5.0 Semiannual Reviews and Post-Approval Monitoring

Twice each year the IACUC inspects all Creighton University facilities where animals are housed and/or used. The IACUC uses *The Guide* and the AWA regulations as the principal reference documents in conducting these reviews.

5.1 Types of Semiannual Review

5.1.1 Review of the IACUC Policies and Procedures

The IACUC is required to semiannually evaluate the Creighton University IACUC Policies and Procedures for animal care and use programs. This semiannual evaluation includes the following:

- IACUC membership and functions, including protocol review practices
- IACUC records and reporting requirements
- Veterinary care, to include:
    - Preventive medicine, animal procurement, and animal transportation
    - Surgery
    - Pain, distress, analgesia, and anesthesia
    - Euthanasia
    - Drug storage and control
- Personnel qualifications and training
- Occupational health and safety of personnel
- Disaster Plan

The IACUC may use the NIH Sample Semiannual Program and Facility Review Checklist as a guide when conducting its review of the Creighton University IACUC Policies and Procedures for animal care and use programs. The IACUC has developed specific semiannual audit forms, which may be used in addition to or in place of the NIH sample forms.

5.1.2 Review and Inspection of Animal Facilities

As part of its semiannual review, the IACUC will inspect all facilities where animals are kept longer than twelve hours and areas in which surgical manipulations are performed. Other areas, such as laboratories in which only routine injections, dosing, and weighing occur, will be monitored by random site visits and evaluations as necessary to ensure compliance. The IACUC maintains an updated list of all facilities to be inspected during its semiannual review. This semiannual review includes the following:

- Animal housing and support areas
- Cage wash
- Aseptic surgery
- Transport Vehicles
- Procedure areas, non-survival surgeries, laboratories, and rodent surgeries

5.2 Semiannual Review Subcommittee and Reports

A subcommittee of the IACUC, composed of at least four members, to include the Chair and Attending Veterinarian, shall conduct the semiannual reviews. No IACUC member wishing to participate in any review shall be excluded. The subcommittee may invite ad hoc consultants to assist in the reviews.

Upon completion of the reviews, the subcommittee shall prepare a written report to be reviewed by the IACUC at a regularly scheduled meeting. The report shall describe Creighton University's adherence to *The Guide* and the AWA and shall state the reasons for any deficiencies. Deficiencies identified during the reviews are categorized as either minor or significant. A significant deficiency is defined, by USDA regulations and the PHS Policy, as something that is or may be a significant threat to animal health or safety. The report shall include a plan and schedule with dates for correction of each program or facility deficiency. All individuals to be involved in the corrections shall be consulted to ensure that the plan is realistic.

The report must be reviewed and signed by a majority of the IACUC members and shall include minority views. The IACUC shall submit the approved report to the Institutional Official and shall maintain a copy in its files. The report shall be made available to USDA, OLAW and any federal funding agencies upon request.

Any failure to adhere to the plan and schedule identified in the report for correcting deficiencies that results in a significant deficiency remaining uncorrected, shall be reported in writing by the IACUC, through the Institutional Official, within 15 business days to APHIS. If the uncorrected deficiency is related to a federally funded activity, the relevant funding agency shall also be informed.

5.3 Monitoring of Corrective Action Plans

The IACUC shall provide a copy of the final semiannual report to the Research Compliance Director. The IACUC Office along with the Research Compliance Quality Assurance Monitor (the QA Monitor) shall follow up to assure that all deficiencies have been resolved by the dates of correction. If any deficiencies are not remedied within the time period set forth in the final semiannual report, the IACUC shall take appropriate corrective action.

5.4 Protocol Post-approval Monitoring

Post-approval monitoring (PAM) of protocols is performed to provide assurance to regulatory agencies and to the IACUC that animal experiments are performed in accordance with approved protocols. The QA Monitor normally performs post-approval monitoring on behalf of the Research Compliance Office and the IACUC. The QA Monitor confirms consistent and accurate performance of the IACUC-approved protocols, standard operating procedures and practices.

The QA Monitor arranges and performs monitoring visits and procedure reviews, and oversees the continuous education for quality assurance in research at Creighton University.

Post-approval monitoring may be performed as a “For Cause” investigation or routinely as a “Not for Cause” review.

The QA Monitor conducts “For Cause” Investigations at the request of the Research Compliance Director or the IACUC for a variety of reasons including:

- Receipt of an internal complaint (i.e. Creighton University Hotline, anonymous report) or internal concern of possible protocol violation or regulatory noncompliance
- Receipt of an external complaint (the FDA, Sponsor, OLAW, or USDA) of potential protocol violation or regulatory noncompliance
- Investigator history of poor adherence to Creighton University policies/procedures or regulatory requirements

The "Not for Cause" or routine post-approval monitoring may include:

- Review of IACUC records and activities to ensure IACUC policies and procedures are consistent with regulatory requirements and federal assurances
- Review of risk areas identified during periodic risk assessments of the Research Compliance Program
- Protocols randomly selected for on-site review

In post-approval monitoring:

- All active and approved protocols and modifications are available for review
- All allegations of misuse, neglect or inappropriate protocol performance will be investigated
- In general, the monitoring reviews will be scheduled with the Principal Investigator or other laboratory personnel in advance. Follow-up audits for the purpose of confirming Principal Investigator reported resolutions may be unscheduled
- "For Cause" monitoring may be conducted at any time, with or without advance notice (i.e., unannounced) to the Principal Investigator
- During each monitoring visit, the QA Monitor will compare procedures conducted in the laboratory with those listed in the approved protocol.
- The QA Monitor will provide a description of any discrepancies between the procedures performed in the lab and those listed in the protocol to the principal investigator
- The QA Monitor will provide information to the IACUC by means of a written report. The report may include identification of:
    - Unapproved personnel who are performing procedures in the protocol
    - Outdated cage cards, incorrect cage cards, or improperly labeled cage card
    - Location of the procedure that does not match the location specified in the protocol

- Anesthetics/analgesics: unapproved regimen or route of administration, expired date, improper use
- Minor unapproved modifications to approved procedures that are performed
- Other procedural deviations that can be corrected by submission of a minor change request
- Incidents of animal distress that were not anticipated

- The QA Monitor will discuss monitoring/auditing results with the principal investigator to confirm the observations for accuracy, and to assure a complete understanding of issues
- The QA Monitor shall refer issues that pose an immediate threat to animal welfare to the Research Compliance Director the Attending Veterinarian, and the IACUC
- The QA Monitor will send a final written report of the monitoring results to the Research Compliance Director, Principal Investigator, and the IACUC
- As the QA Monitor determines necessary, he/she may recommend further training or retraining of personnel or modifications to procedures, and may perform a follow-up monitoring visit to check for compliance and to ensure the welfare of the animals and the integrity of the IACUC protocol process.