

Oklahoma State University Institutional Biosafety Committee		
Noncompliance with IBC Policy/Procedures	SOP #	GA130
	Effective Date	10/6/2023
	Revision Date	
	Revision #	
	IBC Approval Date	10/6/2023

1. POLICY

The Oklahoma State University (OSU) Institutional Biosafety Committee (IBC) works to ensure that all research and instructional activities involving the use of biohazardous materials, and the facilities to conduct such work, are in compliance with all external regulations, laws, and required guidelines, as well as applicable University policies. Reports of noncompliance will be directed to the appropriate Biosafety staff and to the IBC for investigation and corrective action. Complaints about the IBC process or the conduct of research may or may not involve noncompliance with IBC policies or federal regulations and will be handled as potential incidents involving risks to humans, other animals, or plants. This document outlines the procedures that will be used for reporting and investigating any noncompliance with pertinent government regulations, laws, required guidelines, OSU policy, and/or IBC policy, procedures, and decisions (actions).

Specific Procedures

1.1 Definitions

1.1.1 Noncompliance is defined as conducting research in a manner that is not in compliance with federal regulations, laws, required guidelines, OSU IBC policies and procedures, OSU policy, or the decisions of the OSU IBC. May involve a range of actions from relatively minor violations resulting from inadvertent errors, inattention to detail, or inadequate training and supervision of research staff, to more serious violations that pose a risk to the health and/or safety of humans, animals, plants, and the environment.

1.1.2 Minor noncompliance represents isolated incidents such as (but not limited to) unintentional mistakes, oversights, or misunderstandings.

1.1.3 Major noncompliance is a violation of IBC or University requirements or policy. Intentional, willful or a pattern of noncompliance with applicable federal regulations, laws, and/or required guidelines including, but not limited to, the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids (NIH Guidelines), the Select Agent Final Rules (i.e., 7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73), and/or the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern.

Continuing noncompliance is defined as a pattern of repeated actions or omissions taken by an investigator or research personnel that indicates a lack of ability or willingness to comply with federal regulations, laws, required guidelines, OSU policy, OSU IBC policy and procedures, or the determinations and requirements of the IBC.

1.2 Reporting Allegations of Noncompliance

1.2.1 Allegations of noncompliance may be submitted to the IBC Chair, IBC members, Biosafety Office personnel, or the Office of University Research Compliance (URC) either verbally or in writing. In addition, reports of noncompliance may be submitted *via* the EthicsPoint

confidential reporting system used by OSU. The identity of the individual making the report will be kept confidential to the extent possible.

1.3 Processing the Allegation of Noncompliance

1.3.1 Screening and Initial Review of the allegation:

The Biosafety Officer screens the allegation to determine if it involves an active protocol. If an active protocol is involved the Biosafety Officer determines the source of funding, if any, and if there are any issues pertinent to other research review committees (IACUC, IRB, RSC, Laser Safety).

The Biosafety Officer, in consultation with the IBC Chair, will review the allegation to allow an initial determination of the nature and severity of the alleged noncompliance. This may involve discussion with the research team and the complainant (if not anonymous) and others as needed. The Biosafety Officer will document and compile the information into a summary report. Investigator noncompliance may often be the result of communication difficulties; therefore, the IBC will attempt to resolve apparent instances of noncompliance without interrupting the conduct of the study.

1.3.2 Determinations

After the initial review, the Biosafety Officer and the IBC Chair will determine whether:

- The allegation was demonstrably false, or alleges actions that would not constitute noncompliance.
- The allegation, if true, is of minor noncompliance.
- The allegation, if true, is of major noncompliance.

False allegation:

If the Biosafety Officer and the IBC Chair determine that the allegation of noncompliance is false, then the matter will be documented for the protocol file, if appropriate, the Biosafety Officer or IBC Chair will communicate the decision to the complainant (if her or his identity is known) and to the investigator. The IBC will be informed at the next convened meeting.

Minor noncompliance:

If it is determined by the Biosafety Officer and the IBC Chair that the allegation is a minor noncompliance, the investigator will be notified in writing. In addition, the Biosafety Officer and/or IBC Chair will discuss the issue and develop an action plan with the investigator. The final action plan will be forwarded to the investigator via letter or e-mail and the IBC will be informed at the next convened meeting.

Major noncompliance:

If the allegation is a major noncompliance and involves an active protocol, the Biosafety Officer, IBC Chair, and Assistant Vice President for Research will determine if immediate suspension of study procedures and/or enrollment is required for the protocol in question as well as for other protocols being conducted by the same investigator. The investigator(s) involved in the allegations, associated research staff, appropriate school or department heads, college research deans and the Institutional Official are notified in writing about any suspension. Further investigation and review by the convened IBC will determine the length of any suspension.

If, after initial screening, the allegation is considered to be a noncompliance, the IBC will initiate an inquiry. The purpose of the inquiry is fact-finding and may involve examination of study records, discussion with the research team, personnel, witnesses, the complainant (if not anonymous) and others as needed. The IBC Chair may appoint one or more board members to assist in the gathering of information pertaining to the nature of the allegation.

The investigator will be notified of the inquiry by the Biosafety Officer or the IBC Chair and asked to respond in writing to the allegation within 10 workdays. If the investigator needs more time, an extension may be granted by the IBC Chair. The Biosafety Officer will document and compile the information, including the investigator's response, into a summary report.

The summary report will be presented to the IBC at a convened meeting for review. The investigator may be asked by the Biosafety Officer or IBC Chair to attend the next convened IBC meeting.

1.3.3 Review Procedures for Noncompliances

The allegation and inquiry results will be presented at the next scheduled convened IBC meeting. For urgent issues, the IBC Chair may convene an emergency meeting of the IBC. At the convened IBC meeting, the Biosafety Officer will present the allegation(s) to the IBC. All IBC members will receive the investigation report, synopses of any communication with the investigator, the last approved IBC protocol, and any other pertinent information. All members attending the IBC meeting will review all the documents and determine whether:

- There is an isolated or continuing major noncompliance.
- More information is needed and determination is deferred to future meeting pending receipt of additional information.
- There is no major noncompliance.

1.3.4 Review Outcomes/IBC Actions

The convened IBC makes the final determination whether the alleged noncompliance is major based on the materials compiled during the inquiry. The convened IBC may take a variety of actions depending on the outcome of the review, including, but not limited to, the following:

- Approve continuation of research without changes
- Request minor or major changes in the research procedures
- Require audits of other active protocols of the investigator
- Suspend the use of biohazardous materials in research and/or instructional activities
- Terminate the use of biohazardous materials in research and/or instructional activities
- Require confiscation of biohazardous materials
- Require destruction of biohazardous materials
- Recommend further administrative action to the University administration

The IBC resolves questions or concerns raised by a PI regarding the outcome of a specific IBC noncompliance review through direct communication with the PI.

The investigator may submit concerns in writing to the IBC within thirty days of the date the IBC issues the final decision and may request to attend a convened meeting of the IBC to discuss the concerns. The IBC limits concerns to a review of the procedures employed to reach the decision (i.e., claims that the process was faulty in a way that creates a considerable risk that the outcome was incorrect) or grievances against sanctions imposed as a result of a finding of noncompliance. The investigator specifies the nature of any claimed procedural error, or the perceived unfairness of sanctions issued.

1.3.5 Reporting

The IBC informs the following individuals internal to the university of the allegation, the review process, and the findings of the review in writing:

- Investigator(s) (e.g. Co-PIs)
- Complainant via blind carbon copy (if the identity is known)
- Associate Dean(s) for Research

- Institutional Official and Assistant Vice President for Research
- Other administrative personnel as appropriate

If the research is supported by an external sponsor, they will also be notified.

For all non-exempt research (as defined by Section III-F of the NIH Guidelines), if the IBC determines that the incident is serious or continuing noncompliance, the findings will be reported to the appropriate agency (e.g., NIH Office of Biotechnology Activities, National Select Agent Registry, etc.) as applicable.

2. SCOPE

These policies and procedures apply to all allegations of noncompliance submitted to the IBC.

3. RESPONSIBILITY

The IBC Chair and Biosafety Officer are responsible for the initial investigation of reports of noncompliance.

4. APPLICABLE REGULATIONS AND GUIDELINES

- [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids](#) (NIH Guidelines)
- [Select Agent Final Rules](#) (i.e., 7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73)
- [United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern](#)