarding the involvement of research with recombinant and/or synthetic nucleic acid molecules. UND's institutional official is the vice

	president for research and economic development.
Non-compliance	The failure (intentional or unintentional) to comply with applicable federal, state, or local laws or regulations, IBC SOPs, or with an approved IBC protocol. May involve a range of actions from minor violations due to error, inattention to detail, or inadequate training and supervision of research staff to a serious violation posing risk to health and/or safety of humans, animals, plants, and the environment.
Respondent	The person against whom an allegation of non-compliance has been made.
Serious Non-compliance	Non-compliance that has the potential to increase the risks to personnel or adversely affects the environment. Intentional violation of University policy or willful non-compliance with applicable federal regulations, laws, and/or required guidelines including but not limited to, the NIH Guidelines, Federal Select Agent Program, and/or the U.S. Government Dual Use Research of Concern Policy.

PRINCIPLES

Non-compliance may be minor, serious, sporadic, or continuing. The degree of non-compliance is evaluated on a case-by-case basis, considering the degree of exposure and the willfulness of the non-compliance. The determination of non-compliance is based on a thorough investigation and review by the Office of Research Compliance & Ethics, IBC chairperson, laboratory and research safety officer, and/or IBC. The institutional official may investigate non-compliance outside of this process.

Examples of non-compliance include, but are not limited to the following:

- Conducting activities that involve the use of biological materials to include recombinant DNA or synthetic nucleic acid molecules or DNA or RNA derived from synthetic nucleic acid molecules without a proper IBC exemption or approval in place;
- Failing to follow the requirements of an approved IBC protocol ;
- Conducting work involving biological materials after study approval has lapsed;
- Modifying an IBC-approved protocol without approval from the IBC;
- Unreported spills and accidents in BL2 laboratories resulting in an overt exposure; and/or
- Failing to report adverse event(s) or unanticipated problems within the required time frames.

PROCEDURES

Reporting Allegations of Non-Compliance

Allegations of non-compliance may be made known to UND in several ways, including but not limited to:

- New IBC applications or continuing reviews submitted to the IBC may reflect instances of non-compliance in the conduct of previously IBC approved protocols;
- Reports from collaborators, study personnel, or employees; or
- Complaints from anonymous sources.

The preferred method to report allegations of non-compliance in research with recombinant or synthetic nucleic acid molecules is to email IBC or the Office of Safety (see Contacts). Anonymous reports may be submitted through the NDUS reporting hotline (see Related Information).

Allegations should include as much information as the person reporting the allegation knows, including:

- A detailed description of the allegation of non-compliance;
- Name of the principal investigator of the study involved;
- The name(s) of personnel alleged to have committed/be committing the non-compliance; and
- The title and IBC approval number of the protocol (if applicable).

It is a violation for any individual to engage in retaliatory acts against any individual who reports an incident of non-compliance, or assists or participates in a proceeding or investigation relating to allegations of non-compliance.

Non-Compliance with Protocol Submission

Completed or Inactive Projects

The IBC must be notified when a research protocol is completed or no longer active.

Renewal or Resubmission

If the PI fails to provide a renewal or resubmission form to the IBC before the protocol expires, a letter will be sent to the PI and copied to the department chair. All activities pertaining to the research described in the expired IBC protocol must cease. If the PI does not provide a renewal or resubmission by the next IBC meeting, this issue is added to the agenda, and the IBC determines whether to terminate or suspend the IBC protocol. Termination of the IBC protocol may require termination of any related Institutional Animal Care and Use Committee (IACUC) or Institutional Review Board (IRB) protocols and notification of the vice president for research and economic development (VPRED). Additional action may proceed as dictated under Evaluation & Action for Non-compliance.

Delinquent PI Response to IBC Review

Failure to respond to submission review requirements within 30 calendar days will result in a final notice letter from the IBC Chair. If the PI fails to respond to the final notice letter in 30 calendar days, this will result in withdrawal of the original submission. The PI must contact the Office of Research Compliance & Ethics if unable to respond to correspondence on a timely basis.

Annual review non-compliance

Failure to submit an annual review within 30 calendar days of the annual review date will result in suspension of the protocol and a letter will be sent to the PI and copied to the department chair notifying them of the suspension. If the PI does not submit an annual review within 14 calendar days of the date of suspension, the protocol will be closed and all work must cease. Closure of the IBC protocol may require suspension or termination of any associated IRB and IACUC protocols until a new IBC protocol is

submitted for review and approval. Additional action may proceed as dictated under Evaluation & Action for Non-compliance. Note: Protocols of the Project Category “Instructional” do not require annual reviews.

Evaluation & Action for Non-Compliance

Receipt of Allegation & Potential Study Administrative Hold

Upon receiving an allegation of non-compliance, the IBC chair, biological safety officer, and director of research assurance and ethics confer as to whether the allegation is of such nature that it warrants a temporary administrative hold of the study. If so, the IBC chair advises the PI of the allegation of non-compliance and that continuation of the study is on hold pending completion of a review. The PI may submit any documentation the PI wishes to be provided as part of its review.

No Investigation Warranted

If the review determines that the allegation has not received sufficient information to determine whether non-compliance has occurred and/or has no basis in fact, no further investigation will be required. The IBC chair notifies the complainant, if known, of the reasons for the decision. The complainant may provide additional information if such exists. If no additional information is received within 14 calendar days, the inquiry is closed.

IBC Review & Suspension of Research

At any time during the investigation process, the IBC may convene to determine whether research procedures should be modified or whether the study should be suspended while investigating the allegation.

In addition, the VPRED or their designee and the vice president for finance and operations (VPFO) or their 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 without consulting the IBC. A report of such action will be made to the IBC by the VPRED or their designee or the VPFO or their designee for further evaluation.

Complete Investigation

A thorough and timely investigation of whether there was/is, in fact, a situation of non-compliance and whether it was/is serious and/or continuing. The investigation may include, but is not limited to:

- Requesting a written response from the respondent regarding the allegation;
- Interviewing members of the research team, the respondent, and/or the complainant;
- Conducting an unannounced laboratory visit; and/or
- Reviewing research records.

Final Report

Upon conclusion of the investigation, a final written report is sent to the institutional official detailing the investigation process, findings and recommendations. Recommended actions to be taken will be as follows:

Not Serious nor Continuing Non-Compliance

- Letter of reprimand sent to the respondent and the PI, if appropriate, (copied to their respective department chair, dean, institute and/or center director, faculty advisor (student research) and research compliance coordinator);
- Respondent and PI, if appropriate, receive education as well as the department; and/or
- Respondent or PI, if appropriate, create a plan of action to remedy the non-compliance.

Serious and/or Continuing Non-Compliance

A meeting of the IBC will be convened to review:

- A copy of the approved IBC protocol (if applicable);
- The minutes of the relevant IBC meeting, if the protocol warranted a full IBC review;
- A copy of the final report; and
- Any other relevant materials.

The IBC will determine what actions to take to protect the health of researchers, the public and environment. These actions may include, but are not limited to:

- Educating the respondent and the PI, if applicable, and/or all research staff;
- Suspending or terminating the study;
- Suspending all protocols of the PI (temporarily or permanently);
- Conducting random audits of the studies conducted by the respondent or PI and/or all research staff;
- Modifying the research protocol;
- Confiscating all data collected during the period of non-compliance;
- Confiscating and/or destroying all biohazardous material;
- Restricting access to laboratories, rooms, and/or buildings;
- Recommending to the IO suspension or prohibiting the PI from holding a research registration at UND; and/or
- Referral to other organizational entities (e.g., General Counsel, Human Resources).

As required by applicable law, regulation, or UND policies and procedures, the IO will report, in writing, the finding of serious or continuing non-compliance and the action(s) taken by UND to address such non-compliance, to regulatory agencies and to the study sponsor, and to the applicable department chair(s) and/or dean(s), institute(s) and/or director(s), the faculty advisor(s) (for student research), and other UND officials as appropriate.

Non-compliant work which is in direct violation of the NIH Guidelines will be reported to the NIH Office of Science Policy within 30 calendar days.

Resolution

Non-compliant work cannot resume until the IBC has voted to approve continuation. The following must be submitted for review.

- A written assurance from the PI that the issue has been corrected and the associated activities can be accomplished in full compliance with relevant rules and regulations.
- A plan of action detailing preventive measures submitted to the IBC.

If the PI cannot satisfy the necessary requirements, the IBC may vote to terminate the registration and/or proceed with actions as detailed above.

RESPONSIBILITIES

Laboratory & Research Safety Officer	• Determine non-compliance through investigation and review
Institutional Biosafety Committee (IBC)	• Determine non-compliance through investigation and review
Principal Investigator	• Provide a renewal or resubmission form to the IBC before the protocol expires
IBC Chair	• Determine non-compliance through investigation and review • Communicate outcome of investigation and review to appropriate parties
Director of Research Assurance and Ethics	• Determine non-compliance through investigation and review
Vice President for Research & Economic Development (VPRED) or designee / Vice President for Finance & Operations (VPFO) or designee	• Has 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 without consulting the IBC.
Institutional Official	• Speaks for and legally commits the institution to federal regulations

	regarding research using recombinant and/or synthetic nucleic acid molecules. • May investigate non-compliance outside/alongside the Office of Research Compliance & Ethics, IBC, and laboratory and research safety officer. • Receives the final written report detailing the investigation process.

RELATED INFORMATION

- 29 CFR 1910.1030 - Bloodborne Pathogens
- CDC Biosafety in Microbiological and Biomedical Laboratories 6th Edition
- Federal Select Agent Program - Select Agents Regulations
- Institutional Biological Safety
- Laboratory Safety Manual
- NDUS Anonymous Reporting Hotline
- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)
- U. S. Government Policy for the Oversight of Dual Use Research of Concern and Pathogens with Pandemic Potential (DURC)

FORMS

There are no forms associated with this policy.

APPENDICES

There are no appendices/attachments associated with this policy.

Approval Signatures

Step Description	Approver	Date
Campus Comment	Jennifer Rogers: Director of University Policy	Pending
Executive Council (1st Reading)	Jennifer Rogers: Director of University Policy	08/2026

Policy Advisory Group	Jennifer Rogers: Director of University Policy	07/2026
Policy Office	Jennifer Rogers: Director of University Policy	07/2026
Policy Owner	Michelle Bowles: Director of Research Assurance & Ethics	07/2026

References

CDC, CFR, NIH, OSHA