

Oklahoma State University Institutional Biosafety Committee

Policy on Noncompliance

I. Purpose

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.

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).

II. Definitions

Noncompliance: 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.

Non-serious noncompliance: An isolated incident that is not serious or continuing in nature. Includes unintentional mistakes, oversights, or misunderstandings.

Serious noncompliance: An intentional violation of IBC or University policy or willful 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: 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.

III. Allegations, Investigation, and Review

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. In any case, allegations shall be immediately forwarded to the IBC Chair or Vice Chair upon receipt or notification. The identity of the individual making the report will be kept confidential to the extent possible.

The IBC Chair or Vice Chair, in cooperation with URC personnel, including Biosafety Office personnel, will determine the seriousness of the allegation. All allegations of serious noncompliance will be reviewed and inquiries will be initiated when appropriate.

For allegations of serious noncompliance, the IBC Chair and Biosafety Officer will examine all documents and procedures relating to the allegation, interview individuals with knowledge of the circumstances surrounding the allegation, and/or inspect any facilities involved. The Biosafety Officer or a designee will document and compile the findings of the investigation into a summary report, which will be presented to the IBC for review.

The IBC will discuss the results of the investigation at a convened meeting at which a quorum is present and determine if consensus can be reached concerning whether the allegation of noncompliance is substantiated. Individuals involved in the allegation of noncompliance will be given the opportunity to respond to the allegation and/or findings. The summary report and recommendations will be discussed further, and voted upon once those involved have responded to the allegations and exited the meeting at which the matter is considered. The IBC will inform all parties involved, including the submitter of the allegations, of the committee's findings.

IV. Possible Outcomes

The IBC has the authority to address *noncompliance* as defined in this policy. Findings of noncompliance will be reported to the Vice President for Research and may result in one or more of the following actions:

- suspension of use of biohazardous materials in research and/or instructional activities;
- termination of the use of biohazardous materials in research and/or instructional activities;
- confiscation of biohazardous materials;
- destruction of biohazardous materials; and/or
- any other action deemed necessary to protect the health and safety of humans, animals, plants, or the environment.

V. Reporting to External Agencies

Findings of noncompliance will be reported to the appropriate agency (e.g., NIH Office of Biotechnology Activities, National Select Agent Registry, etc.) as applicable.