GUIDING PRINCIPLE

The use of animals in research and teaching is a privilege granted to institutions, investigators, staff, and students that commit to meeting high ethical and regulatory standards. The IACUC is under federal mandate to provide continual monitoring and oversight of all research activities related to animal use. The IACUC will review and investigate any animal welfare concerns. Absent a conflict of interest, no member of the IACUC will be involuntarily excluded from participating in any review or investigation.

To assist the IACUC in fulfilling this requirement, all known incidents adversely affecting the welfare of animals used in research or teaching should be reported to the IACUC. The purpose of reporting incidents to the IACUC is to ensure that animal welfare concerns have been fully addressed by the research team, the veterinary staff, and the IACUC as they occur. Timely reporting allows the institution to provide the highest quality animal care by engaging all available resources, and to determine whether proactive measures could circumvent or alleviate reoccurrence.

Incidents that should be reported to the IACUC include:

1. Adverse Events- outcomes that adversely affect the health or well-being of animals used in research, teaching, or testing; incidents related to experimental procedures that resulted in an increased level of pain or distress in an animal or death of an animal that was not anticipated and described in the approved protocol; OR any occurrence of an unforeseen event that negatively impacted the welfare of animals; usually involving pain, distress, or death of an animal.
2. Protocol Deviation- any departure from methods approved in an IACUC protocol or the conduct of animal related activities without appropriate IACUC review and approval.
3. Noncompliance- failure to adhere to IACUC protocol, policies, procedures, or decisions. Protocol noncompliance can occur in a variety of ways, either intentionally or unintentionally. (USDA Protocol Noncompliance: Overview)
Incidents related to federally funded projects that meet the conditions for reportable noncompliance in the Office of Laboratory Animal Welfare's (OLAW) “Guidance on Prompt Reporting”, will be reported to OLAW by the IACUC in conjunction with the Institutional Official (IO). However, the IACUC and the IO reserve the right to report any noncompliance to OLAW, regardless of funding source.

REQUIREMENTS

Animal Welfare Act in accordance with, (9 CFR Ch. 1), Part 2 – Subpart C, 2.31(c)(4), Review, and if warranted, investigate concerns involving the care and use of animals at the research facility resulting from public complaints received and from reports of noncompliance received from laboratory or research facility personnel or employees.

The Public Health Service (PHS) Policy in accordance with IV.B.4. Review concerns involving the care and use of animals at the institution;

Office of Laboratory Animal Welfare NOT-OD-05-034 “OLAWS Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals”

The Guide Eighth Edition, page 28, “Because of the potential for unexpected outcomes that may affect animal well-being when highly novel variables are introduced, more frequent monitoring of animals may be required.”

PROCEDURE

1. All incidents adversely affecting animal welfare should be reported to the IACUC for immediate review, investigation, and appropriate intervention as needed.
2. Individuals who may report incidents:
   
   2.1. Incidents are identified by a) voluntary reports by the PI, b) anyone witnessing an incident, c) animal care staff observations, d) IACUC semi-annual inspections, or e) institutional employee reports

3. Posted notices advising how to report:
   
   3.1. Notices are located in the animal facilities and on the IACUC website advising individuals how and where to report identified animal welfare concerns.

3.2. The IACUC shall attempt to maintain the confidentiality of an individual who reports concerns or misconduct. However, confidentiality cannot be guaranteed, and disclosure of the individual’s identity may be necessary in order to fully investigate the concern. There is no retribution or discipline for anyone who reports a concern in good faith.

4. The Institutional Official (IO), Attending Veterinarian (AV), IACUC Administrator and IACUC Chair will be immediately notified of the reported incident.

5. Investigation procedures:
   
   5.1. The IACUC Administrator and the Attending Veterinarian in conjunction with facility staff and IACUC members as necessary or requested investigate the allegation. The investigation includes, but is not limited to:
5.1.1. Interviewing personnel involved;
5.1.2. Observing animals and determining if their welfare has or is being jeopardized;
5.1.3. Reviewing pertinent records;
5.1.4. Initiating any necessary immediate preventative/corrective action, e.g., required veterinary intervention; education on the PHS Policy, USDA Regulations, NDSU Policies; or halting of the animal activity.

6. The IACUC Office develops a report documenting the investigation; outlining the incident and all action taken.
6.1. The report is shared with the PI to ensure accuracy of the report and allow the PI to supply additional information.
6.2. The report is presented to the IACUC at a monthly meeting or sooner if circumstances dictate. If necessary, an IACUC Subcommittee (IS) will be formed to further investigate. If an IS is not appointed, determination of the report outcome and action will be made by the quorum of members at a convened meeting. The IS consists of at least, the IACUC Chair/designee, the AV/designee, members of the IACUC, and the IACUC Administrator/designee.

7. If appointed, the IS will meet as soon as possible to review the report.
7.1. All members of the IACUC will be notified of the date and time of the meeting and be invited to attend.

8. The IS will determine the following:
8.1. Whether or not the investigation is complete or if additional investigation is required;
8.2. Whether or not any immediate preventative/corrective action was appropriate or if additional action is required;
8.3. Whether or not there is evidence of negligence or willful disregard of institutional requirements;
8.4. Whether the incident constitutes a violation of the PHS Policy, USDA Regulations, or institutional policies;
8.5. Whether the activity should be halted pending further review;
8.6. Whether the incident/concern constitutes serious and/or continuing noncompliance or a serious deviation from the Guide reportable to OLAW, e.g., conditions that jeopardize the health or well-being of animals; performing activities without appropriate IACUC review and approval; failure to adhere to IACUC approved protocols; failure to monitor animals post-procedurally to ensure well-being; failure to maintain appropriate animal related records; failure to ensure death of animals after euthanasia procedure; failure of animal care and use personnel to carry out veterinary orders, participation of personnel in the animal related activities who have not been determined by the IACUC to be appropriately qualified and trained.
8.7. The type of review required by the full IACUC, i.e. Designated Member Review (DMR) or Full Committee Review (FCR)

9. On behalf of the IS, the IACUC Administrator updates the report summarizing the investigation, preventative/corrective action taken and IS recommendations,
9.1. The PI will be sent a copy of the updated report and will be asked to acknowledge receipt of the report, provide any comments, and be given the opportunity to appeal in accordance with a set deadline.

9.2. The IACUC full committee will review the report containing the IS recommendation.

9.3. Following IACUC review, the IACUC office informs the PI in writing of any decisions, corrective actions, by the IACUC. The final determination is copied to the IO and the relevant administrative head.

10. Incidents reportable to OLAW:

10.1. The IACUC and the IO will ultimately make the final determination that the incident is a reportable incident and the IO reports to OLAW and USDA as applicable.

10.2. In some reported cases, OLAW may request additional information, or that the university contact the funding component with details of the incident to determine whether or not federal funds were used for specific procedures.

10.2.1. The IACUC Administrator works with AV, IACUC chair/designee to provide any additional requested information to OLAW.

10.2.2. Sponsored Programs Administration will be provided with the details of the incident by the IACUC office and following consultation with the department provide the funding agency with the necessary information.

10.3. Upon response from OLAW, as applicable, indicating no further action is required, the IACUC will be notified of the final outcome of the reported incident and the documentation will be filed in the IACUC Office.

Links to related documents

NOT-OD-05-034 Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals, Release Date: February, 24, 2005

DEFINITIONS

Serious Noncompliance: an act or omission that negatively impacts the health or well-being of animals, or compromises the integrity of validity of the research or the animal care program. Examples of serious noncompliance may include, but are not limited to:

- conducting animal-related activities without appropriate IACUC review and approval,
- performing a procedure in such a manner that animals endure pain or suffering that is not addressed by the approved protocol,
- willful acts of abuse, performing a procedure with improper technique or safeguards which puts either the staff or animals at risk,
- failure to adhere to proper aseptic technique for survival surgery,
- failure to provide adequate anesthesia or analgesia according to protocol.

Continuing noncompliance: any noncompliance that occurs repeatedly after appropriate remedial education or corrective action.
Minor Noncompliance: any noncompliance that is not serious or continuing. Examples of minor noncompliance include: not informing the IACUC of additional personnel, failure to document routine animal welfare checks, not maintaining surgical and post-operative care records per IACUC policy and/or protocol requirements, personnel not attending training within the required time frame or not maintaining updated occupational health forms, personnel accessing facilities without authorization.