

## **Center for Biomedical Research / IACUC Standard Operating Procedure - Guidelines**

### **Whistle Blower Program and Procedures for Animal Research**

#### **PROGRAM STATEMENT**

The University of North Dakota (UND) is obligated under the Animal Welfare Act and the Public Health Service Policy (PHS) to ensure that all animal research conducted at UND facilities is carried out in a humane and appropriate fashion. Concerns regarding possible animal abuse or neglect can be reported in confidence to the Director of Research Assurance & Ethics in the Office of Research Compliance & Ethics (RC&E). Alternatively, concerns can be reported to the Attending Veterinarian, the Chair of the Institutional Animal Care and Use Committee (IACUC), or the Institutional Official. In all cases, these concerns will be forwarded to RC&E. RC&E does not have to identify complainant.

No member of the University community (faculty, staff, postdoctoral fellow, or student) will be discriminated against or subject to reprisals for reporting possible violations of animal care standards.

#### **REASON FOR PROGRAM**

To help ensure that laboratory animals receive humane care, use of treatment in accordance with the highest ethical standards, laws, regulations and policies governing animal research, the IACUC must review and, if warranted, address any animal-related concerns raised by the public, employees, or anyone engaged in research at UND. The IACUC will review each concern in a timely and systematic manner and, when necessary, take prompt, appropriate corrective actions.

#### **PRINCIPLES**

**OVERVIEW:** It is the policy of University of North Dakota (UND) that life sciences research that use animals meet the PHS Policy requirements and are submitted to the IACUC committee for review and approval. Additionally, to help ensure that laboratory animals receive humane care, use of treatment in accordance with the highest ethical standards, laws, regulations and policies governing animal research, the IACUC must review and, if warranted, address any animal-related concerns raised by the public, employees, or anyone engaged in research at UND. The Committee will review each concern in a timely and systematic manner and, when necessary, take prompt, appropriate corrective actions.

#### **PROCEDURES**

Personnel are required to report adverse events, unanticipated problems, and instances of suspected non-compliance with laws, rules, regulations and policies to the IACUC. Individuals having concerns involving animal care and use within UND facilities are responsible for reporting these concerns either through their supervisor or independently to the IACUC and can be made through various persons, e.g., any member of the IACUC, Facility Manager of CBR, Veterinarians, the Institutional Official,

or the Office of the Vice President for Research & Economic Development verbally or in writing. IACUC contact information is posted on the IACUC webpage as well as provided to all researchers during their initial orientation with the Attending Veterinarian. Veterinary, CBR, and Research Compliance & Ethics staff telephone numbers are posted within each animal facility.

Although written concerns are more convenient to handle, complainants may not be willing to submit them in this manner. In such cases, the individuals who receive concerns should document them fully to ensure that the issues are clear and to prevent misunderstandings.

UND will take appropriate steps to protect the confidentiality of those who report concerns as well as anyone against whom allegations are directed, while allegations are under investigation. The UND Employee Responsibility and Activities: Theft, Fraud, Abuse and Waste Policy prohibits unlawful retaliation against employees because of good faith actions in the reporting or the participation in an investigation pertaining to allegations of wrongdoing.

### **Oversight System**

Allegations of noncompliance will remain confidential to the extent permitted by North Dakota law, consistent with the need to conduct an adequate investigation. The University will take reasonable steps to protect persons who file reports in good faith from retaliatory actions based on such filing, in accordance with the UND Employee Responsibility and Activities: Theft, Fraud, Abuse and Waste Policy. Upon receipt of the report, RC&E will communicate the concerns to the Chair and the Attending Veterinarian and convene a meeting of the full IACUC at which a quorum will be present. During the meeting, the complainant's concern(s) will be considered by the Committee. The complainant does not have to be identified.

The IACUC may decide to form a subcommittee to fully investigate the concerns. The subcommittee will be formed of members of the IACUC, but it may also include outside experts, at the discretion of the IACUC. The Chair normally oversees the investigation. If the concerns are directed against the Chair, then the investigation will be led by the Vice Chair or a member appointed by the Institutional Official.

At any time, the Chair and the Attending Veterinarian can take immediate action if research activities are taking place that are not approved by an IACUC protocol; these actions can include immediately advising the PI to take corrective actions and/or halting a research activity. If the Chair or the Attending Veterinarian decides to suspend a research activity, then this decision must be immediately communicated to the IACUC.

In the event that a full investigation of the concern(s) is performed, IACUC will inform all persons involved in the investigation about the nature of the complaint. The proceedings and initial findings of the investigation must be kept confidential. However, IACUC may provide the complainant limited feedback on the progress of the investigation and limited results of the investigation once it is complete.

The results of a full investigation must be shared with the full IACUC in a timely manner. The IACUC Office will then convene a meeting of the full IACUC at which a quorum will be present. At this meeting, the IACUC will determine subsequent actions that are required, including notifications or reporting (either internal or external). The following categories of actions are possible:

### **Possible Outcomes**

- 1. No credible concern related to noncompliance or animal welfare:** If the IACUC determines that no further action such as reporting or follow up is required, the discussion is documented in the minutes of the IACUC meeting. No further action is taken.
- 2. Confirmed case of noncompliance and/or animal welfare concern:** If the IACUC determines that the incident constitutes serious non-compliance or an unresolved animal welfare concern, and that no further investigation is needed to determine causes and corrective actions, it may make a decision based on the information provided in the report. Please refer to the section “Final Actions” below for possible courses of action that the IACUC may take.
- 3. Incomplete or insufficient information to make a determination:** If deemed necessary by the IACUC, then the Chair a subcommittee or an individual appointed by the Chair will conduct a further investigation on the facts and circumstances related to the incident and report back to the IACUC by an assigned completion date. Special care will be taken to avoid actual or perceived conflicts of interest in this process.

### **Final Actions**

The IACUC shall consider all reports from the investigation and any information provided by the PI before reaching a decision. The IACUC may then request additional information and/or take action with respect to the investigation, including but not limited to the following:

- Dismissal of the complaint/concern;
- Requirement of submission and approval of a protocol amendment, or placement of specific additional conditions or stipulations on the protocol;
- Imposition of specific remedial education and training for the PI and/or other personnel listed under the protocol;
- Monitoring research, testing, or training that involves animals;
- Temporary revocation of privileges to provide animal care or to conduct research, testing, or training that involves animals, pending compliance with specific, IACUC-mandated conditions;
- Issuing letters of reprimand;
- Restricting research practices, such as limiting the PI to conduct studies with certain procedures, or conducting research under supervision;

- Suspension of approval for one or more of the PI's studies and establishment of conditions for reinstatement;
- Termination of approval for one or more of the PI's studies; and
- Permanent revocation of privileges to provide animal care or to conduct research, testing, or training that involves animals.

The IACUC will notify the PI in writing of any action taken by the IACUC and the reasons for that action. In addition, the IACUC will notify, as it deems appropriate:

- Other investigators involved in the animal care and use activities at issue;
- The PI's department head (and any additional department heads where the PI holds multiple professional appointments);
- Any additional departments involved in the research;
- The Institutional Official (who will contact any additional institutional authorities) and other pertinent program officials as required (such as appropriate supervisory and management staff, the public affairs office, the safety office, the compliance office, the office of the general counsel);
- Any funding, regulatory or accreditation agencies, as required.

### **Suspension of Protocol**

The IACUC is empowered to suspend any protocol or research activity if it finds violations of the PHS Policy, Guide, Assurance, or Animal Welfare Regulations. Suspension normally occurs only after review of the matter at a convened meeting of a quorum of the IACUC, and with a vote for suspension from a majority of the quorum present. However, either the Chair of the IACUC or the Attending Veterinarian may immediately suspend a research activity if a violation occurs (in which case, the IACUC must be immediately informed of this action).

If research activities are suspended, the Institutional Official, in consultation with the IACUC, must promptly report the suspension along with a full explanation to NIH/OLAW and the Federal Agency or Department supporting the research, if the research is funded through a grant award. In the event that the research is supported by a nonfederal funding agency, then IACUC will follow the reporting requirements of those agencies. The Institutional Official cannot override suspensions of research activities approved by IACUC.

### **Reporting noncompliance, deviations from the Guide and suspensions**

Circumstances that must be reported to OLAW by the Institutional Official are: serious or continuing noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals ("the PHS Policy"); serious deviations from the Guide for the Care and Use of Laboratory Animals ("the Guide"); and suspensions of protocols by the IACUC.