Research Compliance & Ethics / IBC
Standard Operating Procedure

Non-Compliance with IBC Policies & Procedures

I. Introduction:

This document describes the process that University of North Dakota Institutional Biosafety Committee (IBC) follows for allegations and findings of non-compliance with policies and regulations governing research involving recombinant and/or synthetic nucleic acid molecules and biological materials.

The IBC encourages those who are aware of, or concerned about the potential non-compliance by Investigators, to report their concerns to the IBC as set forth in this SOP.

II. Applicability:

This SOP applies to all faculty, staff, students, and volunteers conducting work which falls within the purview of the UND IBC.

III. 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. The UND 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.

IV. Non-Compliance:

Non-compliance may be minor, serious, sporadic, or continuing. The degree of non-compliance is evaluated on a case-by-case basis, taking into account considerations such as to what 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 Chair, Biological Safety Officer, IBC, and/or Institutional Official.

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;
- Failing to report adverse event(s) or unanticipated problems within the required time frames

V. 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 UND.ibc@UND.edu or UND.safety@UND.edu

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.

VI. Protocol Submission Non-compliance:

A. <u>Completed or inactive projects</u>. The IBC must be notified when a research protocol is completed or no longer active.

B. <u>Protocol renewal or resubmission non-compliance</u>. 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 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 IACUC or IRB protocols and notification of the Vice President for Research and Economic Development. Additional action may proceed as dictated below under "Evaluation and Action for Non-compliance".

C. <u>Delinquent PI response to IBC review</u>. Failure to respond to submission review requirements within 30 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 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.

VII. Evaluation and Action for Non-compliance*:*

A. <u>Receipt of Allegation and Potential Study Administrative Hold</u>. Upon receiving an allegation of non-compliance, the IBC Chair, Biological Safety Officer, and Director of Research Assurance & Ethics shall confer as to whether the allegation is of such a nature that it warrants a temporary administrative hold of the study. If so, the IBC Chair shall advise 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 be provided as part of its review.

B. <u>No Investigation Warranted</u>. 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 shall notify the complainant, if known, of the reasons for the decision. The complainant may provide additional information if such exists. If no additional information is provided after a reasonable period of time, the inquiry shall be closed.

C. IBC Review and 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 Vice President for Research and Economic Development or his/her designee and the Vice President for Finance and Operations (VPFO) 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 without consulting the IBC. A report of such action will be made to the IBC by the Vice President for Research and Economic Development or his/her designee or the VPFO or his/her designee for further evaluation.

D. 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.

E. Final Report. Upon conclusion of the investigation, a final written report shall be sent to the Institutional Official detailing the investigation process, findings and recommendations. Recommended actions to be taken will be as follows:

1. **For Non-Compliance that is determined not to be Serious or Continuing:**
   a. Sending a letter of reprimand 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);
   b. Educating the respondent and the PI, if appropriate, as well as the department; and/or
   c. Requiring that the respondent or the PI, if appropriate, create a plan of action to remedy the non-compliance.

2. For Non-Compliance that is determined to be Serious or Continuing*:*

a. A meeting of the IBC shall be convened to review:
   i. a copy of the approved IBC protocol (if applicable);
   ii. the minutes of the relevant IBC meeting, if the protocol warranted a full IBC review;
   iii. a copy of the Final Report; and
   iv. any other relevant materials.

b. The IBC shall determine what actions to take to protect the health of researchers, the public and environment. These actions may include, but are not limited to:
   i. Educating the respondent and the PI, if applicable, and/or all research staff;
   ii. Suspending or terminating the study;
   iii. Suspending all protocols of the PI (temporarily or permanently);
   iv. Conducting random audits of the studies conducted by the respondent or PI and/or all research staff;
   v. Modifying the research protocol;
   vi. Confiscating all data collected during the period of non-compliance
   vii. Confiscating and/or destroying all biohazardous material
   viii. Restricting access to laboratories, rooms, and/or buildings
   ix. Recommending to the IO suspension or prohibiting the PI from holding a research registration at UND; and/or
   x. Referral to other organizational entities (e.g., General Counsel, Human Resources).

c. As required by applicable law, regulation or UND policies and procedures, the IO shall 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.

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

F. <u>Resolution.</u> Non-compliant work cannot resume until the IBC has voted to approve continuation. The following must be submitted for review. The PI must provide written assurance 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 must also be 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.