TITLE:	**IBC44 - Allegations of Noncompliance**
OVERVIEW:	The Institutional Biosafety Committee (IBC) has developed this policy for evaluating issues of noncompliance with the UNMC Biosafety Manual, IBC protocols, UNMC IBC policies, Institutional policies, and local, state, and federal biosafety regulations.
APPLIES TO:	All principal investigators conducting experiments with biohazardous or regulated biological materials.
DEFINITIONS:	**Noncompliance*:*** Violation of UNMC IBC policy or noncompliance with the approved IBC protocols, UNMC Biosafety Manual, Institutional policies, the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), the Biosafety in Microbiological and Biomedical Laboratories (BMBL), the Federal Select Agent Program, the federal Oversight of Dual Use Research of Concern (DURC) policy or other applicable federal, state, and local laws or regulations governing the use of biohazardous materials and recombinant or synthetic nucleic acid molecules. **Allegation of Noncompliance:** An assertion of noncompliance. **Minor Noncompliance:** Noncompliance that does not pose a serious threat to the health or safety of University faculty, students, or staff, or to the community or the environment. **Serious Noncompliance:** Noncompliance that, in the judgement of the IBC, poses a potential increased risk to the safety or welfare of personnel, the public, or the environment. **Corrective Action:** Any steps taken to address noncompliance, including detailed plans or modifications to procedure that eliminate existing noncompliance, prevent future noncompliance, and deal with the root causes of noncompliance.
PROCEDURES:	Work performed under IBC-approved protocols must be compliant with the UNMC Biosafety Manual, UNMC IBC policies, Institutional policies, the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), the Federal Select Agent Program (7C.F.R.

	Part 331, 9 C.F.R. Part 21 and 42 C.F.R. part 73) and the federal Oversight of Dual Use Research of Concern (DURC) policy, and consistent with the guidance found in the CDC's Biosafety in Microbiological and Biomedical Laboratories (BMBL). Any person, including any University employee, student, volunteer, or member of the general public, may report concerns of noncompliance involving the use of biohazardous materials and/or recombinant or synthetic nucleic acid molecules at UNMC. **General Noncompliance Review Procedures** <u>Initial Review</u> The investigation begins when the Biosafety Officer (BSO) or IBC Chair becomes aware of potential noncompliance. This may include an allegation (unproved assertion) of noncompliance, a self-disclosure of noncompliance, or any other indication that noncompliance may have occurred. The BSO or IBC Chair will conduct an initial review to determine if, in the judgment of the person(s) conducting the review, there is the potential for serious or continuing noncompliance. The initial review findings are reviewed by the BSO and the IBC chair. Allegations that are determined to be of minor noncompliance are resolved directly with the PI. If it is determined that the alleged noncompliance has the potential to be serious or where questions remain following the initial review, an inquiry (fact finding) process will begin. The IBC may be briefed at any point throughout the fact finding process, as deemed appropriate by the IBC Chair or BSO. <u>Fact Finding Process</u> The fact-finding process will involve the PI, and if applicable, other person(s) involved. In every investigation, the person(s) against whom the complaint has been raised shall be given notice of the concern and is provided an opportunity to address the allegations in writing. Once the initial review and the inquiry/fact finding process are complete, the BSO, the Senior BSO, and the IBC Chair will determine as to whether the noncompliance requires review by the full IBC. This decision will be documented in a summary report that contains the initial evaluation and findings from the fact finding process and a draft corrective action plan. The summary report and draft corrective action plan may include:

	• Recommendations of intervention for the safety of personnel or the environment • Recommendations for the suspension of research activities • Disclosure of pertinent documents to the Department Chair, Associate Vice Chancellor for Research, Compliance Office, legal counsel, or Institutional Officials, as appropriate • Initiate reporting per federal regulations • Initiate a lab inspection • Recommend immediate corrective actions <u>IBC Determination</u> Once the BSO, IBC Chair, and Senior Biosafety Officer have determined the noncompliance requires review by the full IBC, the summary report will be provided to the IBC for consideration at the next convened meeting. Based on the information, the IBC will: 1. Determine if serious noncompliance has occurred as it relates to the NIH Guidelines, BMBL, IBC and Institutional policies, and other applicable regulations; 2. Elect to form an ad hoc subcommittee to further investigate the incident and to act on the behalf of the Full IBC; 3. Identify the need for additional actions, such as further investigation, and notification of other University officials, as appropriate; 4. Develop a corrective action plan that will directly address the finding(s) of noncompliance, take steps to prevent similar noncompliance in the future, and address the root cause(s) of the noncompliance; and 5. Establish response and timeline expectations for the PI. A report of any findings of noncompliance and their severity as well as the corrective actions will be compiled by the IBC Chair in consultation with the IBC. This report will be sent to the PI. Depending on the circumstances, reporting may be necessary to: • The Institutional Official, • The PI's Department Chair,

	• The Vice Chancellor for Research, • The Compliance Office, • The NIH, and/or • Any other relevant oversight body or funding agency The corrective action plan will be provided to the PI for input. Once the plan is satisfactory to both the IBC Chair and the PI, the plan will be signed and dated by both individuals. A copy of the report and the corrective action letter will be attached to the relevant IBC protocols. <u>Reporting to External Agencies</u> The IBC is responsible for reporting any significant problems (e.g. serious non-compliance) with or violations of the NIH Guidelines and any research-related accidents or illnesses to the NIH Office of Science Policy within 30 days of the incident. These reports are not intended to be punitive toward the individuals involved, but rather are intended to assist the Institution in developing new and better policies and practices to prevent future occurrences of non-compliances. <u>Confidentiality</u> Details pertaining to an investigation in progress remain confidential to the extent possible to protect all concerned; however, a final report to a federal regulatory agency may become accessible to the public under the Freedom of Information Act
OTHER INFORMATION:	The *NIH Guidelines* specifically require the reporting of significant problems, violations of the *Guidelines*, or any significant research-related accident or illness by the Institution (Section IV-B-1-j), the IBC (Section IV-B-2-b-[7]), or the Principal Investigator (Section IV-B-7-e-[2]).
REFERENCES:	*NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) April 2019* *UNMC Biosafety Manual*
STATUS:	Last updated: 9/8/22 Last reviewed and approved by the IBC: 9/8/22