

IBC Policy Number: 601 Version: 4.0 Effective Date: 3-2025	Non-Compliance	Supersedes Document Dated: 9-2017
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Section 6: Non-Compliance

6.0 Allegations

6.1 Investigation and Review Process

6.2 IBC Determination

6.3 Possible Outcomes

6.0 Allegations

Any allegations of non-compliance or unsafe working conditions shall be made to the “Anonymous Ethics Hotline”, the IBC Chair, to any member of the IBC, the Office of Research Integrity and Education (ORIE) or to the Institutional Official (IO). In all instances, allegations shall be immediately forwarded to the IBC Chair and IO. The IBC Chair is responsible for investigation and resolution of all allegations of non-compliance. The allegations and resulting investigations will remain confidential to the extent possible.

6.1 Investigation and Review Process

The IO and IBC Chair will appoint a subcommittee to investigate the allegation. The subcommittee will inform all persons involved in the investigation of the purpose and the manner in which it will be conducted. The subcommittee, in its investigation, will examine all documents and procedures relating to the allegation and will interview individuals who are named in the allegation and others who may have knowledge of the circumstances surrounding the allegation and determine if there is a basis in fact to support the allegation. The subcommittee will report its findings to the full IBC for the final determinations (see Section 6.2).

6.2 IBC Determination

At a convened meeting, the IBC will discuss the subcommittee report and determine if there is a consensus that the allegation of non-compliance is substantiated and, if so, the seriousness of the incident. All persons involved in the allegation of non-compliance will be given the opportunity to appear to respond to the allegation and/or findings. After all persons who have appeared to respond have left, the report and recommendations will be further discussed and voted upon. The IBC will inform all parties involved, including the submitter of the allegations, if known, of the committee’s findings.

6.3 Possible Outcomes

The IBC has the authority to address non-compliance with the *NIH Guidelines*, University policies and procedures and other legal requirements. Findings of non-compliance may result in one or more of the following actions:

- Suspension of use of recombinant or synthetic nucleic acid molecules and/or biohazardous materials agents or toxins.
- Termination of approval for use of recombinant or synthetic nucleic acid molecules and/or biohazardous materials agents or toxins.
- Confiscation of the recombinant or synthetic nucleic acid molecules and/or biohazardous materials agents or toxins.

- Destruction of the recombinant or synthetic nucleic acid molecules and/or biohazardous materials agents or toxins.
- Any other action necessary to protect the public and/or University, including restricting access to the laboratory in order to suspend activities.