Policy for Handling Issues of Noncompliance

I. INTRODUCTION

The Johns Hopkins University (JHU) is committed to a uniform standard of excellence in all aspects of its animal care and use program. The Animal Care and Use Committee (ACUC) ensures that animals used for research are treated humanely, as set forth in more detail in the JHU Animal Care and Use Program Policy and other ACUC policies. Research at JHU is performed with the highest scientific and ethical standards. This Policy sets forth the process for reporting, investigating, and correcting noncompliance with JHU Policy and applicable laws and regulations, including the Animal Welfare Act, the Public Health Service (PHS) policy and guidance, and the standards of AAALAC International. This Policy is not intended to overprotect researchers or create an overly rigid compliance environment. Instead, this Policy and other applicable JHU and ACUC policies help to create a collaborative research environment that produces the highest level of scientific research.

In accordance with federal regulation and JHU policies, retaliation against individuals who make good-faith reports of noncompliance is prohibited. Self-reporting is encouraged; the ACUC will work with self-reporting PIs to remedy the issue and implement Corrective Actions to prevent a recurrence in accordance with this Policy. All reports of noncompliance with respect to activities under the scope of the ACUC will be referred to the ACUC for assessment and/or investigation.

II. DEFINITIONS

Adverse Outcome: An unforeseen clinical outcome during a research study reported to the ACUC or discovered by Research Animal Resources (“RAR”) staff or the Attending Veterinarians (“AV”). Adverse Outcomes are not treated as noncompliance concerns unless the Adverse Outcome is determined to be the direct result of a noncompliance event. The RAR staff and the investigators may work together to resolve Adverse Outcome concerns.

Continuing Noncompliance: Repeated episodes of noncompliance (serious or minor) involving the same Principal Investigator (PI), research team, and/or laboratory. Continuing noncompliance issues may require reporting to federal agencies and accreditation bodies. The ACUC will consider all prior non-compliance events when evaluating the possibility of Continuing Noncompliance; three Minor Noncompliance events within a 24-month period will constitute Continuing Noncompliance. Continuing Noncompliance may be reported to federal and state agencies, sponsoring institutions, and accreditation bodies.
Corrective Action: Remediation steps required by the ACUC and/or AV or proposed by a PI to the ACUC describing how a laboratory will resolve noncompliance concerns and prevent the relevant issue from recurring. Corrective Actions may be voted upon by the ACUC.

Minor Noncompliance: Any event that does not comply with the applicable ACUC-approved research protocol, ACUC or JHU Policy, the Public Health Service Guide for the Care and Use of Laboratory Animals (“Guide”), or applicable laws and regulations, but the risk of harm to researchers or animals is minimal at most and the ACUC authority or function has not been compromised. Examples of Minor Noncompliance include delayed submission of animal records and cleanliness issues that are easily addressed. Minor Noncompliance can often be corrected by RAR staff, the AV, or the ACUC.

Post-Approval Monitoring (PAM): Ongoing announced and unannounced review and observation of research protocols and animal facilities. The goal of PAM is to prevent noncompliance.

Serious Noncompliance: Any event that does not comply with the applicable research protocol, ACUC or JHU Policy, the Guide, or applicable laws and regulations and that has a negative impact on the welfare of an animal, the ACUC, RAR, or University animal use program. Continuing noncompliance that does not cease following intervention by the ACUC and/or RAR is considered Serious Noncompliance. Serious Noncompliance may be reported to federal and state agencies, sponsoring institutions, and accreditation bodies.

III. REPORTING NONCOMPLIANCE

Allegations of noncompliance with research protocols, ACUC policies, or applicable regulations/policies may be received from observation during inspection by ACUC or RAR, reports to the ACUC or its staff, the JHU Compliance Hotline, reports to the Institutional Official (as named in the JHU Animal Care and Use Program Policy), as well as reports to any of the individuals listed on an Animal Welfare Concerns document posted in areas where animals are housed or located. Self-reporting is encouraged.

All reports of noncompliance with respect to activities under the scope of the ACUC will be referred to the ACUC.

IV. INTERIM MEASURES AND ASSESSMENT OF NONCOMPLIANCE

1. Upon receipt of a report of possible noncompliance or animal welfare concern, the ACUC Chair will assess the concern and determine if circumstances merit further review. During the initial assessment and thereafter, the ACUC Chair will consult as needed with the AV and other University officials and staff. In the event that there is an urgent safety or welfare concern identified, the ACUC and/or the AV may assess and treat the animal(s), remove the animal(s), euthanize the animal(s), and institute other appropriate interim measures as necessary, up to and including immediate suspension of research protocol(s).
2. Following assessment, the ACUC Chair—in consultation with the AV—will select one or more of the following outcomes:

   a. Dismissal of the report (due to lack of credible or specific allegations, insufficient information, or because the complaint does not fall under ACUC review);

   b. Referral of the report to another appropriate university process (i.e., for allegations of research misconduct or noncompliance with human subject research protocols);

   c. Institute immediate corrective action which may include immediate suspension of a research protocol;

   d. Review at an ACUC convened meeting or ACUC Compliance Subcommittee meeting; and/or

   e. File a preliminary report with federal and/or accrediting agencies as required by applicable law or policy.

3. The PI will be promptly informed in writing of any actions or outcomes taken by the ACUC.

V. DETERMINATIONS OF NONCOMPLIANCE

1. For assessments that are referred for review at an ACUC or ACUC Compliance Subcommittee meeting, information about the noncompliance or animal welfare concern will be distributed in advance to the relevant ACUC body. Committee members will review the provided information and associated protocol. The ACUC shall invite the PI to submit any additional written information regarding the noncompliance event for Committee discussion. Except in exigent circumstances, the PI shall be provided seven days advance notice of the ACUC meeting. The notice to the PI shall include a copy of this Policy and any other applicable ACUC policy. The ACUC may consult with other individuals at its discretion when reviewing a report of noncompliance.

2. Following ACUC or ACUC Compliance Subcommittee deliberations, the relevant body may vote on the following outcomes:

   a. Is the concern a noncompliance or animal welfare concern (Yes/No)?

      i. If further information is required to vote on the issue, the matter shall be tabled until the next convened meeting, and more information shall be gathered.

      ii. If the Committee votes no, no further action is needed.

      iii. If the Committee votes yes, the Committee will deliberate and determine if the issue constitutes Serious Noncompliance, Continuing Noncompliance, or Minor Noncompliance.

      iv. Based on the severity of the non-compliance, the Committee will determine if a report must be sent to any third parties, including regulatory and accrediting agencies.
b. Has the issue been satisfactorily resolved (Yes/No)?

i. If the Committee votes yes, no further action is needed.

ii. If the Committee votes no, the Committee shall develop a Corrective Action plan to remedy the noncompliance.

3. Once the ACUC investigation and deliberation is incomplete, the ACUC will provide the PI with a formal written notification regarding the ACUC’s decision. The written notification shall include the Corrective Action plan.

4. If it has been determined that there was or is Serious or Continuing Noncompliance, the final report and Corrective Action plan will be submitted to the IO and the Vice Dean for Research, Vice Dean for Faculty, and department director of the PI’s primary school or department.

5. For findings of Serious or Continuing Noncompliance, the IO will submit the final ACUC report to OLAW along with the Corrective Action plan. If a USDA regulated species was part of the noncompliance or animal welfare concern, a report, along with the corrective action plan, will also be sent to the Animal and Plant Health Inspection Service, Eastern Regional Office within the USDA within 15 days of the Committee’s determination. If the research is funded by an industry sponsor, the ACUC Chair shall provide a copy of the correspondence to the Director of the Johns Hopkins University Office of Research Administration so the sponsor can be notified of the ACUC’s decision(s).

VI. POSSIBLE CORRECTIVE ACTIONS

Specific Corrective Actions are determined on a case-by-case basis. Corrective Actions are progressive and remediation steps used for the first incident may not be applicable to subsequent incidences.

1. Minor Noncompliance: Required new or revised laboratory protocols, completion or recompletion of relevant training, etc. See Section VII below regarding Corrective Actions for multiple sequential findings of Minor Noncompliance.

2. Continuing Noncompliance: Required new or revised laboratory protocols, completion or recompletion of relevant training, oversight of procedures and/or laboratory by ACUC and/or RAR personnel, regular updates by the PI to ACUC, suspension of research protocol(s), suspension of access to the animal facility, and/or referral to the applicable School for consideration of professional misconduct.

3. Serious Noncompliance: Required new or revised laboratory protocols, completion or recompletion of relevant training, oversight of procedures and/or laboratory by ACUC and/or RAR personnel, regular updates by the PI to ACUC, suspension of research protocol(s), suspension of access to the animal facility, and/or referral to the applicable School for consideration of professional misconduct.
VII. MINOR NONCOMPLIANCE CORRECTIVE ACTION ESCALATION

Three incidents of Minor Noncompliance within a 24-month time period are considered to be Continuing Noncompliance.

1. First incident: See Section IV above for possible Corrective Actions.

2. Second incident within 24 months of first incident: The PI will be required to provide a written Corrective Action plan to the ACUC to prevent future Minor Noncompliance events. The plan will be reviewed by the ACUC Chair with assistance from the AV, ACUC Compliance Subcommittee, or the convened ACUC at the discretion of the ACUC Chair. The final plan shall be sent by the ACUC to the Vice Dean for Research, Vice Dean for Faculty, and department director of the school of the PI’s primary appointment.

3. Third incident within 24 months of first incident: The noncompliance will be considered Continuing Noncompliance. See Section VI above for possible Corrective Actions.

VIII. EXTERNAL REPORTING OF NONCOMPLIANCE

As stated in Section V.5 above, findings of Serious or Continuing Noncompliance will be reported promptly to the IO. The IO will submit the final ACUC report to OLAW along with the Corrective Action plan. If a USDA regulated species was part of the non-compliance or animal welfare concern, a report, along with the corrective action plan, will also be sent to the USDA Animal and Plant Health Inspection Service, Eastern Regional Office within the USDA within 15 days of the Committee’s determination. If the research is funded by an industry sponsor, the ACUC Chair shall provide a copy of the correspondence to the Director of the Johns Hopkins University Office of Research Administration so the sponsor can be notified of the ACUC’s decision(s). All reports made to OLAW and the USDA shall be simultaneously sent to the private accrediting agency AAALAC International, along with the Corrective Action Plan.