



IACUC POLICY ON REPORTING ANIMAL WELFARE CONCERNS, ADVERSE EVENTS, AND ASSESSMENT

A. REPORTING ANIMAL WELFARE CONCERNS AND ADVERSE EVENTS

1. There are several ways to report adverse events or concerns about animal care and welfare to the IACUC. The RFUMS IACUC website has a “Reporting Concerns” link with instructions on who to contact and what information to include. Anonymous reporting is available, and all individuals reporting concerns are protected under “whistleblower protection”.
2. RFUMS is dedicated to humane animal care and expects prompt reporting of any concerns. Animal welfare issues that must be reported to the IACUC include, but are not limited to, the following:
 - Noncompliance with humane endpoints in an approved protocol
 - Deviation from approved procedures or performing unapproved procedures
 - Improper use or failure to administer anesthetics and analgesics
 - Personnel working under a protocol who have not been trained or approved
3. Adverse events are often unexpected but still negatively affect animal welfare beyond what the approved protocol outlines. These events can happen even with strict adherence to the approved animal use protocol and all relevant regulations. It is the responsibility of the PI and/or laboratory staff to report adverse events to the IACUC as soon as possible. Some examples of adverse events include:
 - Testing of a new drug that results in unanticipated pain or distress
 - A transgenic strain that unexpectedly exhibits poor health in the SPF facility
 - Experimental procedures resulting in unintended complications
 - Equipment failures during a procedure that affects animal welfare

B. PROCEDURES FOR IACUC REPORTING AND ASSESSMENT

1. The IACUC Chair will initiate a preliminary investigation upon receipt of a report of an animal welfare concern or adverse event. The Chair will record the events, interview the PI and/or laboratory staff, and then contact the Attending Veterinarian (AV) or their designee as needed.
 - The AV or designee has full authority to decide the course of action for animals under the protocol. In an emergency, if the AV or veterinarian staff cannot be reached promptly, the IACUC Chair can make these decisions.



- If the preliminary investigation suggests a reasonable chance of ongoing or additional animal welfare concerns, the IACUC Chair may impose a “HOLD” on the protocol after consulting with the veterinarian staff. A HOLD means that no new procedures can begin on the protocol, and any animals still on the protocol will be transferred to a BRF holding protocol. Access to the animals by the PI or approved personnel is prohibited until the issue is fully resolved. The PI will be notified of this action immediately.
2. After any immediate threats to animal welfare have been resolved, the IACUC Chair, in consultation with the AV or their designee, will determine whether the event(s) are reportable to the relevant regulatory agencies (e.g., USDA, OLAW, AAALAC). The RFUMS IACUC relies on guidance from both OLAW and USDA to make these decisions. Examples include, but are not limited to, the following:
 - Events that resulted in a significant impact on animal welfare
 - Suspension of a protocol
 - Severe deviations from the Guide or the AWA
 - Continuing noncompliance
 - Using unapproved procedures in a protocol or working with animals without an IACUC-approved protocol
 3. The IACUC Chair will provide a written or verbal report to the Institutional Official (IO) and make recommendations for reporting. The IO will then notify the relevant agencies of the events. The IO may also delegate the task of submitting the reports to the IACUC Chair. Regulatory agencies will receive regular updates on the investigation (if necessary) and a final report once all issues are resolved.
 4. If the issue is not resolved with the PI during the preliminary investigation involving the IACUC Chair and AV, or if the protocol is put on HOLD, the event(s) will be discussed at the next scheduled IACUC meeting, and a course of action will be determined. If the events are resolved with the PI during the preliminary investigation, the issue(s) will still be discussed at the next scheduled IACUC meeting, and potential program changes will be considered to prevent future occurrences.