IBC Noncompliance Policy

Summary

The University of Wisconsin-La Crosse (UWL) Institutional Biosafety Committee (IBC) has developed this policy for evaluating issues of noncompliance with IBC protocols, policies, regulations, and guidelines. Federal regulations require the reporting of serious and continuing noncompliance to the IBC, institutional officials, and certain federal agencies and department heads. This document describes the campus policy regarding noncompliance, how the terms are defined, and requirements for IBC review.

Definition of Noncompliance

UWL defines noncompliance as any failure to follow (1) federal regulations, state laws, or institutional policies relevant to biosafety, or (2) the requirements and determinations of the reviewing IBC. Relevant regulations and policies include, but are not limited to, the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL), UWL Biosafety Manual, and UWL Environmental Health & Safety policies. When noncompliance has occurred, federal regulations and UWL policy require the IBC to determine whether the incident is serious, continuing, or both. UWL defines serious noncompliance as noncompliance that increases the risk of harm to lab personnel, the community, and/or the environment. Continuing noncompliance is defined by UWL as multiple or repeated instances of noncompliance, particularly after written notice from the IBC that the investigator must take action to correct noncompliance. The multiple or repeated instances of noncompliance may occur on one protocol or on more than one protocol and may occur simultaneously or over a period of time. Isolated incidents that do not pose an increased risk of harm to personnel, the community, and/or the environment are not generally categorized as serious or continuing noncompliance.

Examples of **noncompliance** may include but are not limited to the issues listed below. Issues listed below may or may not be categorized as serious or continuing noncompliance based on the IBC's assessment:

- conducting research subject to IBC review without a UWL IBC approved protocol or exemption
- inadequate supervision of research that involves potential risks to subjects and others
- conducting research when a UWL IBC approval has expired or has been suspended or terminated
- initiating changes to the research protocol without prior IBC approval unless the change is necessary to eliminate apparent immediate hazards (Note: Both the discovery of unforeseen risk and a request to update the protocol must be reported to the IBC as soon as possible.)
- failing to adhere to the conditions of approval of a protocol as specified by the UWL IBC
- starting research under a protocol before meeting the conditions required by IBC and receiving an IBC notification of approval
- failing to take UWL-required CITI training
- failing to submit a protocol amendment when changes have been made requiring amendment submission and review

Examples of **serious noncompliance** include:

- one or more instances of conduct defined above as noncompliance that exposes subjects or others to risks of harm that are not an inherent part of the approved research protocol
- misrepresentation of information related to the IBC protocol or performance of the research
- conducting research without IBC approval
- making substantive changes to a previously approved protocol without IBC approval
- conduct that adversely affected the integrity or effectiveness of biosafety protections

Whether the conduct was inadvertent, careless or reckless, or intentional may be taken into consideration by the IBC in a determination of seriousness.

Reporting IBC Noncompliance

Any person who witnesses or suspects any noncompliance with IBC requirements is encouraged to report their concerns. **No adverse action will be taken against anyone making a report**.

The following is a list of ways you may report your concerns:

- Contact the investigator, faculty mentor, IACUC & IBC Coordinator, IBC Chair, Office of Research & Sponsored Programs (ORSP), or Research Integrity Officer (RIO).
- Email your concerns to ORSP at grants@uwlax.edu.
- Anonymous Qualtrics survey

Reports will be forwarded to the IBC Chair and/or the Research Integrity Officer (RIO) for evaluation in collaboration with ORSP. Reports may be referred to the IBC Committee for further review and action.

IBC Determinations about Noncompliance

If a report of alleged noncompliance is referred to the IBC Committee, the committee will review the report and any supporting information to determine whether it meets the definition of a noncompliance and, if so, the extent of noncompliance. Reports determined to be incidents of noncompliance will be categorized as follows:

- Noncompliance involving no or minimal risk
- First occurrences that are believed to be the result of ignorance or misinterpretation of the IBC regulations
- Potentially serious and/or continuing noncompliance

Noncompliance determined to involve no or minimal risk that are believed to be the result of ignorance or misinterpretation of the IBC regulations may still be subject to internal scientific misconduct investigation, sanctions, or requirements for education. Additionally, sponsor reporting requirements may apply if required by project terms and conditions or applicable regulations. Examples of this type of noncompliance include not submitting a protocol or renewal for review when required or failure to secure IBC approval before beginning research.

If the IBC makes an initial assessment of the noncompliance report as representing potentially serious or continuing noncompliance as defined above, it may be referred to the procedure outlined in the UWL Scientific Misconduct policy. Additionally, sponsor reporting requirements,

disciplinary actions, and legal consequences may apply if required by project terms and conditions or applicable regulations.

IBC Review Process & Timeline

Reports of alleged noncompliance referred to the IBC committee will be reviewed according to the following process and timeline:

1. The investigator will be notified a noncompliance report has been referred to the IBC for review within 7 calendar days of its referral to the committee.
2. The committee will meet within 30 calendar days of receiving the initial noncompliance report to review the report and any supporting information. The investigator may be invited to participate and/or submit additional materials for consideration.
3. The committee will render a preliminary determination and, if applicable, required resolution and/or action plan, which will be communicated to the investigator and Research Integrity Officer (RIO) within an additional 15 calendar days.
4. The investigator is then provided with an opportunity to respond to this finding and required resolution/action plan (if applicable) within 15 calendar days and provide, in writing to grants@uwlax.edu, additional relevant information or detail any potential mitigating circumstances that might not have previously been considered. If no appeal is made, the RIO and Provost will be notified of the final finding and required resolution/action plan (if applicable).
5. The IBC will review this response and make a final determination regarding the noncompliance, notifying the investigator, RIO, and Provost of the determination in writing within 30 additional calendar days.
6. If the IBC makes a final determination that a report constitutes serious and/or continuing noncompliance, federal regulations or sponsor terms & conditions may require that such instances be reported to the NIH Office of Science Policy (OSP) and to the sponsor(s). Other relevant personnel, such HR, investigator's chair/unit director, dean/division director, Provost, and/or Chancellor, may also be notified.
7. If there is a required resolution/action plan issued by the IBC, completion of the prescribed actions will be overseen in collaboration by the IBC Chair, ORSP, and RIO. Documentation of completed actions will be kept on record in ORSP.

Actions related to the protocol can include, but are not limited to, the following:

- Requiring the investigator make modifications to the protocol
- Requiring more frequent review of the protocol
- Requiring further corrective actions by the investigator
- Requiring an investigator oversight plan for the study team
- Requiring additional education for the investigator and/or study team
- Reconsideration of IBC approval
- Implementation of monitoring of the research
- Restricting or disallowing use of data collected while the protocol was non-compliant
- Restricting or suspending future related research activities
- Suspension of the research
- Termination of the research
- Referral of the matter to the Research Integrity Officer (RIO) for further consideration
- Referral to the Scientific Misconduct in Research process

- Recommendation for further administrative actions

The IBC may require corrective actions, such as those listed above, even without a finding of serious or continuing noncompliance.

NOTE: Although the IBC can suspend the research study, only the Provost and Chancellor have the authority to suspend an individual's privileges to conduct research.

Completion of Resolution/Action Plans

Upon completion of a mandated IBC resolution/action plan, investigators are required to submit documentation that all required resolutions/actions have been fulfilled. Documentation must be emailed to grants@uwlax.edu. It will be forwarded by ORSP to the Research Integrity Officer (RIO) and IBC Chair for review and approval. Additional information or documentation may be requested of the investigator to confirm completion. Confirmation of final approval will be sent to the investigator and maintained in ORSP records.

IBC Policy on Suspension of Previously Approved Research

The UWL IBC has the authority to suspend previously approved research when the IBC determines that the research:

1. Is not being conducted in accordance with the approved protocol, the IBC's requirements, federal or state laws or regulations, or institutional policies applicable to biological research; or
2. Creates an unexpected serious potential threat to safety, health, or the environment.

The IBC chair or Associate Vice Chancellor for Academic Affairs/Research Integrity Officer (RIO) may suspend previously approved research before a determination is made by the full IBC if the IBC chair or RIO concludes that the suspension must be done immediately to protect safety, health, or the environment.

The IBC recognizes that isolated instances of non-compliance can occur as the result of simple and minor oversight and error with no intent to circumvent applicable requirements. This policy is not intended to eliminate the ability or responsibility of an investigator to immediately report and correct a simple or minor oversight or error, but is intended to address serious compliance and safety, health or environmental issues that, in the determination of the IBC, go beyond simple and minor oversight.

IBC Procedures for the Suspension of Previously Approved Research

In suspending research, the IBC should consider the following:

- What additional measures could be imposed to satisfy the IBC that the research can be conducted safely and/or in compliance of regulations
- How to ensure safety and appropriate containment during the period of suspension
- Reporting obligations to NIH or other agencies
- If necessary, whether the protocol could be assigned to a different Principal Investigator (PI) in order to allow the research to continue. (This would require a protocol amendment.)

The IBC may impose contingencies that must be met in order for the suspension to be lifted.

Where possible, the PI should have the opportunity to address the committee during the discussion (to be held in closed session) about the potential suspension.

If it is determined that the decision to suspend and imposition of contingencies cannot be resolved in one IBC meeting, the Research Integrity Officer (RIO) should assign a case manager from among IBC members to ensure that the process moves forward in a timely manner.

If the IBC suspends authorization of previously approved research, it will promptly notify the investigator and report the suspension to the investigator's department chair, college dean, RIO, and ORSP. This notification should include the basis for the suspension and any contingencies that must be met in order for the suspension to be lifted.

A PI may request that the IBC reconsider its decision to suspend research based on the existence of relevant new information not previously shared with the IBC.