

Minnesota State University, Mankato

Renewal of Assurance A3452-01

**ANIMAL WELFARE ASSURANCE
Submitted August 2008
in accordance with the PHS Policy for
Humane Care and Use of Laboratory Animals**

I, Dr. Anne Blackhurst, as named Institutional Official for animal care and use at Minnesota State University, Mankato, hereinafter referred to as Institution, by means of this document, provide assurance that this Institution will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as PHS Policy.

I. APPLICABILITY OF ASSURANCE

This Assurance is applicable to all research, research training, experimentation, biological testing, and related activities, hereinafter referred to as activities, involving live vertebrate animals supported by the Public Health Service (PHS) and conducted at this Institution, or at another institution as a consequence of the subgranting or subcontracting of a PHS-conducted or -supported activity by this Institution.

"Institution" includes the following branches and major components of Minnesota State University, Mankato: College of Science, Engineering, and Technology.

II. INSTITUTIONAL COMMITMENT

A. This Institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.

B. This Institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."

C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, as well as all other applicable laws and regulations pertaining to animal care and use.

D. This Institution has established and will maintain a program for activities involving animals in accordance with the "Guide for the Care and Use of Laboratory Animals" ("Guide").

III. INSTITUTIONAL PROGRAM FOR ANIMAL CARE AND USE

A. The lines of authority and responsibility for administering the program and ensuring compliance with this Policy are as follows (see Attachment 1):

- Chief Executive Officer: President Richard Davenport

- Institutional Official: Dr. Anne Blackhurst, Dean of Graduate Studies and Research
- Veterinarian and IACUC Chair: Dr. Penny Knoblich, Professor of Biology
- Animal Facility Manager: Brent Pearson

B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:

Name: Dr. Penny Knoblich, Professor of Biological Sciences

Qualifications:

- Degrees: Ph.D., University of North Dakota; DVM, Iowa State University
- Training and/or experience in laboratory animal medicine: Dr. Knoblich has 12 years of veterinary experience in private practice and 10 years of experience with laboratory animals.
- Authority: Dr. Knoblich has direct program authority and responsibility for the Institution's animal care and use program. Dr. Knoblich delegates direct care and use responsibility to Mr. Brent Pearson, Facilities Director. If Dr. Knoblich is not immediately available, Dr. Roger Nelson, a community veterinarian, has been designated as back-up staff veterinarian.
- Time Contributed to Program: Dr. Knoblich is a full-time faculty member at the university. She devotes approximately 10% of her time to the IACUC program.

C. The Institutional Animal Care and Use Committee (IACUC) at this Institution is properly appointed in accordance with the PHS Policy IV.A.3.a and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC consists of at least five members, and its membership meets the composition requirements set forth in the PHS Policy, Section IV.A.3.b. Attached is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations (See Attachment 2).

We recognize that it is not recommended that the institutional veterinarian also chair the IACUC committee. Due to the fact that we are a small institution, with only a few animal researchers, the veterinarian also acts as chair to be certain all reports are completed on time, and that all Assurance procedures are closely followed. To prevent conflicts of interest, or a concentration of power, Dr. Knoblich makes recommendations only on the veterinary aspects of the research, or the compliance of the proposal with standard IACUC requirements. Approval or disapproval of the proposal for animal research rests with the other committee members.

D. The IACUC will:

1. Review at least once every six months the Institution's program for humane care and use of animals, using the "Guide" as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:

- Committee members are contacted for a meeting time
- A date and time are chosen based on availability
- Any business, concerns, and changes are placed on the agenda
- The committee meets for the semi-annual meeting and inspection, using the checklists for the semi-annual program review and facilities inspection as guides (see Attachments 3 and 4).

- The committee conducts a site visit of all facilities
- The evaluation of facilities is signed and any concerns are noted
- The evaluation is forwarded to the Institutional Official and copies are placed in the IACUC office file

2. Inspect at least once every six months all of the Institution's animal facilities, including satellite facilities, using the "Guide" as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:

- After the business agenda is complete, the committee conducts a walk through site visit of all facilities
- The facilities, condition of animals, cleanliness, ventilation, and food storage are evaluated in accordance with the inspection form (see Attachment 4).
- The evaluation is signed by all committee members and concerns are noted
- The evaluation is included in the semi-annual report and forwarded to the Institutional Official and placed in the IACUC files

3. Prepare reports of the IACUC evaluations as set forth in the PHS Policy IV.B.3 and submit the reports to the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows:

The IACUC report to the institutional official is prepared by the IACUC chair, and consists of:

- Meeting minutes
- Completed checklist for semiannual program review
 - Any items checked as minor deficiency, or significant deficiency, will include in the *Notes* section, a plan and timeline for correction.
- Completed facilities inspection.
 - Any items checked as minor deficiency, or significant deficiency, will include in the *Notes* section, a plan and timeline for correction.

4. Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:

- The animal care supervisor is given the authority to directly monitor animal care and researchers' activities to determine compliance with approved protocol
- A list of contact persons, locations, and phone numbers is posted at all times in the animal care ward and in each animal researcher's laboratory for reporting any animal care concerns. In addition to IACUC members, the contact list includes the chair of the Department of Biological Sciences and the Institutional Official as confidential contacts for reports of possible animal care concerns.
- Minor concerns such as availability of food and water, cage cleanliness, animal crowding, or individual animal health, are brought directly to the IACUC chair and investigated immediately
- Major concerns, such as overall condition of animals in a study, require a special meeting of the committee
- The concern is presented and discussed
- Any remedial action is initiated immediately and the department chair, appropriate dean, and Institutional Official are notified in writing

5. Make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are as follows:

- Following the semi-annual meeting or special meeting, the issue is brought to the attention of the department chair, appropriate dean, and Institutional Official
- These individuals are notified both in writing and at a special meeting
- If remedial action is necessary, it is recommended at this meeting

6. In accord with the PHS Policy IV.C.1-3, the IACUC shall review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals. The IACUC procedures for protocol review are as follows:

- The protocol is submitted to the committee chair, using the Proposed Animal Use Form or a similar form.
- The protocol is distributed electronically to all committee members.
- Committee members are asked to respond if they would like to call for a full committee review, or decline to call for a full committee review. Members have 10 days to respond.
- Committee members may request additional information about the protocol before making a decision on calling a meeting.
- If a committee member requests a protocol modification, the request is reviewed by the entire committee. If a consensus is reached, the investigator will be asked to comply, and alter the protocol as suggested.
- If no committee member requests a full committee review, the IACUC chair will approve/require modifications/ or call for a full committee review of the protocol.
- In the case of the submission of a protocol by the IACUC Chair, another committee member (Dr. Steven Mercurio) will approve/request modifications/call for a full committee review of the protocol.
- Once approved, the protocol is given an identification number, and a copy is kept on file with all committee member responses on calling a meeting. Any additional information requested by a committee member is also kept with the document. Time frames for an approved protocol are not to exceed 3 years.
- At each semiannual meeting, ongoing protocols will be reviewed using the following criteria:
 - Adherence of the researcher to the protocol
 - Any problems/concerns reported since the last review
 - Any changes to the protocol
- Investigators with ongoing protocols that will expire within a year will be notified of the need to review their protocol before the next semiannual meeting

7. Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in the PHS Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:

- The change in protocol is submitted to the committee chair.

- The change in protocol is distributed electronically to all committee members, and a copy of the original protocol is made available upon request.
- Committee members are asked to respond if they would like to call for a full committee review of the protocol change, or decline to call for a full committee review. Members have 10 days to respond.
- Committee members may request additional information about the protocol change before making a decision on calling a meeting.
- If a committee member requests a modification of the protocol change, the request is reviewed by the entire committee. If a consensus is reached, the investigator will be asked to comply, and alter the protocol as suggested.
- If no committee member requests a full committee review, the IACUC chair will approve/require modifications/ or call for a full committee review of the protocol change.
- In the case of the submission of a protocol change request by the IACUC Chair, another committee member (Dr. Steven Mercurio) will approve/request modifications/call for a full committee review of the protocol.
- Once approved, the protocol change is filed with the original protocol.
- Any additional information requested by a committee member will also kept with the document.

8. Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:

- The IACUC chair notifies the applicant by email and in writing of the status of the application, including the approval number and approved time period
- A designee of the IACUC records the approval information in a log kept in the IACUC office
- A designee of the IACUC forwards all IACUC decisions to disapprove protocols to the Institutional Official with a written memo immediately following the IACUC decision

9. Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy IV.C.1-4 at least once every three years. The IACUC procedures for conducting continuing reviews are as follows:

- Each protocol is briefly reviewed at the semiannual meeting as to any problems or concerns that may have arisen during the previous 6 months.
- Protocols that are known to be completed are removed from the active list.
- All protocols expire in 3 years and must be resubmitted.
- One year prior to expiration of protocol approval, primary investigators with ongoing studies (beyond three years) are notified that their protocols must be re-submitted prior to the next semi-annual IACUC meeting for a complete review in accordance with PHS Policy IV.C.1-4a

- The review process described in section D.6 of this Assurance is followed

10. Be authorized to suspend an activity involving animals as set forth in the PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows:

- The committee is convened (quorum required) to produce and sign a letter notifying the principal investigator of the suspension
- Copies of the letter specifying the reasons for suspension are provided to the department chair, appropriate dean, and Institutional Official
- If the IACUC suspends an activity involving animals, the Institutional Official in consultation with the IACUC shall review the reason(s) for suspension, take corrective action and provide a written report of that action to OLAW

E. The occupational health and safety program for personnel working in laboratory animal facilities or have frequent contact with animals is as follows:

- A medical work history is required of all personnel prior to working directly in the facility
- All animal personnel are referred to the university health center for a full evaluation
- All personnel are required to attend a health and safety workshop provided to affected university personnel each fall semester
- Each animal care worker is required to have a current tetanus vaccination (within 10 years)
- Animal care personnel are advised of health risks, procedures following injury or illness, and general safety measures during hands-on training, while working directly with the animal care supervisor
- Heavy gloves, particle masks, and disposable shoe covers are available for all personnel
- Injuries are immediately reported to the animal care supervisor, the veterinarian, the primary investigator, or the Chair of the Department of Biological Sciences. Injuries deemed minor (mild skin abrasions, superficial bites) are cleaned and bandaged. Injuries deemed moderate or major result in referral of the injured person to health services.

F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed therein and the average daily inventory of animals, by species, in each facility is provided in the attached Facility and Species Inventory table (See Attachment 5).

G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

- Faculty trained at other institutions are required to be retrained at the university and also required to attend the annual three-hour health and safety seminar
- New faculty meet with the Department Chair and the IACUC chair to discuss their research intentions and needs prior to submission of any protocol. Policies specific to Minnesota State Mankato are discussed at this time. Furthermore, the IACUC Proposed Animal Use Request form lists pertinent university requirements and policies (see Attachment 6).

- Non-faculty and non-trained faculty are trained by Dr. Penny Knoblich, chairperson of the IACUC and staff veterinarian. Staff without prior training are trained by the animal care technician and are required to attend the annual three-hour health and safety seminar.
- Training includes but is not restricted to:
 - Animal care and handling
 - Cage cleaning
 - Food and water handling
 - Rules on newborn care
- Training for faculty:
 - Animal care and handling
 - Anesthesia and surgical techniques if applicable
 - Acceptable euthanasia methods
 - Categories of pain-distress
 - Procedures to minimize pain and distress
 - Alternatives to animal models
- A summary of the training information is presented to the faculty and a signed copy is kept on file in the IACUC office. A list of new animal research faculty and training summaries are presented at the IACUC semiannual meeting.
- The animal care supervisor is updated immediately by the IACUC chair on any changes in federal regulations. The supervisor then updates any student employees working with the supervisor.

IV. INSTITUTIONAL PROGRAM EVALUATION AND ACCREDITATION

All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past six months and will be re-evaluated by the IACUC at least once every six months thereafter, in accord with the PHS Policy IV.B.1-2. Reports have been and will continue to be prepared in accord with the PHS Policy IV.B.3. All IACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to the "Guide." Any departures from the "Guide" will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC's evaluations will be submitted to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

This Institution is Category Two (2)—not accredited by the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC). As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request. The report of the most recent evaluations (program review and facility inspection) is attached (see Attachment 7).

V. RECORDKEEPING REQUIREMENTS

A. This Institution will maintain for at least three years:

1. A copy of this Assurance and any modifications thereto, as approved by the PHS.
2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations.
3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld.
4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, Dr. Anne Blackhurst, Dean of Graduate Studies and Research.
5. Records of accrediting body determinations.

B. This Institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional three years after completion of the activity.

C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. REPORTING REQUIREMENTS

A. This Institution's reporting period is January 1 – December 31. The IACUC, through the Institutional Official, will submit an annual report to OLAW on January 31 of each year. The report will include:

1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked), any change in the description of the Institution's program for animal care and use as described in this Assurance, or any change in the IACUC membership. If there are no changes to report, this Institution will provide written notification that there are no changes.
2. Notification of the dates that the IACUC conducted its semiannual evaluations of the Institution's program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official, Dr. Anne Blackhurst, Dean of Graduate Studies and Research.

B. The IACUC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

1. Any serious or continuing noncompliance with the PHS Policy.
2. Any serious deviations from the provisions of the "Guide."
3. Any suspension of an activity by the IACUC.

C. Reports filed under sections VI.A. and VI.B. of this document shall include any minority views filed by members of the IACUC.

VII. INSTITUTIONAL ENDORSEMENT AND PHS APPROVAL

A. Authorized Institutional Official

Name: Dr. Anne Blackhurst

Title: Dean, Graduate Studies and Research

Name of Institution: Minnesota State University, Mankato

Address: Alumni Foundation Building 115, Mankato, MN 56001

Phone: 507-389-2321

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E-mail: anne.blackhurst@mnsu.edu

Signature: 

Date: August 22, 2008

B. PHS Approving Official

Name:

Title:

Address:

Phone:

Fax:

E-mail:

Signature:

Date:

C. Effective Date of Assurance:

D. Expiration Date of Assurance: