

Mississippi State University IACUC Standard Operating Procedure

Title: **Investigation of Possible Non-Compliance**

Effective Date: **September 19, 2007** Revision # **09**

Standard Operation Procedure Number: **IACUC-RVW-011** Last Committee Review: December 14, 2022

Purpose and Scope:

The purpose of this Standard Operating Procedure (SOP) is to define the IACUC's policy and procedure regarding possible non-compliance.

Reference

IACUC-RPT-001 Reporting of Serious or Continuing Noncompliance

IACUC-RPT-002 Reporting of Suspension of Activity

IACUC-RPT-004 Reporting Animal Welfare Concerns

IACUC-RVW-017 Policy for Appeals

IACUC-RVW-023 Post Approval Monitoring

Definitions

Non-compliance - failure to comply with the regulations, deviation from the previously approved protocol, failure to submit a new Protocol Review Form or Protocol Closure Report (PCR) before expiration of an approved project, failure to fully disclose information relevant to the IACUC review, or conducting animal research prior to IACUC approval, whether intentional or unintentional.

Serious noncompliance – noncompliance which places animals at greater risk of harm than would otherwise existed under the IACUC-approved protocol, or the conduct of animal research without IACUC approval.

Continuing noncompliance – ongoing instances of noncompliance associated with an individual researcher or project; the IACUC may take into consideration the volume and complexity of a researcher's activities or those associated with a particular study in regard to making the designation of continuing noncompliance.

Allegation of noncompliance – report of noncompliance regarding animal research.

Background

Allegations of noncompliance may be reported by anyone with such knowledge, including but not limited to research staff, office staff, research participants, or IACUC staff. University employees aware of noncompliance associated with animal research are encouraged to report such information to the Office of Research Compliance & Security (ORC&S). Allegations of noncompliance may be made directly to the IACUC Chair, an IACUC member, University Laboratory Animal Veterinarian (ULAV), any member of the IACUC staff, or the ORC&S Director. Alternatively, an individual may report instances of noncompliance anonymously through the MSU Ethics Line.

Reports of noncompliance should include as much information about the incident as is known, to include the name of the investigator(s), title of the research, IACUC study number, and a description of the circumstances of the noncompliance. Confidentiality of the complainant will be maintained by the IACUC in accordance with the wishes of the complainant and to the extent possible given the circumstances of the noncompliance. Complainants will be protected in accordance with the MSU "Whistleblower" Policy (OP 01.07).

Procedure:

1. Reports of noncompliance will be forwarded from the individual(s) receiving the report to the IACUC Chair who will determine the appropriate course of action or if the claim warrants further investigation by the IACUC. The IACUC Chair or designee will investigate all claims of possible non-compliance by determining if additional information will be needed and who (either the IACUC Chair, an IACUC member, or a member of the IACUC staff) will gather additional

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- information if necessary, as well as whether the research must halt during the investigation of the noncompliance allegation. The IACUC Chair will contact the investigator to inform him/her of the allegation of noncompliance and request the investigator respond in writing. The IACUC Chair will update the IACUC concerning the report of non-compliance and of his/her action at the next available full committee meeting.
2. If the Chair determines the claim warrants investigation, the Chair will appoint a Noncompliance Subcommittee that will consist of the IACUC Chair, Vice Chair, ULAV and at least 2 additional members of the IACUC named by the Chair. The Noncompliance Subcommittee will meet to determine if there is a basis for referral of a noncompliance matter to Full Committee Review (FCR). The Noncompliance Subcommittee may also make recommendations to the Full Committee (FC) regarding actions to be taken in regard to a matter of noncompliance. At least three members of the Noncompliance Subcommittee must participate to conduct business.
 3. The investigator will be asked to appear before the Noncompliance Subcommittee during an audit hearing to address the allegations and answer questions. The investigator does have the option of having their supervisor present.
 4. At the conclusion of the audit the Noncompliance Subcommittee may determine the allegation does or does not have a basis in fact or request more information in order to make that determination and reconvene at a later time. If the Noncompliance Subcommittee decides via unanimous vote that the allegation of noncompliance has no basis in fact, the matter will be dismissed.
 5. If the Noncompliance Subcommittee does not dismiss the allegation of noncompliance, the following actions will be taken:
 - a. Noncompliance that is neither serious nor continuing, and for which there are no aggravating circumstances, may be addressed and resolved by the Noncompliance Subcommittee without review of the matter by the FC. Such resolution may include but is not limited to sanctions and corrective actions listed below. The Noncompliance Subcommittee will also determine deadlines for completing the recommended corrective actions. Matters meeting these criteria may also be referred to the FC at the discretion of the Noncompliance Subcommittee.
 - b. Noncompliance that does not meet the criteria listed in (5)(a) above will be forwarded along with the determinations of the Noncompliance Subcommittee to the FC at the next available meeting as determined by the meeting schedule and associated deadlines.
 6. In preparation for FCR, IACUC members will receive a written report regarding the findings of the Noncompliance Subcommittee to include recommendations regarding whether the noncompliance is serious and/or continuing, in addition to proposed sanctions and/or corrective actions. IACUC members may be provided any written materials provided either by the complainant or respondent in regard to the noncompliance. The Chair will present the matter of noncompliance at the FCR. The individual against whom the report of noncompliance has been alleged will also be invited to the IACUC meeting to answer questions of the FC.

Acceptance of the Non-compliance Subcommittee's recommendations must be made by majority vote of the IACUC. The IACUC will also determine at its discretion sanctions and corrective actions required in response to the noncompliance. The IACUC may also dismiss the complaint of noncompliance while reserving the right to require corrective actions to prevent future problems.

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7. When determining sanctions and required corrective actions, the IACUC should consider the nature of the noncompliance and the history of the investigator. In considering the nature of the noncompliance, the IACUC should consider matters such as whether the noncompliance appears to have been intentional and whether it harmed animals or placed animals at increased risk of harm. Regarding the history of the investigator, the board may consider the investigator's previous interactions with the IACUC, the level of cooperation exhibited by the investigator with the current matter, and any corrective actions proactively taken by the investigator in response to the noncompliance.

Sanctions and corrective actions that may be defined or required by the IACUC include, but are not limited to the following:

Noncompliance that is neither serious nor continuing:

- a. Additional training in animal research
- b. Increased monitoring of an investigator's animal research (indefinitely or for a specific period of time) to include:
 - i. Requirement of continuing review
 - ii. Monitoring of the research
- c. A corrective action plan written by the investigator to prevent future noncompliance with a 'correct by' deadline
- d. Modification of the research protocol
- e. Referral to other entities (e.g., legal counsel, Research Integrity Officer, Internal Audit, IACUC of collaborating institution(s))

Noncompliance that is serious and/or continuing may include those items listed above as well as the following:

- a. Suspension of privileges to conduct animal research (indefinitely or for a specific period of time)
- b. Suspension or termination of the study

The IACUC should also consider whether systematic changes are needed at the institutional level, such as additional training provided to other investigators to prevent such future noncompliance.

8. The findings and actions of the IACUC regarding reporting will be in accordance with SOP IACUC-RPT-001.
9. Reinstatement of a suspended protocol will be determined by a majority vote at a convened meeting of the IACUC.

Reviewed:

IACUC Chairperson

Date

Research Compliance & Security Director

Date