

The Care and Use of Vertebrate Animals at NDSU

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Institutional Animal Care and Use Committee (IACUC)

For the protection of animal subjects



IACUC Office

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Care and use of animals at NDSU

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Introduction

North Dakota State University's *Guidelines for the Care and Use of Vertebrate Animals* is intended to ensure the humane care of animals used within the NDSU system. These *Guidelines* assist principal investigators and other personnel in the proper procedures and conduct of animal use activities at NDSU.

Universities, hospitals, and other institutions that conduct federally funded research using animals as research subjects are required by federal law to establish a committee responsible for reviewing such proposed research. Federal rules governing animal research are primarily described in the Animal Welfare Act (AWA), the USDA Animal Welfare Regulations (AWRs) (9 Code of Federal Regulations, Chapter I, Subchapter A), and the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals.

To comply with these regulations, North Dakota State University has established an Institutional Animal Care and Use Committee, the "IACUC." This manual, *Guidelines for the Care and Use of Vertebrate Animals*, has been created by the NDSU IACUC and is based on guidelines established by federal animal regulations, as well as additional policies for animal use activities conducted within the NDSU system. For example, federal regulations require compliance only for projects funded or regulated by federal agencies. However, the NDSU IACUC requires that activities involving vertebrate animals – whether funded or regulated by an external organization or not – must comply with NDSU animal use policies and federal regulations.

These *Guidelines* are considered to be in effect upon publication of this manual and remain in effect and enforceable until amended.

Statement of Principles & Purpose

Great strides in medical, pharmaceutical, nutritional, production, and management practices have been made, and benefits have been reaped from research and teaching activities involving the use of vertebrate animals. All living creatures deserve respect, and the use of vertebrate animals in research and teaching carries both scientific and ethical responsibilities. The NDSU IACUC upholds the principles of the “three R’s” – reduction, replacement, and refinement. Principal investigators must justify the numbers of animals used in their research or teaching activity (using the smallest number of animals possible), document how that number was derived, and describe the potential benefit of the research or teaching activity. Principal investigators involved in animal research must make good-faith efforts to answer scientific questions or to achieve educational outcomes without the use of animals. When adequate alternative systems are not available, principal investigators must ensure that the most appropriate species of vertebrate animal is chosen for use in the research or teaching activity. Additionally, investigators must minimize the severity and duration of painful or distressful situations.

It is the intent of NDSU – through the IACUC, the Office of Sponsored Programs Administration, and the division of the Vice President for Research, Creative Activities and Technology Transfer – to assist investigators engaged in animal use to conduct their activity along ethical guidelines reflecting professional, as well as community, standards. This institution recognizes its duty to protect the welfare of animals used, regardless of the source of funding or regulation. Additionally, the Institution recognizes a responsibility to ensure the safety of personnel.

North Dakota State University has an obligation to ensure that activities involving animals comply with the Animal Welfare Regulations (AWRs), Animal Welfare Act (AWA), Public Health Service (PHS) Policy, and other regulations and guidance from federal and private animal offices and organizations. It is not the intent of the University, the IACUC, the Office of Sponsored Programs Administration, or the Office of the Vice President for Research, Creative Activities and Technology Transfer to interfere in any way with competent, ethical, and sound activities involving animals. However, all parties involved are obligated to ensure that the University and its personnel are in compliance with regulations governing animal use. It is important to observe the “spirit” as well as the “letter” of these regulations, since the conduct of these activities involving animals reflects professional, personal, and community commitments to rigorous ethical and scientific standards of conduct.

While every attempt has been made to address the important issues related to conducting animal use activities within the NDSU system, it is likely that not all topics or contingencies have been foreseen or considered in these *Guidelines*. The NDSU IACUC strives to deliver the best possible service regarding review of activities and programs involving animals. To assist in the long-term goal of establishing adequate protection for animals, the IACUC needs the cooperation of the research, teaching, and testing community at NDSU.

The IACUC invites input from investigators and other interested parties regarding revisions and updates to these *Guidelines*. Where possible and appropriate, changes in IACUC-related activity will incorporate such recommendations.

Working together, we can develop a comprehensive, streamlined, and effective system of review and assurance regarding an ethical and professional environment of animal use at NDSU.

Terms and Definitions

The following definitions, wording, and terms are used throughout these *Guidelines*.

- “Animal” means any live vertebrate animal, but excludes carcasses and tissues used for diagnostic/research purposes.
- “AV” refers to the Attending Veterinarian. As per USDA Regulations (9CFR), this individual is “a person who has graduated from a veterinary school accredited by the American Medical Association’s Council on Education, or has a certificate issued by the American Veterinary Medical Association’s Education Commission for Foreign Veterinary Graduates, or has received equivalent formal education as determined by the Administrator; has received training and/or experience in the care and management of the species being attended; and who has direct or delegated authority for activities involving animals at a facility subject to the jurisdiction of the Secretary.”
- “IACUC” stands for Institutional Animal Care and Use Committee. “Committee” or “the committee” may also be used in place of “IACUC.”
- “Institution” and “NDSU” refer to “North Dakota State University,” and the terms may be used interchangeably.
- “Institutional Official” (“IO”) is appointed by the CEO of the institution, which holds an assurance with the Office of Laboratory Animal Welfare (OLAW), as the individual responsible for the animal care and use program. This appointment is mandated by federal regulation (9 CFR Subchapter A, Health Research Extension Act of 1985). With this appointment the IO has the authority to contract with federal agencies to receive funding and to report to them regarding compliance with mandated laws. See appendix B for IO contact information.
- “NDSU system” encompasses all facilities operated by North Dakota State University (e.g., on-campus buildings or facilities, as well as off-campus facilities such as the research extension centers).
- “Personnel” shall be defined as any North Dakota State University (NDSU) employee, student, visiting faculty, adjunct, and volunteer conducting animal use activities with the NDSU System.
- “PHS Policy” means the Public Health Service Policy on Humane Care and Use of Laboratory Animals.
- *Ag Guide* may be used in place of the full title, *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching* (Federation of Animal Science Societies, January 1999).

- *Guide* or *ILAR Guide* may be used interchangeably or in place of the full name of the *Guide for the Care and Use of Laboratory Animals* (ILAR, 1996).

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March 2005

To: Faculty, Staff, and Students at North Dakota State University

From: Phil Boudjouk, Ph.D.
Vice President for Research, Creative Activities and Technology Transfer
Institutional Official for Compliance

This is an exciting time at North Dakota State University. Five years ago President Chapman challenged us to move our research performance and capabilities to the highest possible level. At present, we are achieving this goal. An expanded research endeavor brings with it expanded responsibilities, and the information that follows in this manual is an example of faculty and staff taking on expanded responsibilities.

The Institutional Animal Care and Use Committee (IACUC) has revised and revamped these *Guidelines for the Care and Use of Vertebrate Animals: Policies and Procedures* for the humane treatment of animals at NDSU. This was not a small task, and their efforts are appreciated.

This revised policy is part of the effort by the University to provide all faculty, staff, and students with current information in the responsible conduct of research that involves animals.

I invite you to review this manual. It contains guidelines for responsible care and treatment of animals at NDSU, and procedures for completing the necessary administrative aspects of acquiring and maintaining approval of animal projects. If you use animals in any facet of your duties (research, teaching, testing, exhibition, or any other purpose) at NDSU, please take special note of the guidelines that pertain to your activities and animal species.

We must comply with federal regulations at all times, but more importantly we must treat the animals with the humane and ethical care and respect they deserve. We welcome your comments and questions about the information contained in these *Guidelines*.

Thank you for your support of and cooperation with NDSU IACUC policies and procedures.

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SECTION I: THE IACUC

What It Is and How It Works at NDSU

Part A: The Institutional Animal Care and Use Committee (IACUC)

1. The Federal IACUC Mandate and Responsibilities & Roles of the IACUC.

The existence of an IACUC is mandated by both the Animal Welfare Regulations (9 CFR Ch. I, §2.31) and PHS Policy at institutions which receive federal funding *and* are involved in animal-related activities. North Dakota State University has incorporated the federal regulations into its own policy and is committed to the humane treatment of the animals in its programs.

The IACUC is responsible for ensuring accountability and compliance with AWA and PHS policy. This responsibility minimally requires that the IACUC:

- review all proposed uses of live vertebrate animals in teaching, research, and testing, including regular review of all ongoing activities;
- inspect the NDSU animal facilities at least once every six months. Deficiencies, where found, are to be classified as “significant” or “minor,” and a timeline for correction of significant deficiencies shall be indicated. If the corrections are not completed within the time limit this must be reported to the USDA. The *ILAR Guide for the Care and Use of Laboratory Animals* and the OLAW checklist are to be used as a basis for the evaluation;
- review the NDSU animal care and use program every six months;
- submit semiannual reports based on the semiannual inspections and program reviews to the IO;
- submit an annual report to the NIH's OLAW, detailing changes in the animal care and use program, changes in IACUC membership, and the results of the semiannual inspections and program reviews;
- submit an annual report (form 7023) of the research facility to the USDA detailing annual animal usage.
- investigate and address all concerns involving the care and use of animals within the NDSU system;
- suspend a previously approved animal related activity if the committee determines that the activity is not being conducted in compliance with the Animal Welfare Regulations, AWA, PHS policy, or University policy;
- report all suspensions to OLAW, USDA (if applicable) and any federal funding agency; and
- make recommendations to the IO regarding the animal care and use program, University animal facilities, and the care and use training programs available to University personnel.

The roles of the IACUC are to:

- promote the humane care of animals used in biomedical and behavioral research,

teaching, and testing;

- provide information to the institution that will enhance animal well-being, the quality of biomedical research, and the advancement of biologic knowledge that is relevant to humans or animals;
- advise the IO, who is responsible for the animal care and use program, on our institutional compliance with federal regulations and guidelines; and
- serve as a liaison between NDSU and the Fargo-Moorhead community for all matters involving the use of animals.

2. The IACUC at NDSU.

In compliance with federal regulations, the President of North Dakota State University has appointed an IACUC to oversee NDSU's animal care and use programs, facilities, and procedures.

3. NDSU IACUC Administration.

The NDSU IACUC Office.

The NDSU IACUC is administered through the Office of Sponsored Programs Administration and the Office of the Vice President for Research, Creative Activities and Technology Transfer. The IACUC Office is located in Research I, 1735 NDSU Research Park Drive, P.O. Box 5756, Fargo, ND 58105-5756 (phone 701-231-8114 or 701-231-8045), and includes the IACUC Executive Director and support staff.

The NDSU Institutional Official.

Is authorized to sign the NDSU PHS Animal Welfare Assurance, making a commitment on behalf of the institution that the requirements of PHS Policy on Humane Care and Use of Laboratory Animals will be met;

Is authorized to legally commit on behalf of NDSU, that the requirements of the Animal Welfare Act as set forth under the regulations and Standards in the Code of Federal Regulations of 9 CFR parts 1, 2, and 3 of the Animal Welfare Regulations will be met; to sign the USDA research facility registration application and subsequent USDA annual reports for NDSU;

Is authorized with direct oversight of and with the authority to administer the Institutional Animal Care and Use Program;

Is authorized to appoint an Institutional Animal Care and Use Committee (IACUC), whose members are qualified through experience and expertise to assess the NDSU animal program, facilities, and procedures;

Is authorized to give full support to IACUC, to maintain a direct line of communication with the IACUC; coordinate with administration, the IACUC, investigators and animal resources to ensure a clearly defined chain of authority; and to act upon any and all IACUC recommendations regarding any aspect of the research facility's animal program, facilities, or personnel training;

On behalf of the research facility, the IO is authorized to ensure that the Attending Veterinarian has sufficient and appropriate authority to ensure that adequate veterinary care is provided at all times and that he or she is able to oversee the adequacy of all aspects of animal care and use for all animals.

On behalf of the research facility, the IO is authorized to ensure (through the IACUC, if suitable) that all animal care and use personnel, as well as IACUC members, are qualified to fulfill their responsibilities; and that this responsibility will be met in part through the provision of training and instruction and the review of personnel qualifications with sufficient frequency to fulfill the research facility's responsibilities

Will be kept informed through the IACUC of the extent to which the NDSU Animal Care and Use Program complies with the PHS Policy on Humane Care and Use of Laboratory Animals, the NDSU PHS Animal Welfare Assurance, the *Guide to the Care and Use of Laboratory Animals (Guide)*; and, the Animal Welfare Act, all corresponding USDA Animal Welfare Regulations and Animal Care Policies; and all other applicable federal, state and local animal welfare laws and regulations;

At a minimum, the IO will receive semi-annual program evaluation reports from the IACUC describing its reviews and inspection findings and recommendations regarding any aspect of the research facility's animal program, facilities, or personnel training.

In the event of an IACUC suspension of any animal activity, any serious or continuing noncompliance with PHS Policy or other applicable laws and regulations; or any serious deviation from the provisions of the Guide, the IO is authorized, in consultation with the IACUC, to review the reasons for suspension, take appropriate corrective action, and promptly report that action with a full explanation to OLAW and if applicable, to APHIS within 15 days, and to any federal agency funding that activity

If appropriate, the IO and other officials may conduct further review of IACUC-reviewed animal care and use activities, however, the IO and other facility officials are NOT authorized to approve an activity involving the care and use of animals that has not been approved by the IACUC.

The NDSU IACUC Executive Director.

The IACUC Executive Director handles the administrative duties associated with the IACUC, including: the initial review of animal protocols, determination of the appropriate review channels for protocols (designated reviewer or full-committee review); follow-up of committee protocol actions, organization of IACUC meetings and materials, development and distribution of meeting minutes, and coordination of all IACUC record-keeping activities; participation in inspections; ongoing review of the program and policies and procedures; submission of federally required reports, and ongoing review of federal regulations to ensure continued compliance.

4. Composition of the IACUC.

Composition of the IACUC must adhere to the following guidelines set forth in sections IV.A.3.b. (1)-(4) and IV.A.3.c. of the PHS Policy on Humane Care and Use of Laboratory Animals:

“b. “...the committee shall consist of not less than five members, and shall include at least:

- 1) one Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program responsibility for activities involving animals at the institution;
 - 2) one practicing scientist experienced in research involving animals;
 - 3) one individual whose primary concerns are in a nonscientific area (for example, ethicist, lawyer, member of the clergy); and
 - 4) one individual who is not affiliated with the institution in any way other than as a member of the IACUC and is not a member of the immediate family of a person who is affiliated with the institution.
- c. An individual who meets the requirements of more than one of the categories detailed above may fulfill more than one requirement. However, no committee may consist of less than five members.”

USDA animal welfare regulations (9 CFR Ch.I, Subchapter A, Part 1, §1.1 and §2.31) regarding the composition of the IACUC are exceeded by the above PHS guidelines.

However, in accordance with USDA regulations, if the committee consists of more than three members, not more than three members shall be from the same administrative unit. The NDSU IACUC also strives to ensure that a representative from each college and/or department that regularly conducts animal research is present on the committee.

The IACUC Chair.

The IACUC Chair serves at the request of the IO through a direct appointment based on committee nomination. The Chair is responsible for leadership of the committee and for reviewing and signing important IACUC documents such as certain reports to federal agencies and all protocols, documents, and other information approved by the NDSU IACUC.

Appointment of the Chair is renewable July 1 of each year.

The Attending Veterinarian (AV).

The IO also directly appoints the AV. The AV is a voting member of the IACUC and is responsible for overseeing the veterinary care of all animals used at NDSU. The AV contributes to the establishment of appropriate policies and procedures for ancillary aspects of veterinary care such as advising on experimental models; reviewing protocols with respect to veterinary care and animal welfare; monitoring occupational health, hazard containment, and zoonoses control programs; and supervising animal nutrition, husbandry, and sanitation. (Also see Section IV.A.1. of this manual for more information on the AV and NDSU’s program of veterinary care.) The AV is also a direct appointment of the IO, appointed or re-appointed July 1 of each year.

5. IACUC Membership: Selection, Appointments, and Terms of Office.¹

Appointment.

¹ A list of the current membership of the NDSU IACUC is attached as Appendix B of this manual.

Membership on the IACUC is by appointment of the IO.

Persons from NDSU serving on the NDSU IACUC. Each NDSU college or department, using whatever administrative and electoral procedures are appropriate to that unit, nominates and recommends to the IO a candidate to serve as that college's or department's representative to the IACUC. Faculty appointments to the IACUC are not automatic. The IO must approve a nominee and officially appoint said person to serve as college or department representative to the IACUC. Conversely, the IO can disapprove the college's or department's recommendation of a nominee and request another nominee of that college's or department's choosing.

Persons not from NDSU. Committee members may recommend these individuals for appointment. The nominees' names and credentials shall be presented to the IO for appointment.

Non-Voting members. The Executive Director, the IO and any other applicable appointed personnel are non-voting members of the IACUC. Such members attend IACUC meetings and play an important role in the committee's operation, function, and discussions.

Designated Alternates. According to NIH Notice NOT-OD-01-017 released February 12, 2001, Designated Alternate members serve on the IACUC as voting members when regular members cannot be present at an IACUC meeting. Designated alternates may attend regular IACUC meetings or functions as they wish, but they may contribute to a quorum and function as an IACUC member only if the regular member for whom they serve as alternate is unavailable. There is a one-to-one appointment and designation of IACUC members to alternates.

Designated Alternates are officially appointed by the IO in the same way that regular members are appointed, as outlined above.

Alternates, like regular members, are trained and informed of IACUC policies and procedures by participating in the IACUC training program and by a course of self-instruction (being provided with and becoming familiar with the NDSU IACUC *Guidelines for the Care and Use of Vertebrate Animals*, the NDSU IACUC *Guidelines for Occupational Health and Safety in the Care and Use of Vertebrate Animals*, the *Guide*, the *Ag Guide*, PHS/OLAW Policy, and the USDA regulations). All members, regular and alternate, are required to enroll, participate, and pass an on-line course on IACUC Functions available through a VA training website (<http://www.researchtraining.org/>). Instructions for this course may be requested from the IACUC Office.

Terms of Office.

Each appointed member of the IACUC shall serve a regular term of office of three years. At the expiration of the term of office, the member's college dean or department chair shall either re-nominate him/her or offer another candidate. As with new members, a re-nomination is subject to the approval of the IO.

Terms of the appointment include but are not limited to participation in the following:

Semi-Annual Program Evaluation including Program Review and Facility Inspections

Reports and Recommendations to the Institutional Official

Review and Approval of Proposed Animal Use Activities and Significant Modifications to IACUC-Approved Animal Use Activities and to maintain confidentiality of all materials reviewed

Suspension of On-Going Animal Activities (if warranted)

Assessment of Animal Care and Use Personnel Qualifications

Review of Institutional Training Programs for Animal Care and Use Personnel and the Institutional Animal Care and Use Committee

Provision of and participation in appropriate Occupational Health and Safety Programs and associated training for animal care and use personnel as well as others at risk.

Reporting and Record Keeping Requirements

Provision of training in the recognition and reporting of animal care and use deficiencies and the mechanism for voicing animal welfare concerns

Review and Investigation Animal Welfare Concerns

Endorsement of an Animal Facility Disaster Plan

At the expiration of a non-NDSU member's term of office, the member may be asked by the IO to serve another term, or another off-campus representative may be appointed.

Members of the IACUC have the option of resigning. Such vacancies shall be filled according to procedures outlined above for new and re-nominated members.

Representatives of colleges are appointed on a "staggered" basis so that there are always experienced members serving on the board. Positions shall be filled as vacated, each with a three-year term of office, beginning July 1 of the year of appointment.

Removal of IACUC Members.

Faculty members can be removed from the IACUC by a written request for removal directed to the IO from the Dean of the college from which the faculty members are employed, giving reasons why such persons should no longer serve the university community as IACUC members. Approval of the request by both the IO and the Chair of the IACUC is required. The IO also reserves the right to initiate removal of a member from the committee at his/her discretion.

Non-faculty members of the IACUC can be removed with the direct approval of the IO and/or the Chair of the IACUC.

The IO may present a request for removal of the IACUC Chair to the IACUC. The Chair can only be removed from that office by a majority vote of the full IACUC. A recommendation for removal can be issued in writing to the IO if it is signed by at least three IACUC members. If removed as Chair, that individual member retains a right to participate as a regular IACUC member as a college or department representative for the duration of his/her term, unless he/she is removed from the IACUC as described above.

6. IACUC Meetings.

Meeting Procedures.

A regular meeting of the NDSU IACUC shall occur once per month. Federal regulations require that a meeting take place at least once every six months. Additional special meetings may be called at the discretion of the IO, the Executive Director, or the Chair. Such meetings may be called with short notice, but must have a quorum (simple majority) present in order to conduct official business. Meeting times, dates, and locations for the year shall be determined at the beginning of each academic year. Each month, the Executive Director will send meeting materials and agendas to members at least five working days in advance of all meetings.

The Executive Director will post a notice of the date, time, and location of meetings on the IACUC website, <http://www.ndsu.nodak.edu/research/compliance/iacuc>. A notice will also be posted on or near the door of the meeting room while the meeting is in session.

Notice of special meetings will not be posted on the website, but rather in the same manner as regular meetings, outside of the meeting room door.

The IACUC Executive Director will prepare the agenda, which will be sent to members in advance of the meeting. The Chair will direct the meeting according to the agenda. The following meeting format will be followed:

- A. Call to order
- B. Announcements
- C. Approval of minutes of previous meeting
- D. Unfinished business
- E. New business
- F. Discussion items

Meeting Chairship.

IACUC meetings will be led and directed by the Chair, who will preside over the meeting, directing the agenda, voting, and correct procedures.

A Vice Chair will preside at meetings when the Chair is unavailable or is an investigator on a research project being reviewed or considered. The Vice Chair will assume all duties and responsibilities of the Chair in the event of the Chair's inability to serve. The Vice Chair will preside at the request of the Chair.

Temporary status as Vice Chair will continue until the Chair becomes available to handle IACUC matters.

Voting Procedures.

Members will vote by indicating favor (“aye”) or disfavor (“nay”) of the motion. Members may also abstain from voting (this will be recorded as the member’s action on the vote). At the request of the Chair, a vice Chair will preside at meetings where the Chair is unavailable or is an investigator on a research project. The vice Chair then will assume all duties and responsibilities of the Chair. Temporary status as vice Chair will continue until the Chair is again available. .

Action on IACUC protocols, forms, policies, procedures, or other documents or information must be taken through the voting process. A quorum (simple majority) of voting IACUC members must be present in order for actions or votes to be legitimate. Approval or disapproval of all aforementioned documents and information shall be based on a majority of votes.

In the event that a quorum of regular members is not available, Designated Alternates may contribute to a quorum and function as IACUC members. (See Section I.A.5. of these *Guidelines* for more information).

Meeting Minutes.

The minutes must show the results of every vote taken at the meeting, and must show the recorded vote of each member on every recorded vote. Minutes of IACUC meetings shall be in sufficient detail to show attendance at the meetings; actions taken by the IACUC; the vote on these actions, including the members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a summary of the discussion of controverted issues and their resolution.

These minutes shall serve as IACUC records of proceedings and full-board protocol reviews. All remarks, commentaries, and opinions of board members may become part of the official record of the meeting.

The minutes of IACUC meetings will be kept on file in the IACUC Office indefinitely.

7. Record Keeping of the IACUC.

Types of Records Maintained by the IACUC Office.

The IACUC maintains its records in the Office of Sponsored Programs Administration. The IACUC Office keeps paper record files of IACUC activities and maintains some of the same records in a computer database. The IACUC Executive Director and the Sponsored Programs Administration support staff are charged with maintaining IACUC records.

IACUC records maintained by the Office of Sponsored Programs Administration include (but are not limited to):

- A. NDSU’s approved PHS-OLAW Animal Welfare Assurance statement;

- B. minutes of IACUC meetings, including records of attendance, activities and actions of the committee, and committee deliberations;
- C. records of applications, protocols, and proposed significant changes in the care and use of animals, and whether IACUC approval was given or withheld;
- D. completed or inactive protocols, for at least three years after termination;
- E. records of annual review of IACUC-approved protocols;
- F. records of semiannual IACUC inspections, reports, and recommendations (including minority views) as forwarded to the IO;
- G. copies of the annual reports sent to USDA-APHIS and OLAW;
- H. records of accrediting body determinations;
- I. personnel training records;
- J. facilities and facility managers lists; and
- K. informational materials.

Types of Records Maintained by Facility Managers.

All records concerning a facility must be kept at the facility and must be available for inspection by federal agencies as well as IACUC representatives. Examples of these records include, but are not limited to, the purchase and sale of animals, veterinary records, surgical records, maintenance, monitoring systems for temperature and humidity, personnel access, deaths and illnesses, and adverse events. Cleaning schedules and routine husbandry activities must also be recorded.

There are special regulations regarding dogs and cats. Facility managers must maintain records that fully and correctly disclose information concerning each live dog or cat purchased or otherwise acquired, owned, held, or otherwise in the institution's possession or under its control, transported, euthanized, sold, or otherwise disposed of by the institution. The records must include any offspring born of any animal while in the institution's possession or under its control:

- A. the name and address of the person from whom a dog or cat was purchased or otherwise acquired, whether or not the person is required to be licensed or registered under AWA;
- B. the USDA license or registration number of the person, if he or she is licensed or registered under AWA;
- C. the vehicle license number and state, and the driver's license number and state of the person, if he or she is not licensed or registered under AWA;
- D. the date of acquisition of each dog or cat;
- E. the official USDA tag number or tattoo assigned to each dog or cat (under 9 CFR, Ch. I, §2.38(g));
- F. a description of each dog or cat which includes the species and breed or type of animal, the sex, the date of birth or approximate age, and the color and any distinctive markings;
- G. any identification number or mark assigned to each dog or cat by the institution.

The USDA Record of Acquisition and Dogs and Cats on Hand form (APHIS Form 7005/VS Form 18-5) may be used to keep and maintain the above information. The IACUC Office has Form 7005 and other USDA forms for recording information regarding dogs and cats.

In addition, records or forms disclosing the information listed below must be kept for the transporting, selling, or otherwise disposing of any live dog or cat to another person:

- A. the name and address of the person to whom a live dog or cat is transported, sold, or otherwise disposed of;
- B. the date of transportation, sale, euthanasia, or other disposition of the animal; and
- C. the method of transportation, including the name of the initial carrier or intermediate handler, or, if a privately owned vehicle is used to transport the dog or cat, the name of the owner of the privately owned vehicle.

The Record of Disposition of Dogs and Cats (APHIS Form 7006/VS Form 18-6) forms may be used to keep and maintain the above information.

One copy of the record containing the required information must accompany each shipment of any live dog or cat sold or otherwise disposed of by the institution; however, information which indicates the source and date of acquisition of any dog or cat need not appear on the copy of the record accompanying the shipment. The facility manager or the IACUC Office must retain one copy of the record of acquisition or disposal of the animal.

APHIS regulations specify that inspectors will maintain the confidentiality of the information and will not remove the materials from the research facilities' premises, unless there has been an alleged violation, they are needed to investigate a possible violation, or for other enforcement purposes. Release of any such materials, including reports, summaries, and photographs that contain trade secrets or commercial or financial information that is privileged or confidential, will be governed by applicable sections of the Freedom of Information Act (FOIA).

Availability of Records.

All records must be available for inspection and copying by authorized OLAW (and other PHS), USDA-APHIS, and other federal agency representatives, and the AV, IACUC members, IACUC Director, or IACUC Chair at reasonable times and in a reasonable manner.

Record Maintenance (Duration).

The IACUC Office maintains all records for at least three years. Records that relate directly to proposed activities and proposed significant changes in ongoing activities reviewed and approved by the IACUC are maintained for three years beyond the completion of the activity. After those three years, limited information about such completed projects is kept indefinitely in the computer database. Most other IACUC records, such as inspections reports, meeting minutes, committee membership lists, etc., are maintained indefinitely in the IACUC Office files.

If an APHIS Administrator or other federal representative notifies NDSU in writing that specific records must be retained pending completion of an investigation or a proceeding under AWA or other regulation, NDSU will hold those records until their disposition is authorized in writing by the federal agency administrator or representative.

PART B: New Protocols: Preparation, Submission, Review, and Approval

1. New Protocols.

All faculty, students, and staff involved in animal use have a professional and legal obligation to provide their animals with healthful conditions and humane care at all times. The IACUC review process is designed to assist in the fulfillment of that responsibility and enhance compliance with federal and NDSU policies requiring committee review and approval of activities involving animals. Individuals submitting a new protocol for IACUC review are encouraged to consider carefully the information provided in this section.

In preparing animal care and use protocols, PIs should consider the following sections of the *Guide for the Care and Use of Laboratory Animals* (1996):

- A. Animal Care and Use Protocols, pgs. 10-11; and
- B. PHS Policy and Government Principles Regarding the Care and Use of Animals, pgs. 116-118.

In cases of agricultural animal use the PI should consider applicable sections in the Federation of Animal Sciences Society's "*Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching.*"

PIs are also encouraged to consult with their colleagues, IACUC members, and the NDSU AV during the preparation of their IACUC protocols.

Who must submit activities to the IACUC for review?

NDSU faculty, visiting faculty, staff, students, consultants, advisors or volunteers who are the PI, activity director, supervisor, lead coordinator, etc. for a proposed activity involving animals within the NDSU system, must submit an IACUC Protocol Form (Appendix A).

The IACUC Office should be contacted if there is uncertainty as to whether a protocol must be filed.

Students conducting an IACUC-reviewed activity involving live vertebrate animals must submit a protocol in collaboration with their faculty advisor. The advisor must be listed as the PI and the student listed as the Co-Principal Investigator or other personnel, depending on the student's level of involvement. In cases where either the student or the faculty member will be working outside of NDSU with other institutions, the NDSU IACUC would prefer to see the faculty member as well as the student named on the protocol, approved by the outside institution.

What kinds of activities involving animals must be reviewed by the IACUC?

The NDSU IACUC shall review activities involving the use of live vertebrate animals for teaching, research, and testing within the NDSU system, regardless of funding source. Such activities include, but are not limited to, animal use in agricultural, biomedical, and/or behavioral research, teaching, exhibition, demonstration, and/or testing. Field studies must also be reviewed

by the IACUC. Carcasses and tissue samples collected post-mortem at an approved facility such as a federally inspected abattoir, do not require NDSU IACUC review if no manipulation or conditioning of the live animal was required; such tissue samples may require approval from other federal, state and local agencies. NDSU discourages euthanizing animals for the sole purpose of collecting tissue for analysis. NDSU encourages sharing of tissue between PIs whenever possible. Obtaining tissue from other sources, such as from ATCC or other legitimate vendors, would be encouraged as well.

When must the protocol be submitted to the IACUC for review?

Protocols must be submitted and approved *before* any work with animals is initiated. Purchasing animals is seen as initiating an activity, because approval of proper housing is part of the review process. Purchasing supplies and drugs is not seen as initiating the activity. The IACUC does not condone nor grant “after-the-fact” approval. Depending on the review process, protocols should be submitted a full month before planned initiation of the activity.

How long does the review process take?

The length of the review period varies depending on the nature of the activity. Review of an activity can take from one week (Categories B and C) to several weeks (Categories D and E). The IACUC meets once per month. Protocols in Categories D and E require full-committee review. (See Section I.B.6. below for further information.)

What must be submitted to the IACUC?

A paper copy of the completed protocol form with original signatures must be submitted for review. The blank protocol form is available in hardcopy in the IACUC Office, or in Word format at <http://www.ndsu.nodak.edu/research/compliance/iacuc/>. Questions about the form may be directed to the IACUC Office. Referenced material cited in the protocol must be provided with the protocol. The IACUC will not review incomplete protocols, including those that are missing cited procedures or works.

Where should protocols be submitted?

All IACUC forms and correspondence should be directed to the IACUC Office.

2. Pain Categories and Levels of IACUC Review.

After the completed protocol form has been submitted to the IACUC Office, the IACUC Director will initiate the protocol review process. Activities are classified and reviewed based upon the relative level of pain, discomfort, and/or distress associated with procedures commonly applied to animals. A painful procedure is one that would reasonably be expected to cause more than a slight or momentary pain and/or distress in a human being to which the procedure is applied. The pain category determines the level and extent of review conducted by the IACUC.

Pain Categories.

Category	Review Process	Level of Pain, Discomfort, Distress
B	Designated Reviewer	<i>Animals being bred, conditioned or held for use in teaching, testing experiments, research or surgery, but not yet used for such purposes.</i>
C	Designated Reviewer	<i>Animals upon which teaching, research, experiments, or tests will be conducted involving no use of pain-relieving drugs or pain and distress other than routine venipuncture and handling.</i>
D	Full Committee Review	<i>Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals, and for which appropriate anesthetic, analgesics, or tranquilizer drugs will be used.</i>
E	Full Committee Review	<i>Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals, and for which appropriate anesthetic, analgesics, or tranquilizer drugs will adversely affect the procedures, results, or interpretations of the teaching, research, experiments, surgery, or tests.</i> For examples please contact the Director at 701-231-8114.

Designated Reviewer Review.

Protocols in Pain Category B or C are distributed to the IACUC members for review. Members have five working days to review the protocol, comment, and make recommendations about the review of the protocol.

If all members agree that a protocol acceptably falls under Category **B or C** guidelines, and if there are no concerns with the activity, it will then be reviewed by the designated reviewer for approval. The NDSU IACUC Chair will designate a reviewer. Once approval has been obtained from the designated reviewer, the Chair will offer his/her signature as final approval from the committee. Following IACUC review of the protocol, the PI will receive a letter from the IACUC indicating that the protocol has been either:

- A. Approved; or
- B. Held for full committee review

If the protocol is held over, the PI will be invited to discuss the protocol with the committee at the next scheduled meeting. Typically, review, approval, and processing of designated reviewer protocols takes 7-10 days. During the Designated Review process a protocol may not be disapproved but rather held over for further review.

Full Committee Review.

If all members DO NOT agree that a protocol acceptably falls under Category **B or C** guidelines, or if a member wishes to review and discuss the protocol at a full committee meeting, the protocol will be reviewed at the next scheduled meeting. The PI may be invited to attend the meeting to participate in the discussion of the activity and to answer specific questions. The protocol will then be voted on by the IACUC for approval or disapproval.

If a protocol falls under Pain Categories D or E, it must be reviewed and discussed at a full committee meeting. The PI will generally be invited to attend this meeting to participate in the discussion of the activity and to answer specific questions. The protocol will then be voted on by the IACUC for approval or disapproval.

Review and processing of protocols requiring full committee review takes approximately one month.

Following IACUC review of a full-committee review protocol, the PI will receive a letter (Appendix V) from the IACUC informing him/her of the committee's action on the protocol. The letter will indicate that the protocol has been:

- A. Approved;
- B. Specific modifications must be received before approval will be offered;
- C. Postponed definitely; or
- D. Disapproved.

“Approved” means that the protocol is activated, and the activity may be initiated.

“Specific modifications must be received before approval will be offered” indicates that the PI must make specific changes or modifications to the protocol. As soon as the requested modifications have been made and submitted to the IACUC in writing (no later than three weeks after the receipt of the original letter of request for modifications), the protocol may be approved and thus activated.

“Postponed definitely” means that the IACUC requires additional information and/or has a serious concern. The Chair and/or a member of the IACUC may be assigned to discuss the protocol with the PI. The protocol will then be re-reviewed at another IACUC meeting.

“Disapproved” means that the committee feels that the protocol places animals at unacceptable risk relative to the benefits the activity might produce. The activity cannot be initiated. (See Section I.D.1. for more information on disapproval of activities.)

3. IACUC Protocol Review Considerations.

In reviewing a protocol, the IACUC will consider whether the activity conforms to NDSU and federal regulations and policies.

According to the *Guide*, the following topics are to be considered in the preparation and review of animal care and use protocols:

- A. Rationale and purpose of the proposed use of animals.
- B. Justification of the species and number of animals requested. Whenever possible, the number of animals requested should be justified statistically.
- C. Availability or appropriateness of the use of less-invasive procedures, other species, isolated organ preparation, cell or tissue culture, or computer simulation.
- D. Adequacy of training and experience of personnel in the procedures used.
- E. Unusual housing and husbandry requirements.
- F. Appropriate sedation, analgesia, and anesthesia.
- G. Unnecessary duplication of experiments.
- H. Conduct of multiple major operative procedures.
- I. Criteria and process for timely intervention, removal of animals from a study, or euthanasia, if painful or stressful outcomes are anticipated.
- J. Postprocedural care.
- K. Method of euthanasia or disposition of animal.
- L. Safety of working environment for personnel.

Other review considerations include, but are not limited to:

- A. Investigator Consideration of Pain & Distress and the Selection of Appropriate Pain Categories:

In **Category D and E** procedures, the PI must take all necessary steps to assess, monitor, and control both acute and chronic pain, as well as discomfort or distress. If a procedure will cause more than momentary slight pain or distress to the animals, it is strongly suggested that:

- 1) appropriate sedation, analgesia, or anesthesia be provided, unless withholding such agents is justified by the PI for scientific reasons, in writing, and will continue for only the necessary period of time;
- 2) the PI consult with the AV.

The requirement for the alleviation/reduction of pain applies not only at the time the procedure is being conducted, but also following the procedure, until such time as the pain is either alleviated or reduced to an acceptable level.

The IACUC review of the proposed methods of pain control will include (where appropriate) the assessment of pre-anesthetic and anesthetic drugs and postoperative/procedural analgesics, including appropriateness of the dose, route, and frequency of administration and criteria for administration.

Category E protocols, in which the administration of appropriate anesthetics and/or analgesics would compromise the scientific validity of the experiment, require extensive scientific merit review by the IACUC in order to ensure that the potential benefits of the research outweigh or justify the risks to the animals. Such experiments should be carefully justified on the protocol form, and in addition, pain, discomfort, and distress levels must be carefully monitored.

(See Section IV.F. of these *Guidelines* for further information.)

B. Assessment of the Proposed Method(s) of Pain Control:

The PI should examine carefully all procedures to be applied to animals and determine the associated level (category) of pain, discomfort, or distress. The American Physiological Society has defined stimuli as painful to animals if those stimuli are:

- detected as pain in humans
- approach or exceed tissue damaging proportions
- produce escape behavior in animals

In addition, animal pain, like human pain, is influenced by psychological and physiological variables. Therefore, these factors should be considered in the estimation of pain.

(See Section IV.F. of these *Guidelines* for further information.)

C. Assessment of the potential value of the study or importance of the educational objective:

- 1) When live animals are used in research, teaching or testing, there must be a reasonable expectation that such utilization will contribute to the enhancement of human or animal health, the advancement of knowledge, or the good of society. The relative value of the study is a particularly important consideration in potentially painful **Category D and E** experiments, where there is an ethical imperative that the benefits of the research clearly outweigh any pain, discomfort, and distress experienced by the animals.
- 2) When live animals are used in teaching, research training, or demonstration, the nature and importance of the educational objective must clearly justify the use of animals. The use of animals for instructional purposes is normally restricted to **Category B and C** procedures.

D. Assessment of the availability and usefulness of non-animal or *in vitro* models:

- 1) Virtually every major advance in health care stems in whole or in part from research involving animals, and in many research protocols there is simply no alternative to the use of live animals. Despite this social imperative for animal experimentation, all PIs have an ethical obligation to explore ways in which animals can be partially or totally replaced by other biological or mathematical/computer systems. When a research question can be meaningfully pursued using reasonably available non-animal or *in vitro* models, these

alternatives should be chosen. The IACUC requires that all PIs document on the protocol form that alternatives to the use of live animals have been carefully considered.

- 2) When live animals are used in teaching, research training, or demonstrations, there must be a reasonable expectation that the use of live animals will produce a specific instructional objective which cannot be achieved through available alternative methods such as films, videotapes, or computer simulations. The IACUC requires justification of the use of live animals for instructional purposes.
 - 3) Animals should not be used in public exhibits if the animals will be in pain, anesthetized, or subjected to a restraining device for prolonged durations.
- E. The PI must provide written assurance for **Category D and E** protocols that the activities do not unnecessarily duplicate previous experiments. (See USDA policy #12.)
- F. Assessment of the species selection and required number:
- 1) Selection of an appropriate animal model is important, particularly at a time when alternative models for animal research are being emphasized. It is the PI's responsibility, therefore, to select the optimal species for a particular activity. In addition, the number of animals utilized in a protocol should be minimized consistent with sound scientific and statistical standards. It is also the PI's responsibility to consider the source of the animal and ensure that all animals used for experimental or teaching purposes are lawfully acquired.
 - 2) The IACUC will review the species selection, source, and required number of animals and any special characteristics or requirements of the animals that should be considered in their handling and care.
- G. Assessment of the Proposed Pre-Surgical and Post-Surgical/-Procedural Care.
- (See Section IV.F.4. and 5. of these *Guidelines* for further information.)
- H. The living conditions of animals will be appropriate for their species in accordance with Part 3–Standards of Subchapter A–Animal Welfare (9 CFR Ch. I), and will contribute to their health and comfort.
- Housing, feeding, and non-medical care of the animals will be directed by the AV or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied. NDSU's AV should be contacted with questions about such care issues.
- (See Sections IV.D. and E. of these *Guidelines* for further information.)
- I. Medical care for animals will be available and provided as necessary by a qualified veterinarian. On-campus veterinarian care will be performed directly by the AV or under his/her direction. RECs are expected to contract with local veterinarians to provide adequate care for the research animals under their care.

PIs and researchers are required to call upon the NDSU AV for any questions, concerns, or problems that may arise during the work with animals.

- J. Assessment of the PI's qualifications and experience:
Procedures involving the use of animals must be performed by or under the immediate supervision of a qualified individual. The IACUC will review the PI's qualifications and experience relative to the proposed procedures to be carried out on live animals during protocol review. Students who carry out activities involving animals must have appropriate faculty supervision. All personnel must also complete the required IACUC training. They should be able to provide documentation of training in the lab by the supervisor, as well as demonstrate that they were properly trained and qualified by the PI to conduct the appropriate procedures.

(See Section I.E.3. of these *Guidelines* and also the NDSU Protocol Form in Appendix A.)

- K. No animal will be used in more than one major operative procedure from which it is allowed to recover unless:
- 1) The procedures are justified for scientific reasons by the PI, in writing;
 - 2) required as routine veterinary procedure or to protect the health or well-being of the animal as determined by the AV; or
 - 3) other special circumstances are approved as determined by the Administrator (of APHIS) on an individual basis. Written requests and supporting data should be sent to the Administrator, USDA/APHIS, 4700 River Road, Unit 84, Riverdale, MD 20737-1234.

- L. Assessment of the acceptability of the proposed method of euthanasia/disposition of animals.

(See Section IV.F.8. of these *Guidelines* for further information.)

- M. Monoclonal Antibody (mAb) Production:
PIs contemplating the production of monoclonal antibodies are encouraged to consult the ILAR report, "Monoclonal Antibody Production" (1999), for current, in-depth recommendations.

Other references for background information on monoclonal antibody production include the *Lab Animal* special feature edition, "Small-Scale Monoclonal Antibody Production" (Autumn 1999); the AWIC Newsletter of Winter 1997/1998 (Vol.8, No. 3-4); and the ILAR Journal (37 (3), 1995). All these resources are available in the IACUC Office.

The NDSU IACUC supports the 1999 ILAR report and recommends that PIs follow its recommendations. Deviations from these recommendations must be justified to the IACUC in writing. The protocol filed by the PI must give specific information regarding the frequency and total number of times an individual animal is to be tapped. In all cases,

the AV retains the right to euthanize animals that, in his/her professional judgment, are in pain or distress.

N. Freund's Complete Adjuvant:

The IACUC encourages the use of adjuvant that typically causes less tissue damage than Freund's Complete Adjuvant (FCA). However, when FCA must be used, the IACUC will approve its use for the initial inoculation only. Subsequent inoculations must be done with another adjuvant, such as Freund's Incomplete Adjuvant. Whenever possible, inoculation with FCA should be subcutaneous rather than intradermal, intramuscular, or intravenous. Footpad injections must be specifically justified to the IACUC. The FCA injected must not exceed 10 g mycobacteria per injection site (5 g per site in mice). This guideline can be met by limiting injection of a standard FCA solution (0.1 mg/ml) to 0.1ml/site (0.05 ml/site in mice). Personnel using FCA need to be aware that humans accidentally inoculated with FCA have experienced chronic pain associated with severe inflammation. As reported in *Laboratory Animal Science* (391:400-404, 1989), these individuals also have an increased risk of severe allergic reactions, possible autoimmune disease, uveitis, arthritis, and increased incidence of neoplasia.

O. Cardiac Puncture:

The IACUC may approve the use of survival cardiac puncture when necessary for the completion of an activity. Cardiac puncture must be performed under appropriate anesthesia. The use of alternative procedures is strongly encouraged.

4. Animal-use Certifications for Federal Grant or Contract Activities.

PIs conducting animal use activities funded by federal grants or contracts are required to provide to their funding agency certification that the activity has been reviewed and approved by an IACUC.

Agencies such as the USDA and PHS, including NIH and NSF, require proof of IACUC approval in order to review, process, and/or approve grant or contract applications.¹ Typically, documentation of IACUC approval must be received within 60 days of the receipt of the grant application, or review of the activity may be delayed by the agency until the next review cycle. If the grant is awarded and IACUC verification has not yet been obtained and/or sent to the agency, awarded funds will generally not be released. Individual agency guidelines should be consulted for the particular requirements of each funding agency regarding IACUC approval and verification.

It is strongly encouraged that PIs take steps to obtain IACUC approval *before* submitting a grant application. However, if IACUC review and approval are pending at the time of submission of a grant proposal, it is the PI's responsibility to notify and obtain certifications to be sent to the appropriate agency.

¹ See Appendix J for the policies and forms regarding compliance certifications for NIH, NSF, and USDA grant proposals.

Whether a protocol is submitted to the IACUC before or after submission of the grant or contract application, it is the PI's responsibility to allow adequate time for protocol review (anywhere from seven working days to over one month). The IACUC is not responsible for approving activities that are submitted late or with too little time for review.

The IACUC Director will assist PIs in meeting the IACUC approval documentation and verification requirements of funding agencies either before or after a funding application has been submitted to an agency. The Director may assist in contacting the granting agency and/or assist PIs in completing the necessary documentation and certification forms indicating that appropriate IACUC approval has been obtained. It is the responsibility of the PI to provide the name and address of the agency or program officer to the Director.

5. Dual IACUC Review

The NDSU IACUC reviews and approves activities *only when NDSU is responsible under federal AWA or PHS policy*: i.e., when NDSU facilities are used, or when NDSU has a significant role in the care of the animals, when NDSU provides or receives funding for the activity, or when NDSU owns the animals. If the NDSU IACUC determines that NDSU has no jurisdiction or responsibility, then the committee will relay that decision to the PI. It is the responsibility of the PI to inform the committee if changes are made necessitating re-evaluation of NDSU IACUC involvement; such changes require submission and committee review of appropriate NDSU protocol forms.

In certain circumstances, NDSU is responsible under AWA or PHS policy *even though animal use does not take place at NDSU*. The facility where the activity is conducted (the on-site institution) should be able to demonstrate that it has an established IACUC with an up-to-date assurance with OLAW or registration with the USDA. In this case NDSU will proceed as follows:

If the activity has already obtained IACUC approval from the on-site institution, then the NDSU IACUC Office must receive the approved signed protocol from the on-site IACUC and the approval letter from the on-site IACUC. Based on this documentation, the NDSU IACUC Office will review the protocol for congruency with the grant and assure to the Office of Sponsored Programs that the proper oversight is in place. Because of its responsibility, the NDSU IACUC Office will work with the PI to ensure that the activity is in compliance with NDSU requirements.

If the activity has not been approved through the on-site IACUC, NDSU will request that the PI work with both IACUCs to ensure that all institutional requirements are met.

In cases where animal activities are performed at non-NDSU facilities with **NO** IACUC, the NDSU IACUC will determine if the activity complies with NDSU policies based on federal regulations, and whether appropriate animal care can be provided.

If compliance **can** be met, and NDSU will be able to provide proper animal-use oversight, the IACUC will review the activity.

If compliance needs *cannot* be met, and/or NDSU cannot provide oversight, the committee may work with the PI to find a resolution, or may withhold approval of the activity.

6. Summary: The IACUC Protocol Review Process Step-by-Step.

- A. The PI should develop his/her activity idea. He/she may contact the NDSU AV and/or IACUC members with questions about animal use, procedures, or best practices.
- B. The PI should obtain the IACUC Protocol Forms, either on the Web (<http://www.ndsu.nodak.edu/research/compliance/iacuc/>) or from the IACUC Office.
- C. The PI should *thoroughly* complete the form. Answering all questions will provide enough information for the committee to understand the proposed animal care and use. If a question does not apply to the proposed work, the PI should answer “N/A” so that the committee knows it was not missed. If any questions arise while completing the form, the PI should contact the IACUC Director.
- D. Once the form has been completed, the PI should sign it and obtain the signature of departmental authorization.
- E. The PI should return the completed and signed form to the IACUC Office.
- F. The protocol will be entered in a log by the IACUC staff. It will be assigned a unique protocol number (e.g., A0155).
- G. The protocol will then be passed on to the IACUC Director, who will conduct a brief, initial review.
- H. *If the protocol falls under Pain Category B or C*, it will be distributed to IACUC members for review. IACUC members will discuss the protocol. Members have five working days to review the protocol, comment, and make recommendations about the review and/or approval of the protocol. If all members agree that the protocol acceptably falls under Category *B or C* guidelines, and if there are no concerns with the activity, it will then be processed through the designated reviewer process for review. The PI will be notified of IACUC approval within a few working days of the committee decision.

If the protocol falls under Pain Category B or C, and any member DOES NOT agree that the protocol acceptably falls under Category *B or C* guidelines, or if a member wishes to review and discuss the protocol at a full committee meeting, then the protocol will be reviewed at the next IACUC meeting (held monthly). The PI may be invited to attend this meeting to participate in the discussion of the activity and to answer specific questions. The protocols will be voted on by the IACUC at the meeting.

If the protocol falls under Pain Categories D or E, it must be reviewed and discussed at a full committee meeting. The PI will generally be invited to attend this meeting to

participate in the discussion of the activity and to answer specific questions. The Protocol will be voted on by the IACUC. Review of and actions on protocols in Categories *D or E* take approximately one month.

- I. Once the committee has voted on a protocol, the IACUC Director will inform the PI of the IACUC's decision in writing. The letter will state that: 1) the protocol has been approved by the IACUC; 2) the committee requires clarifications, modifications, or corrections to be made to the IACUC in writing; 3) the protocol has been postponed definitely; *or* 4) the protocol has **not** been approved by the IACUC.
- J. If the IACUC requested that the PI make corrections or modifications to a protocol, he/she should submit them to the IACUC Director within three weeks. If the modifications are not received within a three-week period, the protocol will no longer be approvable and will be tabled definitely until the next meeting.
- K. After the: 1) approval of the activity; 2) approval after receipt of additional corrections or modifications to the activity; *or* 3) disapproval of the protocol, the information about the activity will be entered into the IACUC database and kept on file in the IACUC Office. Approved activity files will be maintained by the IACUC Office for three years beyond the activity's termination date. Disapproved activity files will be discarded three years after the disapproval date.
- L. If the IACUC protocol is related to a grant proposal, the PI should contact the IACUC Director about contacting the appropriate agency and/or completing the necessary certification forms.
- M. Once the activity has IACUC approval, the PI's work with animals in the NDSU system may be initiated.

PART C: Standard Operating Procedures (SOPs)

SOPs describe how single specific procedures are performed. SOPs are intended to eliminate redundancy of procedures that are routinely performed by investigators and, therefore, would be described repeatedly in IACUC protocols. The use of SOPs helps to ensure that the interpretation of observed treatment differences is not confounded by inconsistencies in procedural methodology, to provide a documented historical record of the evolution of a particular procedure, to facilitate the training of new personnel, and to expedite the preparation and IACUC review of protocols.

The following guidelines for preparing SOPs are based on those developed by the USDA/APHIS Denver Wildlife Research Center, Lakewood, Colorado (No. A-1.R3), and on a talk presented at the Workshop on the Guide for the Care and Use of Agricultural Animals (San Diego, CA, March 19, 1997) by Michael E. Mispagel, Ph.D., Quality Assurance Manager at the University of Georgia College of Veterinary Medicine.

SOPs are written in outline form using a succinct prose style. The words “will” or “shall” are to be used in describing procedural steps. The words “should,” “could,” and “may” are to be avoided, as they convey to the reader that an option may exist. SOPs are to have a title, describe the purpose of the procedure, contain a list of the materials and equipment, enumerate the procedural steps, and inform the reader of health or safety concerns. Sections of the SOP are to be numbered using Roman numerals, capitalized alphabetical letters, Arabic numbers, and lower case alphabetical letters.

The person who performs the procedure most often may be the person who is best qualified to write the SOP. The completed SOP should be “tested” or “reviewed” by colleagues and will contain the signature of the principal investigator or facility manager.

Each SOP is given a unique identification number by the IACUC Director. Each SOP will contain the date of creation and the name of the person who created the document. Revision dates, reviser’s name, and the reviser’s initials should also be added to the SOP.

SOPs will be reviewed every three years, or more often, if needed. The PI will distribute revised SOPs to users and ask them to destroy the previous copies. The IACUC Office will maintain archival copies of the SOP.

Copies of current (“Active”) SOPs shall be kept on file in the IACUC Office and must be available in the laboratory or at the work site where the procedures are to be carried out. A list of active SOPs shall also be posted to the IACUC Web site at <http://www.ndsu.nodak.edu/research/compliance/iacuc/sop/SOP.shtml>.

Instructions for drafting SOPs can be obtained from the IACUC Chair, the IACUC Director, or on the IACUC Web site listed above. The New SOP Cover Page is included in Appendix A.

The submission, review, and approval process for SOPs is identical to that of protocols.

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PART D: Protocol Disapproval, Activity Suspensions, and Handling of Animal Welfare Concerns (“Whistleblower” Policy)

1. Disapproval of Animal Protocols.

The IACUC may decline approval of a new activity if the proposed procedures and/or intentions are not in keeping with appropriate animal care and use standards.

A statement of the reasons for disapproval will be included in a letter to the PI. The IACUC will make every effort to discuss and resolve concerns and questions regarding such questionable animal use with the PI. If resolution is impossible, the PI will be informed in writing of the IACUC’s decision to disapprove the protocol. Disapproved activities will be kept on file for three years in the IACUC Office and indefinitely in the IACUC database.

The PI may respond to the IACUC in person or in writing. The IACUC may reconsider its decision, with documentation in Committee minutes, in light of the information provided by the PI. The IACUC may also, upon request of the PI, obtain external review of the protocol by an OLAW-approved IACUC of an equivalent institution. The NDSU IACUC, however, shall be the final authority in determination of the acceptability of the protocol.

2. Suspension of Animal Activities.

The NDSU IACUC expects that all animal use will have an approved protocol on file within its office. If an activity was initiated without IACUC approval, the IACUC and the AV will take immediate action to rectify the situation and to properly advise the appropriate administrative bodies. Dependent on funding, species and type of study this is a reportable offense to OLAW or the USDA. Furthermore, the following provisions have been established by the IACUC:

The IACUC has the regulatory authority to:

- “suspend an activity that it previously approved, if it determines that the activity is not being conducted in accordance with the description of that activity provided by the principal investigator and approved by the Committee. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present; if the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to APHIS and any federal agency funding that activity” (9 CFR §2.31 (d)(xi)(6) and (7)); and
- “suspend an activity that it previously approved, if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the *Guide*, the institution’s Assurance, or IV.C.1.a.-g. of this Policy. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present” (PHS Policy, IV.C.6.).

Thus, the NDSU IACUC reserves the right to discontinue, suspend, or revoke the approval of any previously approved activity that is not being conducted in an ethical manner according to the protocol reviewed and approved by the IACUC, or if the animals involved in the activity are not being properly maintained or are suffering unduly.

The decision to suspend or discontinue an activity is made at the discretion of the IACUC and the AV. When animals are found to be suffering, the AV and/or the IACUC Chair may suspend an activity immediately. The PI involved will be informed (either verbally or in writing) of the IACUC's intention to suspend or discontinue an activity before such action is taken. Efforts may be made to correct the problem(s) with the activity through the cooperation of the PI, involved personnel, the IACUC, the AV, and/or the department chair. If the problem(s) cannot be or is/are not corrected or addressed, or if for any other reason the IACUC and the AV feel that the activity should be suspended or discontinued, action will be taken to suspend or permanently discontinue the activity.

Serious animal care and use deficiencies, problems, suspensions, and discontinuations will be reported to OLAW and/or USDA/APHIS by the IO where applicable. Problems, deficiencies, suspensions, and discontinuations will also be reported to NDSU's IO and the appropriate department chair(s).

3. Handling of Animal Welfare Concerns (“Whistleblower” Policy and Procedures).

An important function of the IACUC, as specified in USDA and PHS regulations, is to “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” (9 CFR 1, §2.31(c)(4) and IV.B.4. of the PHS Policy).

NDSU personnel are to be educated in the “methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility” (9 CFR 1, §2.32 (c)(4)). An institution should have established procedures for reporting, receiving, and handling allegations of animal mistreatment or other noncompliance.

The following section details the NDSU IACUC policy on investigating concerns regarding inappropriate animal care or use.

Definitions of Mistreatment and Noncompliance.

“Mistreatment” is defined as physical, psychological, wrongful, or abusive treatment of an animal. This is a broad definition, and, clearly, areas exist which the IACUC must interpret carefully. Fortunately, it is rare that mistreatment is intentional. “Noncompliance” means that procedures or policies are not being followed, and this may stem from confusion or misunderstanding. There are areas of overlap between mistreatment and noncompliance, and the procedures for handling both are very similar.

Institutional Policies on Mistreatment and Noncompliance.

As indicated in the NDSU Policy Manual (Section 346; see Appendix K), North Dakota State University takes responsibility for the humane care and use of its animals and advocates the humane care and use of animals at NDSU and by NDSU students and employees. NDSU assures the public, researchers, employees, and students, that the institution has a strong commitment to investigating allegations of mistreatment or noncompliance. The IACUC maintains the same commitments.

Therefore, the NDSU IACUC will review and/or investigate any concern or complaint relating to animal care and use brought to the attention of the committee. This includes claims made by the public concerning any aspect of the animal care and use program, or by employees or students who report alleged instances of animal abuse, violation of approved protocols, use of animals not covered by approved protocols, violations of any animal-related regulation of standard (such as those laid out in the Animal Welfare Regulations, the PHS Policy, the Guide, or NDSU IACUC policy), or complaints regarding the care received by animals housed in NDSU facilities.

There must be no implication that reporting such instances could be detrimental to an individual's standing within the institution. Indeed, the USDA Regulations provide specific protections under the law [9 CFR 1, Part 2, Subpart C §2.32(c)(4)]. Section 346 of NDSU's Policy Manual states: "Any individual, whether an employee, student, or member of the general public, may report a concern involving the care and use of animals for which North Dakota State University is responsible. The individual presenting the concern is assured freedom from discrimination, coercion, or reprisal."

Reporting Allegations and IACUC Responses to Complaints.

As animal welfare-related concerns arise, individuals are encouraged first to discuss and attempt to resolve issues within the local unit, before involving the IACUC.

It is not always obvious at which level of alleged mistreatment or noncompliance the IACUC should become involved. Frequently, the AV, animal care personnel, and PIs can work together to prevent or correct problems. However, serious or repeated problems always demand the involvement of the IACUC. If in doubt, it is better to report the problem, as this may well protect the animals, the institution, the complainant, and the alleged violator(s).

Initial reporting may be made via conversation or in writing to:

- A. the IACUC Chair;
- B. the AV;
- C. any member of the IACUC; or
- D. the IO.

Ideally, all concerns brought to the IACUC's attention will be fully documented and signed, and will include the following information:

- A. the complainant's name;
- B. the individual(s) or unit against whom the complaint is alleged;

- C. a description of the event or charge, including dates of observation of the alleged violation(s);
- D. copies of any written, photographic, or taped documentation to substantiate the charges;
- E. the names of any other witnesses to the event/charges being described or made; and
- F. the signatures of the complainant(s).

The IACUC Chair (or his/her alternate,), the IO (or his/her alternate), and the AV (or his/her alternate) will then be notified of the complaint and will be responsible for attempting to resolve the matter at this stage, if possible. The alternates will be suggested in situations where conflict of interest may be an issue. Confidentiality will be maintained to the extent possible to protect all concerned.

If an emergency action (e.g., euthanasia) is necessary in order to alleviate the suffering of animals, such action will be taken immediately by the AV.

The Chair and AV will be responsible for dealing with the complaint initially. At their discretion, the IACUC as a whole, or an identified subcommittee, will review the complaint. In all cases, an investigation must be considered an IACUC action, and all members must have the opportunity to present minority views. All persons involved shall be informed of the purpose of the investigation and the manner in which it will be conducted. Those against whom the complaint is addressed shall have an opportunity to explain their side of the issue.

If necessary, and at the discretion of the IACUC Chair (or his/her alternate, the IO) and the AV (or his/her alternate, another veterinarian member of the IACUC), a meeting of the IACUC may be called to discuss the complaint/alleged violation. With a quorum present and a majority of their votes, the IACUC has authority to suspend a previously approved activity pending a full investigation.

If warranted, the IACUC Chair (or his/her alternate, the IO) and the AV (or his/her alternate) will direct an IACUC investigation. As much documentation as is reasonably needed will be collected (e.g. interviews, inspections, review of animal receiving records, housing and health records, billings, memos, and other written materials). All persons involved will be informed of the purpose of the investigation and the manner in which it will be conducted. The material will then be compiled and studied.

The results of the investigation will be brought before the IACUC for discussion and final action. Those against whom the complaint is addressed will be invited to explain their side of the issue. If warranted, the IACUC is empowered to vote for suspension of a previously approved activity, either temporarily or permanently. All proceedings and actions must be recorded and maintained as minutes of the IACUC.

The IO is ultimately responsible for taking any further action based on the decision of the IACUC.

The results of the investigation will be made available to all parties involved.

Full documentation of investigations and their outcomes will be maintained in the IACUC Office for three years after the completion of the investigation. After such time, a brief record of the complaint and its outcome will be maintained in order to track any future problems or allegations.

Institutional Responses.

Institutional responses to complaints are influenced by legal requirements, institutional policy, and the nature of the investigative findings. If PHS or USDA funds support the activity, the IACUC (through the IO) must file a full report to those agencies. In cases where there is sufficient evidence of serious noncompliance, it may be prudent for the IACUC to suspend an activity pending the outcome of a full investigation. In these cases, a preliminary report should be sent to the appropriate agency through the IO with a promise of a full report upon completion.

The IO, in consultation with the IACUC, has the power to impose further sanctions on a PI found responsible for mistreatment or noncompliance. The institution must also consider whether to publicly announce its findings. While each case must be considered individually, all cases will result in precedents being set, and the implications of these must be considered.

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PART E: Investigator Reporting Requirements: Annual Update, Changes in Protocol, Training of Personnel

1. Annual Updates.

The IACUC is required to perform not only initial review, but also to have been provided an annual update of animal-related activities, by PHS Policy IV.C.5 (annually with de-novo review not less than triennially) and by USDA regulations 9 CFR Ch. I, §2.31(d)(5) (not less than annually).

The purpose of the annual update is threefold: to inform the IACUC of the current status of the activity; to ensure continued compliance with PHS, USDA, and institutional requirements; and to provide for re-evaluation of the animal activities at appropriate intervals. Protocols shall be regularly updated and refined by PIs to comply with current regulatory and scientific standards.

The NDSU IACUC allows a protocol file to be open for three years. After this period the protocol will be closed and the file sent to the PI to assist him/her in redrafting a new protocol, if warranted. The protocol number will be terminated; if a new protocol is drafted and submitted for review, it will be assigned a new number and will proceed through the same review process as all other new protocols submitted.

To satisfy the requirements of the PHS Policy and the USDA review requirements, IACUC will annually review and/or terminate completed protocols accepted by the Chair and AV.

Each year, on the anniversary of the original IACUC approval date for a protocol, an annual update will be required. The IACUC Office notifies the investigator one month before the due date of the annual report. The completed and signed update form must be returned to the IACUC Office by the anniversary date.

The update form is generated from the IACUC database, which automatically completes items in the form such as the number of animals used in an activity, the PI's name and campus address, the type of activity being conducted, and any information that was provided in the original protocol or on any subsequent updates or changes. The PI corrects any misinformation on the form, adds any missing information, and answers each question on the form. The form must then be signed, dated, and returned to the IACUC Office on or before the date due.

Once the form has been completed and submitted by the PI, the IACUC office updates and circulates the protocol update list, including basic information and any changes, adverse events, and progress in the activity. Committee members have five working days to comment on the protocols listed and/or request for a full board review for any protocol. The AV may contact the PI to discuss the progress or problems experienced during work on the activity over the past year. The Chair and the AV sign the form to signify their review of the activity's continuation or termination.

A sample of the Annual update Form is found in Appendix W.

2. Changes in Protocol.

PIs are also required to seek IACUC approval for any proposed change to a previously approved protocol that affects animals. Changes must be reviewed and approved by the IACUC **prior to implementation**, unless a change is necessary to eliminate hazards to personnel or to protect the health and well being (veterinary care issue). The PI must notify the AV within 72 hours of such immediate, emergency changes.

Changes to a protocol include, but are not limited to, the following: increase in the number of animals to be used, change in the pain category, or introduction of new techniques or procedures.

The IACUC Request for Change in Protocol Form (Appendix A) must be completed, signed, and submitted to the IACUC Office in order to seek a change to a previously approved protocol. The Committee votes on approval or disapproval of the requested change(s) to the protocol, following the same procedures outlined for new protocols.

If more than three significant changes have been made, the committee will request a new revised protocol. The entire file may be sent to the PI to assist him/her in redrafting a new protocol.

3. Training of Personnel.

AWA was revised in 1985 to include training requirements for personnel working with animals. The USDA regulations state that “it shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in the animals’ care, treatment, and use, are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel. Training and instruction shall be made available, and the qualification of personnel reviewed, with sufficient frequency to fulfill the research facility’s responsibilities under this section and Sec. 2.31” (9 CFR Ch. I, §2.32). Additionally, the U.S. Government Principle for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training states: “investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals” (PHS Policy, p. 5, VIII).

PIs, supervisors, facility managers, project managers, etc., who are in charge of personnel working with animals, are responsible for informing the IACUC of the names of the individuals they supervise. The IACUC will collaborate with the PI or supervisor to determine in which training modules each individual must participate.

The training modules are offered both on-line in a self-guided, self-paced format and can be offered as “in person” workshops presented at the request of a department or unit. Information on specific training courses can be obtained by calling 1-8114.

The IACUC/Office of Sponsored Programs Administration maintains records of Core IACUC training completed by personnel in both paper and database files. Lab training and protocol specific training must be maintained by each supervisor and faculty member.

A listing of all current IACUC-related training programs can be found in Appendix O of this manual.

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SECTION II: FEDERAL REPORTING REQUIREMENTS

Part A: USDA Registration & Reporting Requirements

1. USDA Registration.

As stated in the USDA Animal Welfare Regulations, “each research facility...shall register with the Secretary” (9 CFR, Ch.1, Subpart C, §2.30). This registration form is filed with USDA’s APHIS REAC Sector Supervisor, and must be updated every three years by completing and filing a new registration form (9 CFR, Ch. I, §2.30).

Under AWA, NDSU is registered as a Class “R” Research Facility with the USDA-APHIS-Animal Care (AC) regional office in Fort Collins, CO. A copy of NDSU’s USDA registration certificate is included in this document as Appendix P.

2. USDA (APHIS-Animal Care) Annual Reports.

As required by Section 13 of the AWA and further explained in 9 CFR Part 2, §2.36, each reporting research facility shall submit an annual report to the Animal Care Regional Director. This annual report shall be signed and certified as correct by the legally responsible IO. The annual report must document all species covered by the AWA used in research, tests, experiments or teaching, and those on hand, at the end of the USDA fiscal year (October 1 to September 30). These reports must be submitted before **December 1** of each year. The APHIS-Animal Care regional office sends the necessary forms for filing the annual report on or about September 15 of each year.

The report must show the number of animals with no pain or distress; the number with pain or distress relieved with anesthetic, analgesic, or tranquilizing drugs; the number with pain or distress not relieved; and the number of animals on hand as of September 30 which were not reported under another category and not assigned to any procedures. For those animals with pain or distress where the appropriate anesthetic, analgesic, or tranquilizing drugs were not used, there must be a detailed statement explaining the procedure producing the pain or distress and the reasons such drugs were not used.

The Annual Reports are also used to verify the NDSU IACUC’s continuing compliance with the regulations and standards set forth in the AWA. Such items that must be verified and certified each year include proper membership of the IACUC and proper protocol approval and review standards and procedures.

In general, according to 9 CFR, Part 2, §2.36, the annual report shall:

- assure that professional acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation, were followed by the research facility;
- assure that each PI has considered alternatives to painful procedures;
- assure that the facility is adhering to the standards and regulations under AWA, and that it has required that exceptions to the standards and regulations be specified and explained by the PI and approved by the IACUC;
- state the location of all facilities where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes;
- state the common names and the numbers of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs;
- state the common names and the numbers of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals, and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used;
- state the common names and the numbers of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals, and for which the use of anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests; and
- state the common names and the numbers of animals being bred, conditioned, or held for use in teaching, experiments, research, or surgery, but not yet used for such purposes.

The IACUC Director, with the assistance of the AV, compiles the necessary information for the report and completes the USDA forms. The IO signs the report. Copies of each year's report are kept on file in the IACUC Office indefinitely.

Part B: PHS/OLAW Registration & Reporting Requirements

1. The Animal Welfare Assurance Statement.¹

In order to obtain funding from PHS for activities involving animals, NDSU must provide written assurance that the institution will comply with the policies and procedures set forth by PHS. This assurance, called the Animal Welfare Assurance (Assurance), is a legally binding institutional commitment to OLAW, a branch of the PHS. In essence, the Assurance is NDSU's self-description of its particular program of animal care and use. The *Guide* is used as a basis for developing and implementing the institutional program for activities involving animals.

According to PHS Policy (IV.A.1., 2., and 3.), "no activity involving animals may be conducted or supported by the PHS until the institution conducting the activity has provided a written Assurance acceptable to the PHS, setting forth compliance with this Policy. Assurances shall be submitted to the Office of Laboratory Animal Welfare (OLAW), Office of the Director, National Institutes of Health."

"All Assurances submitted to the PHS in accordance with this Policy will be evaluated by OLAW to determine the adequacy of the institution's proposed program for the care and use of animals in PHS-conducted or -supported activities. On the basis of this evaluation, OLAW may approve or disapprove the Assurance, or negotiate an approvable Assurance with the institution. Approval of an Assurance will be for a specified period of time (four years with a one-year extension during renewal), after which time the institution must submit a new Assurance. Without an applicable PHS-approved Assurance, no PHS-conducted or -supported activity involving animals at the institution will be permitted to continue."

The Assurance must describe the following:

A. "Institutional Program for Animal Care and Use:

- 1) a list of every branch and major component of the institution, as well as a list of every branch and major component of any other institution, that is to be included under the Assurance;
- 2) the lines of authority and responsibility for administering the program and ensuring compliance with this Policy;
- 3) the qualifications, authority, and responsibility of the veterinarian(s) who will participate in the program, and the percent of time each will contribute to the program;
- 4) the membership list of the IACUC(s) established in accordance with the requirements set forth in the Policy;
- 5) the procedures that the IACUC will follow to fulfill the requirements set forth in this Policy;

¹ This adapted from the *PHS Policy on Humane Care and Use of Laboratory Animals* (IV. A. 1., 2., and 3.).

- 6) the health program for personnel who work in laboratory animal facilities or have frequent contact with animals;
- 7) a synopsis of training or instruction in the humane practice of animal care and use, as well as training or instruction in research or testing methods that minimize the number of animals required to obtain valid results and minimize animal distress, offered to scientists, animal technicians, and other personnel involved in animal care, treatment, or use;
- 8) the gross square footage of each animal facility (including satellite facilities), the species housed therein and the average daily inventory, by species, of animals in each facility; and
- 9) any other pertinent information requested by OLAW.

B. Institutional Status:

Each institution must assure that its program and facilities are in one of the following categories:

Category 1: Accredited by the American Association for Accreditation of Laboratory Animal Care (AAALAC). All of the institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated and accredited by AAALAC, or another accrediting body recognized by PHS. All of the institution's programs and facilities (including satellite facilities) for activities involving animals have also been evaluated by the IACUC and will be reevaluated by the IACUC at least once every six months, in accordance with IV.B.1. and 2. of this Policy, and reports will be prepared in accordance with IV.B.3. of this Policy.

Category 2: Evaluated by the Institution. All of the institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC and will be reevaluated by the IACUC at least once every six months, in accordance with IV.B.1. and 2. of this Policy, and reports prepared in accordance with IV.B.3. of this Policy. The most recent semi-annual report of the IACUC evaluation shall be submitted to OLAW with the Assurance.

C. Institutional Animal Care and Use Committee (IACUC):

- 1) The Chief Executive Officer shall appoint an IACUC, qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and procedures.
- 2) The Assurance must include the names, position titles, and credentials of the IACUC Chair and the members. The Committee shall consist of not less than five members and shall include at least:
 - a. one Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program authority and responsibility for activities involving animals at the institution (see IV.A.1.c.);
 - b. one practicing scientist experienced in research involving animals;

- c. one individual whose primary concerns are in a nonscientific area (for example, ethicist, lawyer, member of the clergy); and
 - d. one individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution.
- 3) An individual who meets the requirements of more than one of the categories detailed in IV.A.3.b.(1)-(4) of this policy may fulfill more than one requirement. However, no Committee may consist of less than five members.”

As noted above, NDSU must reapply for its Assurance every four years with a one-year (fifth year) extension period while the assurance is being approved. See Appendix S for our current approval period and assurance number.

The IACUC Executive Director, with the assistance of the IACUC Chair and members, is responsible for revising as needed and resubmitting the Assurance every four years. The IO also plays an important role in updating the Assurance and signs and certifies the Assurance.

A copy of NDSU’s current Assurance is attached as Appendix S and is on file in the IACUC Office. Past years’ Assurances are maintained on file indefinitely in the IACUC Office.

2. Annual Reports to OLAW.

According to the PHS Policy (IV. F. 1., 2., and 4.), at least once every 12 months, the IACUC, through the IO, shall report in writing to OLAW:

- A. any change in the institution’s program or facilities which would place the institution in a different category than specified in its Assurance (see IV.A.2. of this Policy);
- B. any change in the description of the institution's program for animal care and use as required by IV.A.1.a.-i. of this Policy;
- C. any changes in the IACUC membership; and
- D. notice of the dates that the IACUC conducted its semiannual evaluations of the institution's program and facilities and submitted the evaluations to the IO.

If no changes in the areas listed above have occurred, the IACUC shall submit a report and letter to OLAW through the IO, stating that there are no changes and informing OLAW of the dates of the required IACUC evaluations and submissions to the IO.

The IACUC, through the IO, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

- A. any serious or continuing noncompliance with this Policy;
- B. any serious deviation from the provisions of the *Guide*; or
- C. any suspension of an activity by the IACUC.

Annual reports should also include any minority views filed by members of the IACUC.

The NDSU IACUC Executive Director compiles the PHS Annual Reports, and the IO and IACUC Chair certify and sign them. The report is submitted as soon as possible after the close of the calendar year (December 31). Copies of the PHS Annual Reports are kept on file in the IACUC Office indefinitely.

PART C: PHS and USDA Reporting Requirement.

Semiannual Program Reviews, Inspections, and Reports to Institutional Official.

Both USDA regulations and PHS Policy require that NDSU self-evaluate its animal care and use program and facilities at least once every six months. The semiannual program reviews and inspections are a means for the NDSU IACUC to evaluate its own strengths and weaknesses – to identify the areas that are acceptable according to the regulations, and those areas that may need improvement. These evaluations must be submitted as written reports to the IO.

Public Health Service Policy on Semiannual Reviews, Inspections, and Reports.

The PHS Policy states that, as an agent of the institution, the IACUC shall (with respect to PHS-conducted or -supported activities):

- A. “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;
- B. 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;
- C. prepare reports of the IACUC evaluations conducted as required by A and B above, and submit the reports to the IO. (NOTE: the reports shall be updated at least once every six months upon completion of the required semiannual evaluations and shall be maintained by the institution and made available to OLAW upon request. The reports must contain a description of the nature and extent of the institution’s adherence to the *Guide* and Policy and must identify specifically any departures from the provisions of the *Guide* and Policy, and must state the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, consistent with Policy, and, in the judgment of the IACUC and the IO, is, or may be, a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule for correcting each deficiency. If some or all of the institution's facilities are accredited by AAALAC or another accrediting body recognized by PHS, the report should identify those facilities as such.);
- D. review concerns involving the care and use of animals at the institution;
- E. make recommendations to the IO regarding any aspect of the institution's animal program, facilities, or personnel training;
- F. review and approve, require modifications in (to secure approval), or withhold approval of those components of PHS-conducted or -supported activities related to the care and use of animals as specified in IV.C. of this Policy;
- G. review and approve, require modifications in to secure approval, or withhold approval of proposed significant changes regarding the use of animals in ongoing activities; and
- H. be authorized to suspend an activity involving animals in accordance with the specifications set forth in IV.C.6 of this Policy.”

OLAW recommends that the report to the IO also include a narrative describing the process of program evaluation and facility inspection, and IACUC findings, positive and negative. While

the IACUC may determine the best means of conducting an evaluation of the institution's programs and facilities, it remains responsible for the evaluation and report. Final reports of the semiannual evaluations/inspections are considered full-committee actions and should be reviewed and endorsed by a majority of the IACUC.

Semiannual program and facility review reports should be submitted to OLAW only if requested, or if the institution is submitting a new or renewed Animal Welfare Assurance and is not accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International). NDSU is not currently AAALAC-accredited.

USDA Regulations on Semiannual Reviews, Inspections, and Reports.

The USDA requirements for semiannual reviews, inspections, and reports, are essentially the same as those for PHS, with four exceptions (9 CFR, §2.31(c)(1, 2, and 3):

- A. USDA regulations include additional reporting requirements if the schedule and plan for correcting a deficiency is not followed. Failure to correct a significant deficiency in accordance with the specified schedule and plan must be reported in writing within 15 business days by the IACUC, through the IO, to APHIS and any federal agency funding the activity.
- B. USDA requires that reports be reviewed and signed by a majority of IACUC members. Any minority views must also be included in the report.
- C. USDA does not require the identification of facilities accredited by AAALAC.
- D. USDA requires at least 2 voting members participate in the inspection process

NDSU also requires that minor facility deficiencies be brought to the attention of the facilities' managers after the inspection. Memos from the IACUC will be sent to the particular facility manager(s), citing the minor deficiency/deficiencies and requesting that the deficiency/deficiencies be corrected within 30 days. The facility manager(s) will inform the IACUC, in writing, once the deficiency has been corrected. Significant deficiencies including corrective course of action and timetable for correction will be submitted to the IO. If the corrective action is not made according to the timetable, the IO will report within 15 days to USDA and PHS/OLAW as applicable.

The semiannual reports are maintained by the NDSU IACUC Office and are available to APHIS and other officials of federal funding agencies for inspection and copying.

Part D: NDSU Procedures for Semiannual Inspections, Program Reviews, and Reports.

Semiannual Inspections.

The AV and at least one other member (two voting members) of the IACUC perform the semiannual facilities inspections. However, in the event that the AV is not able to perform the inspection, he/she may appoint a voting member who is knowledgeable and experienced to perform the inspection in his/her place. The procedures for inspections are outlined in an approved standard operating procedure, SOP #IACUC-01 (on file in the IACUC Office and attached as Appendix M of these *Guidelines*). No IACUC member will be excluded, should he/she wish to attend a particular inspection, and additional *ad hoc* consultants may be used. The inspection team must have a working knowledge of the *Ag Guide*, the *Guide*, and the USDA regulations, in order to fully evaluate the facilities that are being inspected. The IACUC may determine whether the supervisory personnel of various facilities should be notified in advance of the date and time of an inspection.

The IACUC Office maintains a list of all NDSU facilities to be inspected. The USDA regulations require inspection of the centrally designated or managed animal resource facilities, as well as any other animal-containment facilities where animals are held, or cared for or surgeries performed. PHS Policy requires inspection of all surgical facilities and areas in which animals are maintained longer than 24 hours.

The AV and additional member(s) use the IACUC's Semiannual Facilities Inspection Form (Appendix Q) to complete the inspection and note any deficiencies. Detailed notes must be taken throughout the visit to assist in the preparation of the final report. Any deficiencies must be categorized as minor or significant; the latter is defined by USDA Regulations and PHS Policy as one of significant threat to animal health or safety. A plan and timetable for correction of minor and significant deficiencies must be included in the final report. Apparent deficiencies shall be discussed with the person in charge of the facility to ensure that the team's perception of the situation is correct. In some cases, an apparent deficiency will be due to the experimental proposal in process, for example, withholding of food prior to surgery. As noted above in this section, significant deficiencies that are not corrected within the time allowed, where noted, will be reported to APHIS-AC and OLAW. NDSU requires that minor deficiencies be corrected within a reasonable time period. If the institution is unable to meet the plan for correction of significant deficiencies, the IACUC, through the IO, must inform APHIS officials within 15 working days of the lapsed deadline. If the activity is federally funded, the relevant funding agency must also be informed.

Semiannual Program Reviews.

Semiannual IACUC program reviews and evaluations deal principally with administrative aspects of the animal care and use program. When changes are made in program aspects, a comprehensive evaluation by the committee should be conducted, while the review of that aspect six months later may be merely a brief evaluation of its implementation to date. Ongoing review of established practices provides an opportunity for institutions to detect gradual changes in practice as compared to written procedures, thereby allowing modification of one or the other as appropriate.

Key aspects of an animal care and use program that should be emphasized in the semiannual program reviews include IACUC functions and procedures, such as proposal review practices, provisions for dealing with “whistleblower” or other concerns regarding animal care and use, and procedures employed to meet reporting requirements. In addition, the institution’s occupational health program, veterinary care procedures, and personnel qualification review process should be evaluated.

Compilation and Completion of Semiannual Reports.

The IACUC Director completes the Semiannual Program Review Form with the assistance of at least two voting members. Any other IACUC members who wish to aid in the completion of the report are free to do so. A veterinarian completes the Veterinary Medical Care Checklist with the input of at least two voting members participating as well. The IACUC Director prepares the semiannual report with the help of the IACUC Chair and the AV.

The full committee then reviews the report at an IACUC meeting and votes on its approval. A majority of the members must sign the report, indicating their approval or disapproval and concerns with the report (minority views). After the report has been reviewed, discussed, voted on, and signed by a majority of the IACUC members, the report is submitted to the IO. The IACUC Director (and any other necessary IACUC members or personnel) discusses the report and any deficiencies or changes that need to be made to the program and/or facilities, with the IO.

The report then remains on file in the IACUC Office indefinitely.

Part E: Other Reporting Requirements.

- A. Each research facility shall furnish to any APHIS official any information concerning the business of the research facility that the APHIS official may request in connection with the enforcement of the provisions of the Act, the regulations, and the standards in 9 CFR Ch.1 of the APHIS regulations. The information shall be furnished within a reasonable time and as may be specified in the request for information.
- B. Each research facility shall, during business hours, allow APHIS officials to:
- 1) enter its place of business;
 - 2) examine records required to be kept by the Act and 9 CFR Ch.1;
 - 3) make copies of the records;
 - 4) inspect the facilities, property, and animals, as the APHIS officials consider necessary to enforce the provisions of the Act and 9 CFR Ch.1;
 - 5) document, by the taking of photographs and other means, conditions and areas of noncompliance;
 - 6) use a room, table, or other facilities necessary for the proper examination of the records and for inspection of the property or animals.
- C. Each research facility shall allow, upon request and during business hours, police or officers of other law enforcement agencies with general law enforcement authority (not those agencies whose duties are limited to enforcement of local animal regulations) to enter its place of business to inspect animals and records for the purpose of seeking animals that are missing.

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SECTION III: OCCUPATIONAL HEALTH AND SAFETY FOR PERSONNEL WORKING WITH ANIMALS

IACUC Program for Occupational Health and Safety in the Care and Use of Vertebrate Animals

The *Guidelines for Occupational Health and Safety in the Care and Use of Vertebrate Animals* (1997; revised 2001, 2005) can be found on both the Office of Police and Safety (OPS) website and the IACUC websites, as well as hard copy from the two offices (see Appendix S). The *Guidelines* detail more specifically NDSU's program for occupational health and safety, and they should be referred to for the complete program. This section of the IACUC policy manual on occupational health and safety is intended only as a summary of, and reference to, the comprehensive *Guidelines*. The OPS will be responsible for the Occupational Health and Safety Program as related to animal use on campus as with all hazards and risks associated with employment at the Institution.

The IACUC and the OPS will:

- A. provide students and employees with appropriate guidelines that outline general health and safety issues associated with working with vertebrate animals;
- B. provide an avenue for students and employees to participate in the required NDSU occupational health and safety training program;
- C. provide students and employees with a hazard and risk assessment; and
- D. establish protocol for students and employees to obtain the necessary medical evaluations, vaccinations, and immunizations (e.g., tetanus and rabies).

Some general health and safety issues associated with working with vertebrate animals include personal hygiene, vaccinations, zoonoses, concerns for pregnant women and women of child-bearing age, the use of personal protective equipment (e.g., gloves, masks, face shields), and hazards such as animal bites and scratches. These health and safety issues are examined in detail in the NDSU *Guidelines for Occupational Health and Safety in the Care and Use of Vertebrate Animals*.

Special Qualifications for Personnel Using Hazardous Agents and Controlled Substances

Professional staff conducting and supporting research programs involving hazardous biological, chemical, or physical agents must be qualified to assess dangers associated with these programs and capable of selecting safeguards appropriate to the dangers of using hazardous agents.

Animal care staff should understand the hazards involved and should be proficient in implementing the required safeguards. Individuals working with hazardous agents or substances must be trained in these specific areas. The OPS provides this training and maintains

documentation of the individuals trained. Contact the OPS at (701) 231-7759 for more information.

Radioisotopes and Contaminated Animal Waste.

Hazardous materials should be handled according to the procedures described in the University's Radiation Safety Manual. For a copy of the manual, contact the OPS or a member of the Radiation Safety Committee.

Animal wastes contaminated with radioactive materials, infectious agents, or hazardous chemicals, must be carefully managed to avoid human exposure or damage to the environment. Special efforts should be made in experimental design to minimize the generation of wastes containing hazardous chemicals. Those containing radioactivity in addition to hazardous chemicals are particularly difficult to deal with. Wastes containing infectious agents should be decontaminated before disposal. Incineration is the recommended disposal method for contaminated feed and bedding.

Questions and concerns regarding radioisotopes and contaminated waste should be directed to the OPS.

SECTION IV: THE ANIMALS AND ANIMAL FACILITIES

Part A: Program of Veterinary Care.

According to the *Guide* (pgs. 12-13), USDA regulations, and the PHS Policy, each research facility must establish and maintain a program of adequate veterinary care that includes:

- an appointed AV who is a voting member of the IACUC and who has the direct or delegated authority to provide adequate veterinary care to the institution's research animals;
- the availability of appropriate facilities, personnel, equipment, and services to comply with the provisions of regulations;
- access to all animals for evaluation of their health and well-being;
- medical care for animals provided by a qualified veterinarian;
- the use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries;
- the availability of emergency, weekend, and holiday care;
- daily observation of all animals to assess their health and well-being, with a mechanism in place for direct and frequent communication with the AV, so that timely and accurate information on problems of animal health, behavior, and well-being may be addressed;
- guidance to PIs and other personnel involved in the care and use of animals;
- adequacy of husbandry and nutrition, sanitation practices, zoonoses control, hazard containment, handling, immobilization, anesthesia/analgesia, tranquilization, and euthanasia; and
- adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures.

1. NDSU Attending Veterinarian (AV).

NDSU is required to provide adequate veterinary care for its activities with animals.

Each research facility must have an AV to provide adequate veterinary care to its animals in compliance with PHS Policy and USDA regulations, as follows:

- A. "shall include...(1) one Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program authority and responsibility for activities involving animals at the institution" (IV.A.2.b. (1));
- B. "at least one [voting member of the IACUC] shall be a doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program responsibility for activities involving animals at the research facility" (9 CFR, §2.31 (b) (i)).

- C. “(a) Each research facility shall have an AV who shall provide adequate veterinary care to its animals in compliance with this section:
- 1) Each research facility shall employ an AV under formal arrangements. In the case of a part-time AV or consultant arrangements, the formal arrangements shall include a written program of veterinary care and regularly scheduled visits to the research facility;
 - 2) Each research facility shall assure that the AV has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use; and
 - 3) The AV shall be a voting member of the IACUC...” (9 CFR §2.33).

The duties and responsibilities of the NDSU AV include, but are not limited to, the following:

- A. being responsible for addressing and correcting any deficiencies found in the semiannual Veterinary Care and Program Reviews and semiannual Animal Facilities Inspections (see Appendix Q);
- B. serving as an IACUC member;
- C. overseeing and helping to coordinate evening, weekend, emergency, and holiday animal care;
- D. participating in Annual Reviews;
- E. leading the semiannual facilities inspections of campus and satellite animal facilities;
- F. conducting frequent, informal observations (“walk-through”) of on-campus animal facilities;
- G. being a known and available resource for PIs in the development of animal protocols and as questions or problems may arise with animals within the NDSU system;
- H. being a “point person” for animal research-related questions from on- and off-campus; and
- I. having the authority and responsibility to oversee and address problems in areas including, but not limited to: husbandry, nutrition and feeding, sanitation, preventive medicine procedures, anesthesia and analgesia, zoonoses control, drug storage and control, surgery and post-surgical care, euthanasia, disease prevention (quarantine and species separation), hazard containment, assistance with the handling of whistleblower activities, and animal procurement and disposal.

All correspondence detailing the appointment and reviews of the AV by the IO is kept on file in the IACUC Office.

2. Daily Observation of Animals.

A part of the duties of the veterinary care program is the daily inspection of the animal facilities.

This is required by animal welfare regulations: “daily observation of all animals to assess their health and well-being; provided, however, that daily observation of animals may be

accomplished by someone other than the Attending Veterinarian; and provided, further, that a mechanism of direct and frequent communication is required, so that timely and accurate information on problems of animal health, behavior, and well-being are conveyed to the Attending Veterinarian” (9 CFR §2.33 (b)(3)).

The AV makes frequent visits to animal facilities on campus. Facility managers and animal care staff (see Appendix N) accomplish the daily observation of facilities which the AV is unable to visit every day. Such personnel shall promptly notify the AV of any concerns or problems related to animal health or well-being.

Each facility shall develop an SOP or file a herd management protocol that outlines the daily animal care and veterinary care. If the AV is not used for daily care, a contract shall be established with a local veterinarian for services rendered. The AV shall be the main contact and will help organize and approve each contracted veterinarian used for NDSU animals. These SOPs should be updated every three years, as needed.

3. Emergency, Weekend, Evening/Night, and Holiday Care of Animals.

The NDSU AV is also responsible for overseeing a program of emergency, weekend, and evening/night care of NDSU animals (9 CFR §2.33 (b)(2)).

The AV is in charge of emergency, weekend, evening/night, and holiday animal care. If the AV is unavailable, the alternate AV shall provide veterinary care.

Individual departments are primarily responsible for ensuring and maintaining adequate staffing for and care of animals (e.g., watering, feeding, cleaning cages, etc.) during non-business hours, weekends, and holidays. The names and telephone numbers of the individuals assigned these responsibilities (Appendix N) are to be prominently displayed in the animal facility. The IACUC provides placards listing the contact people for that particular location to each animal facility.

4. Adverse Events and Unexpected Deaths.

Unexpected animal deaths and other adverse events should be communicated directly to the AV. An unexpected death as a single event may not be indicative of a large problem, but over a course of time several of these isolated events may indicate health or safety problems associated with animal handling or husbandry.

In all cases of adverse events a written documented communication shall be conveyed to the AV. A corrective action should be discussed, and any treatment of the remaining animals associated with the project or housed in the facility should be worked out in writing with the AV. This should later be communicated to the IACUC for further discussion and action needed by the committee. The end goal is to assure health and well being of the animals while maintaining

close communication between the AV and the researchers or managers of NDSU's animal facilities.

PART B: Animal Facilities.

Proper housing and management of animal facilities are essential to animal well-being, to the quality of research data and teaching or testing programs in which animals are being used, and to the health and safety of personnel. A good management program provides the environment, housing, and care that permit animals to grow, mature, reproduce, and maintain good health; provides for their well-being; and minimizes variations that can affect results (the *Guide*, pg. 21).

Facilities utilized for activities involving animals shall be appropriate to the animals to be used or housed therein, the procedures to be conducted with the animals, and the personnel using the animals (and also the personnel located by those not involved with the animals). **Animals should be housed in facilities dedicated to or assigned for that purpose and should not be housed in laboratories merely for convenience** (the *Guide*, pg. 71).

A well-planned, properly maintained facility is an important element in good animal care. The *Guide* and the *Ag Guide* provide for specific information on animal facility requirements including animal housing, space recommendations, temperature and humidity, ventilation, illumination, noise, behavioral and social environments, activity, husbandry, population management, construction guidelines, and surgery facilities. Each facility must have an approved protocol for general care or herd management as it applies to its animal use, weekend care, and general operations according to facility design and capacities. For facilities that do not maintain herds or colonies, a laboratory SOP must outline general care, weekend care, and general operations according to facility design and capacities.

1. Animal Facilities Covered by NDSU's PHS Assurance.

NDSU's PHS Assurance statement (A3244-01) is applicable to all research, teaching, or testing involving live, vertebrate animals within the NDSU system or at another institution as a consequence of the sub-granting or subcontracting of an activity by this institution.

The IACUC Office maintains a list of facilities deemed acceptable for conducting animal-related activities within the NDSU system. Other locations may be approved for animal use through IACUC-approved protocols or through temporary consent of the AV with notification to the IACUC.

Each location is managed by individual, departmental, or facility animal care and use staff. A listing of the responsible personnel for each location may be requested from the NDSU IACUC Office.

2. Off-Campus ("Satellite") Facilities.

Animal use facilities not physically located on the Fargo campus of NDSU are referred to as satellite facilities.

Research, teaching, or testing activities conducted at satellite facilities must be approved by the NDSU IACUC. As with on-campus personnel and facilities, satellite facilities and their personnel are subject to NDSU IACUC policies and procedures – including, but not limited to animal care and use training, facilities inspections, and continuing reviews. Cooperator sites where work will be performed will not be inspected, but IACUC protocols shall be filed for them if NDSU personnel have a significant role in the care of the animals.

3. Animal Facilities and Laboratories Located Near Non-Animal Spaces.

Good animal husbandry, human comfort, and health protection require separation of animal facilities from personnel areas such as offices, conference rooms, and most laboratories. Separation can be accomplished by having the animal quarters in a separate building, wing, floor, or room. Careful planning should make it possible to place animal-housing areas next to or near research laboratories but separated from them by barriers such as entry locks, corridors, or floors. See the *Guide* (pgs. 71- 80) for specific information on animal locations and facilities.

4. Monitoring and Inspection of Animal Facilities.

The IACUC is ultimately responsible for oversight and evaluation of NDSU's animals and animal facilities. To fulfill those expectations, and to comply with federal regulations and policies, the following inspection and monitoring mechanisms are in place at NDSU:

A. Daily Observation of Animals and Animal Facilities.

The health and well-being of NDSU animals and the proper maintenance of their facilities are monitored daily by the staff in charge of the areas and animals under the protocols.

See Section IV.A.2. of this manual for information on the daily monitoring and inspection of animal facilities.

B. Semiannual Facilities Inspections.

In compliance with USDA and PHS regulations, the NDSU AV and IACUC conduct inspections of all NDSU animal facilities at least twice per year.

See Sections II.C. and II.D. of this manual for NDSU's policies and procedures regarding the semiannual animal facilities inspections.

C. Annual USDA Inspection.

Each year, a Veterinary Medical Officer (VMO) from USDA-APHIS-Animal Care inspects the animal facilities at NDSU that are covered by AWA and USDA regulations (animals used strictly for agricultural purposes are excluded from their inspection).

As outlined in USDA regulations (9 CFR, Ch. I, §2.38), the APHIS inspector must be allowed to:

- examine records required to be kept by AWA and the regulations;
- make copies of the records;
- inspect the facilities, property, and animals; and
- document conditions and areas of noncompliance.

The inspector visits both the IACUC Office (to review IACUC protocols, records, reports, and administrative procedures) and the animal facilities on campus.

During and after the inspection, the inspector completes an inspection report, which is kept on file in the IACUC Office indefinitely. Any findings of noncompliance or suggestions for improvement made by the inspector (either verbally or in the written report) will be reviewed, addressed, and corrected by the AV, the IACUC, the PI or supervisor, any personnel involved with the deficiency, and/or any other necessary personnel (e.g., the IO, department chair, etc.). Serious deficiencies will be reported to the appropriate on-campus personnel (including those involved and the IO) and to all applicable federal agencies and authorities (see Section I.D. and II.C. of this manual for more information and procedures). If the seriousness of the deficiency warrants it, the AV may initiate the procedures outlined in Section I.D.2-3. of this manual to immediately discontinue the animal use.

D. Randomized Compliance Audits

The IACUC will also perform compliance audits. These audits will take two forms:

- 1) randomized file audits and program audits to assure our compliance with the PHS policy, AWA and our own policies and Assurance filed with OLAW
- 2) randomized and informal visits to assist in compliance concerns and to offer information and guidance to our facilities and PIs.

The IACUC Office will perform these audits through the Compliance Officer or IACUC Director. If during audits there are findings of deficiencies that could impact animal well-being, or if the health of the animals is at risk, the AV will be immediately informed for follow-up action. The IACUC will be informed immediately as well and the deficiency will be discussed promptly at a convened meeting. The IACUC Office fully expects that the guidance given during these audits will be followed. If the guidance is not followed, the matter may be forwarded in writing to the committee to be discussed at the next convened meeting.

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PART C: Animal Procurement & Disposal.

Refer to the *Guide*, the *Ag Guide*, and the Animal Welfare Regulations for further, detailed information about animal procurement, identification, sale, donation, and disposal.

1. Animal Procurement & Identification.

Procurement.

All animals used for research, teaching, or testing within the NDSU system must be lawfully acquired. An evaluation should be made of animal quality for each potential vendor. A health surveillance program for screening incoming animals is essential to assess animal quality and to maintain colony health. Methods of transportation should also be evaluated. Each shipment of animals should be inspected for compliance with procurement specifications, and the animals should be quarantined and stabilized according to procedures appropriate for the species and circumstances. Vendor quality-control data can be helpful in selecting these procedures.

All purchases from vendors must be documented and are subject to inspection during the year. The IACUC Office maintains an approved list of local vendors, as well as national vendors. Each purchase must clearly indicate on the receipt or PO the protocol number for which the animals are being ordered.

Large animal purchases will be applied directly to the herd management protocol. After the animals are quarantined for a time determined by the manager, they can be pulled for studies or use. Once pulled for use, they must be transferred onto an approved IACUC protocol for research, teaching, testing, or demonstration. Areas which order directly for research purposes or teaching purposes must document that either on the PO or in a shipping receipt logbook.

Animal Identification and Records.

Methods of animal identification include room, rack, and cage cards; collars, bands, plates, and tabs; colored stains; ear notches and tags; tattoos; freeze brands; and micro-chip implants. Records on animals are essential, from limited information on identification cards to detailed reports on individual animals' health and surgical records. Identification cards should include such information as the source of the animals, strain or stock, names and locations of the responsible investigators, dates received, protocol numbers, and dates of procedures. Research protocols sometimes require records on individual animals. Individual clinical records are required, for dogs, cats, and farm animals in biomedical research. Records shall include such information as a history of surgical procedures, experimental use, and pertinent clinical and diagnostic information. The source and eventual disposition of animals is valuable and essential information, which must be included in individual records as required.

Records pertaining to the procurement of animals used within the NDSU system shall be kept by individual investigators and departments. Such records must be available for review upon request by the IACUC, the AV, and any federal officials.

2. Purchase, Gifting, Sale, or Donation of Animals.

Records pertaining to the purchase, gifting, sale, or donation of animals used within the NDSU system will be kept by individual investigators and departments. Such transactions involving animals shall be conducted according to all applicable industry standards and federal, state, and local regulations. (9 Ch. I, Part 2, Subchapter C, §2.35 offers specific requisites for record-keeping involving cats and dogs in particular.)

Such records must be available for review upon request by the IACUC, the AV, and any federal officials.

3. Dispersal of Animals and Disposal of Animal Carcasses Upon Activity Completion.

Once the use of animals in a research, teaching, or testing activity has been completed, the investigator should take appropriate steps to disperse or dispose of the animal.

As the circumstance allows, animals may be euthanized, adopted out, returned to a herd, returned to the wild, marketed, or sold for slaughter, or may remain at the facilities. The PI is responsible for ensuring that the most appropriate action for the animal has been taken upon activity completion. Federal regulations exist, and specific forms must be completed for certain types of animals and certain types of dispersal (e.g., adopting out of animals previously used in research activities) or disposal (e.g., slaughter).

Questions about the best methods of dispersing animals after an activity, and which federal forms and records must be completed, may be directed to the AV or the IACUC Director.

Dead animals shall be disposed of promptly by a commercial rendering service or other appropriate means (e.g., burial or incineration) and according to applicable ordinances and regulations. When warranted and feasible, waste and bedding that have been removed from facilities occupied by an animal that has died should be moved to an area that is inaccessible to other animals (the *Ag Guide*, pg. 16).

Carcasses at NDSU may be disposed of using the incinerator in Van Es Hall or the contracted renderer. Consult with the NDSU AV for questions about the appropriate means of disposing of animal carcasses.

PART D: General Animal Care.

1. Animal Husbandry.

Refer to the Guide and the Ag Guide for further detailed and species-specific information on animal husbandry.

The *Guide* states, “Proper management of animal facilities is essential to the welfare of animals, validity of research data, and health and safety of the animal care staff. A good husbandry program provides a system of housing and care that permits animals to grow, mature, reproduce, and maintain good health. Good husbandry minimizes variations that can modify an animal’s response to experimentation. Specific operating practices depend on many subjective and objective factors unique to individual institutions. Well-trained and motivated personnel can often ensure high quality animal care, even in institutions with less than optimal physical plans or equipment.”

Well-constructed and well-maintained caging and housing systems facilitate adequate animal husbandry practices and health maintenance. Animal housing must not only confine the animal(s), but also promote animal comfort and safety by providing sufficient space and accommodations for normal postural and behavioral activities. USDA regulations and the *Guide* provide minimum cage size requirements or recommendations for the most common laboratory animal species.

Cages shall allow for adequate ventilation and enable ready access to food and water receptacles. They shall be constructed of materials that can be easily cleaned and sanitized, with common materials including polycarbonate plastic, stainless steel, and fiberglass. Unsealed wood generally is not acceptable in animal cages or pens, as it cannot be satisfactorily cleaned or sanitized.

Many animal species are social in their natural state. Some, such as the dog and cat, are readily socialized to humans. Encouragement of intra- and inter-species socialization is recommended by USDA regulations and the *Guide* and is widely recognized as advantageous to animal well-being and the research endeavor. A sound husbandry program will include provision of the opportunity for animals to establish and/or reinforce social activities, including physical exercise.

Environmental factors can have a profound effect on the health and well-being of animals, as well as the outcome of experimental manipulation. Temperature, humidity, air pressure, rate of air turnover, and noise levels may all affect animal well-being and research results. A review of an animal care and use program shall include consideration of environmental standards adopted for the facilities with adequate justification available for significant deviations. While environmental control in outdoor facilities is much less stringent, acceptable ranges in temperature for several species are available in USDA regulations. Reliable methods for monitoring environmental control systems are highly desirable. Protocols for caring for animals and personnel during failures in environmental control systems shall be established, with personnel informed of proper procedures.

Solid-bottom housing is preferred over wire or grid-floor caging. Grid-floor housing will not be approved by the NDSU IACUC unless it is an essential, scientifically justified part of the experimental procedure. Solid-bottom caging with appropriate absorbent material is preferred for smaller rodents, and it also provides environment enrichment, assists in thermoregulation, and encourages nesting behaviors.

A. Cleaning and Sanitation.

Cleanliness and sanitation are essential to the operation of an animal facility. The *Guide* and USDA regulations set forth recommended frequency and methods for cleaning and sanitation of facilities, equipment, and accessories. In general, the frequency and methods shall ensure that animals are maintained in a clean, dry environment, free from exposure to harmful contamination and excessive animal odors. Cleaning equipment such as mops and pails must not be moved from room to room unless disinfected between room uses.

The most effective method of cleaning and sanitizing cages and accessories (e.g., feeders, water bottles, sipper tubes) is the use of a mechanical washing machine that provides rinse water temperature of at least 83° C (180° F). Alternatively, portable high-pressure spray washing and chemical disinfection may be used. Least effective is mechanical scrubbing and chemical disinfection of such equipment. The supply lines of automatic watering systems must be flushed and disinfected on a regular basis.

Reduction of odors shall be a factor in the cleaning program established for a room or colony. Certain animals, such as rabbits, produce high levels of urea, which will increase the level of nitrogen in the air. High levels of nitrogen can be harmful for both the caregiver and the animals. It is very important for many reasons to have an established and documented schedule for cleaning that is frequent.

B. Feeding.

All animals must receive food that is palatable, free from contamination, and of sufficient quantity and nutritive value to maintain their good health. Specific diets shall be selected based on the needs of each species. Animals shall be fed at least once a day, except under conditions of hibernation, veterinary treatment, pre-procedural fasts, or other justified circumstances.

It is known that standard commercial dry bulk foods, when stored properly, retain their nutritional value for six months (three months for those containing Vitamin C). To assure that age deterioration of food does not occur, the milling date should be known (it is usually stamped on the bag), and bags shall be stored off the floor and so that the oldest food is used first. Large amounts of food should not be stored in animal rooms. Small quantities may be kept in animal rooms if stored in tightly covered, leak- and vermin-proof containers; these should not be moved from room to room.

Food shall be provided in receptacles that are accessible to all animals in a cage or pen and placed so as to minimize contamination. Food receptacles shall be easily cleaned and sanitized, and those functions should be preformed on a schedule that meets the *Guide* and USDA regulation requirements. With limited exceptions, e.g., germ-free animals in

microisolator cages, food should not be placed on the bottom of the cage. Although some species may prefer this presentation, it results in waste and contamination of food.

C. Watering.

Potable drinking water shall be available continuously or provided as often as necessary for the health and well-being of the animals, considering the animals' species, age, condition, and any research requirements. Water may be provided via bowls, bottles, or automatic watering systems. Whatever method is used, care shall be taken to ensure that water does not become contaminated. Automatic watering systems for larger animals must be cleaned to reduce algae and other contaminants. Sipper tubes and automatic watering devices shall be checked routinely for patency.

D. Bedding.

Bedding may be used for a variety of commonly used laboratory animals. Bedding material shall be absorbent and free of any substances that might harm the animals or interfere with research results. Cedar and pine products can affect liver enzymes, which may, in turn, affect immunologic, metabolic, or other physiologic parameters. The IACUC office or the AV can provide further guidance on appropriate types of bedding.

Animals may be placed directly on approved bedding material, a common practice with many rodent species. An absorbent material may be placed under a wire or slat-bottom cage (rodent hanging racks are not recommended and must be scientifically justified). This latter method is used occasionally for rabbits, dogs, and farm animals. Bedding and absorbent material shall be changed as often as necessary to keep the animals clean and dry and the animal room relatively odor free.

E. Waste Disposal.

Animal housing generates a significant amount of waste that must be disposed of on a regular, frequent basis. Disposal methods, including incineration and removal to landfill, must conform to federal, state, and local requirements. Some jurisdictions consider all soiled animal bedding from a research facility to be "medical waste," with consequently more stringent disposal requirements (autoclaving all waste before landfill or incineration).

If waste must be stored before disposal, the storage area should be outside the animal holding and clean equipment areas. Animal carcasses and tissues require a separate cold storage area and regularly scheduled removal. Hazardous waste, including carcasses of animals exposed to radioactive or biohazardous agents, must be adequately sterilized and/or contained prior to removal and disposal.

F. Hazardous Waste.

Animal wastes contaminated with radioactive materials, infectious agents, or hazardous chemicals must be carefully managed to avoid human exposure or damage to the environment. Special efforts shall be made in experimental design to minimize the generation of wastes containing hazardous chemicals. Wastes containing infectious agents shall be decontaminated, preferably in a steam autoclave, before disposal. Incineration is the recommended treatment for contaminated feed and bedding, but not for radioactively contaminated materials.

When animal care protocols involve hazardous materials, institutional policies shall be reviewed and assistance sought from the professional health and safety staff who are responsible for hazardous waste management at NDSU. Protocols shall clearly address contamination containment. The Office of Safety and Environmental Health may be contacted for specific guidance.

2. Physical Environment.

The physical environment in which animals are maintained shall be the best possible with regard to the species, its life history, and its intended use (the *Guide*, pg. 22). Personnel responsible for NDSU animals shall select the best possible physical environment for them. PIs shall consider both *microenvironment* (the physical environment immediately surrounding the animals, its temperature and humidity, and the gaseous and particulate composition of the air) and *macroenvironment* (the physical environment of the secondary enclosure, e.g., a room, barn, or outdoor habitat) when accommodating animals (the *Guide*, pg. 22). Factors such as housing, space recommendations, temperature and humidity, ventilation, illumination, and noise, shall all be considered. Consult the *Guide*, pages 21-36; and the *Ag Guide* for detailed information on physical environments for animals.

3. Social Environment, Animal Activity, Enrichment.

In addition to an animal's physical health and housing conditions, consideration shall also be given to an animal's social needs. The social environment usually involves physical contact and communication among members of the same species (conspecifics), although it can include non-contact communication among individuals through visual, auditory, and olfactory signals (the *Guide*, pg. 37). Opportunities for exercise, interaction with conspecifics, social housing, or other forms of enrichments (e.g., toys) shall be provided whenever possible for all animals. Loafing areas, exercise lots and pastures are suitable for large animals, such as sheep, horses, and cattle (the *Guide*, pg. 38).

Consult the *Guide* and the *Ag Guide* for more information about social environments, animal activity, and enrichment. The IACUC office and the AV can also provide further details and information for environmental enrichment.

PART E: Species-Specific Guidelines.

(For further, more detailed information on particular species, consult the resources listed in this section and the Guide and Ag Guide).

1. Separation by Species, Source, and Health Status

Physical separation of animals by species is generally recommended to prevent interspecies disease transmission, reduce anxiety due to interspecies conflict, and meet experimental requirements. This is usually accomplished by housing different species in separate rooms. In some situations, it might be appropriate to house different species of rodents in the same room, such as when they are to be used for similar studies and have a similar health status, or when special containment is provided within rooms (e.g., laminar flow cabinets, or filtered or microisolation cages). Intraspecies separation is advisable when animals obtained from multiple sources differ in microbiological status.

Separation to Avoid Interspecies Disease Transmission.

Some species carry subclinical or latent infections that can cause clinical disease or death when transmitted to other species. A few examples are provided as a guide in determining the need for separate housing by species:

- *Rodents.* Rats infected with *Streptobacillus moniliformis* (Freundt, 1956) should be housed separately from mice, which are usually free from this disease.
- *Lagomorphs.* Rabbits frequently harbor *Pasturella multocida* and *Bordetella bronchiseptica* (Flatt, 1974). These microorganisms are potentially pathogenic to other animals; guinea pigs are especially susceptible to *B. bronchiseptica*. Although definitive studies demonstrating transmission of these agents between rabbits and other species have not been reported, it seems prudent to maintain rabbits in separate rooms.

Separation by Source or Microbiological Status.

It is not uncommon for animals from one source to harbor microbial agents not found in animals from another source, e.g., rats with *Mycoplasma pulmonis*. Therefore, it is recommended that animals from different sources be housed in separate rooms or that some other means, such as laminar flow units, used to minimize the possibility of cross-infections. If such housing is not feasible because of space limitations or experimental objectives, animals shall be grouped according to their known exposure to microbial agents.

Transfers or movements of animals from room to room should also be considered in the same regard. Rooms shall be sanitized between species and between re-colonization. A deep-cleaning schedule should be implemented into each room as part of the health management and facilities management program.

Sentinel programs have been set up where appropriate for rodent colonies.

2. Farm Animals.

The use of farm animals is subject to the same ethical considerations as the use of other animals in research. All activities involving the use of farm animals at NDSU must be reviewed and approved by the NDSU IACUC. The focus of the IACUC review for these activities is to ensure compliance with contemporary standards and NDSU policy.

Activities conducted for strictly **agricultural** objectives (food and fiber production) are not subject to inspection by the USDA inspector (USDA Policy 26) like the rest of NDSU's animal facilities, but they are still subject to all NDSU policies and procedures and semiannual inspections. Activities using farm animals in work that clearly deals with food and fiber production must be carried out in accordance with contemporary farm-management and farm-production practices. The *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching* (January 1999) contains information concerning acceptable contemporary farm-management and farm-production practices.

Unlike animals involved in agricultural activities, farm animals utilized for **biomedical** activities are subject to regulation and inspection by USDA-APHIS and PHS. As set forth in USDA-APHIS Policy 29, all the standards and provisions set forth in the *Guide* and the *Ag Guide* are applicable to farm animals involved in biomedical research.

The *Guide*, the *Ag Guide*, and the NDSU AV or the IACUC Office should be consulted for more information on activities involving the use of farm animals in biomedical research activities.

Herds used for teaching production management are also maintained at NDSU. Even though they are not being used daily for classes or research, their care must be approved via the general herd management protocols filed with the IACUC.

3. Field Studies.

If studies conducted on free-living wild animals in their natural habitat involve an invasive procedure or may harm or materially alter the behavior of the animals, the protocol must be reviewed by the IACUC to ensure that invasive procedures and collection of specimens comply with NDSU, state, and federal regulations.

Studies conducted on free-living wild animals in their natural habitat that **do not** involve an invasive procedure and that **do not** harm or materially alter the behavior of the animals under study, must also be reviewed by the IACUC to minimize risk of zoonoses, and to assure the health and well-being of other animals that may be affected by the study. Research and/or teaching field studies are exempted from IACUC approval, if the field study is strictly observational and does not involve capturing/trapping, physical/chemical restraint, disturbance of habitat, and/or invasive procedures. Only the IACUC can make the determination for exempt status. The IACUC Office will maintain those protocols for three years from the determination of exempt status.

Prior to conducting field research, investigators are responsible for obtaining all applicable permits and licenses. Such permits must be submitted to the IACUC as part of the Protocol Form where applicable.

4. Amphibians, Reptiles, and Fishes.

(From http://grants.nih.gov/grants/olaw/references/faq_labanimals1997.htm)

The PHS Policy is intentionally broad in scope and does not prescribe specifics about the care and use of any species, assigning that task to the IACUC, and allowing for professional judgment. Many of the principles embodied in the *Guide*, although not specifically addressing cold-blooded vertebrates, generally can be adapted to animal care and use programs for various kinds of amphibians, reptiles, and fishes. Substantive guidance pertinent to specific species and situations is available in publications prepared by organizations having interest in the appropriate care and use of these species in laboratory and field studies.¹ It is clear, however, that individual requirements for these three classes of vertebrates, which contain more than 28,000 species that have a diversity of requirements, cannot be addressed in a single set of guidelines. Consequently, OLAW recommends that the advice of experts be obtained to design and develop studies and suitable housing and care procedures when species not commonly used in research are being considered. OLAW also suggests that the results of their efforts to devise methods for the care and use of these species be published to serve as an aid to others.

The *Guide's* Appendix A provides a list of suggested readings for activities involving amphibians, reptiles, and fishes.

Activities involving the use of amphibians, reptiles, or fishes must also be submitted for review and approval, as with other vertebrates.

5. Birds.

Activities involving birds are subject to review and regulation by the NDSU IACUC. Investigators observing or capturing birds in the wild should refer to the section of this policy manual that discusses field studies (IV.E.3.).

The *Guide's* Appendix A provides a list of suggested readings for activities involving birds.

6. Breeding Colonies.

Breeding colonies are subject to the same standards and policies of the NDSU IACUC as any other animals. Breeding colonies shall be adequately maintained (e.g., sanitation, feeding, watering), and the IACUC shall have record of the colony (through protocol review and semiannual inspections).

¹ *Resources for activities involving amphibians, reptiles, or fishes:*

Ferguson HW. 1984. Fish, pg. 1-10. In: Guide to the care and use of experimental animals, Vol 2., Canadian Council on Animal Care, Ottawa, Ontario, Canada.

Institute for Laboratory Animal Resources. 1974. Amphibians. In: Guidelines for the breeding, care and management of laboratory animals. National Academy of Sciences, Washington, D.C.

Institute for Laboratory Animal Resources. 1991. Recommendations for the care of amphibians and reptiles in academic institutions. National Academy of Sciences, Washington, D.C.

Scientists Center for Animal Welfare. 1992. The care and use of amphibians, reptiles, and fish in research. Schaeffer, D.O., K. M. Kleinow, L. Krulisch (eds.). Scientists Center for Animal Welfare, Greenbelt, MD.

American Society of Ichthyologists and Herpetologists, American Fisheries Society, American Institute of Fisheries Research Biologists. 1987. Guidelines for the use of fishes in field research. Fish. J. 13(2): 1-14.

American Society of Ichthyologists and Herpetologists, The Herpetologists' League, and Society for the Study of Amphibians and Reptiles. 1987. Guidelines for the use of live amphibians and reptiles in field research. J. Herpetology (Suppl) 4:1-14.

Orlans, F. B. 1988. Field research guidelines: impact on animal care and use committees. Scientists Center for Animal Welfare, Greenbelt, MD.

DeTolla, L. J., S. Srinivas, B. R. Whitaker, et al. 1995. Guidelines for the care and use of fish in research. ILAR J. 37:159-173.

DeNardo, D. 1995. Amphibians as laboratory animals. ILAR J. 37:173-181.

Greene, H. W. 1995. Nonavian reptiles as laboratory animals. ILAR J. 37:182-186.

PART F: Special Procedures.

1. Quarantine.

(Also see the Guide, pgs. 58-59; and the Ag Guide, pg. 22.)

Quarantine is the separation of newly received animals from those already in the facility until the health of the newly received animals has been evaluated. Effective quarantine minimizes the introduction of disease agents into established colonies.

Quality control by the vendor and knowledge of the history of the animals are acceptable parts of a quarantine plan. This information may limit the quarantine period for rodents to the time necessary for inspection on arrival; however, all newly received animals should be allowed a stabilization period of at least one week prior to their use. This results in a more stable physiological and behavioral state. The need for this stabilization period has been demonstrated in mice, rats, and guinea pigs, and it is probably required for other species as well.

If the history of newly received animals is incomplete, quarantine procedures should be more comprehensive and of sufficient duration to allow expression of diseases present in the incubation stages. If needed, the following should be achieved during the quarantine and stabilization period:

- diagnosis, control, prevention, and treatment of diseases (including zoonoses);
- physiological and nutritional stabilization; and
- grooming (including bathing, dipping, and clipping, as required).

2. Surveillance, Diagnosis, Treatment, and Control of Disease.

(Adapted from the Guide, pgs. 59-60.)

Animals shall be observed daily for signs of illness, injury, or abnormal behavior, by a person trained to recognize such signs. Unexpected deaths and deviations from normal health and behavior must be reported promptly to the AV utilizing the health and illness reporting sheets (Appendix U). Sick or injured animals shall receive prompt veterinary medical care. Animals that are suspected of having a contagious disease should be isolated from healthy animals. When an entire group or room of animals is known or believed to have been exposed to an infectious agent, the group shall be kept intact during the process of diagnosis, treatment, and control.

Methods of prophylaxis, diagnosis, therapy, and disease control should follow currently accepted practice. Diagnostic laboratory services supplement physical examination and facilitate diagnosis of diseases. These services should include gross and microscopic pathology, clinical pathology, hematology, microbiology, clinical chemistry, and other appropriate laboratory procedures.

Inapparent viral infections of rodents, which can occur with mouse hepatitis virus, minute virus of mice, and lactate dehydrogenase elevating virus, can have an effect on some types of research (Hsu et al., 1980). Although there are usually no clinical signs in rodents infected with these viruses, there are often profound changes in the immune, reticuloendothelial, and other systems (Hsu et al., 1980). Serological surveillance (sentinel programs) of rodent colonies, particularly breeding colonies, shall be considered when there is a potential for inapparent viral infections to affect research results. Viral infections can also be transmitted through transplantable tumors and cell lines (Stansly, 1965; Collins et al., 1972; Biggar et al., 1976; Riley et al., 1978) which should be evaluated prior to their introduction into a research colony.

3. Anesthesia and Analgesia.

(Also see the Guide, pgs. 64-65; and the Ag Guide, pg. 21.)

The proper use of anesthetics, analgesics, and tranquilizers in animals is necessary for humane and scientific reasons. In accordance with AWA, the choice and use of the most appropriate drugs are ultimately matters for the AV's professional judgment. The veterinarian must provide research personnel with advice concerning choice and use of these drugs.

If a painful procedure must be conducted without the use of an anesthetic, analgesic, or tranquilizer because such use would interfere with the experiment, the procedure must be approved by the IACUC and supervised directly by the responsible investigator, with oversight and close communication and contact with the AV.

4. Pre- and Post-Surgical and Procedural Care.

(Also see the Guide, pgs. 60-64; and the Ag Guide, pgs. 21-22.)

Aseptic surgery shall be conducted only in facilities intended for that purpose. These facilities must be maintained and operated to ensure cleanliness, and must be staffed by trained personnel. Surgery must be performed or directly supervised by trained, experienced personnel. Training in aseptic surgery must be provided for those who require it.

Aseptic technique must be used for animals undergoing survival surgery. This technique includes wearing of sterile surgical gloves, gowns, caps, and facemasks; use of sterile instruments; and aseptic preparation of the surgical field.

Appropriate facilities and equipment shall be available for postsurgical care. Postsurgical care shall include observing the animal to ensure uneventful recovery from anesthesia and surgery; administering supportive fluids, analgesics, and other drugs as required; providing adequate care for surgical incisions; and maintaining appropriate medical records. Equipment and supply items that can be helpful for intensive care include heating pads, vaporizers, vacuum equipment, respirator, cardiac monitor, and oxygen. Proper monitoring by trained personnel shall be provided during recovery.

Animals may not be transferred to other facilities until a suitable and appropriate recovery period has passed. Animals returning to a general herd environment should be isolated for an appropriate period prior to reintroducing them to the herd. Individual housing should be provided post-surgery.

Minor surgical procedures, such as wound suturing and peripheral vessel cannulation, can be performed under less stringent conditions if they are performed in accordance with standard veterinary practices.

5. Survival Surgery.

Major survival surgery is defined as any surgical intervention that penetrates a body cavity or has the potential for producing a permanent handicap in an animal that is expected to recover. Survival surgery on rodents does not require a special facility but should be performed using sterile instruments and surgical gloves, and shall be conducted in a dedicated area for surgeries and aseptic procedures to prevent clinical infections. The AV must approve these areas prior to the PI dedicating the space.

(This section on survival surgery is from the Guide, pgs. 63-64.)

Presurgical planning should specify the requirements of postsurgical monitoring, care, and record keeping, including the personnel who will perform these duties. The investigator and veterinarian share responsibility for ensuring that postsurgical care is appropriate. An important component of postsurgical care is observation of the animal and intervention as required during recovery from anesthesia and surgery. The intensity of monitoring necessary will vary with the species and the procedure and might be greater during the immediate anesthetic-recovery period than later in postoperative recovery. During the anesthetic-recovery period, the animal should be in a clean, dry area where trained personnel can observe it often. Particular attention should be given to thermoregulation, cardiovascular and respiratory function, and postoperative pain or discomfort during recovery from anesthesia. Additional care might be warranted, including administration of parenteral fluids for maintenance of water and electrolyte balance (FBR 1987), analgesics, and other drugs; care for surgical incisions; and maintenance of appropriate medical records.

After anesthetic recovery, monitoring is often less intense but should include attention to basic biological functions of intake and elimination and behavioral signs of postoperative pain, monitoring for postsurgical infections, monitoring of the surgical incision, bandaging as appropriate, and timely removal of skin sutures, slips, or staples (UFAW 1989). Post surgical records must be maintained.

6. Distress.

(Also see the Ag Guide, pgs. 20-21.)

USDA-APHIS regulations define distress as “any procedure that would reasonably be expected to cause more than slight or momentary pain or distress in a human being to which that procedure was applied.” Stress shall be monitored in animal subjects by means of behavioral changes such as anorexia, depression, malaise, loss of condition, abnormal reproductive behavior, clinical signs of disease, and abnormal temperament. Animal caretakers must be trained to observe these changes in the animal and to inform both PIs and/or the AV to alleviate distress. Training for animal caretakers is mandatory and available through the NDSU IACUC. Species-specific and more detailed information can be provided beyond the IACUC training from the AV.

The USDA classifies procedures that cause pain and distress in three general categories:

- A. procedures involving no pain, distress, or use of pain-relieving drugs;
- B. procedures for which appropriate anesthetic, analgesic, or tranquilizing drugs are used; and
- C. procedures for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would adversely affect the procedures, results or interpretation of the teaching, research, experiments, surgery, or tests.

It is the responsibility of the NDSU IACUC to make determinations about pain and distress relative to the procedures and protocols of PIs. Wherever possible, pain and distress should be alleviated through protocol modification (i.e. sample size, sampling techniques, use of analgesics/anesthetics/tranquilizers, restraint, and housing).

Pain and distress signs in laboratory animals

Species	Mild to moderate signs	Severe or chronic signs
Cat	Increased aggression when approached, decreased food intake, licking	Generally silent, may growl or hiss if approached, attempt to hide, crouching, hunching or stretching posture, wild escape behavior, vocalizing, un-groomed appearance, papillary dilation, anorexia
Cattle	Depressed, little interest in surroundings, weight loss and sudden drop in milk yield, lack of grooming	Rapid, shallow respiration, increased aggression, rigid posture, grunting and grinding of teeth, weight loss
Dog	Decreased alertness, stiff posture, panting, biting, licking or scratching, increased vocalization, increased aggression	Unwillingness to move, crouching posture, increased restlessness, increased aggression, crying when handled or moved
Gerbil	Ocular discharge, eyelids partially closed and matted with dry material, may “faint” when handled, changes in activity and burrowing behavior, arched back, hunched posture	Loss of weight and condition, sores on face, hair loss on tail

Guinea Pig	Eyes sunken and dull, changes in respiration, increased timidity, increased sleepiness, arched back, increased vocalization	Weight loss, hair loss, scaly skin, dehydration, decreased timidity, unresponsive, excessive salivation (oral problems), increased barbing, loss of righting reflex, decreased vocalization, hypothermia
Hamster	Ocular discharge, increased aggression, hunched posture, reluctance to move	Loss of coat and body condition, increasing depression, extended daytime sleep periods, lateral recumbency, hypothermia, sores on lips, paws
Horse	Interrupted feeding, papillary dilation, glassy eyes, increased respiration, increased heart rate, profuse sweating, rigid stance, restlessness	Depression, biting, kicking, circling, self mutilation, reluctance to be handled
Mouse	Eyelids partially closed, changes in respiration, rough hair coat, increased vibrissae movement, unusually apprehensive or aggressive, possible writhing, scratching, biting, self mutilation, hunched posture, sudden running, aggressive vocalization, guarding	Weight loss, dehydration, incontinence, soiled hair coat, eyes sunken, lids closed, wasting of muscles on back, sunken or distended abdomen, decreased vibrissae movement, unresponsive, separates from group, hunched posture, ataxia, circling, hypothermia, decreased vocalization
Pigs	Changes in gait or posture, increased efforts to avoid handling, increased squealing when approached or handled	Depression, unwillingness to move, attempts to hide, withdrawn from pen mates, anorexia
Rabbits	Ocular discharge, constipation or diarrhea, depression, facing back of cage, excessive self grooming, stretched posture, early failure to eat and drink, dull attitude or increased aggression when handled, possible vocalization when handled, tooth grinding, respiratory rate may increase	Tooth grinding, apparent sleepiness, dehydration, weight loss, fecal staining, wasting of lower back muscles, decreased production of night feces, unresponsive
Rodents	Aggressive vocalization, licking, biting, scratching, guarding, rough hair coat \pm hair loss, reduced exploratory behavior	Eyes closed, piloerection and un-groomed appearance, dehydration, weight loss, incontinence, soiled hair coat, self mutilation, recumbent position with head tucked into abdomen. Decreased vocalization, hypothermia, staggering/falling, squirming, poor gait, writhing, poor posture

Sheep/goat	Lying with legs extended, stamping feet, swaying stance, mild ataxia, restlessness or depression, increased aggression on handling, guarding, tooth grinding	Rolling frequently looking of kicking at abdomen, falling over, walking backward, rapid shallow respiration, weight loss, tooth grinding, grunting, vocalization on handling (goats especially), rigidity, unwillingness to move
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These are general signs of pain and distress not generally associated with procedures performed on research animals. Those signs will be associated specifically with the severity and extent of the procedure and the appropriateness of analgesics and anesthetics used during and after the procedure in the following time period.

It shall also be considered that some species, particularly rodents, mask their pain so that they are not perceived as weak by predators. Care shall be taken to consider the potential pain associated with a procedure regardless of observed signs post-procedurally.

7. Restraint.

(Also see the Ag Guide, pg. 24.)

Methods of restraint will vary with the species of animal subject involved in a particular activity. For instance, handling of mice and rats will be quite different from handling bison. Proper training of all personnel in the handling of animal species is the responsibility of the PI. Training modules for handling procedures are available through the NDSU IACUC training program. Proper equipment and safety procedures must be used in all situations. Shortcuts lead to injury. Restraint of an animal must always insure the safety of both the animal and the handler. Restraint must minimize or eliminate distress while accomplishing the goals of the procedure. It is the responsibility of the IACUC to ascertain whether a specified restraint procedure is adequate and will accomplish the goal of minimizing distress while insuring the safety of the handler.

Prolonged restraint is unacceptable under any condition, unless it will aide in the safety of the animal, herd, or the personnel utilizing the animals. Restraint must only be as long as needed to complete the procedure that the animals are restrained. Conditioning to restraint devices and monitoring during restraint shall be outlined in applicable protocols and SOP's.

8. Euthanasia.

(Also see the Guide, pgs. 65-66; and the Ag Guide, pgs. 24, 35, 43, 54, 64, 71, 78, and 82.)

The *Guide* describes euthanasia as producing rapid unconsciousness while killing animals rapidly and painlessly. Only trained personnel using acceptable techniques in accordance with institutional policies and applicable laws should be performing appropriate euthanasia techniques. The method used should not interfere with postmortem evaluation.

Techniques for euthanasia must follow the current guidelines established by the American Veterinary Medical Association (AVMA) Panel on Euthanasia (2000) and endorsed by the NDSU IACUC. This report is available at <http://www.avma.org/resources/euthanasia.pdf>. Any method of euthanasia not approved by the AVMA Panel must be thoroughly justified and be reviewed and approved by the IACUC and the AV.

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List of IACUC & Animal Science Acronyms

(Adapted from a list on the ILAR homepage at <http://www4.nas.edu/cls/ilarhome.nsf/>.)

AAALAC	Association for Assessment and Accreditation of Laboratory Animal Care
AACC/AD	American Association for Clinical Chemistry /Animal Division
AACR	American Association of Cancer Research
AAHA	American Animal Hospital Association
AALAS	American Association for Laboratory Animal Science
AAMC	Association of American Medical Colleges
AASR	American Academy of Surgical Research
ATA	Animal Air Transport Association
AAU	American Association of Universities
AAV	Association of Avian Veterinarians
AAZP	American Association of Zoological Veterinarians
AAZPA	American Association of Zoological Parks and Aquaria
ABS	Animal Behavior Society
AC	Animal Care, APHIS, USDA
ACF	Animal Care Facility
ACLAM	American College of Laboratory Animal Medicine
ACMAL	Association Canadienne de la Médecine des Animaux de Laboratoire
ACP	Animal Care Panel
ACS	American Cancer Society
ACS	American Chemical Society
ACTAL	Association Canadienne pour la Technologie des Animaux de Laboratoire
ACVB	American College of Veterinary Behaviorists
ACVP	American College of Veterinary Pathologists
ACVPM	American College of Veterinary Preventive Medicine
ADA	American Dental Association
ADC	Andean Development Corporation
AFIP	Armed Forces Institute of Pathology
AGAH	Animal Health Service (Agricultural Department FAO)
AHA	American Heart Association
AHA	American Humane Association
AHES	American Humane Education Society
ALAT	Assistant Laboratory Animal Technician
AHT	Animal Health Technician
ALF	Animal Liberation Front
ALDF	Animal Legal Defense Fund
AMA	American Medical Association
ANZCCART	Australian and New Zealand Council for the Care of Animals in Research and Teaching
AORN	Association of Operating Room Nurses
APA	American Pharmaceutical Association
APA	American Psychological Association
APHIS	Animal and Plant Health Inspection Service (USDA)

APS	American Pain Society
APS	The American Physiological Society
ARC	Animal Research Committee
ARENA	Applied Research Ethics National Association
ARF	Animal Research Facility
ARP	Animal Resources Program
ARS	Agricultural Research Service (USDA)
ASLAP	American Society of Laboratory Animal Practitioners
ASM	American Society for Microbiology
ASR	Academy of Surgical Research
ATA	Allied Trade Association
ATA	Animal Transportation Association
ATCB	Animal Technician Certification Board
ATS	Animal Thoracic Society
AV	Attending Veterinarian
AVMA	American Veterinary Medical Association
AVSAB	American Veterinary Society of Animal Behavior
AVTE	Association of Veterinary Technician Educators
AWA	Animal Welfare Act
AWI	Animal Welfare Institute
AWIC	Animal Welfare Information Center
AWRs	Animal Welfare Regulations
BA	Board on Agriculture
BCLAS	Belgian Council for Laboratory Animal Science
CAAT	Center for the Alternatives for Animal Testing
CALAM	Canadian Association for Laboratory Animal Medicine
CALAS	Canadian Association for Laboratory Animal Science
CAMDA	Center for the Application of Methodology for the Diagnosis of Animal Diseases
CARAPHIN	Caribbean Animal & Plant Health Information Network
CBM	Current Bibliographies in Medicine
CCAC	Canadian Council on Animal Care
CDC	Centers for Disease Control and Prevention
CEC	Commission of European Communities
CFBS	Canadian Federation of Biological Sciences
CFHS	Canadian Federation of Humane Societies
CFR	Code of Federal Regulations
CIRA	Center for Information on Research with Animals
CITES	Convention on International Trade in Endangered Species of Wild Flora and Fauna
CLAW	Center for Laboratory Animal Welfare
COLSALFA	South American Commission for the Control of Foot & Mouth Disease
CORESA	Committee Regional de Animal Health
CSREES	Cooperative State Research, Education, and Extension Service (USDA)
CVMA	Canadian Veterinary Medical Association
DHEW	Department of Health, Education and Welfare

DHHS	Department of Health and Human Services
DOE	Department of Energy
DOI	Department of Interior
DRR	Division of Research Resources
DRS	Division of Research Services
DVM	Doctor of Veterinary Medicine
EPA	Environmental Protection Agency
FAO	Food and Agriculture Organization of the United Nations
FASEB	Federation of American Societies of Experimental Biology
FBR	Foundation for Biomedical Research
FDA	Food and Drug Administration
FOIA	Freedom of Information Act
FR	Federal Register
FWS	Fish and Wildlife Service
GICSA	Inter-American Group for the Coordination of Animal Health
GLP	Good Laboratory Practices Act
GPO	Government Printing Office
HEPA	High-Efficiency Particulate Air-Filter
HSUS	Humane Society of the United States
HVAC	Heating, Ventilation and Air-Conditioning
IAAAM	International Association for Aquatic Animal Medicine
IACUC	Institutional Animal Care and Use Committee
IBC	Institutional Biosafety Committee
IBAR	Inter-African Bureau for Animal Resources
ICLA	International Committee on Laboratory Animals
ICLAS	International Council for Laboratory Animal Science
IEF	International Equestrian Federation
IFAD	International Fund for Agricultural Development
IICA	Inter-American Institute for Cooperation on Agriculture
iiFAR	Incurably Ill for Animal Research
ILAR	Institute for Laboratory Animal Research
ILRAD	International Laboratory for Research on Animal Diseases
INPPAZ	Pan-American Institute for Food Protection and Zoonoses
IO	Institutional Official
IOM	Institute of Medicine
IRAC	Interagency Research Animal Committee
IRB	Institutional Review Board for the Protection of Human Subjects
ISIS	International Species Inventory System
ITCVDR	International Technical Consultation on Veterinary Drug Registration
JALAS	Japanese Association for Laboratory Animal Science
JICA	Japanese International Cooperation Agency
JUNAC	Junta del Acuerdo de Cartagena (Andean Program for Animal Health)
LAM	Laboratory Animal Medicine
LAMA	Laboratory Animal Management Association
LAS	Laboratory Animal Science
LASA	Laboratory Animal Science Association

LAT	Laboratory Animal Technician
LATg	Laboratory Animal Technologist
LD	Lethal dose
MRC	Medical Research Council
MSPCA	Massachusetts Society for Prevention of Cruelty to Animals
MZCC	Mediterranean Zoonoses Control Center
NABR	National Association for Biomedical Research
NAL	National Agricultural Library
NAS	National Academy of Sciences
NASA	National Aeronautics and Space Administration
NAVTA	North American Veterinary Technician Association
NCI	National Cancer Institute
NCRR	National Center for Research Resources
NCTR	National Center for Toxicological Research
NCURA	National Council of University Research Administrators
NEAVS	New England Anti-vivisection Society
NIEHS	National Institute of Environmental Health Safety
NIH	National Institutes of Health
NIOSH	National Institute of Occupational Safety and Health
NRC	National Research Council
NRI	National Research Initiative (USDA)
NSF	National Science Foundation
OHS	Occupational health and safety
OIE	Office International des Epizootics
OLAW	Office for Laboratory Animal Welfare
OMB	Office of Management and Budget
OPRR	Office for Protection from Research Risks
ORI	Office for Research Integrity
OSHA	Occupational Safety and Health Administration
PETA	People for the Ethical Treatment of Animals
PHS	Public Health Service
PRIM&R	Public Responsibility in Medicine and Research
RCR	Responsible Conduct of Research
SCAW	Scientists Center for Animal Research
SOP	Safe Operating Procedure
SOP	Standard Operating Procedure
SPCA	Society for the Prevention of Cruelty to Animals
SRA	Society of Research Administrators
SSP	Species Survival Plan
UFAW	Universities Federation for Animal Welfare
ULAWS	University of London Animal Welfare Society
UNESCO	United Nations Education, Science and Cultural Organization
USAMRIID	U.S. Army Medical Research Institute of Infectious Diseases
USDA	United States Department of Agriculture
USDI	United States Department of the Interior
USFWS	U.S. Fish and Wildlife Service

VA	Veterans Administration
VAMC	Veterans Administration Medical Center
VMD	Veterinary Medical Doctor
VMO	Veterinary Medical Officer (USDA inspector)
WAVLD	World Association of Veterinary Laboratory Diagnostician
WHO	World Health Organization
WVA	World Veterinary Association

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Works Cited

Animal Welfare Act (7 U.S.C. § § 2131 et. seq.). 1966. Revised or amended 1970, 1976, 1985, 1990. <http://www.aphis.usda.gov:80/ac/publications.html>.

APHIS/Animal Care Web site. <http://www.aphis.usda.gov/ac/>.

AWIC Newsletter. Vol. 8, No. 3-4. Winter 1997/1998.

Biosafety in Microbiological and Biomedical Laboratories. Centers for Disease Control-National Institutes of Health. 1993.

Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching. Federation of Animal Science Societies. First Revised Edition, January 1999.

Guide for the Care and Use of Laboratory Animals. Institute of Laboratory Animal Resources. National Research Council. National Academy Press. 1996.

Guidelines for Occupational Health and Safety in the Care and Use of Vertebrate Animals. NDSU IACUC. 1997. Revised 2001.

Guidelines for Research Involving Recombinant DNA Molecules. National Institutes of Health. 1994.

ILAR Journal. Vol. 37, No. 3. 1995.

Monoclonal Antibody Production. National Research Council. Nation Academy Press. 1999.

Lab Animal. Special Feature issue, Autumn 1999.

Lab Animal. Volume 30, No.4. April 2001.

“Model for Performing Institutional Animal Care and Use Committee Continuing Review of Animal Research.” Gwenn Oki, Ernest Prentice, Nelson Garnett, Dale Schwindaman, Carol Wigglesworth. 1996. <http://grants.nih.gov/grants/olaw/references/contop96.htm>.

NDSU IACUC Web site. <http://www.ndsu.nodak.edu/research/compliance/iacuc/>.

NDSU Human Resources/Workers Compensation Web site.
http://www.ndsu.nodak.edu/human-resources/comp/workers_ref.shtml.

NDSU Occupational Safety and Environmental Health Web site
http://www.ndsu.nodak.edu/ndsu/physical_plant/oseh/.

NDSU Policy Manual. Section 346: Animal Welfare.
<http://www.ndsu.nodak.edu/policy/346.htm>.

Occupational Health and Safety in the Care and Use of Research Animals. National Research Council. National Academy Press. 1997.

OLAW Web site. <http://grants.nih.gov/grants/olaw/olaw.htm>.

OLAW Frequently Asked Questions Web site.
http://grants.nih.gov/grants/olaw/references/faq_labanimals1997.htm.

Public Health Service Policy on Humane Care and Use of Laboratory Animals. Office of Laboratory Animal Welfare. National Institutes of Health. Revised September 1986. Reprinted October 2000.

NDSU PHS Assurance Statement (A3244-01), exp. June 30, 2001.

Risk Self-Assessment Questionnaire. University of California-San Diego. 2001.

Office of Research Integrity (ORI) Responsible Conduct of Research (RCR) Program.
http://ori.dhhs.gov/html/programs/rcr_requirements.asp.

USDA/APHIS lecture at a workshop on the *Guide for the Care and Use of Agricultural Animals*. Presented by Michael E. Mispagel, Ph.D. San Diego, CA. March 19, 1997.

USDA Animal Welfare Regulations (9 CFR, Ch. I, Subchapter A). January 1, 2000 edition.

USDA Policies 12, 26, and 29. <http://www.aphis.usda.gov/ac/polmanpdf.html>.

NDSU USDA Registration (45-R-0002). Expires October 20, 2002.

Works Consulted

Education and Training in the Care and Use of Laboratory Animals: A Guide for Developing Institutional Programs. National Research Council. National Academy Press. 1991.

The Care and Feeding of an IACUC: The Organization and Management of an Institutional Animal Care and Use Committee. Eds. M. Lawrence Podolsky, M.D. and Vistor S. Lukas, D.V.M. CRC Press. 1999.

Information Resources for Institutional Animal Care and Use Committees, 1985-1999. USDA. AWIC Resource Series No. 7. Revised September 2000.

Institutional Animal Care and Use Committee Guidebook. OPRR/ARENA. NIH Publication No. 92-3415. 1992.

The IACUC Handbook. Eds. Jerald Silverman, Mark A. Suckow, and Sreekant Murthy. CRC Press. 2000.

APPENDIX A

NDSU IACUC FORMS

Institutional Animal Care and Use Committee (IACUC)

For the protection of animal subjects



IACUC Office

Department of Sponsored Programs Administration
Office of the Vice President for Research, Creative Activities and Technology Transfer
1735 NDSU Research Park Drive, P.O. Box 5756
Fargo, ND 58105-5756, Phone (701) 231-8114, Fax (701) 231-8089

Definitions for Protocol Classes:

Agricultural: studies conducted on farm animals where the animals are used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber. For fistulated/cannulated cattle, protocols can refer to the approved SOP and they can still file with this protocol. No surgical protocol would be needed. If the surgery will take place the same holds true and the SOP may be described in the Agricultural protocol.

Field/wildlife Study: any study conducted on free-living wild animals in their natural habitat that involves procedures that may harm or materially alter the behavior of the animals under study (*i.e.*, trapping/capture, physical/chemical restraint, and/or invasive procedures including stress and removal from nest and habitat for short durations). IACUC Policy exempts those field studies that do not harm or materially alter the behavior of the animals under study (*i.e.*, observational in nature and do not involve trapping/capture, physical/chemical restraint, and/or invasive procedures) from having to submit ion full an animal use protocol or obtain IACUC approval. Those studies certified exempt will be noted and administratively filed as “exempt.”

Teaching: *courses* that utilize animals in the course activities for the purposes of training and teaching methods and procedures as well as skills should be covered under this type of protocol. Research projects conducted during the course of a approved class should not be covered here but rather under another type of protocol pending the use.

Biomedical/surgical: simply stated, any study that cannot be classified as a field study, teaching activity, breeding activity or an agricultural study falls into the biomedical classification. This classification includes all biology and/or medicine disciplines (*i.e.*, biology, zoology, nutrition, medicine, physiology, pharmacology, pathology, psychology, genetics, etc.), hence the term Bio-Medical. Types of activities that do fall in this area are surgeries, drug test, toxicology, behavioral experimentation, and studies that would result in benefits to humans as a whole. Agricultural studies that have large components of surgery and operative procedures shall be filed with this protocol. Production of antibodies in dairy cow milk would be included here as well as selenium trials when the results are aimed at benefiting humans.

Breeding Colony: shall be used in the cases where a herd or colony will be specifically bred for specific genetic or behavioral outcomes. This protocol shall not be used for general breeding for animal numbers.

Herd Management: any activity intended for the production of animals not associated with a project or directly related to a research goal or aim. Animals under this type of activity would be later transferred to a project or activity that would be covered by one of the types of protocols listed above. The intent here is to cover all our animals when not under teaching or research protocols. This would include the general herds and colonies that we maintain at our REC's and Main Campus. Demonstration activities shall be covered under the herd management protocol if the demonstration is a common daily management practice. This would also cover animals relocated to other facilities outside of their normal facilities, i.e. out of state shows, demonstrations and exhibits.

All demonstrations resulting from the research or to teach a procedure for proficiency in a study should be outlined in the protocol in terms of demonstrating research results or procedures. If the animals will be in altered holding areas then the research areas simply indicate that a different location similar to the research area will be used for the demonstration.

If you feel your project would fall under two protocols you must look at what is the main goal of the activity. If you feel you are unable to make this separation call the IACUC office (1-8114) and they will assist you in filing the proper protocol. The only exclusion from this is if it is a teaching activity you must file the teaching protocol regardless if you are performing surgery or breeding.

Complete protocols in word format can be found at:

<http://www.ndsu.edu/research/compliance/iacuc/index.shtml>

The protocols found below are not in complete format in an effort to reduce the file size.

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IACUC Protocol Submission Checklist

This checklist is for your benefit. IF the protocol is missing any items or is found to be submitted incomplete it will be sent back to you for completion. Some of the items may not be required with the protocol but must be completed and retained within your office.

Protocols should be submitted and received one week prior to the next scheduled meeting date if they require full board review

(<http://www.ndsu.nodak.edu/research/forms/onfile/acrobat/iacucpolicy.pdf>). Our meeting dates are posted on our website:

<http://www.ndsu.nodak.edu/research/compliance/iacuc/meetings.shtml>. The IACUC office has made these requests so that your protocol can be copied and sent to the committee with enough time for review prior to the meeting.

To submit a new Protocol for review you should:

- Make sure all pages and sections are completed (if not applicable please put "N/A")
- Make sure that all information is in sufficiently detailed so that a proper and speedy review by the committee may take place
- Make sure that all information is truthful and can be completed as outlined
- Check all SOP citations to assure they are correct and attach them to the protocol if you have cited them in the protocol
- If other articles or resources are cited please provide **13 copies** (i.e. if rather than detailing a procedure you reference it). Your protocol will not be reviewed without the proper material
- Review certification/signature page and make sure all points are checked (where applicable)
- Make sure all personnel listed have been through all training for the procedures you perform and that you can document it within your lab;

Training that must be completed:

- given by NDSU OSEH – baseline safety (annual), chemical and lab safety (3 years), Radiation training is every five years if you use radiation in the lab (mandatory).
- occupational health and safety when working with animals offered on blackboard (voluntary)
- given by the NDSU IACUC – “Animal Welfare & IACUC” (mandatory) and any others on blackboard you feel your personnel should review (voluntary)

If not all training has been completed please contact either the OSEH or the IACUC offices, depending on training needed, so that we can assist your personnel in obtaining their training.

- All persons listed have been asked to participate in the OHS program and/or have completed a health evaluation, and a risk assessment for their duties
- You have secured the proper housing for your animals
- Copy of other protocols if two IACUC's are involved (please contact office for further help)
- Copy of permits (federal and State where applicable)
- Proper DEA approval for controlled substances (if used)
- You have obtained all the proper signatures (PI and departmental)

If portions of the protocol have not been fully completed the IACUC office may send your protocol back or contact you by phone to clear up any potential confusion. If during the initial review the IACUC office feels the committee would require more information the Director may contact you to help expedite the review process.

In there are no concerns initially from the IACUC office the protocol will be either processed through the Designated Review process or through the Full Board Review process. In either case it could take up to one month or as little as ten calendar days. The IACUC Director will notify you as to the outcome of the review in writing as well as provide a signed and approved copy of the protocol filed.

Best wishes in your activities, and thank you for your attention to this ever-important compliance process.

Agricultural Animal Use Form

To request IACUC review of an activity, complete this form, and send a hardcopy with original signatures to the IACUC Office, Research 1, NDSU Research & Technology Park.

*The IACUC must review and approve **all** activities involving the use of vertebrate animals prior to their initiation. This includes animals used for research, teaching and testing.*

Title

Personnel: *ALL individuals (including PI and co-PI) must complete required training courses (please review protocol instructional page) in order to be approved for work with animals. Please include positions within the University (Faculty, Grad. Student etc) Complete **Appendix A.** for training documentation.*

Principal Investigator

Department

Campus Address *prefer to be contacted by*

Phone *prefer to be contacted by*

E-mail Address *prefer to be contacted by*

Co-Investigator(s)

Primary Contact for protocol issues/renewals/approvals

If working collaboratively it is the PI's responsibility to provide a copy of the protocol to everyone listed and involved in this activity and it is recommended that they receive administrative approval from other departments and directors prior to primary departmental approval.

Graduate Student(s), Staff, Assistant(s) & Technician(s)

Name	Title	Duties in regards to animals
	Graduate Student	
	Graduate Student	
	Graduate Student	

	Graduate Student	
	Graduate Student	

To add persons after approval, email the IACUC.office@ndsu.edu describing their role on the project, when they completed training and the title and protocol number. Initiation of their work can not start until after the person has been added to the protocol and they have completed training through the IACUC.

Project Type: Feedlot trials Grazing trials Production, management trials

Funding Source:

Notes:

Grant Submitted: No Yes Pending
 (If the grant is not funded, notice should be given to the IACUC office as promptly as possible. Email notice is acceptable.)

Anticipated Start Date: _____ Anticipated End Date: _____
IACUC does not grant retroactive approval.

Category: Category B Category C Category D Category E

If marked category B or C you may skip to section 2, if category D or E please complete section 1 of the protocol form.

Classifications

Category B: Animals being bred, conditioned or held for use in teaching, testing experiments, research or surgery, but not yet used for such purposes.

Category C: Animal upon which teaching, research, experiments, or test will be conducted involving no pain, distress other than routine venipuncture and handling not requiring the use of pain-relieving drugs.

Categories D or E must document alternatives to animal use.

Category D: Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesics, or tranquilizer drugs will be used.

Category E: Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesics, or tranquilizer drugs will adversely affect the procedures, results, or interpretations of the teaching, research, experiments, surgery, or tests

For examples please see IACUC website or call the IACUC office at 231-8114

1. Alternatives to Animal Use (Categories D and E)

☎ Contact the University Safety Office at 231-7759.
[\(http://facilities-mgmt.ndsu.nodak.edu/oseh/\)](http://facilities-mgmt.ndsu.nodak.edu/oseh/)

Approval must be obtained from all other applicable committees before final approval can be obtained from the IACUC office.

3. Animals to be used in this activity:

Species/ Common name	Sex	Age	Housing Location	Animal Source or Vendor	Total Number of Animals

4. Will surgery be involved in this activity?

No Yes. If yes, please attach **Appendix B**

5. Will anesthesia or analgesia be involved in this activity?

No Yes. If yes, please attach **Appendix C**.

If No, briefly explain why (e.g. “none needed or used in course of study” or “would interfere with study objective because...”).

6. Summary of Research Activities (Layperson’s Overview). Write clearly and simply. Briefly describe the goals, potential benefits and animal species used and their importance to the activity. Be concise and use terms that non-scientist can understand. This information may be used in press releases to satisfy a freedom of information request:

7. What is the specific goal/aim of this activity?

Such as:

- What is the research or development question?
- Describe the relevance of the activity to advancing scientific knowledge and/or the benefits of the study to human and/or animal health.
- Provide sufficient information to indicate that the potential new knowledge from the activity justifies the use of animals.

8. Provide a complete and accurate description of the experimental procedures that will be applied to the animals. Provide sufficient detail to allow evaluation by the IACUC. (You may refer to a previously IACUC-approved Standard Operating Procedure [SOP] here, if applicable. Approved NDSU SOP's are listed at

<http://www.ndsu.nodak.edu/research/compliance/iacuc/sop/SOP.shtml>.)

- Describe procedures (blood draws to diet regiments), their frequency, and time points over the course of the activity.
- Include how long the animals will be maintained (habituation period to sale).
- Describe methods used in behavioral studies (if applicable).

9. Justify the species and number of animals to be used, statistically if possible.

<http://www.ndsu.nodak.edu/ndsu/doetkott/StatConsult.html> for help on justifying numbers

10. Will the animals be transported from one area to another during the course of the study? This will include moving animals from one city to another within ND, Across state lines or simply from one pasture to another.

Yes No

How will they be transported or moved? (Trailers, horseback, ATV, dogs. You may refer to a previously IACUC-approved Standard Operating Procedure [SOP] here, if applicable)

11. Who will be your primary and secondary contact for veterinary care during emergencies? (e.g. local veterinarians you use or the AV if applicable)

12. Who will provide general Veterinary Care (routine care, vaccinations or general treatment during the project) while animals are under your care? (e.g. technician, vet tech, etc.)

Name	Position at facility

13. Will the animals be housed in pens/stalls/stanchions?

Yes if yes, complete the following No (if no, skip to section 14)

You may refer to a previously IACUC-approved Standard Operating Procedure [SOP] here regarding housing conditions and care.

NDSU IACUC Approved SOP # *If citing an SOP you may skip to the next section.*

If yes is it a: pen stall/freestall Stanchion

Dimensions of pen/stall:	
Number of animals per pen/stall:	
Slope of pen/stall:	
Ground make up e.g. Dirt, concrete, bedded, etc:	
Shelter (e.g. windbreak, shelterbelt, housing):	
Feed bunks construction:	
Feed bunk apron construction (e.g. concrete fly ash etc:	
Water supply:	
Type of feed:	

14. Will the animals be in pastures?

Yes *if yes, complete the following* No (if no skip to section 15)

You may refer to a previously IACUC-approved Standard Operating Procedure [SOP] here regarding housing conditions and care.

NDSU IACUC Approved SOP # *If citing an SOP you may skip to the next section.*

If yes what is the size of the pasture and typical forage species?

If yes how many animals will be in each pasture?

How often will the animals be monitored?

- Monthly
 Weekly
 Daily
 2x Daily
 More than 2x Daily
 Other (e.g. every other day)

Describe the water supply:

Describe the feeding regiment and supplemental diet, if any:

Describe the shelter provided: i.e. nature contour of landscape or man made.

15. Will the animals be restrained for procedures relating to the study? Yes

No

If yes, does it fall within acceptable limits under the AG Guide?

Yes

No

If no please provide a description and justification for method and duration.

16. How will pain, distress, or **discomfort be identified and monitored?** Cite **specific examples** of **signs** and **behaviors** that will be used to assess pain and distress. Health and illness reports can be found on the IACUC website for reporting to the attending veterinarian.

Every person who is listed and those who will be in a position to observe the animals should be well aware of the signs of pain and distress and should be able to recognize them. All personnel as well, should have knowledge of who to call for emergencies and what course of actions they should take in order to maintain scientific validity and animal welfare issues for each project. Please have all personnel involved read this protocol as a notice of their responsibilities and awareness of the specifics of your project.

17. What steps will be taken to alleviate any pain, distress, or discomfort the animals may experience as a result of the **experimental procedures, or in the event an animal experiences any adverse reactions?**

18. What will be the disposition of the animals used in this project? (please check one)

- Euthanized in the lab for further sampling and /or carcasses disposed of by Incineration or other approved method.
- Harvested in commercial facilities under state or federal inspection with carcasses entering the food chain.
- Maintained under animal management conditions for future use in research
- Normal commercial marketing channels
- Other. Please provide a brief description.

If euthanized please describe the euthanasia method and how the carcasses will be disposed.

Is the euthanasia method consistent with the standards set forth by the AVMA Panel on Euthanasia (2000) (See <http://www.avma.org/resources/euthanasia.pdf>)?

- YES NO. If no, explain why the unapproved method has been chosen

19. Is it planned that the animals will die as a result of the treatment protocol of the experiment, i.e. will the treatment of the animals result in death?

- NO YES. If yes provide a scientific justification

20. PI Qualifications, Certifications, and/or Training for this particular experiment, procedure, and/or project:

NDSU is a decentralized animal care program and thus each PI is responsible for the adequate care of the animals for each project. For each project they must demonstrate to the IACUC that they are qualified and trained to care for the animals and are proficient in the procedures they perform. All technicians and assistants are also required to demonstrate proficiency and ability to manage the animal care for this project under their mentors or the Principle Investigator.

Principal Investigator Certifications:

As Principal Investigator for this project, I certify that I have:

- (Category D or E)** carefully considered alternatives to the use of live animals for this project (e.g. mathematical models, computer simulation, *in vitro* biological systems) and have attached the written documentation of the search as a part of this protocol;
- completed the institutionally required investigator training course(s);
- certified that all individuals working on this project who are at risk are participating in the Institution's Occupational Health and Safety program (**Appendix A**);
- certified that the individuals listed as personnel on this project are authorized to conduct procedures involving animals under this proposal and have completed the institutionally required training courses (**Appendix A**);
- (Category D or E)** considered alternatives to procedures that may cause more than a momentary or slight pain or distress to the animals and *have attached a written narrative description of the methods and sources I used to determine that alternatives were not available*; and
- (Category D or E)** determined that the activities described in this study do not unnecessarily duplicate previous experiments (if activities will duplicate previous experiments, I have included a written explanation of and justification for the duplicative procedures).

and I agree to:

- execute this work as described in this protocol;
- request approval from the IACUC for changes in the project;
- notify the Attending Veterinarian and/or the IACUC of any unexpected study results that impact animal welfare;
- comply with the guidelines in the University's IACUC Policies and Procedures Manual;
- be familiar with and comply with all pertinent institutional, state, and federal rules and policies;
- follow all Occupational Health and Safety guidelines; and
- be responsible for the supervision and work of my staff.

Principal Investigator

Date

By signing this animal use protocol the **department** certifies that the proposed animal use protocol has been reviewed for scientific merit, or is an essential validated diagnostic/safety/efficacy/research test method and that appropriate resources are available to conduct this project in a human manner along common practice set in the *Ag Guide*.

Departmental Authorization (Chair or Dean)

Date

Final authorization of IACUC

IACUC Chair

Date

Appendix A Personnel Documentation

Training Documentation: Animal Supervisor Checklist

Note: Other training courses offered by the IACUC can be found on the NDSU Blackboard web site at: <http://blackboard.ndsu.nodak.edu/?bbatt=Y>. Please contact the IACUC office for enrollment information. Please note below training of seasonal employees and temporary employees.

Name (last) PI (first) (MI)

Department Title/Position

Campus Address Phone E-mail

Personnel Name: One name per box	Animal Species/ Common Name(s)	Animal Welfare and the NDSU IACUC	Other: (please indicate)	Other: (please indicate)	Laboratory and Chemical Safety Training	Date Last completed	Baseline Safety Training	Date Last completed	Completed the employee Health Assessment and Risk Assessment for the duties
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab					YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab					YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab					YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab					YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab					YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab					YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab					YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab					YES <input type="checkbox"/> NO <input type="checkbox"/>

NOTES:

If extra Sheets and spaces are needed, copy this page.

Appendix B
Surgery

Where will the surgery be performed?

Building

Room Number

Sterile surgery Non-sterile surgery

Please describe the surgical procedure(s) to be performed.

Appendix C
Anesthesia/Analgesia

Anesthesia:

Type of anesthesia to be used:

Dose:

Route of administration:

Frequency of anesthesia:

Length of anesthesia:

Who is responsible for maintaining the anesthesia?

Methods used to monitor anesthesia:

If inhalation anesthetics are used, describe the system for scavenging waste anesthetic gas?

Describe post-anesthetic care?

Analgesics and/or tranquilizers:

Type of analgesic to be used:

Dose:

Route of administration:

Restraint devices used:

Duration of Restraint:

The use of expired medical materials in animals is prohibited ([Animal Care Policy #3](#)). The only acceptable use of expired materials is in animals that will not recover from surgical procedures where the materials used are used in that procedure. Expired drugs may not be used unless it is a euthanizing dose not intended to maintain a plain of anesthesia

Biomedical/Surgical Protocol Form

To request IACUC review of a project, complete this form, and send a hardcopy with original signatures to the IACUC Office, Research 1, NDSU Research & Technology Park.

*The IACUC must review and approve **all** activities involving the use of vertebrate animals prior to their initiation. This includes animals used for research, teaching and testing.*

Title

Personnel: *ALL individuals (including PI and co-PI) must complete required training courses (please review protocol instructional page) in order to be approved for work with animals. Please include positions within the University (Faculty, Grad. Student etc) Complete **Appendix A.** for training documentation.*

Principal Investigator

Department

Campus Address prefer to be contacted by

Phone prefer to be contacted by

E-mail Address prefer to be contacted by

Co-Investigator(s)

Primary Contact for protocol issues/renewals/approvals

If working collaboratively it is the PI's responsibility to provide a copy of the protocol to everyone listed and involved in this activity and it is recommended that they receive administrative approval from other departments and directors prior to primary departmental approval.

Graduate Student(s), Staff, Assistant(s) & Technician(s)

Name	Title	Duties in regards to animals
	Graduate Student	
	Graduate Student	
	Graduate Student	
	Graduate Student	

	Graduate Student	
--	-------------------------	--

To add persons after approval, email the IACUC.office@ndsu.edu describing their role on the project, when they completed training and the title and protocol number. Initiation of their work can not start until after the person has been added to the protocol and they have completed training through the IACUC.

Anticipated Project Start Date:

Anticipated Project End Date:

IACUC does not grant retroactive approval.

Funding Source:

Grant Submitted: No Yes Pending
 (If the grant is not funded, notice should be given to the IACUC office as promptly as possible. Email notice is acceptable.)

Category: Category B Category C Category D Category E

If marked category B or C you may skip to section 2, if category D or E please complete section 1 of the protocol form.

Classifications

Category B: Animals being bred, conditioned or held for use in teaching, testing experiments, research or surgery, but not yet used for such purposes.

Category C: Animal upon which teaching, research, experiments, or test will be conducted involving no pain, distress other than routine venipuncture and handling not requiring the use of pain-relieving drugs.

Categories D or E must document alternatives to animal use.

Category D: Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesics, or tranquilizer drugs will be used.

Category E: Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesics, or tranquilizer drugs will adversely affect the procedures, results, or interpretations of the teaching, research, experiments, surgery, or tests

For examples please see IACUC website or call the IACUC office at 231-8114

1. Alternatives to Animal Use (Categories D and E)

Federal regulations require the use of alternatives to procedures that may cause more than momentary or slight pain or distress to animals (USDA Policy 12 - Written Narrative for Alternatives to Painful Procedures: <http://www.aphis.usda.gov/ac/policy/policy12>). Alternatives include the following concepts:

3. Animals to Be Used in this activity:

Species/ Common name	Sex	Age	Pain Cat. (B, C, D or E)*	Housing Location	Animal Source or Vendor	Total Number of Animals

4. Summary of Research Activities (Layperson's Overview) Write clearly and simply.

Describe the goals, potential benefits and animal species used and their importance to the project. Be concise and use terms that non-scientist can understand. This information may be used in press releases to satisfy a freedom of information request:

5. What is the specific goal/aim of this project?

Such as:

- What is the research or development question?
- Describe the relevance of the study to advancing scientific knowledge and/or the benefits of the study to human and/or animal health.
- Provide sufficient information to indicate that the potential new knowledge from the project justifies the use of animals.

6. Provide a complete and accurate description of the experimental procedures that will be applied to the animals.

Provide sufficient detail to allow evaluation by the IACUC. (You may refer to a previously IACUC-approved Standard Operating Procedure [SOP] here, if applicable. Approved NDSU SOP's are listed at

<http://www.ndsu.nodak.edu/research/compliance/iacuc/sop/SOP.shtml>.)

- Describe procedures, their frequency, and time points over the course of the experiments.
- Include how long the animals will be maintained.
- Describe methods used in behavioral studies.

7. Justify the species and number of animals to be used, statistically if possible.

<http://www.ndsu.nodak.edu/ndsu/doetkott/StatConsult.html> for help on justifying numbers

Surgery

8. Will surgery (major or minor) be involved in this project? (You may refer to a previously IACUC-approved Standard Operating Procedure [SOP] here, if applicable.)

Major Surgery penetrates and exposes a body cavity or produces substantial impairment of physical or physiological function. **Minor surgeries** are less invasive. Examples of minor surgical procedures would be cutdowns, muscle biopsies, and subcutaneous osmotic pump placement. **Multiple major survival** surgical procedure on any animal are **discouraged** but may be permitted if scientifically justified by the user and approved by the IACUC. For example, multiple major survival surgical procedures can be **justified** if they are related components of a research project, if they will conserve scarce animal resources, or they are needed for clinical reasons. Aseptic/sterile procedures must be followed for all survival surgeries.

No Yes. If yes, please complete the following.

Describe the surgical procedure(s) to be performed including pre and postoperative care.

9. Where will the surgery be performed?

Building	Room Number

Sterile surgery Non-sterile surgery

10. Will anesthesia or analgesia be involved in this project?

No Yes, complete section A. and B.

If No, briefly explain why (e.g. "none needed or used in course of study" or "would interfere with study objective because...").

A.) Anesthesia:

Type of anesthesia to be used:

Dose:

Route of administration:

Frequency of anesthesia:

Length of anesthesia:

Who is responsible for maintaining the anesthesia?

Methods used to monitor anesthesia:

If inhalation anesthetics are used, describe the system for scavenging waste anesthetic gas?

Describe post-anesthetic care as well as who is responsible for it?

Who will be responsible for pre and post-operative care?

B.) Analgesics and/or tranquilizers/sedatives:

Type of analgesic to be used:

Dose:

Route of administration:

Restraint devices used:

Preconditioning of animal to restraint:

Duration of Restraint:

The use of expired medical materials in animals is prohibited ([Animal Care Policy #3](#)). The only acceptable use of expired materials is in animals that will not recover from surgical procedures where the materials used are used in that procedure. Expired drugs may not be used unless it is a euthanizing dose not intended to maintain a plain of anesthesia

11. Will blood/ tissue be collected?

No Yes. If yes, please complete the following.

Route:

Volume:

Collection devise (Vacutainer syringe):

Gauge of needle:

Notes:

12. How will pain, distress, or discomfort be identified and monitored? Cite specific examples of signs and behaviors that will be used to assess pain and distress. Health and illness reports can be found on the IACUC website for reporting to the attending veterinarian.

Every person who is listed and those who will be in a position to observe the animals should be well aware of the signs of pain and distress and should be able to recognize them. All personnel as well, should have knowledge of who to call for emergencies and what course of actions they should take in order to maintain scientific validity and animal welfare issues for each project. Please have all personnel involved read this protocol as a notice of their responsibilities and awareness of the specifics of your project.

13. What steps will be taken to alleviate any pain, distress, or discomfort the animals may experience as a result of the experimental procedures, or in the event an animal experiences any adverse reactions?

14. What will be the disposition of the animals used in this Study? (please check one)

- Euthanized in the lab for further sampling and /or carcasses disposed of by Incineration or other approved method.
- Disposed of through commercial markets
- Donated
- Harvested in commercial facilities state or federally inspected with carcasses entering the food chain.
- Maintained under animal management conditions for future use in research
- Other. Please provide a brief description.

If euthanized please describe the euthanasia method and how the carcasses will be disposed.

Is the euthanasia method consistent with the standards set forth by the AVMA Panel on Euthanasia (2000) (See <http://www.avma.org/resources/euthanasia.pdf>)?

- YES NO. If no, explain why the unapproved method has been chosen.

15. Is it planned that the animals will die as a result of the treatment protocol of the experiment, i.e. will the treatment of the animals result in death?

- NO YES. If yes provide a scientific justification.

16. PI Qualifications, Certifications, and/or Training for this particular experiment, procedure, and/or project:

NDSU is a decentralized animal care program and thus each PI is responsible for the adequate care of the animals for each project. For each project they must demonstrate to the IACUC that they are qualified and trained to care for the animals and are proficient in the procedures they perform. All technicians and assistants are also required to demonstrate proficiency and ability to manage the animal care for this project under their mentors or the Principle Investigator.

Principal Investigator Certifications:

As Principal Investigator for this project, I certify that I have:

- (Category D or E)** carefully considered alternatives to the use of live animals for this project (e.g. mathematical models, computer simulation, *in vitro* biological systems) and have filled out the written documentation of the search as a part of this protocol;
- completed the institutionally required investigator training course(s);
- certified that all individuals working on this project who are at risk are participating in the Institution's Occupational Health and Safety program (**Appendix A**);
- certified that the individuals listed as personnel on this project are authorized to conduct procedures involving animals under this proposal and have completed the institutionally required training courses (**Appendix A**);
- (Category D or E)** considered alternatives to procedures that may cause more than a momentary or slight pain or distress to the animals and *have attached a written narrative description of the methods and sources I used to determine that alternatives were not available*; and
- (Category D or E)** determined that the activities described in this study do not unnecessarily duplicate previous experiments (if activities will duplicate previous experiments, I have included a written explanation of and justification for the duplicative procedures).

and I agree to:

- execute this work as described in this protocol;
- request approval from the IACUC for changes in the project;
- notify the Attending Veterinarian and/or the IACUC of any unexpected study results that impact animal welfare;
- comply with the guidelines in the University's IACUC Policies and Procedures Manual;

- be familiar with and comply with all pertinent institutional, state, and federal rules and policies;
- follow all Occupational Health and Safety guidelines; and
- be responsible for the supervision and work of my staff.

Principal Investigator

Date

By signing this animal use protocol the department certifies that the proposed animal use protocol has been reviewed for scientific merit, or is an essential validated diagnostic/safety/efficacy/research test method and that appropriate resources are available to conduct this project.

Departmental Authorization

Date

Final authorization of IACUC

IACUC Chair

Date

Appendix A Personnel Documentation

Training Documentation: Animal Supervisor Checklist

Note: Other training courses offered by the IACUC can be found on the NDSU Blackboard web site at: <http://blackboard.ndsu.nodak.edu/?bbatt=Y>. Please contact the IACUC office for enrollment information. Please note below training of seasonal employees and temporary employees.

Name (last) PI (first) (MI)

Department Title/Position

Campus Address Phone E-mail

Personnel Name: One name per box	Animal Species/ Common Name(s)	Animal Welfare and the NDSU IACUC	Other: (please indicate)	Other: (please indicate)	Laboratory and Chemical Safety Training	Date Last completed	Baseline Safety Training	Date Last completed	Completed the employee Health Assessment and Risk Assessment for the duties
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab					YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab					YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab					YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab					YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab					YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab					YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab					YES <input type="checkbox"/> NO <input type="checkbox"/>

NOTES:

If extra Sheets and spaces are needed, copy this page.

Breeding Protocol Form

To request IACUC review of a course, complete this form, and send a hardcopy with original signatures to the IACUC Office, Research 1, NDSU Research & Technology Park.

*The IACUC must review and approve **all** activities involving the use of vertebrate animals prior to their initiation. This includes animals used for research, teaching and testing.*

Title

Personnel: *ALL individuals (including PI and co-PI) must complete required training courses (please review protocol instructional page) in order to be approved for work with animals. Please include positions within the University (Faculty, Grad. Student etc) Complete **Appendix A.** for training documentation.*

Principal Investigator

Department

Campus Address *prefer to be contacted by*

Phone *prefer to be contacted by*

E-mail Address *prefer to be contacted by*

Co-Investigator(s)

Primary Contact for protocol issues/renewals/approvals

If working collaboratively it is the PI's responsibility to provide a copy of the protocol to everyone listed and involved in this activity and it is recommended that they receive administrative approval from other departments and directors prior to primary departmental approval.

Graduate Student(s), Staff, Assistant(s) & Technician(s)

Name	Title	Duties in regards to animals
	Graduate Student	
	Graduate Student	
	Graduate Student	
	Graduate Student	
	Graduate Student	

To add persons after approval, email the IACUC.office@ndsu.edu describing their role on the project, when they completed training and the title and protocol number. Initiation of their work can not start until after the person has been added to the protocol and they have completed training through the IACUC.

Funding Source:

Notes:

Grant Submitted: No Yes Pending
(If the grant is not funded, notice should be given to the IACUC office as promptly as possible. Email notice is acceptable.)

Anticipated Colony Start Date: Anticipated Colony End Date:
IACUC does not grant retroactive approval.

For what purposes are these animals being bred/held?

- Agricultural studies
 Biomedical studies

Category: Category B Category C Category D Category E

If marked category B or C you may skip to section 2, if category D or E please complete section 1 of the protocol form.

Classifications

Category B: Animals being bred, conditioned or held for use in teaching, testing experiments, research or surgery, but not yet used for such purposes.

Category C: Animal upon which teaching, research, experiments, or test will be conducted involving no pain, distress other than routine venipuncture and handling not requiring the use of pain-relieving drugs.

Categories D or E must document alternatives to animal use.

Category D: Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesics, or tranquilizer drugs will be used.

Category E: Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesics, or tranquilizer drugs will adversely affect the procedures, results, or interpretations of the teaching, research, experiments, surgery, or tests

For examples please see IACUC website or call the IACUC office at 231-8114

1. Alternatives to Animal Use (Categories D and E)

❶ Contact the Biosafety Committee Office at 231-8114.
<http://www.ndsu.edu/research/compliance/ibc/index.shtml>

❷ Contact the University Safety Office at 231-7759.
<http://facilities-mgmt.ndsu.nodak.edu/oseh/>

3. Animals to Be Bred/Held:

Species/ Common name	Sex	Age	Category (B, C, D or E)*	Housing Location	Total Number of Animals to be bred per year

You should clearly outline the number of rooms/pens you have and the total number of animals you are able to maintain in each. You can attach a separate sheet or excel file indicating species name, ages, housing location, pen/stall/room size, caging type and size, total number of animals you can maintain under these conditions.

4. Summary of Research Activities (Layperson’s Overview). Write clearly and simply. Briefly describe the goals, potential benefits and animal species used and their importance to the activity. Be concise and use terms that non-scientist can understand. This information may be used in press releases to satisfy a freedom of information request:

5. What is the specific goal/aim of this activity?

Such as:

- What is the research or development question?
- Describe the relevance of the activity to advancing scientific knowledge and/or the benefits of the study to human and/or animal health.
- Provide sufficient information to indicate that the potential new knowledge from the activity justifies the use of animals.

6. Provide a complete and accurate description of the experimental procedures that will be applied to the animals. Provide sufficient detail to allow evaluation by the IACUC. (You may

refer to a previously IACUC-approved Standard Operating Procedure [SOP] here, if applicable. Approved NDSU SOP's are listed at <http://www.ndsu.nodak.edu/research/compliance/iacuc/sop/SOP.shtml>.)

- Describe procedures (blood draws to diet regiments), their frequency, and time points over the course of the activity.
- Include how long the animals will be maintained (habituation period to sale).
- Describe methods used in behavioral studies (if applicable).

7. From where will you originally procure the animals?

Vender Name	Address	City	State

8. Are health records provided with the shipment from the vender?

- Yes No *If no, please provide explanation e.g. not the normal practice in cattle shipments. You may refer to a previously IACUC-approved Standard Operating Procedure [SOP] here regarding housing conditions and care.*

NDSU IACUC Approved SOP # *If citing an SOP you may skip to the next section.*

9. Will the vender be the same when introducing new breeders/stock?

- Yes No *If no, please provide anticipated sources.*

10. How will they be housed and who is responsible for the day-to-day care? (You may refer to a previously IACUC-approved Standard Operating Procedure [SOP] here, if applicable. Approved NDSU SOP's are listed at <http://www.ndsu.nodak.edu/research/compliance/iacuc/sop/SOP.shtml>.)

Please provide the following information regarding the housing and care of the animals.

You may refer to a previously IACUC-approved Standard Operating Procedure [SOP] here regarding housing conditions and care.

NDSU IACUC Approved SOP # *If citing an SOP you may skip to the next section.*

Is special housing required e.g. ventilation chambers, isolators?

- Yes No

Please describe the housing provided, the number of animals per unit (cage, shoebox, pen, pasture) size of unit: *please delineate between seasonal differences in housing*

Source of water and availability:

Rotation of water and frequency of cleaning water bottles, sippers and stoppers:

Source of feed and availability:

Rotation of feed and frequency of cleaning holders/bins:

Bedding type:

Rotation of bedding and frequency:

Enrichment devices:

Filter tops used? Yes No

Sentinel Program implemented? Yes No

If yes please describe the program,

11. What will be done with any extra or overstock of animals? In the process of breeding animals for specific purposes not animals will be used or may not meet requirements for the study, please indicate how those animals that are culled will be handled/removed/disposed. What will be the specific criteria for removal and estimated number produced monthly? What other factors may determine removal from the colony?

12. How will pain, distress, or discomfort be identified and monitored? Cite specific examples of signs and behaviors that will be used to assess pain and distress. Health and illness reports can be found on the IACUC website for reporting to the attending veterinarian.

Every person who is listed and those who will be in a position to observe the animals should be well aware of the signs of pain and distress and should be able to recognize them. All personnel as well, should have knowledge of who to call for emergencies and what course of actions they should take in order to maintain scientific validity and animal welfare issues for each project. Please have all personnel involved read this protocol as a notice of their responsibilities and awareness of the specifics of your project.

13. What steps will be taken to alleviate any pain, distress, or discomfort the animals may experience.

14. What will be the disposition of the animals bred/held? (Please check one)

- Euthanized in the lab for further sampling, judging, evaluation and /or carcasses disposed of by Incineration or other approved method.
- Culled and euthanized
- Culled and disposed of through commercial market practices
- Donated
- Transferred to another protocol for research teaching purposes.
- Other. Please provide a brief description.

Is the euthanasia method consistent with the standards set forth by the AVMA Panel on Euthanasia (2000) (See <http://www.avma.org/resources/euthanasia.pdf>)?

- YES NO. If no, explain why the unapproved method has been chosen.

15. PI Qualifications, Certifications, and/or Training for this particular procedure, and/or project:

NDSU is a decentralized animal care program and thus each PI is responsible for the adequate care of the animals for each project. For each project they must demonstrate to the IACUC that they are qualified and trained to care for the animals and are proficient in the procedures they perform. All technicians and assistants are also required to demonstrate proficiency and ability to manage the animal care for this project under their mentors or the Principle Investigator.

Principal Investigator Certifications:

As Principal Investigator for this course, I certify that I have:

- (Category D or E)** carefully considered alternatives to the use of live animals (e.g. mathematical models, computer simulation, *in vitro* biological systems) and have given written documentation of the search as a part of this protocol.
- completed the institutionally required investigator training course(s);
- certified that all individuals working on this project who are at risk are participating in the Institution's Occupational Health and Safety program (**Appendix A**);

- certified that the individuals listed as personnel for this course are authorized to conduct procedures involving animals under this proposal and have completed the institutionally required training courses (**Appendix A**);
- (**Category D or E**) considered alternatives to procedures that may cause more than a momentary or slight pain or distress to the animals and *have attached a written narrative description of the methods and sources I used to determine that alternatives were not available* and
- (**Category D or E**) determined that the activities described in this course do not unnecessarily duplicate previous experiments (if activities will duplicate previous experiments, I have included a written explanation of and justification for the duplicative procedures).

and I agree to:

- execute this work as described in this protocol;
- request approval from the IACUC for changes in the project;
- notify the Attending Veterinarian and/or the IACUC of any unexpected study results that impact animal welfare;
- comply with the guidelines in the University's IACUC Policies and Procedures Manual;
- be familiar with and comply with all pertinent institutional, state, and federal rules and policies;
- follow all Occupational Health and Safety guidelines; and
- be responsible for the supervision and work of my staff.

I certify that the information in this application is truthful and that the proper resources have been secured to provide aforementioned care to the animals. The IACUC will be notified of any changes in the proposed activity, or personnel, relative to this application, prior to proceeding with any animal manipulation. I will not proceed with any animal manipulation until approval by the IACUC is granted.

Principal Investigator

Date

As this breeding project is conducted and is non-peered reviewed, I endorse the above assurance and certify that I have reviewed this protocol description as adequately funded and the proper resources have been provided to assure the proper care of the animals..

Departmental Authorization

Date

Final authorization of IACUC

IACUC Chair

Date

Appendix A Personnel Documentation

Training Documentation: Animal Supervisor Checklist

Note: Other training courses offered by the IACUC can be found on the NDSU Blackboard web site at: <http://blackboard.ndsu.nodak.edu/?bbatt=Y>. Please contact the IACUC office for enrollment information. Please note below training of seasonal employees and temporary employees.

Name (last) PI (first) (MI)

Department Title/Position

Campus Address Phone E-mail

Personnel Name: One name per box	Animal Species/ Common Name(s)	Animal Welfare and the NDSU IACUC	Other: (please indicate)	Other: (please indicate)	Laboratory and Chemical Safety Training Date Last completed	Baseline Safety Training Date Last completed	Completed the employee Health Assessment and Risk Assessment for the duties
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab			YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab			YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab			YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab			YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab			YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab			YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab			YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab			YES <input type="checkbox"/> NO <input type="checkbox"/>

NOTES:

If extra Sheets and spaces are needed, copy this page.

**Appendix B
Surgery**

Where will the surgery be performed?

Building

Room Number

--	--

- Sterile surgery Non-sterile surgery

Please describe the surgical procedure(s) to be performed.

**Appendix C
Anesthesia/Analgesia**

Anesthesia:

Type of anesthesia to be used:

Dose:

Route of administration:

Frequency of anesthesia:

Length of anesthesia:

Who is responsible for maintaining the anesthesia?

Methods used to monitor anesthesia:

If inhalation anesthetics are used, describe the system for scavenging waste anesthetic gas?

Describe post-anesthetic care?

Analgesics and/or tranquilizers:

Type of analgesic to be used:

Dose:

Route of administration:

Restraint devices used:

Duration of Restraint:

The use of expired medical materials in animals is prohibited ([Animal Care Policy #3](#)). The only acceptable use of expired materials is in animals that will not recover from surgical procedures where the materials used are used in that procedure. Expired drugs may not be used unless it is a euthanizing dose not intended to maintain a plain of anesthesia

Teaching Protocol Form

To request IACUC review of a course, complete this form, and send a hardcopy with original signatures to the IACUC Office, Research 1, NDSU Research & Technology Park.

*The IACUC must review and approve **all** activities involving the use of vertebrate animals prior to their initiation. This includes animals used for research, teaching and testing.*

Course Title

Personnel: *ALL individuals (including PI and co-PI) must complete required training courses (please review protocol instructional page) in order to be approved for work with animals. Please include positions within the University (Faculty, Grad. Student etc) Complete **Appendix A.** for training documentation.*

Principal Investigator

Department

Campus Address *prefer to be contacted by*

Phone *prefer to be contacted by*

E-mail Address *prefer to be contacted by*

Co-Investigator(s)

Primary Contact for protocol issues/renewals/approvals

If working collaboratively it is the PI's responsibility to provide a copy of the protocol to everyone listed and involved in this activity and it is recommended that they receive administrative approval from other departments and directors prior to primary departmental approval.

Graduate Student(s), Staff, Assistant(s) & Technician(s)

Name	Title	Duties in regards to animals
	Graduate Student	
	Graduate Student	
	Graduate Student	
	Graduate Student	
	Graduate Student	

To add persons after approval, email the IACUC.office@ndsu.edu describing their role on the project, when they completed training and the title and protocol number. Initiation of their work can not start until after the person has been added to the protocol and they have completed training through the IACUC.

Funding Source: *(if applicable)*

Notes:

Grant Submitted: No Yes Pending
(If the grant is not funded, notice should be given to the IACUC office as promptly as possible. Email notice is acceptable.)

Anticipated Course Start Date: _____ Anticipated Course End Date: _____
IACUC does not grant retroactive approval.

Category: Category B Category C Category D Category E

If marked category B or C you may skip to section 2, if category D or E please complete section 1 of the protocol form.

Classificationss

Category B: Animals being bred, conditioned or held for use in teaching, testing experiments, research or surgery, but not yet used for such purposes.

Category C: Animal upon which teaching, research, experiments, or test will be conducted involving no pain, distress other than routine venipuncture and handling not requiring the use of pain-relieving drugs.

Categories D or E must document alternatives to animal use.

Category D: Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesics, or tranquilizer drugs will be used.

Category E: Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesics, or tranquilizer drugs will adversely affect the procedures, results, or interpretations of the teaching, research, experiments, surgery, or tests

For examples please see IACUC website or call the IACUC office at 231-8114

1. Alternatives to Animal Use (Categories D and E)

Federal regulations require the use of alternatives to procedures that may cause more than momentary or slight pain or distress to animals (USDA Policy 12 - Written Narrative for Alternatives to Painful Procedures: <http://www.aphis.usda.gov/ac/policy/policy12>). Alternatives include the following concepts:

3. Animals to be used in this activity::

Species/ Common name	Sex	Age	Housing Location	Animal Source or Vendor	Total Number of Animals

4. Summary of Teaching Activities (Layperson’s Overview): Write clearly and simply. Describe the goals, potential benefits and animal species used and their importance to the project. Be concise and use terms that non-scientist can understand. This information may be used in press releases to satisfy a freedom of information request:

5. What is the specific goal/aim of this activity?

Such as:

- Describe the relevance of the course in advancing scientific knowledge and/or the benefits of the course to human and/or animal health.

6. Provide a complete and accurate description of the course procedures that will be applied to the animals. Provide sufficient detail to allow evaluation by the IACUC. (You may refer to a previously IACUC-approved Standard Operating Procedure [SOP] here, if applicable. Approved NDSU SOP’s are listed at

<http://www.ndsu.nodak.edu/research/compliance/iacuc/sop/SOP.shtml>.)

- Describe any surgical procedures in **Appendix B** and complete **Appendix C** if using anesthesia or analgesia.
- Describe procedures, their frequency, and time points over the course.
- Include how long the animals will be maintained for the course.

7. Justify the species and number of animals to be used, statistically if possible.

<http://www.ndsu.nodak.edu/ndsu/doetkott/StatConsult.html> for help on justifying numbers.

8. Will the animals be utilized outside of their normal housing areas? *Does the class come to the facility where the animals are housed or does the animal leave it's facility to come to a different location for the class. This would not include moving the animals out of state or in demonstrations outside of the course.*

No *if no, skip to section 10* Yes

If yes how will they be transported?

How will they be housed in this alternate area (include duration) and who is responsible for the care while in the alternate area?

9. Will the animals be restrained for procedures relating to the study?

No Yes

If yes please describe the length and manner of restraint. (You may refer to a previously IACUC-approved Standard Operating Procedure [SOP] here, if applicable)

10. Will surgery be involved in this course?

No Yes. If yes, please complete **Appendix B**.

11. Will anesthesia or analgesia be involved in this course?

No Yes. If yes, please complete **Appendix C**.

If No, briefly explain why (e.g. "none needed or used in course of study" or "would interfere with study objective because...").

12. How will pain, distress, or **discomfort be identified and monitored? Cite specific examples of signs and behaviors that will be used to assess pain and distress.**

Every person who is listed and those who will be in a position to observe the animals should be well aware of the signs of pain and distress and should be able to recognize them. All personnel as well, should have knowledge of who to call for emergencies and what course of actions they should take in order to maintain scientific validity and animal welfare issues for each project. Please have all personnel involved read this protocol as a notice of their responsibilities and awareness of the specifics of your project.

13. What steps will be taken to alleviate any pain, distress, or discomfort the animals may experience as a result of the experimental procedures, or in the event an animal experiences any adverse reactions?

14. What will be the disposition of the animals used in this course? (please check one)

- Euthanized in the lab for further sampling, judging, evaluation and /or carcasses disposed of by Incineration or other approved method.
- Harvested in commercial facilities with carcasses entering the food chain.
- Maintained under animal management conditions for future use in research
- Other. Please provide a brief description.

If euthanized please describe the euthanasia method and how the carcasses will be disposed.

Is the euthanasia method consistent with the standards set forth by the AVMA Panel on Euthanasia (2000) (See <http://www.avma.org/resources/euthanasia.pdf>)?

- YES NO. If no, explain why the unapproved method has been chosen

15. Is it planned that the animals will die as a result of the treatment during the course, i.e. will the treatment of the animals result in death?

- NO YES. If yes provide a scientific justification

16. PI Qualifications, Certifications, and/or Training for this particular course, procedure, and/or project:

NDSU is a decentralized animal care program and thus each PI is responsible for the adequate care of the animals for each project. For each project they must demonstrate to the IACUC that

they are qualified and trained to care for the animals and are proficient in the procedures they perform. All technicians and assistants are also required to demonstrate proficiency and ability to manage the animal care for this project under their mentors or the Principle Investigator.

Principal Investigator Certifications::

As Principal Investigator for this project, I certify that I have:

- (Category D or E)** carefully considered alternatives to the use of live animals for this project (e.g. mathematical models, computer simulation, *in vitro* biological systems) and have attached the written documentation of the search as a part of this protocol;
- completed the institutionally required investigator training course(s);
- certified that all individuals working on this project who are at risk are participating in the Institution's Occupational Health and Safety program (**Appendix A**);
- certified that the individuals listed as personnel on this project are authorized to conduct procedures involving animals under this proposal and have completed the institutionally required training courses (**Appendix A**);
- (Category D or E)** considered alternatives to procedures that may cause more than a momentary or slight pain or distress to the animals and *have attached a written narrative description of the methods and sources I used to determine that alternatives were not available*; and
- (Category D or E)** determined that the activities described in this study do not unnecessarily duplicate previous experiments (if activities will duplicate previous experiments, I have included a written explanation of and justification for the duplicative procedures).

and I agree to:

- execute this work as described in this protocol;
- request approval from the IACUC for changes in the project;
- notify the Attending Veterinarian and/or the IACUC of any unexpected study results that impact animal welfare;
- comply with the guidelines in the University's IACUC Policies and Procedures Manual;
- be familiar with and comply with all pertinent institutional, state, and federal rules and policies;
- follow all Occupational Health and Safety guidelines; and
- be responsible for the supervision and work of my staff.

I certify that the information in this application is essentially the same as contained in the course outline. The IACUC will be notified of any changes in the proposed teaching exercises, or personnel, relative to this application, prior to proceeding with any animal manipulation. I will not proceed with any animal manipulation until approval by the IACUC is granted.

Principal Investigator

Date

As this teaching, testing and or research project conducted during a course will be supported by departmental/internal/personal or non-peered reviewed funds, I endorse the above assurance and certify that I have reviewed this protocol description and it is judged to be of scientific merit and the proper resources have been allocated to properly care for and use the animals described in the protocol.

Departmental Authorization

Date

Final authorization of IACUC

IACUC Chair

Date

Appendix A Personnel Documentation

Training Documentation: Animal Supervisor Checklist

Note: Other training courses offered by the IACUC can be found on the NDSU Blackboard web site at: <http://blackboard.ndsu.nodak.edu/?bbatt=Y>. Please contact the IACUC office for enrollment information. Please note below training of seasonal employees and temporary employees.

Name (last) PI (first) (MI)

Department Title/Position

Campus Address Phone E-mail

Personnel Name: One name per box	Animal Species/ Common Name(s)	Animal Welfare and the NDSU IACUC	Other: (please indicate)	Other: (please indicate)	Laboratory and Chemical Safety Training	Date Last completed	Baseline Safety Training	Date Last completed	Completed the employee Health Assessment and Risk Assessment for the duties
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab					YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab					YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab					YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab					YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab					YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab					YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab					YES <input type="checkbox"/> NO <input type="checkbox"/>

NOTES:

If extra Sheets and spaces are needed, copy this page.

Appendix B
Surgery

Where will the surgery be performed?

Building

Room Number

Sterile surgery Non-sterile surgery

Please describe the surgical procedure(s) to be performed.

Appendix C
Anesthesia/Analgesia

Anesthesia:

Type of anesthesia to be used:

Dose:

Route of administration:

Frequency of anesthesia:

Length of anesthesia:

Who is responsible for maintaining the anesthesia?

Methods used to monitor anesthesia:

If inhalation anesthetics are used, describe the system for scavenging waste anesthetic gas?

Describe post-anesthetic care?

Analgesics and/or tranquilizers:

Type of analgesic to be used:

Dose:

Route of administration:

Restraint devices used:

Duration of Restraint:

The use of expired medical materials in animals is prohibited ([Animal Care Policy #3](#)). The only acceptable use of expired materials is in animals that will not recover from surgical procedures where the materials used are used in that procedure. Expired drugs may not be used unless it is a euthanizing dose not intended to maintain a plain of anesthesia

Free Ranging Wildlife Protocol

To request IACUC review of a project, complete this form, and send a hardcopy with original signatures to the IACUC Office, Research 1, NDSU Research & Technology Park.

*The IACUC must review and approve **all** activities involving the use of vertebrate animals prior to their initiation. This includes animals used for research, teaching and testing.*

Title

Personnel: *ALL individuals (including PI and co-PI) must complete required training courses (please review protocol instructional page) in order to be approved for work with animals. Please include positions within the University (Faculty, Grad. Student etc) Complete **Appendix A.** for training documentation.*

Principal Investigator

Department

Campus Address prefer to be contacted by

Phone prefer to be contacted by

E-mail Address prefer to be contacted by

Co-Investigator(s)

Primary Contact for protocol issues/renewals/approvals

If working collaboratively it is the PI's responsibility to provide a copy of the protocol to everyone listed and involved in this activity and it is recommended that they receive administrative approval from other departments and directors prior to primary departmental approval.

Graduate Student(s), Staff, Assistant(s) & Technician(s)

Name	Title	Duties in regards to animals
	Graduate Student	
	Graduate Student	
	Graduate Student	
	Graduate Student	

	Graduate Student	
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To add persons after approval, email the IACUC.office@ndsu.edu describing their role on the project, when they completed training and the title and protocol number. Initiation of their work cannot start until after the person has been added to the protocol and they have completed training through the IACUC.

Anticipated Start Date:
IACUC does not grant retroactive approval.

Anticipated End Date:

Funding Source:

Notes:

Grant Submitted: No Yes Pending
(If the grant is not funded, notice should be given to the IACUC office as promptly as possible. Email notice is acceptable.)

Category: Category B Category C Category D Category E

If marked category B or C you may skip to section 2, if category D or E please complete section 1 of the protocol form.

Classifications

Category B: Animals being bred, conditioned or held for use in teaching, testing experiments, research or surgery, but not yet used for such purposes.

Category C: Animal upon which teaching, research, experiments, or test will be conducted involving no pain, distress other than routine venipuncture and handling not requiring the use of pain-relieving drugs.

Categories D or E must document alternatives to animal use.

Category D: Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesics, or tranquilizer drugs will be used.

Category E: Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesics, or tranquilizer drugs will adversely affect the procedures, results, or interpretations of the teaching, research, experiments, surgery, or tests

For examples please see IACUC website or call the IACUC office at 231-8114

1. Alternatives to Animal Use (Categories D and E)

Federal regulations require the use of alternatives to procedures that may cause more than momentary or slight pain or distress to animals (USDA Policy 12 - Written Narrative for Alternatives to Painful Procedures: <http://www.aphis.usda.gov/ac/policy/policy12>). Alternatives include the following concepts:

Be concise and use terms that non-scientist can understand. This information may be used in press releases to satisfy a freedom of information request. *(You must include enough detail here to allow the committee to judge if this is observational only)*

4. Animals to Be Used in this project:

Species/ Common name	Sex	Age	Category (B, C, D or E)*	Total Number of Animals

Research and or teaching field studies are exempted from animal care and use approval, provided that the field study are only observational in nature and do not involve capturing/trapping, physical/chemical restraint, disturbance of habitat and or invasive procedures. Observational only studies will be filed exempt. The IACUC office will maintain them for three years after anticipated completion date.

I certify that this project is only observational in nature and if I plan to make changes that will alter the activities to include more than just observations, I will notify the IACUC in writing by a submission of a wildlife protocol if those altered activities include capturing/trapping, physical/chemical restraint, disturbance of habitat and or invasive procedures.

Principal Investigator

Date

IACUC Chair

Date

Please do not file the rest of this protocol if you have certified here.

5. Why use this number of animals? Justify the number used either statistically or cite publications or experience. <http://www.ndsu.nodak.edu/ndsu/doetkott/StatConsult.html> for help on justifying numbers

6. Will surgery be involved in this project?

- No Yes. *If yes, please complete **Appendix B***

7. Will anesthesia or analgesia be involved in this project?

- No Yes. *If yes, please complete **Appendix C***

If No, briefly explain why (e.g. “none needed or used in course of study” or “would interfere with study objective because…”).

8. What is the specific goal/aim of this project?

Such as:

- What is the research or development question?
- Describe the relevance of the study to advancing scientific knowledge and/or the benefits of the study to human and/or animal health.
- Provide sufficient information to indicate that the potential new knowledge from the project justifies the use of animals.

9. Provide a complete and accurate description of the experimental procedures that will be applied to the animals. Provide sufficient detail to allow evaluation by the IACUC. (You may refer to a previously IACUC-approved Standard Operating Procedure [SOP] here, if applicable. Approved NDSU SOP’s are listed at <http://www.ndsu.nodak.edu/research/compliance/iacuc/sop/SOP.shtml>.)

- *Describe procedures, their frequency, and time points over the course of the experiments.*
- *Will the animals be captured or restrained? If yes, describe the capture and handling technique, including an estimate of how long the animal will remain in captivity and how you will minimize negative effects on the health of the animals.*
- *Manipulations to the surrounding environment (vocalizations, food or breeding sites altered, manipulated, models of conspecifics presented or broadcast for example) should be described in this section, as well as any other special procedures.*
- *Will any tissues be collected from the animals (e.g., blood samples, scales, feathers, hair, fat or muscle tissue, etc.)? If yes, describe the procedure and how discomfort will be minimized; include literature citations, when possible.*

To help with the evaluation, the IACUC needs information providing a comprehensive understanding of the techniques involved and any potential problems. Therefore, for each

procedure you must list possible problems that may be encountered using the technique, whether or not this is a standard and accepted technique, and the experience of any personnel who will use the technique. References should be provided if available. Use additional space if necessary.

10. Are Federal or State permits required?

No Yes

It is up to each PI to obtain and inquire about the needs for permits/permission for research on private and public lands.

If yes, have they been obtained (attach copies).

Yes No Pending

Please list permits:

Federal Permits

Agency	Type of permits	Permit Number

State Permits

Agency	Type of permits	Permit Number

11. Do the permits cover all personnel involved in this project and listed on the protocol?

Yes No,

if no explain (The IACUC must see updated permits for approval)

12. Where will the study take place? State, County, City, Address, township, who owns the land, provide as accurate as a description as possible. Addresses of sections # and townships are not expected, but if you are researching on lands at the Moorhead Crystal Sugar lagoons, for example, an address would be expected.

13. Will the animals be brought back to an alternate housing location for an extended period of time?

Yes No

If yes, describe the housing and period of time they will be housed, how they will be cared for and what will be the intent of housing them at this location.

How will they be transported? (Describing caging, vehicles used, provisions for food, water, and access/interaction/sight of other animals during transportation.)

14. What will be the disposition of the animals used in this Study? (Please check one)

- Euthanized in the lab for further sampling and /or carcasses disposed of by Incineration or other approved method.
- Released back into the natural habitat.
- Maintained under animal management conditions for future use in research
- Other. Please provide a brief description.

If euthanized please describe the euthanasia method and how the carcasses will be disposed.

Is the euthanasia method consistent with the standards set forth by the AVMA Panel on Euthanasia (2000) (See <http://www.avma.org/resources/euthanasia.pdf>)?

Yes No

If no, explain why the unapproved method has been chosen.

15. Is it planned that the animals will die as a result of the treatment protocol of the experiment, i.e. will the treatment of the animals result in death?

Yes No

If yes provide a scientific justification.

16. How will pain, distress, or discomfort be identified and monitored? Cite specific examples of signs and behaviors that will be used to assess pain and distress. Health and illness reports can be found on the IACUC website for reporting to the attending veterinarian.

Every person who is listed and those who will be in a position to observe the animals should be well aware of the signs of pain and distress and should be able to recognize them. All personnel as well, should have knowledge of who to call for emergencies and what course of actions they

should take in order to maintain scientific validity and animal welfare issues for each project. Please have all personnel involved read this protocol as a notice of their responsibilities and awareness of the specifics of your project.

17. What steps will be taken to alleviate any pain, distress, or discomfort the animals may experience as a result of the experimental procedures, or in the event an animal experiences any adverse reactions?

18. PI Qualifications, Certifications, and/or Training for this particular project or procedure:

NDSU is a decentralized animal care program and thus each PI is responsible for the adequate care of the animals for each project. For each project they must demonstrate to the IACUC that they are qualified and trained to care for the animals and are proficient in the procedures they perform. All technicians and assistants are also required to demonstrate proficiency and ability to manage the animal care for this project under their mentors or the Principle Investigator.

Principal Investigator Certifications:

As Principal Investigator for this project, I certify that I have:

- (Category D or E)** carefully considered alternatives to the use of live animals (e.g. mathematical models, computer simulation, *in vitro* biological systems) and have given written documentation of the search as a part of this protocol.
- completed the institutionally required investigator training course(s);
- certified that all individuals working on this project who are at risk are participating in the Institution's Occupational Health and Safety program (Appendix A);
- certified that the individuals listed as personnel for this course are authorized to conduct procedures involving animals under this proposal and have completed the institutionally required training courses (Appendix A);
- (Category D or E)** considered alternatives to procedures that may cause more than a momentary or slight pain or distress to the animals and *have attached a written narrative description of the methods and sources I used to determine that alternatives were not available* and
- (Category D or E)** determined that the activities described in this course do not unnecessarily duplicate previous experiments (if activities will duplicate previous experiments, I have included a written explanation of and justification for the duplicative procedures).

and I agree to:

- execute this work as described in this protocol;
- request approval from the IACUC for changes in the project;

- notify the Attending Veterinarian and/or the IACUC of any unexpected study results that impact animal welfare;
- comply with the guidelines in the University's IACUC Policies and Procedures Manual;
- be familiar with and comply with all pertinent institutional, state, and federal rules and policies;
- follow all Occupational Health and Safety guidelines; and
- be responsible for the supervision and work of my staff.

Principal Investigator

Date

By signing this animal use protocol the department certifies that the proposed animal use protocol has been reviewed for scientific merit, or is an essential validated diagnostic/safety/efficacy/experimental/test method.

Departmental Authorization

Date

Final authorization of IACUC

IACUC Chair

Date

Appendix A Personnel Documentation

Training Documentation: Animal Supervisor Checklist

Note: Other training courses offered by the IACUC can be found on the NDSU Blackboard web site at: <http://blackboard.ndsu.nodak.edu/?bbatt=Y>. Please contact the IACUC office for enrollment information. Please note below training of seasonal employees and temporary employees.

Name (last) PI (first) (MI)

Department Title/Position

Campus Address Phone E-mail

Personnel Name: One name per box	Animal Species/ Common Name(s)	Animal Welfare and the NDSU IACUC, Occupational health and safety with animals.	Other: (please indicate)	Other: (please indicate)	Laboratory and Chemical Safety Training	Date Last completed	Baseline Safety Training	Date Last completed	Completed the employee Health Assessment and Risk Assessment for the duties of employment
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab					YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab					YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab					YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab					YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab					YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab					YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab					YES <input type="checkbox"/> NO <input type="checkbox"/>

NOTES:

If extra Sheets and spaces are needed, copy this page.

**Appendix B
Surgery**

Where will the surgery be performed?

Building

Room Number

Sterile surgery Non-sterile surgery

Please describe the surgical procedure(s) to be performed.

**Appendix C
Anesthesia/Analgesia**

Anesthesia:

Type of anesthesia to be used:

Dose:

Route of administration:

Frequency of anesthesia:

Length of anesthesia:

Who is responsible for maintaining the anesthesia?

Methods used to monitor anesthesia:

If inhalation anesthetics are used, describe the system for scavenging waste anesthetic gas?

Describe post-anesthetic care?

Analgesics and/or tranquilizers:

Type of analgesic to be used:

Dose:

Route of administration:

Restraint devices used:

Duration of Restraint:

The use of expired medical materials in animals is prohibited ([Animal Care Policy #3](#)). The only acceptable use of expired materials is in animals that will not recover from surgical procedures where the materials used are used in that procedure. Expired drugs may not be used unless it is a euthanizing dose not intended to maintain a plain of anesthesia

Herd Management Protocol Form

To request IACUC review, complete this form, and send a hardcopy with original signatures to the IACUC Office, Research 1, NDSU Research & Technology Park.

The IACUC must review and approve activities involving the use of vertebrate animals prior to their initiation.

Title

Personnel: *ALL individuals (including PI and co-PI) must complete required training courses (please review protocol instructional page) in order to be approved for work with animals. Please include positions within the University (Faculty, Grad. Student etc) Complete **Appendix A.** for training documentation.*

Principal Investigator

Department

Campus Address prefer to be contacted by

Phone prefer to be contacted by

E-mail Address prefer to be contacted by

Co-Investigator(s)

Primary Contact for protocol issues/renewals/approvals

If working collaboratively it is the PI's responsibility to provide a copy of the protocol to everyone listed and involved in this activity and it is recommended that they receive administrative approval from other departments and directors prior to primary departmental approval.

Graduate Student(s), Staff, Assistant(s) & Technician(s)

Name	Title	Duties in regards to animals
	Graduate Student	
	Graduate Student	
	Graduate Student	
	Graduate Student	
	Graduate Student	

To add persons after approval, email the IACUC.office@ndsu.edu describing their role on the project, when they completed training and the title and protocol number. Initiation of their work can not start until after the person has been added to the protocol and they have completed training through the IACUC.

Anticipated Colony Start Date:
IACUC does not grant retroactive approval.

Anticipated Colony End Date:

It is understood that these animals are being bred and maintained to support other research efforts and teaching programs. It is understood that these animals may be transferred from one active protocol to another dependent on time of year and usage.

***** This protocol may also be used if an active protocol expires or animals are transferred to your facility prior to approval of a research or teaching protocol.**

Category: Category B [use of this protocol form is not permitted for animals in other categories]

Classifications

Category B: Animals being bred, conditioned or held for use in teaching, testing experiments, research or surgery, but not yet used for such purposes.

Category C: Animal upon which teaching, research, experiments, or test will be conducted involving no pain, distress other than routine venipuncture and handling not requiring the use of pain-relieving drugs.

Categories D or E must document alternatives to animal use.

Category D: Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesics, or tranquilizer drugs will be used.

Category E: Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesics, or tranquilizer drugs will adversely affect the procedures, results, or interpretations of the teaching, research, experiments, surgery, or tests

For examples please see IACUC website protocol instructional page or call the IACUC office at 231-8114

1. Animals to be bred/held:

Species/ Common name	Sex	Age	Total number of progeny anticipated per birthing season	Housing Location	Maximum number of animals anticipated to be held at any point in the year
	M/ F	Varies			

You should clearly outline the number of rooms/pens that you have and the total number of animals you are able to maintain in each. You can attach a separate sheet or Excel file indicating species name, ages, housing location, pen/stall/room size, caging type and size, total number of animals you can maintain under these conditions. You can review the "Ag Guide" for recommendations.

2. Where will you procure new animals? *(public market, private cooperator producer, legal vender of research animals)*

Source Name	Address	City	State

It is understood that animals will flow from active protocols back to the general herd management protocol throughout a year and unless these animals are new to the herd they need not be represented above.

3. Are health records provided with the shipment from the vender?

Yes No *If no, please provide explanation e.g. not the normal practice in cattle shipments.*

4. Describe the normal practices used for breeding (AI, natural service, harem) and parturition (calving or lambing for example) that will be used at your facility.

Who will be the primary person responsible during your parturition season?

Who will perform AI if done?

5. How will the animals be housed?

A. Please provide the following information regarding the housing and care of the animals.

1. Is special housing required e.g. ventilation chambers, isolation chambers, metabolism chambers farrowing pens?

Yes No

2. Please describe the housing provided, the number of animals per unit (cage, shoebox, pen, pasture) size of respective unit(s): *please delineate between seasonal differences in housing*

3. Please address these areas specifically.

Isolation and quarantine areas:

Source of water and availability:

Rotation of water and frequency of cleaning water bottles, sippers and stoppers:

Source of feed and availability:

Rotation of feed and frequency of cleaning holders/bins:

Bedding type:

Rotation of bedding and frequency:

Enrichment devices(scratchers, toys, exercise items):

6. How will pain, distress, or discomfort be identified and monitored? Cite specific examples of signs and behaviors that will be used to assess pain and distress in the species that you manage. Health and illness reports can be found on the IACUC website for reporting to the attending veterinarian.

Every person who is listed and those who will be in a position to observe the animals should be well aware of the signs of pain and distress and should be able to recognize them. All personnel as well, should have knowledge of who to call for emergencies and what course of actions they should take in order to maintain scientific validity and animal welfare issues for each project. Please have all personnel involved read this protocol as a notice of their responsibilities and awareness of the specifics of your project.

7. What steps will be taken to alleviate any pain, distress, or discomfort the animals may experience? Cite specific treatments for your specific examples listed above.

8. Who will be responsible for the primary veterinary care?

The use of expired medical materials in animals is prohibited ([Animal Care Policy #3](#)). The only acceptable use of expired materials is in animals that will not recover from surgical procedures where the materials used are used in that procedure. Expired drugs may not be used unless it is a euthanizing dose not intended to maintain a plain of anesthesia

9. Who will address basic/daily veterinary needs such as vaccines minor injuries and initial assessments and care for illnesses and injuries.

10. Please outline the vaccination schedule and specific vaccines drugs and treatments given to all animals.

11. PI Qualifications, Certifications, and/or Training for this particular management practices:

NDSU is a decentralized animal care program and thus each PI is responsible for the adequate care of the animals for each project. For each project they must demonstrate to the IACUC that they are qualified and trained to care for the animals and are proficient in the procedures they perform. All technicians and assistants are also required to demonstrate proficiency and ability to manage the animal care for this project under their mentors or the managers.

It is understood, that during the times of housing animals for special events and demonstrations other than at the location indicated as the primary location, these animals will be provided with similar and adequate care as the location will provide within acceptable care and practices as outlined in this protocol.

Managers Certifications:

As Manager for this facility, I certify that I have:

- completed the institutionally required training course(s);
- certified that all individuals working at the facility and caring for these animals who are at risk are participating in the Institution's Occupational Health and Safety program ([Appendix A](#));
- certified that the individuals listed as personnel for this protocol are authorized to conduct procedures involving animals under this proposal and have completed the institutionally required training courses ([Appendix A](#));

and I agree to:

- execute this work as described in this protocol;
- request approval from the IACUC for changes in the project;
- notify the Attending Veterinarian and/or the IACUC of any unexpected study results that impact animal welfare;
- comply with the guidelines in the University’s IACUC Policies and Procedures Manual;
- be familiar with and comply with all pertinent institutional, state, and federal rules and policies;
- follow all Occupational Health and Safety guidelines; and
- be responsible for the supervision and work of my staff.

I certify that the information in this application is truthful and that the proper resources have been secured to provide aforementioned care to the animals. The IACUC will be notified of any changes in the proposed activity, or personnel, relative to this application, prior to proceeding with any animal manipulation. I will not proceed with any animal manipulation until approval by the IACUC is granted.

Manger

Date

As the herd management of this protocol is conducted, I endorse the above assurance and certify that as a departmental authority I have reviewed this protocol description as adequately funded and the proper resources have been provided to assure the proper care of the animals.

Departmental Authorization

Date

Final authorization of IACUC

IACUC Chair

Date

Appendix A Personnel Documentation

Training Documentation: Animal Supervisor Checklist

Note: Other training courses offered by the IACUC can be found on the NDSU Blackboard web site at: <http://blackboard.ndsu.nodak.edu/?bbatt=Y>. Please contact the IACUC office for enrollment information. Please note below training of seasonal employees and temporary employees.

Name (last) manager (first) (MI)

Department Title/Position

Campus Address Phone E-mail

Personnel Name: One name per box	Animal Species/ Common Name(s)	Animal Welfare and the NDSU IACUC, Occupational health and safety with animals.	Other: (please indicate)	Other: (please indicate)	Laboratory and Chemical Safety Training Date Last completed	Baseline Safety Training Date Last completed	Completed the employee Health Assessment and Risk Assessment for the duties of employment
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab			YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab			YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab			YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab			YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab			YES <input type="checkbox"/> NO <input type="checkbox"/>
		<input type="checkbox"/> In-person <input type="checkbox"/> Online	<input type="checkbox"/> Online <input type="checkbox"/> In-lab	<input type="checkbox"/> Online <input type="checkbox"/> In-lab			YES <input type="checkbox"/> NO <input type="checkbox"/>

NOTES:

If extra Sheets and spaces are needed, copy this page.

Request for Change in Protocol Form

Any proposed change in a previously approved protocol, which affects animals, used for research, testing, teaching, exhibition, or any other purpose within the NDSU system must be reviewed and approved by the IACUC prior to implementation. This form must be filled out in full in order to be reviewed.

To request IACUC review of a change in protocol, complete this form, and send a hardcopy with original signatures to the IACUC Office, Research 1 Building, NDSU Research & Technology Park.

Changes that will not increase levels of pain, discomfort, or distress beyond those described by the guidelines of Pain Category C (see [Appendix A](#) for description of pain categories) may be reviewed by the expedited review procedure. Changes that increase levels of pain, discomfort, or distress to those described in Pain Categories D and E must be reviewed by the full IACUC at a convened meeting.

Principal Investigator:

Department:

Campus Address:

Phone:

E-mail Address:

Co-Investigator(s):

Primary Contact for protocol issues/renewals/approvals

Protocol Title:

IACUC Protocol #:

Original Protocol Type:

- Biomedical
- Agricultural
- Teaching
- Wildlife
- Breeding
- Herd management

1. I am proposing a change that would (check all that apply):

- Change the previously approved category.

3. Please provide a description or explanation of the proposed changes. Provide sufficient detail to allow evaluation by the IACUC. (Questions that might be addressed include: Has the research or development question changed? Describe any changes to procedures, their frequency and time points, over the course of the experiments. Include any changes in the dose and/or route of administration for any drugs used. Describe changes to methods used in behavioral studies.)

The information provided in this form accurately represents the changes I propose to make to a previously approved IACUC protocol. I am aware that the Principal Investigator Certifications that I agreed to (on the original protocol form) remain in effect with this change in protocol.

Principal Investigator

Date

By signing this animal use protocol the department certifies that the proposed animal use protocol has been reviewed for scientific merit, or is an essential validated diagnostic/safety/efficacy/research test method and that appropriate resources are available to conduct this project.

Departmental Authorization

Date

Final authorization of IACUC

IACUC Chair

Date

Appendix A
NDSU Pain and Distress Classifications

Category B: Animals being bred, conditioned or held for use in teaching, testing experiments, research or surgery, but not yet used for such purposes.

Category C: Animal upon which teaching, research, experiments, or test will be conducted involving no pain, distress other than routine venipuncture and handling not requiring the use of pain-relieving drugs.

Categories D or E must document alternatives to animal use.

Category D: Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesics, or tranquilizer drugs will be used.

Category E: Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesics, or tranquilizer drugs will adversely affect the procedures, results, or interpretations of the teaching, research, experiments, surgery, or tests

For examples please call the IACUC office at 231-8114

SOP: Cover Page

Standard Operating Procedures (SOPs) are documents or "recipes" that describe how a particular procedure is performed. SOPs are intended to eliminate redundancy of procedures that are routinely performed by investigators. The person who performs the procedure most often may be the person who is best qualified to write the SOP.

To request IACUC review of a revision of a current SOP, complete this form, attach your previous SOP, and return them to the IACUC Office.

Principal Investigator:

Department:

Campus Address:

Phone:

E-mail Address:

Co-Investigator(s):

Primary Contact for SOP issues/renewals/approvals

SOP Title:

Writing the SOP: *SOPs shall be written in an outline form using a succinct prose style. The words "will" or "shall" are to be used in describing procedural steps. The words "should," "could," and "may" are to be avoided as they convey to the reader that an option may exist. Sections of the SOP will be numbered using roman numerals, capitalized alphabetical letters, numbers, and lower case alphabetical letters. SOPs will have a title, describe the purpose of the procedure, contain a list of the materials and equipment, enumerate the procedural steps, and inform the reader of health or safety concerns. See <http://www.ndsu.nodak.edu/research/compliance/iacuc/sop/SOP.shtml> for examples and proper format of NDSU SOPs. Draft the SOP on separate pages (i.e., as a Word document) and attach to this cover page.*

Principal Investigator

Date

Departmental Authorization

Date

IACUC Approval (Chair)

Date

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APPENDIX B**Institutional Animal Care and Use Committee (IACUC)**

For the protection of animal subjects

**FY 2006 (July 1, 2005- June 30, 2006)**

Institutional Official: Dr. Philip Boudjouk – VP for Research, Creative Activities & Technology
 Transfer (Philip.Boudjouk@ndsu.edu, (701) 231-6542)

Name/Department	Office	Phone	E-Mail	Term
Dr. Jayma Moore Plant Pathology (Chair)	NCSL – rm 109	231-8435	jayma.moore@ndsu.edu	2005-2006
Dr. Neil Dyer Veterinary Diagnostic Services (Attending Veterinarian)	161 Van Es	231-7521	neil.dyer@ndsu.nodak.edu	2005-2006
Dr. Don Galitz Biological Sciences (Botany/Biology) (ethicist)	322 Stevens Hall	237-0773	donald.galitz@ndsu.nodak.edu	2004-2007
Dr. Penelope Gibbs Vet and Microbiological Sciences (scientist)	Van Es 152	231-6726	Penelope.gibbs@ndsu.nodak.edu	2004-2007
Dr. Dale Redmer Animal & Range Sciences (scientist)	187 Hultz Hall	231-7991	Dale.redmer@ndsu.nodak.edu	2006-2009
Vacant - TBA				
REC representative - TBA				2006-2009
Dr. Sarah Wagner, Alternate A.V. Animal & Range Sciences (Vet Tech Program) (scientist)	101 Robinson	231-5393	Sarah.wagner@ndsu.nodak.edu	2004-2007
Dr. Mark Clark Biological Sciences (Biology) (scientist)	Stevens Hall 119	231-8246	m.e.clark@ndsu.nodak.edu	2004-2007
Dr. Michelle Mostrom Veterinary & Microbiological Science (DVM/scientist)	Van Es 186	231-7529	Michelle.mostrom@ndsu.edu	2005-2008
Jim Levitt Bethel Evangelical Free Church (non-affiliated member, non-scientist)	2702 30 th Ave. S.W. Fargo, ND 58103	232-7776	jlevitt@bethelfc.com	2004-2007
Tim Johnson ANPC, Research Specialist (ARS) (scientist)	ANPC (Hultz Hall)	231-7612 799-7847	timothy.johnson@ndsu.edu	2005-2007
Bin Guo Pharmaceutical Sciences (scientist)	Sudro Hall 11	231-5164	Bin.guo@ndsu.edu	2005-2008

Ex-Officio Members (Non-Voting)

Valrey Kettner Asst. VP for Sponsored Programs Administration	106 Research 1 Tech Park	231-9608	val.kettner@ndsu.nodak.edu	Permanent
Pierre A. Freeman Sponsored Programs Admin. (IACUC Executive Director)	132 Research 1 Tech Park	231-8114	Pierre.freeman@ndsu.nodak.edu	Permanent
Jolean Pederson Office of Police and Safety (Public Health and Safety Coordinator).	ANPC Building	231-9587	Jolean.Pederson@ndsu.nodak.edu	Permanent

APPENDIX C

U.S. GOVERNMENT PRINCIPLES FOR THE UTILIZATION AND CARE OF VERTEBRATE ANIMALS USED IN TESTING, RESEARCH, AND TRAINING

The development of knowledge necessary for the improvement of the health and well-being of humans as well as other animals requires in vivo experimentation with a wide variety of animal species. Whenever U.S. Government agencies develop requirements for testing, research, or training procedures involving the use of vertebrate animals, the following principles shall be considered; and whenever these agencies actually perform or sponsor such procedures, the responsible Institutional Official shall ensure that these principles are adhered to:

- I. The transportation, care, and use of animals should be in accordance with the Animal Welfare Act (7 U.S.C. 2131 et. seq.) and other applicable Federal laws, guidelines, and policies.*
- II. Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.
- III. The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and *in vitro* biological systems should be considered.
- IV. Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.
- V. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents.
- VI. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.
- VII. The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, the housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied. In any case, veterinary care shall be provided as indicated.

* For guidance throughout these Principles, the reader is referred to the *Guide for the Care and Use of Laboratory Animals* prepared by the Institute of Laboratory Animal Resources, National Academy of Sciences.

- VIII. Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals.

- IX. Where exceptions are required in relation to the provisions of these Principles, the decisions should not rest with the investigators directly concerned but should be made, with due regard to Principle II, by an appropriate review group such as an institutional animal care and use committee. Such exceptions should not be made solely for the purposes of teaching or demonstration.

APPENDIX D

USDA ANIMAL WELFARE REGULATIONS

from

Code of Federal Regulations
Title 9, Volume 1, Parts 1 to 199
Revised as of January 1, 2000

TITLE 9 – ANIMALS AND ANIMAL PRODUCTS

CHAPTER I – ANIMAL AND PLANT HEALTH INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

SUBCHAPTER A – ANIMAL WELFARE

PARTS 1, 2, and 3

*[As the chapter is too long to reprint here, please download it from
<http://www.aphis.usda.gov/ac/9CFR99.html>, or send an e-mail to Ace@usda.gov for the most
recent version.]*

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APPENDIX E

ANIMAL WELFARE ACT

[Available at <http://www.aphis.usda.gov:80/ac/publications.html>]

ANIMAL WELFARE ACT as amended
(7 U.S.C. §§ 2131 et. seq.)

Section 1.

(a) This Act may be cited as the “Animal Welfare Act”.

(b) The Congress finds that animals and activities which are regulated under this Act are either in interstate or foreign commerce or substantially affect such commerce or the free flow thereof, and that regulation of animals and activities as provided in this Act is necessary to prevent and eliminate burdens upon such commerce and to effectively regulate such commerce, in order—

(1) to insure that animals intended for use in research facilities or for exhibition purposes or for use as pets are provided humane care and treatment;

(2) to assure the humane treatment of animals during transportation in commerce; and

(3) to protect the owners of animals from the theft of their animals by preventing the sale or use of animals which have been stolen.

The Congress further finds that it is essential to regulate, as provided in this Act, the transportation, purchase, sale, housing, care, handling, and treatment of animals by carriers or by persons or organizations engaged in using them for research or experimental purposes or for exhibition purposes or holding them for sale as pets or for any such purpose or use. The Congress further finds that—

(1) the use of animals is instrumental in

certain research and education for advancing knowledge of cures and treatment for diseases and injuries which afflict both humans and animals;

(2) methods of testing that do not use animals are being and continue to be developed which are faster, less expensive, and more accurate than traditional animal experiments for some purposes and further opportunities exist for the development of these methods of testing;

(3) measures which eliminate or minimize the unnecessary duplication of experiments on animals can result in more productive use of Federal funds; and

(4) measures which help meet the public concern for laboratory animal care and treatment are important in assuring that research will continue to progress.

(7 U.S.C. § 2131) (P.L. 89-544, § 1, Aug. 24, 1966, 80 Stat. 350; P.L. 91-579, § 2, Dec. 24, 1970, 84 Stat. 1560; renumbered and amended by P.L. 94-279, § 2, Apr. 22, 1976, 90 Stat. 417)

Section 2. When used in this Act—

(a) The term “Person” includes any individual, partnership, firm, joint stock company, corporation, association, trust, estate, or other legal entity;

(b) The term “Secretary” means the Secretary of Agriculture of the United States or his representative who shall be an employee of the United States Department of Agriculture;

(c) The term “commerce” means trade, traffic, transportation, or other commerce (1) between a place in a State and any place outside of such State, or between points within the same State but through any place outside thereof, or within any territory, possession, or the District of Columbia; (2) which affects trade, traffic, transportation, or other commerce described in paragraph (1),

(d) The term “State” means a State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, or any other territory or possession of the United States;

(e) The term “research facility” means any school (except an elementary or secondary school), institution, organization, or person that uses or intends to use live animals in research, tests, or experiments, and that (1) purchases or transports live animals in commerce, or (2) receives funds under a grant, award, loan, or contract from a department, agency, or instrumentality of the United States for the purpose of carrying out research, tests, or experiments: Provided, That the school, institution, organization, or person that does not use or intend to use live dogs or cats, except those schools, institutions, organizations, or persons, which use substantial numbers (as determined by the Secretary) or live animals the principal function of which schools, institutions, organizations, or persons, is biomedical research or testing, when in the judgment of the Secretary, any such exemption does not vitiate the purpose of this Act;

(f) The term “dealer” means any person who, in commerce, for compensation or profit, delivers for transportation, or transports, except as a carrier, buys, or sells, or negotiates the purchase or sale of, (1) any dog or other animal whether alive or dead for research, teaching, exhibition, or use as a pet, or (2) any dog for hunting,

security, or breeding purposes, except that this term does not include

(i) a retail pet store except such store which sells any animals to a research facility, an exhibitor, or a dealer; or

(ii) any person who does not sell, or negotiate the purchase or sale of any wild animal, dog, or cat and who derives no more than \$500 gross income from the sale of other animals during any calendar year;

(g) The term “animal” means any live or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or such other warm-blooded animal, as the Secretary may determine is being used, or is intended for use, for research, testing, experimentation, or exhibition purposes or as a pet; but such term excludes horses not used for research purposes and other farm animals, such as, but not limited to livestock or poultry, used or intended for use as food or fiber, or livestock or poultry used or intended for improving animal nutrition, breeding, management or production efficiency, or for improving the quality of food or fiber. With respect to a dog the term means all dogs including those used for hunting, security, or breeding purposes;

(h) The term “exhibitor” means any person (public or private) exhibiting any animals, which were purchased in commerce or the intended distribution of which affects commerce, or will affect commerce, to the public for compensation, as determined by the Secretary, and such term includes carnivals, circuses, and zoos exhibiting such animals whether operated for profit or not; but such term excludes retail pet stores, organizations sponsoring and all persons participating in State and country fairs, livestock shows, rodeos, purebred dog and cat shows, and any other fairs or exhibitions intended to advance agricultural arts and sciences, as may be determined by the Secretary;

(i) The term “intermediate handler” means any person including a department, agency, or instrumentality of the United States or of any State or local government (other than a dealer, research facility, exhibitor, any person excluded from the definition of a dealer, research facility, or exhibitor, an operator of an auction sale, or a carrier) who is engaged in any business in which he receives custody of animals in connection with their transportation in commerce; and

(j) The term “carrier” means the operator of any airline, railroad, motor carrier, shipping line, or other enterprise, which is engaged in the business or transporting any animals for hire.

(k) The term “Federal agency” means an Executive agency as such term is defined in section 105 of Title 5, United States Code, and with respect to any research facility means the agency from which the research facility means the agency from which the research facility receives a Federal award for the conduct of research, experimentation, or testing, involving the use of animals;

(l) The term “Federal award for the conduct of research, experimentation, or testing, involving the use of animals” means any mechanism (including a grant, award, loan, contract, or cooperative agreement) under which Federal funds are provided to support the conduct of such research;

(m) The term “quorum” means a majority of the Committee members;

(n) The term “Committee” means the Institutional Animal Committee established under section 13(b); and

(o) The term “Federal research facility” means each department, agency, or instrumentality of the United States which uses live animals for research of experimentation.

(7 U.S.C. § 2132) (P.L. 89-544, § 2, Aug. 24, 1966, 80 Stat. 350; P.L. 91-579, § 3, Dec. 24, 1970, 84 Stat. 1560; P.L. 94-279 §§

3, 4, Apr. 22, 1976, 90 Stat. 417, 418; P.L. 99-198, Title XVII, § 1756(a), Dec. 23, 1985,, 99 Stat. 1650)

Section 3. The Secretary shall issue licenses to dealers and exhibitors upon application therefore in such form and manner as he may prescribe and upon payment of such fee established pursuant to section 23 of this Act: Provided, That no such license shall be issued until the dealer or exhibitor shall have demonstrated that his facilities comply with the standards promulgated by the Secretary pursuant to section 13 of this Act: Provided, however, That any retail pet store or other person who derives less than a substantial portion of his income (as determined by the Secretary) from the breeding and raising of dogs or cats on his own premises and sells any such dog or cat to a dealer or research facility shall not be required to obtain a license as a dealer or exhibitor under this Act. The Secretary is further authorized to license, as dealers or exhibitors persons who do not qualify as dealers or exhibitors within the meaning of this Act upon such persons complying with the requirements specified above and agreeing, in writing, to comply with all the requirements of this Act and the regulations promulgated by the Secretary hereunder.

(7 U.S.C. § 2133) (P.L. 89-544, § 3, Aug. 24, 1966, 80 Stat. 351; P.L. 91-579, § 4, Dec. 24, 1970, 84 Stat. 1561)

Section 4. No dealer or exhibitor shall sell or offer to sell or transport or offer for transportation, in commerce, to any research facility or for exhibition or for use as a pet any animal, or buy, sell, offer to buy or sell, transport or offer for transportation, in commerce, to or from another dealer or exhibitor under this Act any animal, unless and until such dealer or exhibitor shall have obtained a license from the Secretary and

such license shall not have been amended or revoked.

(7 U.S.C. § 2134) (P.L. 89-544, § 4, Aug. 24, 1966, 80 Stat. 351; P.L. 91-579, § 5, Dec. 24, 1970, 84 Stat. 1561; P.L. 94-279, § 5, Apr. 22, 1976, 90 Stat. 418)

Section 5. No dealer or exhibitor shall sell or dispose of any dog or cat within a period of 5 business days after the acquisition of such animal or within such other period as may be specified by the Secretary: Provided, that operators of auction sales subject to section 12 of this Act shall not be required to comply with the provisions of this section.

(7 U.S.C. § 2135) (P.L. 89-544, § 5, Aug. 24, 1966, 80 Stat. 351; P.L. 91-579, § 6, Dec. 24, 1970, 84 Stat. 1561)

Section 6. Every research facility, every intermediate handler, every carrier, and every exhibitor not licensed under section 3 of this Act shall register with the Secretary in accordance with such rules and regulations as he may prescribe.

(7 U.S.C. § 2136) (P.L. 89-544, § 6, Aug. 24, 1966, 80 Stat. 351; P.L. 91-579, § 7, Dec. 24, 1970, 84 Stat. 1561; P.L. 94-279, § 6, Apr. 22, 1976, 90 Stat. 418)

Section 7. It shall be unlawful for any research facility to purchase any dog or cat from any person except an operator of an auction sale subject to section 12 of this Act or a person holding a valid license as a dealer or exhibitor issued by the Secretary pursuant to this Act unless such person is exempted from obtaining such license under section 3 of this Act.

(7 U.S.C. § 2137) (P.L. 89-544, § 7, Aug. 24, 1966, 80 Stat. 351; P.L. 91-579, § 8, Dec. 24, 1970, 84 Stat. 1561)

Section 8. No department, agency, or instrumentality of the United States which uses animals for research or experimentation or exhibition shall purchase or otherwise acquire any dog or cat for such purposes from any person except an operator of an auction sale subject to section 12 of this Act or a person holding a valid license as a dealer or exhibitor issued by the Secretary pursuant to this Act unless such person is exempted from obtaining such license under section 3 of this Act.

(7 U.S.C. § 2138) (P.L. 89-544, § 8, Aug. 24, 1966, 80 Stat. 351; P.L. 91-579, § 9, Dec. 24, 1970, 84 Stat. 1562)

Section 9. When construing or enforcing the provisions of this Act, the act, omission, or failure of any person acting for or employed by a research facility, a dealer, or an exhibitor or a person licensed as a dealer or an exhibitor pursuant to the second sentence of section 3, or an operator of an auction sale subject to section 12 of this Act, or an intermediate handler or a carrier, within the scope of his employment or office, shall be deemed the act, omission, or failure of such research facility, dealer, exhibitor, licensee, operator of an auction sale, intermediate handler, or carrier, as well of such person.

(7 U.S.C. § 2139) (P.L. 89-544, § 9, Aug. 24, 1966, 80 Stat. 351; P.L. 91-579, § 10, Dec. 24, 1970, 84 Stat. 1562; P.L. 94-279, § 7, Apr. 22, 1976, 90 Stat. 418)

Section 10. Dealers and exhibitors shall make and retain for such reasonable period of time as the Secretary may prescribe, such records with respect to the purchase, sale, transportation, identification, and previous

ownership of animals as the Secretary may prescribe. Research facilities shall make and retain such records only with respect to the purchase, sale, transportation, identification, and previous ownership of live dogs and cats. At the request of the Secretary, any regulatory agency of the Federal Government which requires records to be maintained by intermediate handlers and carriers with respect to the transportation, receiving, handling, and delivery of animals on forms prescribed by the agency, shall require there to be included in such forms, and intermediate handlers and carriers shall include in such forms, such information as the Secretary may require for the effective administration of this Act. Such information shall be retained for such reasonable period of time as the Secretary may prescribe. If regulatory agencies of the Federal Government do not prescribe requirements for any such forms, intermediate handlers and carriers shall make and retain for such reasonable period as the Secretary may prescribe such records with respect to the transportation, receiving, handling, and delivery of animals as the Secretary may prescribe. Such records shall be made available at all reasonable times for inspection and copying by the Secretary.

(7 U.S.C. § 2140) (P.L. 89-544, § 10, Aug. 24, 1966, 80 Stat. 351; P.L. 91-579, § 11, Dec. 24, 1970, 84 Stat. 1562; P.L. 94-279, § 8, Apr. 22, 1976, 90 Stat. 418)

Section 11. All animals delivered for transportation, transported, purchased, or sold, in commerce, by a dealer or exhibitor shall be marked or identified at such time and in such humane manner as the Secretary may prescribe: Provided, That only live dogs and cats need be so marked or identified by a research facility.

(7 U.S.C. § 2141) (P.L. 89-544, § 11, Aug. 24, 1966, 80 Stat. 351; P.L. 91-579, § 12, Dec. 24, 1970, 84 Stat. 1562; P.L. 94-279, § 5, Apr. 22, 1976, 90 Stat. 418)

Section 12. The Secretary is authorized to promulgate humane standards and recordkeeping requirements governing the purchase, handling, or sale of animals, in commerce, by dealers, research facilities, and exhibitors at auction sales and by the operators of such auction sales. The Secretary is also authorized to require the licensing of operators of auction sales where any dogs or cats are sold, in commerce, trader such conditions as he may prescribe, and upon payment of such fee as prescribed by the Secretary under section 23 of this Act.

(7 U.S.C. § 2142) (P.L. 89-544, § 12, Aug. 24, 1966, 80 Stat. 351; P.L. 91-579, § 13, Dec. 24, 1970, 84 Stat. 1562; P.L. 94-279, § 5, Apr. 22, 1976, 90 Stat. 418.)

Section 13. (a)(1) The Secretary shall promulgate standards to govern the humane handling, care, treatment, and transportation of animals by dealers, research facilities, and exhibitors.

(2) The standards described in paragraph (1) shall include minimum requirements—
(A) for handling, housing, feeding, watering, sanitation, ventilation, shelter from extremes of weather and temperatures, adequate veterinary care, and separation by species where the Secretary finds necessary for humane handling, care, or treatment of animals; and

(B) for exercise of dogs, as determined by an attending veterinarian in accordance with the general standards promulgated by the Secretary, and for a physical environment adequate to promote the psychological well-being of primates.

(3) In addition to the requirements under

paragraph (2), the standards described in paragraph (1) shall, with respect to animals in research facilities, include requirements—

(A) for animal care, treatment, and practices in experimental procedures to ensure that animal pain and distress are minimized, including adequate veterinary care with the appropriate use of anesthetic, analgesic or tranquilizing drugs, or euthanasia;

(B) that the principal investigator considers alternatives to any procedure likely to produce pain or distress in an experimental animal;

(C) in any practice which could cause pain to animals—

(i) that a doctor of veterinary medicine is consulted in the planning of such procedures;

(ii) for the use of tranquilizers, analgesics, and anesthetics;

(iii) for presurgical and postsurgical care by laboratory workers in accordance with established veterinary medical and nursing procedures;

(iv) against the use of paralytics without anesthesia; and

(v) that the withholding of tranquilizers, anesthesia, analgesia, or euthanasia when scientifically necessary shall continue for only the necessary period of time;

(D) that no animal is used in more than one major operative experiment from which it is allowed to recover except in cases of—

(i) scientific necessity; or

(ii) other special circumstances as determined by the Secretary; and

(E) that exceptions to such standards may be made only when specified by research protocol and that any such exception shall be detailed and explained in a report outlined under paragraph (7) and filed with the Institutional Animal Committee.

(4) The Secretary shall also promulgate standards to govern the transportation in commerce to govern the transportation in commerce, and the handling, care, and

treatment in connection therewith, by intermediate handlers, air carriers, or other carriers, of animals consigned by a dealer, research facility, exhibitor, operator of an auction sale, or other person, or any department, agency, or instrumentality of the United States or of any State or local government, for transportation in commerce.

The Secretary shall have authority to promulgate such rules and regulations as he determines necessary to assure humane treatment of animals in the course of their transportation in commerce including requirements such as those with respect to containers, feed, water, rest, ventilation, temperature, and handling.

(5) In promulgating and enforcing standards established pursuant to this section, the Secretary is authorized and directed to consult experts, including outside consultants where indicated.

(6)(A) Nothing in this Act—

(i) except as provided in paragraph (7) of this subsection, shall be construed as authorizing the Secretary to promulgate rules, regulations, or orders with regard to design, outlines, guidelines or performance of actual research or experimentation by a research facility as determined by such research facility;

(ii) except as provided in subparagraphs(A) and (C)(ii) through (v) of paragraph (3) and paragraph (7) of this subsection, shall be construed as authorizing the Secretary to promulgate rules, regulations, or orders with regard to the performance of actual research or experimentation by a research facility as determined by such research facility; and

(iii) shall authorize the Secretary, during inspection, to interrupt the conduct of actual research or experimentation.

(B) No rule, regulation, order, or part of this Act shall be construed to require a research facility to disclose publicly or to the Institutional Animal Committee during its inspection, trade secrets or commercial or

financial information which is privileged or confidential.

(7)(A) The Secretary shall require each research facility to show upon inspection, and to report at least annually, that the provisions of this Act are being followed and that professionally acceptable standards governing the care, treatment, and use of animals are being followed by the research facility during actual research or experimentation.

(B) In complying with subparagraph (A), such research facilities shall provide—

(i) information on procedures likely to produce pain or distress in any animal and assurances demonstrating that the principal investigator considered alternatives to those procedures;

(ii) assurances satisfactory to the Secretary that such facility is adhering to the standards described in this section; and (iii) an explanation for any deviation from the standards promulgated under this section.

(8) Paragraph (1) shall not prohibit any State (or a political subdivision of such State) from promulgating standards in addition to those standards promulgated by the Secretary under paragraph (1).

(b)(1) The Secretary shall require that each research facility establish at least one Committee. Each Committee shall be appointed by the chief executive officer of each such research facility and shall be composed of not fewer than three members. Such members shall possess sufficient ability to assess animal care, treatment, and practices in experimental research as determined by the needs of the research facility and shall represent society's concerns regarding the welfare of animal subjects used at such facility. Of the members of the Committee—

(A) at least one member shall be a doctor of veterinary medicine;

(B) at least one member—

(i) shall not be affiliated in any way with such facility other than as a member of the Committee—

(ii) shall not be a member of the immediate family of a person who is affiliated with such facility; and

(iii) is intended to provide representation for general community interests in the proper care and treatment of animals; and

(C) in those cases where the Committee consists of more than three members, not more than three members shall be from the same administrative unit of such facility.

(2) A quorum shall be required for all formal actions of the Committee, including inspections under paragraph (3).

(3) The Committee shall inspect at least semiannually all animal study areas and animal facilities of such research facility and review as part of the inspection—

(A) practices involving pain to animals, and

(B) the condition of animals, to ensure compliance with the provisions of this Act to minimize pain and distress to animals. Exceptions to the requirement of inspection of such study areas may be made by the Secretary if animals are studied in their natural environment and the study area is prohibitive to easy access.

(4)(A) The Committee shall file an inspection certification report of each inspection at the research facility. Such report shall—

(i) be signed by a majority of the Committee members involved in the inspection;

(ii) include reports of any violation of the standards promulgated, or assurances required, by the Secretary, including any deficient conditions of animal care or treatment, any deviations of research practices from originally approved proposals that adversely affect animal welfare, any notification to the facility regarding such conditions and any corrections made thereafter;

(iii) include any minority views of the

Committee; and

(iv) include any other information pertinent to the activities of the Committee.

(B) Such report shall remain on file for at least 3 years at the research facility and shall be available for inspection by the Animal and Plant Health Inspection Service and any funding Federal agency.

(C) In order to give the research facility an opportunity to correct any deficiencies or deviations discovered by reason of paragraph (3), the Committee shall notify the administrative representative of the research facility of any deficiencies or deviations from the provisions of this Act. If, after notification and an opportunity for correction, such deficiencies or deviations remain uncorrected, the Committee shall notify (in writing) the Animal and Plant Health Inspection Service and the funding Federal Agency of such deficiencies or deviations.

(5) The inspection results shall be available to Department of Agriculture inspectors for review during inspections. Department of Agriculture inspectors shall forward any Committee inspection records which include reports of uncorrected deficiencies or deviations to the Animal and Plant Health Inspection Service and any funding Federal agency of the project with respect to which such uncorrected deficiencies and deviations occurred.

(c) In the case of Federal research facilities, a Federal Committee shall be established and shall have the same composition and responsibilities provided in subsection (b) of this section, except that the Federal Committee shall report deficiencies or deviations to the head of the Federal agency conducting the research rather than to the Animal and Plant Health Inspection Service. The head of the Federal agency conducting the research shall be responsible for—

(1) all corrective action to be taken at the facility; and

(2) the granting of all exceptions to inspection protocol.

(d) Each research facility shall provide for the training of scientists, animal technicians, and other personnel involved with animal care and treatment in such facility as required by the Secretary. Such training shall include instruction on—

(1) the humane practice of animal maintenance and experimentation;

(2) research or testing methods that minimize or eliminate the use of animals or limit animal pain or distress;

(3) utilization of the information service at the National Agricultural Library, established under subsection (e) of this section; and

(4) methods whereby deficiencies in animal care and treatment should be reported.

(e) The Secretary shall establish an information service at the National Agricultural Library. Such service shall, in cooperation with the National Library of Medicine, provide information—

(1) pertinent to employee training;

(2) which could prevent unintended duplication of animal experimentation as determined by the needs of the research facility; and

(3) on improved methods of animal experimentation, including methods which could—

(A) reduce or replace animal use; and

(B) minimize pain and distress to animals, such as anesthetic and analgesic procedures.

(f)₁ (See footnote on last page) In any case in which a Federal agency funding a research project determines that conditions of animal care, treatment, or practice in a particular project have not been in compliance with standards promulgated under this Act, despite notification by the Secretary or such Federal agency to the research facility and an opportunity for correction, such agency shall suspend or revoke Federal support of the project. Any research facility losing

Federal support as a result of actions taken under the preceding sentence shall have the right of appeal as provided in sections 701 through 706 of Title 5, United States Code. (f)²No dogs or cats, or additional kinds or classes of animals designated by regulation of the Secretary, shall be delivered by any dealer, research facility, exhibitor, operator of an auction sale, or department, agency, or instrumentality of the United States or of any State or local government, to any intermediate handler or carrier for transportation in commerce or received by any such handler or carrier for such transportation from any such person, department, agency, or instrumentality, unless the animal is accompanied by a certificate issued by a veterinarian licensed to practice veterinary medicine, certifying that he inspected the animal on a specified date, which shall not be more than 10 days before such delivery, and, when so inspected, the animal appeared free of any infectious disease or physical abnormality which would endanger the animal or animals or other animals or endanger public health: Provided, however, That the Secretary may by regulation provide exceptions to this certification requirement, under such conditions as he may prescribe in the regulations, for animals shipped to research facilities for purposes of research, testing or experimentation requiring animals not eligible for such certification. Such certificates received by the intermediate handlers and the carriers shall be retained by them, as provided by regulations of the Secretary, in accordance with section 10 of this Act.

(g) No dogs or cats, or additional kinds or classes of animals designated by regulation of the Secretary, shall be delivered by any person to any intermediate handler or carrier for transportation in commerce except to registered research facilities if they are less than such age as the Secretary may by

regulation prescribe. The Secretary shall designate additional kinds and classes of animals and may prescribe different ages for particular kinds or classes of dogs, cats, or designated animals, for the purposes of this section, when he determines that such action is necessary or adequate to assure their humane treatment in connection with their transportation in commerce.

(h) No intermediate handler or carrier involved in the transportation of any animal in commerce shall participate in any arrangement or engage in any practice under which the cost of such animal or the cost of the transportation of such animal is to be paid and collected upon delivery of the animal to the consignee, unless the consignor guarantees in writing the payment of transportation charges for any animal not claimed within a period of 48 hours after notice to the consignee of arrival of the animal, including, where necessary, both the return transportation charges and an amount sufficient to reimburse the carrier for all out-of-pocket expenses incurred for the care, feeding, and storage of such animals.

(7 U.S.C. 2143) (P.L. 89-544, §13, Aug.24, 1966, 80 STAT. 352; P.L. 91-579, §14, Dec. 24, 1970, 84 Stat- 1562; P-L94-279, §§ 9, 10, April 22, 1976, 90 Stat- 418; P.L. 99-198, Title XVII, § 1752, Dec. 23, 1985, 99 Stat- 1645)

Section 14. Any department, agency or instrumentality of the United States having laboratory animal facilities shall comply with the standards and other requirements promulgated by the Secretary for a research facility under section 13 (a), (f), (g), and (h). Any department, agency, or instrumentality of the United States exhibiting animals shall comply with the standards promulgated by the Secretary under section 13 (a), (f), (g), and (h).

(7 U.S.C. 2144) (P.L. 89-544, §14, Aug. 24, 1966, 80 Stat. 352; P.L-91-579, § 15, Dec. 24, 1970, 84 Stat. 1563; P-L 94-279, § 19, April 22, 1976, 90 Stat. 423; P.L. 99-198, Title XVII, § 1758, Dec. 23, 1985, 99 Stat. 1650)

Section 15. (a) The Secretary shall consult and cooperate with other Federal departments, agencies, or instrumentalities concerned with the welfare of animals used for research, experimentation or exhibition, or administration of statutes regulating the transportation in commerce or handling in connection therewith of any animals when establishing standards pursuant to section 13 and in carrying out the purposes of this Act. The Secretary shall consult with the Secretary of Health and Human Services prior to issuance of regulations. Before promulgating any standard governing the air transportation and handling in connection therewith, of animals, the Secretary shall consult with the Secretary of Transportation who shall have the authority to disapprove any such standard if he notifies the Secretary, within 30 days after such consultation, that changes in its provisions are necessary in the interest of flight safety. The Interstate Commerce Commission, the Secretary of Transportation, and the Federal Maritime Commission, to the extent of their respective lawful authorities, shall take such action as is appropriate to implement any standard established by the Secretary with respect to a person subject to regulation by it.

(b) The Secretary is authorized to cooperate with the officials of the various States or political subdivisions thereof in carrying out the purposes of this Act and of any State, local, or municipal legislation or ordinance on the same subject.

(7 U.S.C. 2145) (P.L. 89-544, § 15, Aug. 24, 1966, 80 Stat. 352; P.L. 91-579, § 16, Dec.

24, 1970, 84 Stat. 1563; P.L. 94-279, § 11, April 22, 1976, 90 Stat. 419; P.L. 98-443 § 9(i) Oct. 4, 1984, 98 Stat. 1708; P.L-99-198, Title XVII, § 1757, Dec. 23, 1985, 99 Stat. 1650).

Section 16. (a) The Secretary shall make such investigations or inspections as he deems necessary to determine whether any dealer, exhibitor, intermediate handler, carrier, research facility, or operator of an auction sale subject to section 12 of this Act, has violated or is violating any provision of this Act or any regulation or standard issued thereunder, and for such purposes, the Secretary shall, at all reasonable times, have access to the places of business and the facilities, animals, and those records required to be kept pursuant to section 10 of any such dealer, exhibitor, intermediate handler, carrier, research facility, operator of an auction sale. The Secretary shall inspect each research facility at least once each year and, in the case of deficiencies or deviations from the standards promulgated under this Act, shall conduct such follow-up inspections as may be necessary until all deficiencies or deviations from such standards are corrected. The Secretary shall promulgate such rules and regulations as he deems necessary to permit inspectors to confiscate or destroy in a humane manner any animal found to be suffering as a result of a failure to comply with any provision of this Act or any regulation or standard issued thereunder if (1) such animal is held by a dealer, (2) such animal is held by an exhibitor, (3) such animal is held by a research facility and is no longer required by such research facility to carry out the research, test or experiment for which such animal has been utilized, (4) such animal is held by an operator of an auction sale, or (5) such animal is held by an intermediate handler or a carrier.

(b) Any person who forcibly assaults, resists, opposes, impedes, intimidates, or interferes with any person while engaged in or on account of the performance of his official duties under this Act shall be fined not more than \$5,000, or imprisoned not more than 3 years, or both. Whoever, in the commission of such acts, uses a deadly or dangerous weapon shall be fined not more than \$10,000, or imprisoned not more than 10 years, or both. Whoever kills any person while engaged in or on account of the performance of his official duties under this Act shall be punished as provided under sections 1111 and 1114 of Title 18, United States Code.

(c) For the efficient administration and enforcement of this Act and the regulations and standards promulgated under this Act, the provisions (including penalties) of sections 6, 8, 9, and 10 of the Act entitled “An Act to create a Federal Trade Commission, to define its powers and duties, and for other purposes,” (15 U.S.C. 46, and 48-50; 38 Stat. 721-723, as amended) (except paragraph (c) through (h) of section 6 and the last paragraph of section 9, and the provisions of Title II of the “Organized Crime Control Act of 1970” (18 U.S.C. 60001 et. seq., 62 Stat, 856), are made applicable to the jurisdiction, powers, and duties of the Secretary in administering and enforcing the provisions of this Act and to any person, firm, or corporation with respect to whom such authority is exercised. The Secretary may prosecute any inquiry necessary to his duties under this Act in any part of the United States, including any territory, or possession thereof, the District of Columbia, or the Commonwealth of Puerto Rico. The powers conferred by said sections 9 and 10 of the Act of September 26, 1914, as amended, on the district courts of the United States may be exercised for the purposes of this Act by any district court of the United States. The United States district

courts, the District Court of Guam, the District Court to the Virgin Islands, the highest court of American Samoa, and the United States courts of the other territories, are vested with jurisdiction specifically to enforce, and to prevent and restrain violations of this Act, and shall have jurisdiction in all other kinds of cases arising under this Act, except as provided in section 19(c) of this Act.

(7 U.S.C. 2146) (P.L. 89-544, § 16, Aug. 24, 1966, 80 Stat. 352; P.L.91-579, § 17, Dec. 24, 1970, 84 Stat. 1563; P.L.94-279, § 12, April 22, 1976, 90 Stat. 420; P.L. 99-198, Title XVII, § 1753, Dec. 23, 1985, 99 Stat. 1649)

Section 17. The Secretary shall promulgate rules and regulations requiring dealers, exhibitors, research facilities, and operators of auction sales subject to section 12 of this Act to permit inspection of their animals and records at reasonable hours upon request by legally constituted law enforcement agencies in search of lost animals.

(7 U.S.C. 2147) (P.L. 89-544, § 17, Aug. 24, 1966, 80 Stat. 352; P.L.91-579, § 18, Dec. 24, 1970, 84 Stat. 1564)

Section 18. Repealed. Pub. L. 91579. Similar provisions incorporated in section 13 by P.L. 91- 579, SS 19, Dec. 24, 1970, 84 Stat. (7 U.S.C. 2148)

Section 19. (a) If the Secretary has reason to believe that any person licensed as a dealer, exhibitor, or operator of an auction sale subject to section 12 of this Act, has violated or is violating any provision of this Act, or any of the rules or regulations or standards promulgated by the Secretary hereunder, he may suspend such person’s license temporarily, but not to exceed 21 days, and after notice and opportunity for hearing,

may suspend for such additional period as he may specify, or revoke such license, if such violation is determined to have occurred.

(b) Any dealer, exhibitor, research facility, intermediate sale subject to section 12 of this Act, that violates any provision of this Act, or any rule, regulation, or standard promulgated by the Secretary thereunder, may be assessed a civil penalty by the Secretary of not more than \$2,500 for each such violation, and the Secretary may also make an order that such person shall cease and desist from continuing such violation. Each violation and each day during which a violation continues shall be a separate offense. No penalty shall be assessed or cease and desist order issued unless such person is given notice and opportunity for a hearing with respect to the alleged violation, and the order of the Secretary assessing a penalty and making a cease and desist order shall be final and conclusive unless the affected person files an appeal from the Secretary's order with the appropriate United States Court of Appeals. The Secretary shall give due consideration to the appropriateness of the penalty with respect to the size of the business of the person involved, the gravity of the violation, the person's good faith, and the history of previous violations. Any such civil penalty may be compromised by the Secretary. Upon any failure to pay the penalty assessed by a final order under this section, the Secretary shall request the Attorney General to institute a civil action in a district court of the United States or other United States court for any district in which such person is found or resides or transacts business, to collect the penalty, and such court shall have jurisdiction to hear and decide any such action. Any person who knowingly fails to obey a cease and desist order made by the Secretary under this section shall be subject to a civil penalty of \$1,500 for each offense,

and each day during which such failure continues shall be deemed a separate offense.

(c) Any dealer, exhibitor, research facility, intermediate handler, carrier, or operator of an auction sale subject to section 12 of this Act, aggrieved by a final order of the Secretary issued pursuant to this section may, within 60 days after entry of such an order, seek review of such order in the appropriate United States Court of Appeals in accordance with the provisions of section 2341, 2343 through 2350 of Title 28, United States Code, and such court shall have exclusive jurisdiction to enjoin, set aside, suspend (in whole or in part), or to determine the validity of the Secretary's order.

(d) Any dealer, exhibitor, or operator of an auction sale subject to section 12 of this Act, who knowingly violates any provision of this Act shall, on conviction thereof, be subject to imprisonment for not more than 1 year, or a fine of not more than \$2,500, or both. Prosecution of such violations shall, to the maximum extent practicable, be brought initially before United States magistrates as provided in section 636 of Title 28, United States Code, and sections 3401 and 3402 of Title 18, United States Code, and, with the consent of the Attorney General, may be conducted, at both trial and upon appeal to district court, by attorneys of the United States Department of Agriculture.

(7 U.S.C. 2149) (P.L.- 89-544, § 19, Aug. 24, 1966, 80 Stat. 352; P.L. 91-579, § 20, Dec. 24, 1970, 84 Stat. 1564; P.L. 94-279, § 13, April 22, 1976, 90 Stat. 420; P.L. 99-198, Title XVII, § 1755, Dec. 23, 1985, 99 Stat. 1650)

Section 20. Repealed. Similar provisions incorporated in section 19 by P.L. 94-279, § 14, April 22, 1976, 90 Stat. 421. (7 U.S.C. § 2150)

Section 21. The Secretary is authorized to promulgate such rules, regulations, and orders as he may deem necessary in order to effectuate the purposes of this Act.

(7 U.S.C. 2151)(P.L. 89-544, § 21, Aug. 24, 1966, 80 Stat. 353)

Section 22. If any provision of this Act or the application of any such provision to any person or circumstances shall be held invalid, the remainder of this Act and the application of any such provision to persons or circumstances other than those as to which it is held invalid shall not be affected thereby.

(7 U.S.C. 2152) (P.L. 89-544, § 22, Aug. 24, 1966, 80 Stat. 353)

Section 23. The Secretary shall charge, assess, and cause to be collected reasonable fees for licenses issued. Such fees shall be adjusted on an equitable basis taking into consideration the type and nature of the operations to be licensed and shall be deposited and covered into the Treasury as miscellaneous receipts. There are hereby authorized to be appropriated such funds as Congress may from time to time provide: Provided, That there is authorized to be appropriated to the Secretary of Agriculture for enforcement by the Department of Agriculture of the provisions of section 26 of this Act an amount not to exceed \$100,000 for the transition quarter ending September 30, 1976, and not to exceed \$400,000 for each fiscal year thereafter.

(7 U.S.C. 2153) (P.L. 89-544, § 23, Aug. 24, 1966, 80 Stat. 353; P.L. 94-279, § 18, April 22, 1976, 90 Stat. 423)

Section 24. The regulations referred to in section 10 and section 13 shall be prescribed

by the Secretary as soon as reasonable but not later than 6 months, from the date of enactment of this Act. Additions and amendments thereto may be prescribed from time to time as may be necessary or advisable. Compliance by dealers with the provisions of this Act and such regulations shall commence 90 days after the promulgation of such regulations.

Compliance by research facilities with the provisions of this Act and such regulations shall commence 6 months after the promulgation of such regulations (August 24, 1966), except that the Secretary may grant extensions of time to research facilities which do not comply with the standards prescribed by the Secretary pursuant to section 13 of this Act provided that the Secretary determines that there is evidence that the research facilities will meet such standards within a reasonable time.

Notwithstanding the other provisions of this section, compliance by intermediate handlers, and carriers, and other persons with those provisions of this Act, as amended by the Animal Welfare Act Amendments of 1976, and those regulations promulgated thereunder, which relate to actions of intermediate handlers and carriers, shall commence 90 days after promulgation of regulations under section 13 of this Act, as amended, with respect to intermediate handlers and carriers, and such regulations shall be promulgated no later than 9 months after April 22, 1976; and compliance by dealers, exhibitors, operators of auction sales and research facilities with other provisions of this Act, as so amended, and the regulations thereunder, shall commence upon the expiration of 90 days after April 22, 1976: Provided, however, That compliance by all persons with paragraphs (f), (g), and (h) of section 13 and with section 26 of this Act, as so amended, shall commence upon the expiration of said 90-day period. In all other respects, said

amendments shall become effective upon April 22, 1976.

(7 U.S.C. 2154) (P.L. 89-544, § 24, Aug. 24, 1966, 80 Stat. 353; P.L. 94-279, § 15, April 22, 1976, 90 Stat. 421)

Section 25. Not later than March of each year the Secretary shall submit to the President of the Senate and the Speaker of the House of Representatives a comprehensive and detailed written report with respect to—

- (1) the identification of all research facilities, exhibitors, and other persons and establishments licensed by the Secretary under section 3 and section 12 of this Act;
- (2) the nature and place of all investigations and inspections conducted by the Secretary under section 16 of this Act, and all reports received by the Secretary under section 13 of this Act;
- (3) recommendations for legislation to improve the administration of this Act or any provision thereof; and
- (4) recommendations and conclusions concerning the aircraft environment as it relates to the carriage of live animals in air transportation. This report as well as any supporting documents, data, or findings shall not be released to any other persons, non-Federal agencies, or organizations unless and until it has been made public by an appropriate committee of the Senate or the House of Representatives.

(7 U.S.C. 2155) (P.L. 89-544, § 25, as added by P.L. 91-579, § 22, Dec. 24, 1970, 84 Stat. 1565; P.L. 94-279, § 16, April 22, 1976, 90 Stat. 421)

Section 26. (a) It shall be unlawful for any person to knowingly sponsor or exhibit an animal in any animal fighting venture to which any animal was moved in interstate or foreign commerce.

(b) It shall be unlawful for any person to knowingly sell, buy, transport, or deliver to another person or receive from another person for purposes of transportation, in interstate or foreign commerce, any dog or other animal for purposes of having the dog or other animal participate in an animal fighting venture.

(c) It shall be unlawful for any person to knowingly use the mail service of the United States Postal Service or any interstate instrumentality for purposes of promoting or in any other manner furthering an animal fighting venture except as performed outside the limits of the States of the United States.

(d) Notwithstanding the provisions of subsection (a), (b), or (c) of this section, the activities prohibited by such subsections shall be unlawful with respect to fighting ventures involving live birds only if the fight is to take place in a State where it would be in violation of the laws thereof.

(e) Any person who violates subsection (a), (b), or (c) shall be fined not more than \$5,000 or imprisoned for not more than 1 year, or both, for each such violation.

(f) The Secretary or any other person authorized by him shall make such investigations as the Secretary deems necessary to determine whether any person has violated or is violating any provision of this section, and the Secretary may obtain the assistance of the Federal Bureau of Investigation, the Department of the Treasury, or other law enforcement agencies of the United States, and State and local governmental agencies, in the conduct of such investigations, under cooperative agreements with such agencies. A warrant to search for and seize any animal which there is probable cause to believe was involved in any violation of this section may be issued by any judge of the United States or of a State court of record or by a United States magistrate within the district wherein the animal sought is located. Any United States

marshal or any person authorized under this section to conduct investigations may apply for and execute any such warrant, and any animal seized under such a warrant shall be held by the United States marshal or other authorized person pending disposition thereof by the court in accordance with this subsection. Necessary care including veterinary treatment shall be provided while the animals are so held in custody. Any animal involved in any violation of this section shall be liable to be proceeded against and forfeited to the United States at any time on complaint filed in any United States district court or other court of the United States for any jurisdiction in which the animal is found and upon a judgment of forfeiture shall be disposed of by sale for lawful purposes or by other humane means, as the court may direct. Costs incurred by the United States for care of animals seized and forfeited under this section shall be recoverable from the owner of the animals if he appears in such forfeiture proceeding or in a separate civil action brought in the jurisdiction in which the owner is found, resides, or transacts business.

(g) for purposes of this section-

(1) the term “animal fighting venture” means any event which involves a fight between at least two animals and is conducted for purposes of sport, wagering, or entertainment except that the term “animal fighting venture” shall not be deemed to include any activity the primary purpose of which involves the use of one or more animals in hunting another animal or animals, such as waterfowl, bird, raccoon, or fox hunting;

(2) the term “interstate or foreign commerce” means—

(A) any movement between any place in a State to any place in another State or between places in the same State through another State; or

(B) any movement from a foreign country

into any State;

(3) the term “interstate instrumentality” means telegraph, telephone, radio, or television operating in interstate or foreign commerce;

(4) the term “State” means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, and any territory or possession of the United States;

(5) the term “animal” means any live bird, or any live dog or other mammal, except man; and

(6) the conduct by any person of any activity prohibited by this section shall not render such person subject to the other sections of this Act as a dealer, exhibitor, or otherwise.

(h)(1) The provisions of this section shall not supersede or otherwise invalidate any such State, local, or municipal legislation or ordinance relating to animal fighting ventures except in case of a direct and irreconcilable conflict between any requirements thereunder and this section or any rule, regulation, or standard hereunder.

(7 U.S.C. 2156)(P.L- 89-544, § 26(a)-(h)(1), as added by P.L- 94-279, § 17, April 22, 1976, 90 Stat. 421)

Note: P.L. 94-279 also amended 39 U.S.C. 3001(a) on material that may not be mailed.

Section 27. (a) It shall be unlawful for any member of an Institutional Animal Committee to release any confidential information of the research facility including any information that concerns or relates to—

(1) the trade secrets, processes, operations, style of work, or apparatus; or

(2) the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures, of the research facility.

(b) It shall be unlawful for any member of such Committee—

- (1) to use or attempt to use to his advantages; or
- (2) to reveal to any other person, any information which is entitled to protection as confidential information under subsection (a) of this section. (c) A violation of subsection (a) or (b) of this section is punishable by—
- (1) removal from such Committee; and
- (2)(A) a fine of not more than \$1,000 and imprisonment of not more than 1 year; or
- (B) if such violation is willful, a fine of not more than \$10,000 and imprisonment of not more than 3 years.
- (d) Any person, including any research facility, injured in its business or property by reason of a violation of this section may recover all actual and consequential damages sustained by such person and the cost of the suit including a reasonable attorney's fee.
- (e) Nothing in this section shall be construed to affect any other rights of a person injured in its business or property by reason of a violation of this section. Subsection (d) shall not be construed to limit the exercise of any such rights arising out of or relating to a violation of subsections (a) and (b) of this section.

(7 U.S.C. 2157) (P.L. 89-544, § 27, as added by P.L. 99-198, Title XVII, § 1754, Dec. 23, 1985, 99 Stat. 1649)

Section 28. Protection of Pets (a) Holding Period. —

- (1) Requirement.- In the case of each dog or cat acquired by an entity described in paragraph
- (2), such entity shall hold and care for such dog or cat for a period of not less than five days to enable such dog or cat to be recovered by its original owner or adopted by other individuals before such entity sells such dog or cat to a dealer.

- (2) Entities Described. An entity subject to paragraph (1) is-
- (A) each State, county, or city owned and operated pound or shelter;
- (B) each private entity established for the purpose of caring for animals, such as a humane society, or other organization that is under contract with a State, county, or city that operates as a pound or shelter and that releases animals on a voluntary basis; and
- (C) each research facility licensed by the Department of Agriculture.(b)
- Certification.—

(1) In General — A dealer may not sell, provide, or make available to any individual or entity a random source dog or cat unless such dealer provides the recipient with a valid certification that meets the requirements of paragraph (2) and indicates compliance with subsection (a).

(2) Requirements.— A valid certification shall contain

- (A) the name, address, and Department of Agriculture license or registration number (if such number exists) of the dealer;
- (B) the name, address, and Department of Agriculture license or registration number (if such number exists), and the signature of the recipient of the dog or cat,
- (C) a description of the dog or cat being provided that shall include —
- (i) the species and breed or type of such;
- (ii) the sex of such;
- (iii) the date of birth (if known) of such,
- (iv) the color and any distinctive marking of such- and
- (v) any other information that the Secretary by regulation shall determine to be appropriate;
- (D) the name and address of the person, pound, or shelter from which the dog or cat was purchased or otherwise acquired by the dealer, and an assurance that such person, pound, or shelter was notified that such dog or cat may be used for research or education

(E) the date of the purchase or acquisition referred to in subparagraph (D);

(F) a statement by the pound or shelter (if the dealer acquired the dog or cat from such) that it satisfied the requirements of subsection (a) and

(G) any other information that the Secretary of Agriculture by regulation shall determine appropriate.

(3) Records. — The original certification required under paragraph (1) shall accompany the shipment of a dog or cat to be sold, provided, or otherwise made available by the dealer, and shall be kept and maintained by the research facility for a period of at least one year for enforcement purposes. The dealer shall retain one copy of the certification provided under this paragraph for a period of at least one year for enforcement purposes.

(4) Transfers. — In instances where one research facility transfers animals to another research facility, a copy of the certificate must accompany such transfer.

(5) Modification. — Certification requirements may be modified to reflect technological advances in identification techniques, such as microchip technology, if the Secretary determines that adequate information such as described in this section, will be collected, transferred, and maintained through such technology.

(c) Enforcement. —

(1) In General — Dealers who fail to act according to the requirements of this section or who include false information in the certification required under subsection (b) shall be subject to the penalties provided for under section 19.

(2) Subsequent Violations Any dealer who violates this section more than one time shall be subject to a fine of \$5,000 per dog or cat acquired or sold in violation of this section.

(3) Permanent Revocations.—Any dealer who violates this section three or more times shall have such dealer’s license permanently revoked.

(d) Regulation.— Not later than 180 days after the date of enactment of this section, the Secretary shall promulgate regulations to carry out this section.

Section 29. Authority to Apply for Injunctions.

—

(a) Request. — Whenever the Secretary has reason to believe that any dealer, carrier, exhibitor, or intermediate handler is dealing in stolen animals, or is placing the health of any animal in serious danger in violation of this Act or the regulations or standards promulgated thereunder, the Secretary shall notify the Attorney General who may apply to the United States district court in which such dealer, carrier, exhibitor, or intermediate handler resides or conducts business for a temporary restraining order or injunction to prevent any such person from operating in violation of this Act or the regulations and standards prescribed under this Act.

(b) Issuance. The court shall, upon a proper showing, issue a temporary restraining order or injunction under subsection (a) without bond. Such injunction or order shall remain in effect until a complaint pursuant to section 19 is issued and dismissed by the Secretary or until an order to cease and desist made thereon by the Secretary has become final and effective or is set aside on appellate review. Attorneys of the Department of Agriculture may, with the approval of the Attorney General, appear in the United States district court representing the Secretary in any action brought under this section.

LEGISLATIVE HISTORY

P.L. 89-544:

H. Rept. 89-1418, House Committee
S. Rept. 89-1281, Senate Committee on
Commerce
Passed House Apr. 28, 1966
Passed Senate June 22, 1966
H. Rept- 89-1848, Conference Committee
House agreed to conference report Aug. 16,
1966
Senate agreed to conference report Aug 17,
1966
Approved Aug. 24, 1966

P.L. 91-579

H. Rept. 91-1651, House Committee on
Agriculture
Passed House Dec. 7, 1970
Passed Senate Dec. 8, 1970
Approved Dec. 24, 1970

P.L. 94-279

H. Rept. 94-801, House Committee on
Agriculture
S. Rept. 94-580, Senate Committee on
Commerce
H. Rept. 94-976, Conference Committee
S. Rept. 94-727, Conference Committee
Passed Senate Dec. 18, 1975
Passed House Feb. 9, 1976
House agreed to conference report Apr. 6,
1976
Senate agreed to conference report Apr. 7,
1976
Approved Apr. 22, 1976

P. L. 99-198

H. Rept. 99-271, Part 1 Committee on
Agriculture
S. Rept. 99-145 Committee on Agriculture,
Nutrition, and Forestry
Passed House Oct. 8, 1985
Passed Senate Nov. 23, 1985

H. Rept. 99-447 Conference Committee
House and Senate agreed to Conference
Report, Dec. 18, 1985
Approved Dec. 23, 1985

P.L- 101-624

Legislative History -S.
2830 (H.R. 3581)(H.R. 3950) (H.R. 4077):
House Reports: No. 101-413 accompanying
H.R. 4071 and No. 101-415
accompanying H.R. 3581 (both from Comm.
on Agriculture); No. 101-569, Pt.1
(Comm. on Agriculture), Pt. 2
(Comm. on Foreign Affairs), Pt 3
(Comm. on Agriculture), Pt. 4
(Comm. on Education and Labor) and Pt. 5
(Comm. on Ways and Means), all
accompanying
H.R. 3950. Senate Reports: No. 101-357
(Comm. on Agriculture, Nutrition and
Forestry)
Congressional Record - Vol. 136 (1990):
Mar.
6, H.R. 4077 considered and passed House.
Mar. 14, 15, 22, H.R. 3581 considered and
passed House.
July 19, 20, 23-27, S. 2830 considered and
passed Senate. July
23-25, 27, Aug. 1, H.R. 3950 considered and
passed House. Aug. 3, S.
2830 considered and passed House,
amended,
in lieu of H.R. 3581, H.R.
3950, and H.R. 4077
Oct. 23, House agreed to conference report.
Oct. 25, Senate agreed to conference report.
Weekly Compilation of Presidential
Documents
Vol. 26 (1990): Nov. 18,
Presidential remarks and statement.

**NOTE: This copy of the Animal Welfare
Act is provided for information only.
Before relying on any portion of the Act
as it appears here, reference should be**

made to the official report of the Act in the United States Code (7 U.S.C. § 2131 et. seq.).

Footnote:

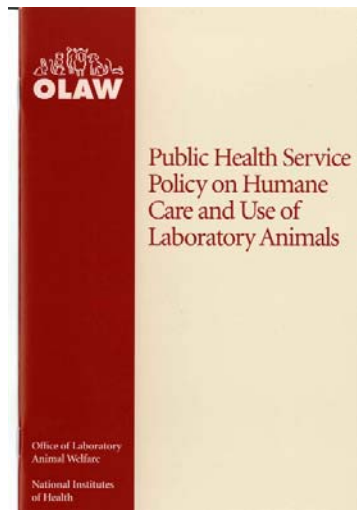
¹P.L- 99-198, Title XVII § 1752, Dec. 23, 1985, 99 Stat. 1645, made significant amendments to § 13 of the Act and inadvertently duplicated paragraph (f) of § 13. The new paragraph (f) in the 1985 amendments has been designated as paragraph (f)¹ and the old paragraph (f) has been designated as paragraph (f)² for clarity.

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APPENDIX F

PUBLIC HEALTH SERVICE POLICY ON HUMANE CARE AND USE OF LABORATORY ANIMALS

(Revised September, 1986; Reprinted August, 2002)



[Copies of this Policy may be obtained from the IACUC Office at NDSU or by writing to: OLAW at the National Institutes of Health, RKL1, Suite 1050, MSC 7982, 6705 Rockledge Drive, Bethesda, MD, 20892-7982.]

Full Text may be viewed at: <http://grants1.nih.gov/grants/olaw/references/phspol.htm>

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APPENDIX G

HEALTH RESEARCH EXTENSION ACT OF 1985

PUBLIC LAW 99-158, November 20, 1985

“ANIMALS IN RESEARCH”

Sec.495.

(a) The Secretary, acting through the Director of NIH, shall establish guidelines for the following:

“(1) The proper care of animals to be used in biomedical and behavioral research.

“(2) The proper treatment of animals while being used in such research. Guidelines under this paragraph shall require-

“(A) the appropriate use of tranquilizers, analgesics, anesthetics, paralytics, and euthanasia for animals in such research; and

“(B) appropriate pre-surgical and post-surgical veterinary medical and nursing care for animals in such research.

Such guidelines shall not be construed to prescribe methods of research.

“(3) The organization and operation of animal care committees in accordance with subsection (b).

“(b) (1) Guidelines of the Secretary under subsection (a)(3) shall require animal care committees at each entity which conducts biomedical and behavioral research with funds provided under this Act (including the National Institutes of Health and the national research institutes) to assure compliance with the guidelines established under subsection (a).

“(2) Each animal care committee shall be appointed by the chief executive officer of the entity for which the committee is established, shall be composed of not fewer than three members, and shall include at least one individual who has no association with such entity and at least one doctor of veterinary medicine.

“(3) Each animal care committee of a research entity shall-

“(A) review the care and treatment of animals in all animal study areas and facilities of the research entity at least semiannually to evaluate compliance with applicable guidelines established under subsection (a) for appropriate animal care and treatment;

“(B) keep appropriate records of reviews conducted under sub-paragraph (A); and

“(C) for each review conducted under subparagraph (A), file with the Director of NIH at least annually (i) a certification that the review has been conducted, and (ii) reports of any violations of guidelines established under subsection (a) or assurances required under paragraph (1) which were observed in such review and which have continued after notice by the committee to the research entity involved of the violations.

Reports filed under subparagraph (C) shall include any minority views filed by members of the committee.

“(c) The Director of NIH shall require each applicant for a grant, contract, or cooperative agreement involving research on animals which is administered by the National Institutes of Health or any national research institute to include in its application or contract proposal, submitted after the expiration of the twelve-month period beginning on the date of enactment of this section-

“(1) assurances satisfactory to the Director of NIH that-

“(A) the applicant meets the requirements of the guidelines established under paragraphs (1) and (2) of subsection (a) and has an animal care committee which meets the requirements of subsection (b); and

“(B) scientists, animal technicians, and other personnel involved with animal care, treatment, and use by the applicant have available to them instruction or training in the humane practice of animal maintenance and experimentation, and the concept, availability, and use of research or testing methods that limit the use of animals or limit animal distress; and

“(2) a statement of the reasons for the use of animals in the research to be conducted with funds provided under such grant or contract.

Notwithstanding subsection (a)(2) of section 553 of title 5, United States Code, regulations under this subsection shall be promulgated in accordance with the notice and comment requirements of such section.

“(d) If the Director of NIH determines that-

“(1) the conditions of animal care, treatment, or use in an entity which is receiving a grant, contract, or cooperative agreement involving research on animals under this title do not meet applicable guidelines established under subsection (a);

“(2) the entity has been notified by the Director of NIH of such determination and has been given a reasonable opportunity to take corrective action; and

“(3) no action has been taken by the entity to correct such conditions; the Director of NIH shall suspend or revoke such grant or contract under such conditions as the Director determines appropriate.

“(e) No guideline or regulation promulgated under subsection (a) or (c) may require a research entity to disclose publicly trade secrets or commercial or financial information which is privileged or confidential.”

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APPENDIX H

SELECT ANIMAL SCIENCE ORGANIZATIONS

American Association for Accreditation of Laboratory Animal Care (AAALAC), 11300 Rockville Pike, Suite 1211, Rockville, MD 20852-3035 (phone: 301-231-5353; e-mail: accredit@aaalac.org).

American Association for Laboratory Animal Science (AALAS), 70 Timber Creek Drive, Suite 5, Cordova, TN 38108 (phone: 901-754-8620; e-mail: info@aalas.org; URL: <http://www.aalas.org/>).

American College of Laboratory Animal Medicine (ACLAM), 200 Summerwinds Drive, Cary, NC 27511 (phone 919-859-5985).

American Humane Association (AHA), 236 Massachusetts Avenue, ND, Suite 203, Washington, D.C. 20002 (phone: 202-543-7780).

American Society of Laboratory Animal Practitioners (ASLAP), Dr. Bradford S. Goodwin, Jr., Secretary-Treasurer, University of Texas, Medical School-CLAMC, 6431 Fannin Street, Room 1132, Houston, TX 77030-1501 (phone: 713-792-5127).

American Veterinary Medical Association (AVMA), 1931 North Meacham Road, Suite 100, Schaumburg, IL 60173-4360 (phone: 800-248-2862; URL: <http://www.avma.org>).

Animal Welfare Information Center (AWIC), National Agricultural Library, 5th floor, Beltsville, MD 20705-2351 (phone: 301-504-6212; e-mail: awic@nal.usda.gov; URL: <http://netvet.wustl.edu/awic.htm> or <http://www.nalusda.gov>).

Animal Welfare Institute (AWI), P.O. Box 3650, Washington, DC 20007 (phone: 202-337-2332; e-mail: awi@igc.apc.org).

Australia and New Zealand Council for the Care of Animals in Research and Teaching (ANZCCART): ANZCCART Australia, The Executive Officer, P.O. Box 19, Glen Osmond, South Australia 5064, (phone: +61-8-303-7393; e-mail: anzccart@waite.adelaide.edu.au; URL: <http://www.adelaide.edu.au/ANZCCART/>); ANZCCART New Zealand, The Executive Officer, C/- The Royal Society of New Zealand, P.O. Box 59, Wellington, New Zealand (phone: +64-4-472-7421; e-mail: anzccart@rsnz.govt.nz)

Canadian Association for Laboratory Animal Medicine/L'Association canadienne de la médecine des animaux de laboratoire (CALAM/ACMAL), Dr. Brenda Cross, Secretary-Treasurer, 102 Animal Resources Centre, 120 Maintenance Road, University of Saskatchewan, Saskatoon, Saskatchewan, Canada S7N 5C4.

Canadian Association for Laboratory Animal Science/L'association canadienne pour la technologie des laboratoires (CALAS/ACTAL), Dr. Donald McKay, Executive Secretary, CW401 Biological Science Building, Bioscience Animal Service, University of Alberta, Edmonton, Alberta, Canada T6G 2E9 (phone: 403-492-5193; e-mail: dmckay@gpu.srv.ualberta.ca).

Canadian Council on Animal Care (CCAC), Constitution Square, Tower II, 315-350 Albert, Ottawa, Ontario, Canada K1R 1B1 (phone: 613-238-4031; e-mail: ccac@carleton.ca).

Center for Alternatives to Animal Testing (CAAT), Johns Hopkins University, 111 Market Place, Suite 840, Baltimore, MD 21202-6709 (phone: 410-223-1693; e-mail: caat@jhuhyg.sph.jhu.edu; URL: <http://infonet.welch.jhu.edu/~caat/>).

Center for Animals and Public Policy, Tufts University, School of Veterinary Medicine, 200 Westboro Road, N. Grafton, MA 01536 (phone: 508-839-7991; e-mail: dpease@opal.tufts.edu).

Foundation for Biomedical Research (FBR), 818 Connecticut Avenue, NW, Suite 303, Washington, DC 20006 (phone: 202-457-0654; e-mail: nabr-fbr@access.digex.net; URL: <http://www.fiesta.com/fbr>).

The Humane Society of the United States (HSUS), 2100 L Street, NW, Washington, DC 20037 (phone: 202-452-1100; e-mail: HSUSLAB@ix.netcom.com).

Institute of Laboratory Animal Resources (ILAR), National Research Council, National Academy of Sciences, 2101 Constitution Avenue, NW, Washington, DC 20418 (phone: 202-334-1687; e-mail: ILAR@nas.edu; URL: <http://www2.nas.edu/ilarhome>).

International Council for Laboratory Animal Science (ICLAS), Dr. Steven Pakes, Secretary General, Division of Comparative Medicine, University of Texas Southwestern Medical Center, 5323 Harry Hines Boulevard, Dallas, TX (phone: 214-648-3340; e-mail: spakes@mednet.swmed.edu).

Laboratory Animal Management Association (LAMA), Mr. Paul Schwikert, Past-President, P.O. Box 1744, Silver Spring, MD 20915 (phone: 313-577-1418).

Massachusetts Society for the Prevention of Cruelty to Animals/American Humane Education Society (MSPCA/AHES), 350 South Huntington Avenue, Boston, MA 02130 (phone: 617-522-7400).

National Association for Biomedical Research (NABR), 818 Connecticut Avenue, NW, Suite 303, Washington, DC 20006 (phone: 202-857-0540; e-mail: nabr-fbr@access.digex.net; URL: <http://www.fiesta.com/nabr>).

Office for Laboratory Animal Welfare (OLAW), National Institutes of Health, RKL1, Suite 1050, MSC 7982, 6702 Rockledge Drive, Bethesda, MD 20892-7982 (phone: 301-496-7163).

Purina Mills, Inc., 505 North 4th and D Street, Richmond, IN 47374.

Scientists Center for Animal Welfare (SCAW), 7833 Walker Drive, Suite 340, Greenbelt, MD 20770 (phone: 301-345-3500).

Universities Federation for Animal Welfare (UFAW), 8 Hamilton Close, South Mimms, Potters Bar, Herts EN6 3QD, United Kingdom (phone: 44-707-58202).

United States Department of Agricultural, Animal and Plant Health Inspection Service, Regulatory Enforcement of Animal Care (REAC), 4700 River Road, Unit 84, Riverdale, MD 20737-1234 (phone: 301-734-4981; e-mail: sstith@aphis.usda.gov).

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APPENDIX I

ARS/CSREES/ERS/NASS POLICIES & PROCEDURES (<http://www.ars.usda.gov/afm2/ppweb/635-01.htm>)

United States Department of Agriculture
Research, Education, and Economics

ARS * CSREES * ERS * NASS
Policies and Procedures

Title: Humane Animal Care and Use

Number: 635.1

Date: 8/29/90

Originating Office: Office of the Deputy Administrator, National Program Staff

This Replaces: Remove AM 535 Dated 6/1/77

Distribution: Headquarters, Areas, and Locations

This Directive:

- States ARS Policy
- Lists coverage of animals under Public Laws, Policies, and ARS practices.
- Assigns responsibilities for assuring Humane animal care and use.

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 - Area/Center/Location Procurement Officer and Area/Center/Location Property Officer

RLs/SYs assure
Attending Veterinarian
Consulting Veterinarian
Animal Caretakers
IACUCs

1. References

For additional information see DIRECTIVE 130.4, Animal Care and Use Committee.

2. Abbreviations

- AALAS - American Association for Laboratory Animal Science
- AD - Area Director
- AV - Attending Veterinarian
- AWA - Animal Welfare Act
- APHIS - Animal and Plant Health Inspection Service, USDA
- CFR - Code of Federal Regulations
- Ag Guide - Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching
- IACUC - Institutional Animal Care and Use Committee
- LERB - Labor and Employee Relations Branch, Personnel Division, ARS
- NIH Guide - NIH Guide for the Care and Use of Laboratory Animals
- NPS - National Program Staff, ARS
- OPRR - Office for the Protection from Research Risks, NIH
- PHS - Public Health Service (Agencies of the PHS include the National Institutes of Health [NIH], Food and Drug Administration [FDA], Centers for Disease Control [CDC], and the Alcohol, Drug Abuse, and Mental Health Administration [ADAMHA]).
- PL - Public Law
- REAC - Regulatory Enforcement Animal Care, APHIS
- RL - Research Leader (ARS)
- SY - Research Scientist (ARS)
- VS - Veterinary Services, APHIS

3. Definition

Cooperator. As used in this Directive, taken to mean any non-ARS personnel caring for or using any vertebrate animal at an ARS Location.

4. Coverage

ARS Policy:

- **Includes:** All vertebrate animals in all ARS Locations, or other locations in which ARS funds or ARS personnel are involved.
- **Excludes:** Invertebrate animals.

AWA:

- **Includes:** Any live or dead dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or any other warm-blooded animal, used or intended for use in research, teaching, testing, experimentation, or exhibition purposes, or as a pet.
- **Excludes:** Birds, rats of the genus *Rattus* and mice of the genus *Mus* bred for use in research, and horses and other farm animals, such as, but not limited to livestock and poultry used or intended for use as food or fiber, or livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber.

PHS Policy:

- **Includes:** Any animal (including farm animals) used in biomedical research and testing funded by a PHS Agency or in any institution that receives funds from a PHS Agency.
- **Excludes:** Livestock and poultry used or intended for use that also is excluded from coverage by the AWA.

Ag Guide:

- **Includes:** Livestock and poultry used in agricultural research and teaching.
- **Excludes:** Animals covered by AWA or PHS.

5. Authorities

- Laboratory Animal Welfare Act of 1966 as amended by the Animal Welfare Act of 1970, 1976 and 1985.
- 9 CFR 1, 2 (Subpart 2C), and 3.
- U.S. PHS Policy on Humane Care and Use of Laboratory Animals
- NIH Guide for the Care and Use of Laboratory Animals, 1985 revision (NIH Publication No. 86-23).

- Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching, First Revised Edition, January 1999.

6. Policy

It is ARS policy to assure that all ARS research animals are treated humanely. Allegations of animal abuse must be reported promptly, in writing, to the Chairperson, IACUC, and the AD. It is ARS Policy to assure that all ARS research facilities and other facilities using ARS animals, funds or personnel for any animal use comply with the following:

The AWA, for animals used in biomedical research, testing or teaching and covered by the AWA including:

- The AWA, its amendments, regulations, and standards concerning procurement, transportation, care, handling, and treatment of animals, training of personnel, and employee health programs (Exhibit 1).
- Requirement to maintain IACUCs in all ARS Locations that have animals covered by the AWA (except that ARS requires a minimum of five members whereas AWA requires a minimum of three). See also Directive 130.4, Animal Care and Use Committee.
- Assurance that animals not covered under the AWA receive the same level of humane animal care and treatment.
- Review, and, if warranted, investigate concerns involving care and use of animals resulting from complaints or reports of noncompliance.

PHS Policy, for ARS facilities receiving funds from any PHS agency including:

- PHS Policy and also the NIH Guide concerning procurement, transportation, care, handling, and treatment of animals, training of personnel, and employee health programs (Exhibit 2).
- Maintain IACUCs that comply with PHS Policy in all ARS Locations that use animals. Note that ARS and PHS Policy concerning IACUC size and composition are identical. See also Directive 130.4, Animal Care and Use Committee.
- Assurance that animals not covered under PHS Policy receive the same level of humane animal care and treatment.

Ag Guide, for ARS facilities or facilities receiving ARS funds and using farm animals for any purpose with the following stipulations:

Ag Guide chapters 5-II. outlining appropriate husbandry practices for various species of farm animals (Exhibit 3).

7. Licensing And Registration

- Not required for Federal agencies under the ANA.
- Filing of an annual PHS Assurance with OPRR/NIH is required for all ARS Locations that receive funds from any PHS agency. Many other public and private funding entities also require filing of a PHS Assurance as a condition of grant/contract completion.

8. Responsibilities

The Administrator, where applicable, through the NPS, assures compliance with AWA, PHS Policy and NIH Guide, Ag Guide, and ARS Policy concerning humane care and use of all vertebrate animals.

AD's assure:

- IACUCs are established where required and maintained in operation.
- IACUC members and Chairpeople are appointed and function according to Directive 130.4, Animal Care and Use Committee.
- That all employees who work with animals are appropriately trained. d Regulations, standards, and policies are enforced.
- Reporting requirements for AWA, PHS Policy (where applicable), and ARS are met in a timely manner.
- Deficiencies, including those involving physical facilities, are corrected promptly.
- Procurement of all vertebrate animals in Areas/Centers/Locations is covered by an IACUC approval for the stipulated number of animals.
- Consultation to IACUC, Attending Veterinarians, and/or other employees concerning animal care and welfare is provided.
- That upon request of APHIS representatives, information required under the AWA is furnished.
- That, if needed, assistance is requested from APHIS and/or OPRR/NIH concerning attainment of policy goals.

- Funds and time are provided for employees to receive training required under the AWA.
- Reported noncompliance with ARS Policy, the AWA and/or PHS Policy are investigated promptly and resolved.
- That prompt disciplinary action is taken regarding any employee or cooperator found to have abused animals.

Area/Center/Location Procurement Officer and Area/Center/Location Property Officer will assure that all orders for acquisition and disposition of all vertebrate animals comply with the AWA and ARS Directives concerning approved sources, and assurance that appropriate documentation accompanies all acquisitions and dispositions of animals.

RLs/SYs assure:

- Acquisition of all animals comply with the AWA and ARS Policy.
- Recordkeeping complies with the AWA, including the special recordkeeping required for dogs and cats that is described in Subpart 2C, Section 2.35.
- Compliance with all special requirements concerning dogs and cats (Directive 130.4, Animal Care and Use Committee) that are delegated to RLs/SYs.
- Dogs and cats obtained from sources other than dealers, exhibitors, and exempt persons are held for at least 5 full days before they are used.
- All animals held or used for any purpose are covered by IACUC approval.
- Recordkeeping provisions of the AWA, Subpart 2C, Section 2.35 concerning dogs and cats are followed and forms/records are forwarded to the appropriate Area IACUC (the official Area Record).
- They personally, as well as their technicians, caretakers, students, and others are aware of and follow regulations and standards for humane care of animals used in any manner by them and/or their subordinates.
- Any inadequacies in care, handling, or environmental conditions concerning animals are promptly reported and corrected.
- Maintenance of training on regulatory requirements and humane care and use of animals.
- Disposition of all healthy surplus animals comply with ARS property disposal procedures for disposition of surplus government animals. In addition, disposition of all dogs and cats also must comply with the AWA concerning recordkeeping (Subpart 2C, Section 2.35), euthanasia, sale, or transportation.

Attending Veterinarian:

- Serves on the IACUC.
- Assures that:
 - All vertebrate animals receive adequate veterinary care in compliance with the AWA, NIH Guide, and Ag Guide.
 - Guidance is provided to appropriate research and care personnel concerning, including but not limited to, care and use of animals regarding humane handling, immobilization, anesthesia, analgesia, euthanasia, tranquilization, as well as pre- and post-procedural care in accordance with established veterinary and nursing procedures and the AWA.
 - VS Form 18-23 covering the previous fiscal year ending September 30 is accurately completed, receives concurrence by IACUC, and forwarded to AD for transmission to REAC/APHIS and NPS/ARS in a timely manner.
 - ARS Form 605 covering the previous fiscal year ending September 30 is accurately completed, receives concurrence by IACUC, and forwarded to AD for transmission to NPS/ARS in a timely manner.
 - Animal caretakers receive an adequate level of training to provide optimum care of animals.
 - Chairperson, IACUC, RL, Center Director, and AD are promptly notified about all failures to comply with provisions of AWA, NIH Guide, and Ag Guide concerning regulations and standards.
 - Knowledge of new veterinary medical developments and regulatory requirements is maintained through a continuing program of training.

Consulting Veterinarian assumes same responsibilities as attending veterinarian.

Animal Caretakers assure:

- All animals under their responsibility receive care consistent with the AWA, NIH Guide, and Ag Guide on a daily basis, except for free ranging animals where Location IACUCs set the appropriate frequency.
- All management and environmental requirements for animals are met in a timely manner.
- Maintenance of current knowledge of all aspects of care for the species in their charge through a continuing program of training.

- That during the first year of employment as animal caretaker, they take a course leading to certification given by AALAS (for laboratory animal caretakers) or by another organization/institution (for caretakers of species for which AALAS training is inappropriate). This course must contain training in current animal care practices and regulatory requirements relevant to the species in use. Lists of appropriate training courses leading to employee certification may be obtained from the IACUC. Employee certifications will be updated periodically to assure that they reflect current animal care practices, regulatory requirements, and relevance to the species being cared for.
- On or before the first year of employment as animal caretaker, receive certification in the appropriate training course (described in H.7.d above). Failure to meet the certification requirement within a year after entering on duty will be grounds for dismissal.

IACUCs will fulfill all of the requirements in Directive 130.4, Animal Care and Use Committee.

R. D. PLOWMAN

Administrator

Exhibits (NOT AVAILABLE IN ELECTRONIC FORMAT)

1 Animal Welfare Act, 9 CFR Parts 1, 2C, and 3 1A Amendment to 9 CFR Part 3 (Animal Welfare: Guinea Pigs; Hamsters; and Rabbits)

2 Humane Animal Care and Use

2a PHS Policy on Human Care and Use of Laboratory Animals, revised 1986

2b NIH Guide for the Care, Use of Laboratory Animals, revised 1985

3 Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching (Chapters 5-11)

APPENDIX J

GUIDELINES AND REGULATIONS PERTAINING TO FEDERAL CERTIFICATIONS FOR SPONSORED PROJECTS INVOLVING ANIMALS

Public Health Service (PHS).

(From *Application for a Public Health Service Grant* [form PHS 398], http://grants.nih.gov/grants/funding/phs398/section_3.html#assurances)

“2. Vertebrate Animals

“The PHS Policy on Humane Care and Use of Laboratory Animals requires that applicant organizations proposing to use vertebrate animals file a written Animal Welfare Assurance with the Office for Protection from Research Risks [renamed the Office of Laboratory Animal Welfare (OLAW), 2000], establishing appropriate policies and procedures to ensure the humane care and use of live vertebrate animals involved in research activities supported by the PHS. The PHS policy stipulates that an applicant organization, whether domestic or foreign, bears responsibility for the humane care and use of animals in PHS-supported research activities. This policy implements and supplements the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, and requires that institutions use the Guide for the Care and Use of Laboratory Animals as a basis for developing and implementing an institutional animal care and use program. This policy does not affect applicable State or local laws or regulations that impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply, as applicable, with the Animal Welfare Act as amended (7 USC 2131 et sec.) and other Federal statutes and regulations relating to animals. These documents are available from the Office for Protection from Research Risks [OLAW], National Institutes of Health, Bethesda, MD 20892, (301) 496-7163.

“The PHS policy defines ‘animal’ as ‘any live, vertebrate animal used or intended for use in research, research training, experimentation or biological testing or for related purposes.’

“No PHS award for research involving vertebrate animals will be made to an applicant organization unless that organization is operating in accordance with an approved Animal Welfare Assurance and provides verification that the Institutional Animal Care and Use Committee (IACUC) has reviewed and approved the proposed activity in accordance with the PHS policy. Applications may be referred by the PHS back to the IACUC for further review in the case of apparent or potential violations of the PHS policy. No award to an individual will be made unless that individual is affiliated with an assured organization that accepts responsibility for compliance with the PHS policy. Foreign applicant organizations applying for PHS awards for activities involving vertebrate animals are required to comply with PHS policy or provide evidence that acceptable standards for the humane care and use of animals will be met.”

Applicants for Public Health Service Grants using animals as part of their sponsored projects must complete Section 5 (Vertebrate Animals) of the form below.

Form Approved Through 09/30/2007		OMB No. 0925-0001		
Department of Health and Human Services Public Health Services Grant Application <i>Do not exceed character length restrictions indicated.</i>		LEAVE BLANK—FOR PHS USE ONLY.		
		Type	Activity	Number
		Review Group		Formerly
		Council/Board (Month, Year)		Date Received
1. TITLE OF PROJECT <i>(Do not exceed 81 characters, including spaces and punctuation.)</i>				
2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION <input type="checkbox"/> NO <input type="checkbox"/> YES <i>(If "Yes," state number and title)</i> Number: _____ Title: _____				
3. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR		New Investigator <input type="checkbox"/> No <input type="checkbox"/> Yes		
3a. NAME (Last, first, middle)		3b. DEGREE(S)	3h. eRA Commons User Name	
3c. POSITION TITLE		3d. MAILING ADDRESS <i>(Street, city, state, zip code)</i>		
3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT				
3f. MAJOR SUBDIVISION				
3g. TELEPHONE AND FAX <i>(Area code, number and extension)</i> TEL: _____ FAX: _____				
4. HUMAN SUBJECTS RESEARCH <input type="checkbox"/> No <input type="checkbox"/> Yes		5. VERTEBRATE ANIMALS <input type="checkbox"/> No <input type="checkbox"/> Yes		
4b. Human Subjects Assurance No.		5a. If "Yes," IACUC approval Date		
4c. Clinical Trial <input type="checkbox"/> No <input type="checkbox"/> Yes		5b. Animal welfare assurance no.		
4d. NIH-defined Phase III Clinical Trial <input type="checkbox"/> No <input type="checkbox"/> Yes				
4a. Research Exempt <input type="checkbox"/> No <input type="checkbox"/> Yes				
If "Yes," Exemption No. _____				
6. DATES OF PROPOSED PERIOD OF SUPPORT <i>(month, day, year—MM/DD/YY)</i>		7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD		
From _____ Through _____		7a. Direct Costs (\$)		
		7b. Total Costs (\$)		
		8a. Direct Costs (\$)		
		8b. Total Costs (\$)		
9. APPLICANT ORGANIZATION Name Address		10. TYPE OF ORGANIZATION Public: → <input type="checkbox"/> Federal <input type="checkbox"/> State <input type="checkbox"/> Local Private: → <input type="checkbox"/> Private Nonprofit For-profit: → <input type="checkbox"/> General <input type="checkbox"/> Small Business <input type="checkbox"/> Woman-owned <input type="checkbox"/> Socially and Economically Disadvantaged		
		11. ENTITY IDENTIFICATION NUMBER DUNS NO. _____ Cong. District _____		
12. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE Name Title Address Tel: _____ FAX: _____ E-Mail: _____		13. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION Name Title Address Tel: _____ FAX: _____ E-Mail: _____		
14. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.		SIGNATURE OF PI/IPD NAMED IN 3a. <i>(In ink. "Per" signature not acceptable.)</i>		
15. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.		SIGNATURE OF OFFICIAL NAMED IN 13. <i>(In ink. "Per" signature not acceptable.)</i>		
		DATE		
		DATE		

U.S. Department of Agriculture (USDA).

(From the USDA Standard Research Grants Application Kit,
<http://www.reeusda.gov/nri/howto/applkit/rqstdgnt.htm#assurance>)

“Assurance Statements (Form CSREES-2008)

“A number of situations encountered in the conduct of research require special information and supporting documentation before funding can be approved for the project [as described in 7 CFR 3411.4(c)(9)]. If any such situation is anticipated, this information must be included in the proposal. If the project is expected to involve recombinant DNA molecules, human subjects at risk, or experimental vertebrate animals, Form CSREES-662 must be completed and signed according to directions below or directions found on the form and should be included in the proposal at the time of submission.

“Experimental Vertebrate Animal Care. The responsibility for the humane care and treatment of any experimental vertebrate animal, which has the same meaning as ‘animal’ in section 2(g) of the Animal Welfare Act of 1966, as amended (7 U.S.C. 2132(g)), used in any project supported with NRICGP funds rests with the performing organization. In this regard, all key personnel associated with any supported project and all endorsing officials of the proposed performing entity are required to comply with applicable provisions of the Animal Welfare Act of 1966, as amended (7 U.S.C. 2131 et seq.), and the regulations promulgated there under by the Secretary of Agriculture in 9 CFR parts 1, 2, 3, and 4. In this regard, the applicant must submit a statement certifying that the proposed project is in compliance with the aforementioned regulations, and that the proposed project is either under review by or has been reviewed and approved by an Institutional Animal Care and Use Committee (IACUC). Grant funds from a possible award will not be released until the project has been approved by an IACUC. In the event a project involving the use of living vertebrate animals results in a grant award, funds will be released only after a qualified Institutional Animal Care and Use Committee has approved the project.

“Proposing scientists who lack organizational affiliation or whose organization finds it impractical to maintain the required institutional committee may wish to negotiate with a local university or other research organization to have this service performed for them.

“Questions specifically related to the completion of Form CSREES-662 should be directed to the CSREES Office of Extramural Programs, Grants Management Branch at (202) 401-5050.”

Applicants for USDA Grants who intend to use animal subjects as part of their sponsored projects must complete Form CSREES-2008 below (part “B.”).

**UNITED STATES DEPARTMENT OF AGRICULTURE
COOPERATIVE STATE RESEARCH, EDUCATION, AND EXTENSION SERVICE
ASSURANCE STATEMENT(S)**

OMB approved 0524-0039

STATEMENT OF POLICY - Institutions receiving CSREES funding for research are responsible for protecting human subjects, providing humane treatment of animals, and monitoring use of recombinant DNA. To provide for the adequate discharge of this responsibility, CSREES policy requires an assurance by the institution's Authorized

Organizational Representative (AOR) that appropriate committees in each institution have carried out the initial reviews of protocol and will conduct continuing reviews of supported projects. CSREES also requires AOR certification by citing a timely date that an appropriate committee issued an approval or exemption.

NOTE: Check appropriate statements, supplying additional information when necessary.

1. INSTITUTION	2. CSREES PROJECT NUMBER OR AWARD NUMBER (if known)
	3. PROJECT DIRECTOR(S)
4. TITLE OF PROJECT	

A. BIOSAFETY OF RECOMBINANT DNA

- Project does not involve recombinant DNA.
- Project involves recombinant DNA and was either approved () or determined to be exempt (✓) from the NIH Guidelines by an Institutional Biosafety Committee (IBC) on _____ (Date).

This performing organization agrees to assume primary responsibility for complying with both the intent and procedures of the National Institutes of Health (NIH), DHHS Guidelines for Research Involving Recombinant DNA Molecules, as revised.

B. CARE AND USE OF ANIMALS

- Project does not involve vertebrate animals.
- Project involves vertebrate animals and was approved by the Institutional Animal Care and Use Committee (IACUC) on _____ (Date).

This performing organization agrees to assume primary responsibility for complying with the Animal Welfare Act (7 USC, 2131-2156), Public Law 89-544, 1996, as amended, and the regulations promulgated thereunder by the Secretary of Agriculture in 9 CFR Parts 1, 2, 3, and 4. In the case of domesticated farm animals housed under farm conditions, the institution shall adhere to the principles stated in the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching, Federation of Animal Science Societies, 1999.

C. PROTECTION OF HUMAN SUBJECTS

- Project does not involve human subjects.
- Project involves human subjects and
 - Was approved by the Institutional Review Board (IRB) on _____ (Date). Performing Institution holds a Federalwide assurance number _____; if not, a Single Project Assurance is required.
 - Is exempt based on exemption number _____.
 - Specific plans involving human subjects depend upon completion of survey instruments, prior animal studies, or development of material or procedures. No human subjects will be involved in research until approved by the IRB and a revised Form CSREES-2008 is submitted.

This performing organization agrees to assume primary responsibility for complying with the Federal Policy for Protection of Human Subjects as set forth in 45 CFR Part 46, 1991, as amended, and USDA regulations set forth in 7 CFR 1c, 1992. All nonexempt research involving human subjects must be approved and under continuing review by an IRB. If the performing organization submits a Single Project Assurance, supplemental information describing procedures to protect subjects from risks is required.

SIGNATURE OF AUTHORIZED ORGANIZATIONAL REPRESENTATIVE	TITLE	DATE

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0524-0039. The time required to complete this information collection is estimated to average .50 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

CSREES-2008 (12/02/00)

National Science Foundation (NSF).

(From the National Science Foundation Grant Proposal Guide, NSF 01-2, http://www.nsf.gov/pubs/2001/nsf012/nsf0102_2.html#IIC11, scroll down to “d.”)

“d. Proposals Involving Vertebrate Animals

“For proposals involving the use of vertebrate animals, sufficient information must be provided within the 15-page project description to allow for evaluation of the choice of species, number of animals to be used, and any necessary exposure of animals to discomfort, pain or injury. All projects involving vertebrate animals must have approval from the organization’s Institutional Animal Care and Use Committee (IACUC) prior to the issuance of an NSF award. The box for “Vertebrate Animals” must be checked on the Cover Sheet with the IACUC approval date (if available) identified in the space provided. If the IACUC has not reviewed the proposed work, the proposer should include the date at which the review is scheduled to be completed.”

The NSF Cover Sheet “form” is not included in this Appendix, as all NSF proposals are submitted on-line via FastLane. Visit <https://www.fastlane.nsf.gov/fastlane.htm> to submit your proposal and complete all necessary NSF animal-use certifications on the Cover Sheet.

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APPENDIX K

NORTH DAKOTA STATE UNIVERSITY POLICY MANUAL SECTION 346: ANIMAL WELFARE *[from <http://www.ndsu.nodak.edu/policy/346.htm>]*

[**NOTE:** This section of the NDSU Policy Manual has been revised by the IACUC to update the language, the Institutional Official, Web addresses, etc. At press time, Section 346 was being processed for review and approval by the Policy Coordination Committee, the Staff Senate, and the University Senate. This section should be approved by spring 2006. Thus, always refer to the Web address listed above for the most recent version of Section 346.]

SECTION 346: ANIMAL WELFARE

SOURCE: NDSU President

North Dakota State University is committed to complying with all applicable laws and regulations regarding the humane care and use of live vertebrate animals utilized for research, teaching, testing, and/or exhibition purposes conducted at NDSU or by NDSU personnel. The University's animal care and use policies are administered by the Institutional Official, who is appointed by the NDSU President.

An Institutional Animal Care and Use Committee (IACUC) has been appointed to oversee the University's animal care program. The IACUC is responsible for review and approval of protocols concerning animals, inspection of animal facilities, and reporting to appropriate government agencies.

Examples of activities that require prior IACUC approval include but are not limited to the following:

1. activities utilizing live vertebrate animals owned by NDSU or housed at NDSU facilities, including off-campus facilities such as the Research Extension Centers around the state.
2. activities involving live vertebrate animals conducted by faculty, students, staff, or other representatives of NDSU, regardless of funding.

Guidance regarding specific animal-related activities and the need for IACUC approval should be directed to the IACUC office.

Principal Investigators and other personnel working on animal-related activities are required to complete IACUC training before submitting a new protocol for review by the IACUC.

Any individual may report a concern involving the care and use of animals for which North Dakota State University is responsible. Any IACUC official or member will receive animal-welfare-related concerns, questions or complaints, which then will be reviewed by the committee. Reports received by other University personnel must be forwarded immediately to the IACUC office. The individual presenting the concern is assured freedom from incrimination,

coercion, or reprisal. After committee review, responsible officials will report committee findings to the appropriate regulatory agency if warranted and take corrective actions if needed.

Detailed policies and procedures governing the care and use of live vertebrate animals are described in the handbook, *The Care and Use of Vertebrate Animals at NDSU*. They also may be viewed electronically at <http://www.ndsu.nodak.edu/research/compliance/iacuc/> and are available in hardcopy from the IACUC office.

HISTORY: Amended April 1992; October 1997; May 2001, September 2003, November 2005.

APPENDIX L

GUIDE FOR THE CARE AND USE OF LABORATORY ANIMALS

GUIDE FOR THE CARE AND USE OF AGRICULTURAL ANIMALS IN AGRICULTURAL RESEARCH AND TEACHING

The *Guide for the Care and Use of Laboratory Animals* is available from the National Academy Press, 2101 Constitution Avenue, NW, Lockbox 285, Washington, DC 20055 (phone toll-free 1-800-624-6242). Orders may also be placed electronically via Internet at <http://www.nap.edu>.

The *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching* is available from the Federation of Animal Science Societies, 1111 North Dunlap Avenue, Savoy, IL 61874 (or call 217-356-3182).

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APPENDIX M

NDSU IACUC STANDARD OPERATING PROCEDURE (SOP), IACUC-01

SOP IACUC-01 (Approved 05/28/1997; Changes Approved 03/16/2006)

Date Prepared: 04/24/1997:jwg

Date Revised: 01/17/2001:bas

Date Revised: 03/16/2006:paf

Title: Animal Facilities Inspection

I. Purpose:

To provide IACUC members resources and guidelines for the inspection of NDSU animal facilities.

II. Background:

Institutional Animal Care and Use Committees (IACUC) are responsible for all animal-related activities of an institution regardless of where the animals are maintained or the duration of their stay (ILAR News 33(4):68-70, 1991). The IACUC will inspect, at least once every six months, all of the institution's animal facilities (including satellite facilities) using The Guide for the Care and Use of Laboratory Animals as a basis for evaluation. The IACUC may, at its discretion, determine the best means of conducting an evaluation of animal facilities (Public Health Service Policy on Humane Care and Use of Laboratory Animal, rev. September 1986, reprinted 2000, Section IV.B.2., footnote 7, p. 12 or <http://grants.nih.gov/grants/olaw/references/phspol.htm#f7>). This document is intended to establish a standard operating procedure for the performance of NDSU animal facilities inspections.

III. Inspection Team:

At least two voting IACUC members, including the NDSU Attending Veterinarian, will comprise the inspection team.

- A. When possible, the IACUC member accompanying the Attending Veterinarian will have prior knowledge of or an association with the animal facility to be inspected.
- B. The Attending Veterinarian or the Director of the IACUC will notify facilities managers and/or principal investigators, either by phone or in writing, of the planned inspection dates and times when possible.
 1. Inspections will be performed at least six months after the previous inspection (typically in December and June), and inspection reports will be reviewed by the IACUC at the full committee meeting following the inspection.
 2. Inspection teams are encouraged to be flexible in arranging inspection dates and times.

3. The presence of the facilities manager or principal investigator is encouraged to facilitate the inspection of the animal facilities by providing immediate responses to questions or concerns of the inspection team.

IV. Inspection Procedure:

Inspection teams will review the OLAW-based checklist for Semiannual Facility Inspections (Attachment 1) prior to undertaking an inspection. NDSU has devised a laboratory animal checklist (attachment 1) and an agricultural animal use checklist based on the Ag Guide. Inspection teams will review the appropriate checklist before undertaking semiannual facility inspections

- A. Inspection notes, in a transcribable form, will be taken by the inspection team.
 1. If appropriate, the condition of the facilities will be listed as Acceptable.
 2. Deficiencies, where noted, will be graded as Minor or Significant. Significant deficiencies are those that are or may become a threat to animal health and well-being or to the safety and well-being of personnel who work in the facility.
 3. After the inspection, facilities managers or principal investigators will be notified of minor or significant deficiencies in animal care or well-being.
 - a. The IACUC Director or Attending Veterinarian will inform the manager or investigator of the deficiencies to be corrected verbally or in writing. The inspection team and the Attending Veterinarian (in cooperation with the facilities manager or principal investigator) will agree on the means and date by which deficiencies should be remedied.
 - b. When deficiencies are the cause of severe, unacceptable animal pain and distress that cannot be alleviated, the Attending Veterinarian will euthanize the animal(s). A reasonable attempt will be made to contact and consult with the facilities manager or principal investigator before this action is taken.
 4. Original copies of the inspection notes will be delivered to the IACUC Director. The Director incorporates the inspection results into the Semiannual Reports to the Institutional Official and maintains the original notes and reports in the IACUC files. Copies of the semiannual reports and inspections are also provided to all IACUC members.

V. Assurance:

I have read this document and approve of its contents. I certify that it will be made available to all IACUC members, principal investigators, and identified facilities managers.

Jayma Moore, D.V.M., MS.
Chair. NDSU IACUC

Neil Dyer, D.V.M.
Attending Veterinarian

(Revised by Pierre Freeman, IACUC Director, March 16, 2006.)

APPENDIX N

LIST OF NDSU ANIMAL FACILITIES MANAGERS

NOTE: NDSU retained this list in the IACUC office and within the Facilities management offices for Emergency purposes only. This list may also be found on Blackboard under the IACUC course documents. Each facility should have posted on the entrance doors who to contact in case of an emergency. These Placards may also be found on the Blackboard IACUC course Documents

(The 2005 Emergency contact list begins on the following pages for the IACUC members.)

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Institutional Animal Care and Use Committee (IACUC)

For the protection of animal subjects



IACUC Office

Department of Sponsored Programs Administration
Office of the Vice President for Research, Creative Activities and Technology Transfer
1735 NDSU Research Park Drive, P.O. Box 5756
Fargo, ND 58105-5756, Phone (701) 231-8114, Fax (701) 231-8089

NDSU System Facilities Housing Live Animals: Emergency Contact List

Generally, for any animal questions, concerns, problems, or emergencies contact the NDSU Attending Veterinarian, Neil Dyer, at 231-7521, 231-8307, or (218) 233-9278.

Facility/Group	Contact Person 1*	Contact Person 2	Contact Person 3
NDSU Attending Veterinarian	Neil Dyer, D.V.M. 231-7521, 231-8307, or 218-233-9278		
NDSU Institutional Animal Care & Use Committee (IACUC)	Jayma Moore, D.V.M. Chair 231-8435	Pierre Freeman, Director 231-8114 or 231-8045	Phil Boudjouk, Institutional Official 231-8045 or 231-6542
NDSU Campus Police	231-8998 (non-emergency)	911 (emergency)	Mueller, Chief (William MacDonald, Night Supervisor) 231-7835
Back-up Veterinarian (only contact if unable to reach Dr. Dyer and facilities managers)	Sarah Wagner, D.V.M. 231-5393, 701-232-5687		
Sudro 207	Jagdish Singh 231-7943	Charles Peterson 231-7609	
Stevens 104	Mark Sheridian 231-8110	Jim Grier 231-8444	
Stevens 111	Jim Grier 231-8444	William Bleier 231-8421	
Stevens Hall Greenhouse, Winter housing	Mark Clark 231-8246	Wendy Reed 231- 5921	William Bleier 231-8421

* Unless otherwise noted, the area code for all phone numbers is 701.

Van Es 106	Jane Schuh 231-7841 or 237-5456	Scott Hoselton 231-7905 or 277-8816	
Robinson Hall Rooms 116-125, 127- 146	Tom Colville 231-7530 or 293-3772	Amy Ellwein 231-6369 or 218-233-6961	Teresa Sonsthagen 231-7531 or 588-4523
Robinson 126	Thomas Gustad 231-7530 or 293-3772	Rick Feldman 231-7518 or 235-3293	
Pole Barns West of ANPC	Tim Johnson 799-7847, 231-7612 or 232-0510 (H)	Terry Skunberg 231-7611, 231-7612	Teresa Sonsthagen 231-7531 or 588-4523
Animal Nutrition and Physiology Center	Tim Johnson 799-7847, 231-7612 or 232-0510 (H)	Terry Skunberg 231-7611, 231-7612	Al Misek 280-2729, 793-0512
Beef Barn	Ty Klein 231-7039	Matt Laubach 231-7022	Casselton Veterinary 347-5496
Sheep Barn	Wes Limesand 231-7782	Doug Tufte 231-7782	Casselton Veterinary 347-5496
Dairy Barn	Dan Shimek 231-7955	Todd Molden 231-7955	Valley Veterinary 232-3391
Swine Barn	Ron Zimprich 231-7039	Casselton Veterinary 347-5496	
Quarantine Barns West of I-29	Al Misek 280-2729, 793-0512	Dale Redmer 231-7991	
Horse Park <i>September – May only</i>	Carrie Hammer 231-5682, 793-0421	Bobbi Bingeman 793-4351	Al Misek 280-2729, 793-0512
Hettinger Research Extension Center (REC)	Tim Faller 567-4323	Chris Schauer 567-4323, 567-3582	West River Veterinary Clinic 567-4333
Central Grasslands (Streeter) REC	Brian Kreft 424-3406	Steele Veterinary Clinic 475-2300	Ritchie Cargo 424-3639
Carrington REC	Vern Anderson 652-2951	Southwood Veterinary Clinic Jamestown, ND (701) 252-3430	
Dickinson REC (Manning)	Gary Ottmar 573-4553	Dr. David Hacker 764-5626	
Dickinson REC (Dickinson)	Kris Ringwall 483-2427	Yost Veterinary Clinic 225-4863	Dr. Pat Williams 225-8719

APPENDIX O

LIST OF NDSU TRAINING COURSES

Baseline Training (administered and sponsored by the Office of Occupational Safety and Environmental Health and Workers Compensation):

Required of all university employees:

- Baseline Safety Training: Includes basic safety information like fire safety, emergency procedures, ergonomics, reporting injuries, etc. (administered and sponsored by the Office of Occupational Safety and Environmental Health),

Required of all university employees working with chemicals and in labs:

- Lab and Chemical Safety (administered and sponsored by the Office of Occupational Safety and Environmental Health)

NDSU IACUC training program (administered and sponsored by the Office of the Vice President for Research, Creative Activities and Technology Transfer unless otherwise noted):

Required training modules for all individuals involved with animal care and use:

- Animal Care & Use at NDSU



Additional training modules that may be recommended or required (by supervisors, departments, PIs, the IACUC, Attending Veterinarian, etc.) for certain individuals based on their specific work or involvement with animals: (NOTE: Additional modules are continually developed and added.)

- Animal Care & Use: Occupational Health and Safety
- Animal Environment, Housing, and Management
- Biology & Husbandry of the Gerbil
- Biology & Husbandry of the Guinea Pig
- Biology & Husbandry of the Hamster
- Biology & Husbandry of the Mouse
- Biology & Husbandry of the Rabbit
- Biology & Husbandry of the Rat
- Beef Cattle Husbandry
- Bison Management
- Dairy Cattle Husbandry
- Horse Husbandry
- Swine as a Research Animal
- Sheep Management
- Euthanasia
- Aseptic Technique
- Johnes Disease
- Surgery Module
- Zoonoses Module

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APPENDIX P

**NDSU USDA REGISTRATION NUMBER AND
CERTIFICATE**

	United States Department of Agriculture	Marketing and Regulatory Programs	Animal and Plant Health Inspection Service	Animal Care	EXPIRATION DATE: OCTOBER 20, 2008
<p>This is to certify that NORTH DAKOTA STATE UNIVERSITY is a registered CLASS R RESEARCH FACILITY under the</p>					Animal Welfare Act (7 U.S.C. 2131 et seq.)
Certificate No. 45-R-0002 Customer No. 1565					 Deputy Administrator

APHIS FORM 7021 (NOV 99)

Previous editions are obsolete

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APPENDIX QNDSU IACUC SEMIANNUAL INSPECTION, PROGRAM REVIEW, AND VETERINARY
MEDICAL CARE REVIEW FORMS**Institutional Animal Care and Use Committee (IACUC)**

For the protection of animal subjects

**IACUC Office**

Department of Sponsored Programs Administration
Office of the Vice President for Research, Creative Activities and Technology Transfer
1735 NDSU Research Park Drive, P.O. Box 5756
Fargo, ND 58105-5756, Phone (701) 231-8114, Fax (701) 231-8089

Semiannual On Campus Facilities Inspection Form

Inspection Date: _____ **For FY** _____ **-1** **-2**

Inspection Team: _____

Please consider and/or make note of the following during the inspection:**General Concerns to Note (Procedure Areas, Non-Survival Surgeries, Laboratories, Rodent Surgeries):**

- Drug storage, control, and expiration dates
- Sharps disposal
- Anesthetic monitoring
- Gas cylinder immobilized
- Scavenging or anesthetic gases
- Warning signs
- Carcass disposal

Rodent Areas or Minor Procedures:

- Rodent survival surgery clean and uncluttered (not used for anything else during surgery)
- Records of perioperative care
- Aseptic procedures
- Autoclave monitoring procedures
- Storage of autoclaved materials
- Cold sterilization procedures are appropriate

General Considerations:

- Location minimizes traffic/contamination
- Functional components (surgical support, animal preparation, surgeon scrub, operating room, postoperative recovery) are designed and separated (physically or otherwise) according to the *Guide*

- Appropriate drug storage, control, expiration date monitoring
- Safe sharps disposal system
- Adequate records of anesthesia and perioperative care
- Aseptic procedures in use for all survival surgery

Operating Room:

- Effective contamination control procedures/dedicated tools
- Effective cleaning procedures/dedicated tools
- Interior surfaces smooth and impervious to moisture
- HVAC system meets *Guide* requirements
- Lighting safe and appropriate
- Scavenging of anesthetic gases implemented
- Warning signs posted where needed
- Fixed equipment is sanitizable

Surgical support:

- Facility for washing, sterilizing, storing instruments and supplies
- Autoclave monitoring procedures are implemented
- Storage of autoclaved materials maintains sterility
- Cold sterilization procedures are appropriate

Animal Preparation: contains large sink to facilitate cleaning of animal and operative site

Surgeon Scrub: outside operating room, non-hand-operated sink

Postoperative recovery: allows adequate observation, easily cleaned, supports physiologic functions, minimizes risk of injury

Dressing area: place for personnel to change

Construction:

- Doors, windows, floors, drainage, walls, ceilings (see *Guide*)
- Convenient to animal areas/waste disposal
- Ease of access (including door size) facilitates use
- Sufficient space for workload
- Safety precautions/clothing/equipment used for bedding disposal/prewash/acid wash
- Traffic flow clean to dirty with no contamination of clean equipment by dirty equipment
- Insulation and/or sound attenuation present as needed
- Utilities are appropriate
- Ventilation meets heat and humidity load and *Guide* requirements
- Safety features (SOP's, warning signs, eyewash station) are in use
- Cagewash temperatures are monitored and records are available
- Appropriate clean cage storage

[A = Acceptable, M = Minor Deficiency, S = Significant Deficiency, * = Repeat Deficiency]

Location	A	M	S	Species	Deficiency & Plan for Correction	Correction Schedule	Date Completed	Notes

Additional Notes:

Signed: _____ **Date** _____

Signed: **NDSU Attending Veterinarian** _____ **Date** _____

Signed: **NDSU IACUC Chair** _____ **Date** _____

NDSU IACUC Director _____

Institutional Animal Care and Use Committee (IACUC)

For the protection of animal subjects



IACUC Office

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Semiannual Satellite Facilities Inspection Form

Location:

Inspection Date:

For FY

-1

-2

Inspection Team:

Construction:

This checklist was based on the *Ag Guide*

- Doors, windows, floors, drainage, walls, ceilings (see *Ag Guide*) Indoor facilities
- Convenient to animal areas/waste disposal
- Ease of access (including door size) facilitates use
- Traffic flow clean to dirty with no contamination of clean equipment by dirty equipment
- Ventilation meets heat and humidity load and *Guide* requirements
- Water supply for sanitation, animals, fire and emergency
- Storage of equipment to handle feed and waste
- Storage of small tools and repair of equipment
- Electrical service backup too
- Feed storage
- Bedding storage
- Utilities are appropriate
- Storage of toxic materials and hazardous substances
- Contact with wet and corrosive animals waste acidic silage or cleaning solutions
- Moisture and fire resistant
- Absence of stray voltage and proper grounding of electrical equipment indoors and outdoors
- Vermin control

Processes, Procedures:

- Animal traction and safety
- Sufficient space for workload
- Safety precautions/clothing/equipment used for bedding disposal
- Safety features (SOP's, warning signs, eyewash station) are in use

- Waste storage, excreta, contaminated drainage, slope, ponds, and environment
- Veterinary examination treatment and supply storage
- Quarantine of animals
- Handling sorting weighing loading and unloading animals
- Slaughter and processing facilities
- Carcass composting
- Waste handling sanitary requirements for food products
- Procurement of animals
- Training records
- Occupation Safety and Environmental Health

Handling and use:

- Animals are fenced, penned, or enclosed areas with waters and feeders
- Water supply for animals within 1.5 miles in pastures
- Animal shelter solar, wind rain and snow
- Maternity care
- Supplements for deficiencies in the local area forage
- Shade and wind breaks appropriate in pasture lands
- Species separation
- Semen collection and storage and artificial insemination
- Experimental surgery
- Sick and injured animals
- Animal ID
- Restraint devices
- Ground type for bins, feeders, stanchions and pens

[A = Acceptable, M = Minor Deficiency, S = Significant Deficiency, * = Repeat Deficiency]

Location/Room	A	M	S	Species	Deficiency & Plan for Correction	Correction Schedule	Date Completed	Notes

Additional Notes:

Signed: _____ **Date** _____

NDSU Attending Veterinarian

Signed: _____ **Date** _____

NDSU IACUC Chair

Signed: _____ **Date** _____

NDSU IACUC Director

Institutional Animal Care and Use Committee (IACUC)

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Semiannual Program Review

Date: _____ **For FY** _____ **-1** **-2**

Reviewer(s): _____

[A = Acceptable, M = Minor Deficiency, S = Significant Deficiency, * = Repeat Deficiency]

	A	M	S	Deficiency & Plan for Correction
1) IACUC Membership & Functions				
- at least 5 members, appointed by Institutional Official				
- members include veterinarian, scientist, non-scientist, and non-affiliated non-lab animal user				
- responsible for oversight & evaluation of institution's program				
- reports to Institutional Official				
- conducts semiannual evaluations of institutional animal care & use program				
- conducts semiannual inspections of institutional animal facilities				
- reviews & investigates concerns about animal care & use at institution				
- procedures for review, approval, and suspension of animal activities				

- procedures for review & approval of significant changes to approved activities				
- policies for special procedures (e.g. restraint, multiple survival surgery, fluid restriction)				
	A	M	S	Deficiency & Plan for Correction
2) IACUC Records & Reporting Requirements				
Reports to Institutional Official (IO)				
- reports of semiannual program reviews & Facility inspections are submitted to IO				
- include minority IACUC views				
- describe departures from Guide or PHS Policy and reasons for departure				
- distinguish significant from minor deficiencies				
- include plan & schedule for correction of each deficiency identified				
Reports to Office for Laboratory Animal Welfare (OLAW)				
- reports include any minority IACUC views				
- annual report to OLAW documents program changes & dates of IACUC semiannual review				
- promptly advises OLAW of serious/ongoing Guide deviations of PHS policy noncompliances				
- promptly advises OLAW of any suspension of activity by the IACUC				
Reports to USDA				
- annual report contain required information				
- reporting mechanism in place for IACUC-approved exceptions to the regulations & standards				
- reports within 15 days failure to adhere to timetable for correction of deficiencies				
- reports suspension of activity by the IACUC to USDA & federal funding agency				

Records				
- minutes of IACUC meetings and semiannual reports maintained for 3 years				
- IACUC review documentation maintained for 3 years after end of study				
- IACUC review of activities involving animals includes all required information				
	A	M	S	Deficiency & Plan for Correction
3) Veterinary Care				
- institutional arrangement for veterinarian with training or experience in lab animal medicine				
- veterinary access to all animals				
- provision for backup veterinary care				
- must provide guidance on handling, immobilization, sedation, analgesia, anesthesia, euthanasia				
- must provide guidance/oversight on surgery programs and oversight of postsurgical care				
- veterinary authority to oversee all aspects of animal care & use				
Disaster Preparedness				
- facilities have developed a disaster plan specific to their species				
- plans are based on risk and hazard assessments appropriate for our area				
- plans have indicated resources that can be used when needed such as local assistance groups during an emergency				
- plans are reviewed and practiced annually				
- plans include animal as well as university personnel				
	A	M	S	Deficiency & Plan for Correction
4) Personnel Qualifications & Training				
- institution has established and implemented an effective training program				
- includes professional/management/supervisory personnel				

- includes animal personnel				
- includes research investigators, instructors, technicians, trainees, students				
Training Program Content				
- humane practices of animal care (e.g. husbandry, housing, handling)				
- humane practices of animal use (e.g. research procedures, use of anesthesia, pre- & post-operative care)				
- research/testing methods that minimize animal pain or distress				
- research/testing methods that minimize numbers necessary to obtain valid results				
- use of hazardous agents, including access to OSHA chemical hazard notices where applicable				
	A	M	S	Deficiency & Plan for Correction
5) Occupational Health & Safety of Personnel				
Institutional program for a safe & healthy workplace				
- program is established & implemented				
- covers <i>all</i> personnel who work in laboratory animal facilities				
- based on hazard identification & risk assessment				
- personnel training (e.g. zoonoses, hazards, pregnancy/illness/immunosuppression precautions)				
- personal hygiene procedures (e.g. work clothing, eating/drinking/smoking policies)				
- procedures for use, storage, and disposal of hazardous biological, chemical, and physical agents				
- specific procedures for personnel protection (e.g. shower/change facilities, injury protection)				
Program for medical evaluation and preventive medicine for personnel				
- pre-employment evaluation including health history				
- immunizations as appropriate (e.g. rabies, tetanus) & tests				

- zoonosis surveillance as appropriate (e.g. Q-fever, tularemia, Hantavirus, plague)				
- procedures for reporting and treating injuries, including bites, etc.				

Additional Notes and Comments:

Signed: _____ **Date** _____

Signed: **NDSU Attending Veterinarian** _____ **Date** _____

Signed: **NDSU IACUC Chair** _____ **Date** _____

NDSU IACUC Director

Institutional Animal Care and Use Committee (IACUC)

For the protection of animal subjects



IACUC Office

Department of Sponsored Programs Administration
 Office of the Vice President for Research, Creative Activities and Technology Transfer
 1735 NDSU Research Park Drive, P.O. Box 5756
 Fargo, ND 58105-5756, Phone (701) 231-8114, Fax (701) 231-8089

Semiannual Program Review of Veterinary Medical Care

Date: _____ **For FY** _____ **-1** **-2**

[A = Acceptable, M = Minor Deficiency, S = Significant Deficiency, * = Repeat Deficiency]

	A	M	S
<u>1. Preventive Medicine/Animal Procurement & Transportation</u>			
- evaluation of animal vendors			
- procedures for lawful animal procurement, evaluation of animals, & transport			
- procedures for quarantine, stabilization			
- policies on separation by species, source, health status			
- policies for isolation of sick animals			
- program of surveillance, diagnosis, treatment and control of disease			
- availability of diagnostic resources for preventive health program			
- provision for emergency, weekend, and holiday veterinary care			
<u>2. Surgery</u>			
- procedures for monitoring surgical anesthesia and analgesia			

- pre-surgical plan (e.g. identify space, supplies, conduct pre-op exam, define post-op care)			
- appropriate training or experience of personnel in surgery & anesthesia			
- major procedures distinguished from minor			
- use of effective aseptic procedures for survival surgery			
- implemented procedures for use of surgical facility			
- implemented procedures for using/scavenging volatile anesthetics			
- effective procedures for sterilizing instruments & monitoring expiration dates on sterile packs			
- documentation of post-operative monitoring and care			
<u>3. Pain, Distress, Analgesia, and Anesthesia</u>			
- guidelines for assessment and categorization of pain			
- IACUC guidelines for avoiding unnecessary pain and distress			
- appropriate anesthetics, analgesics, tranquilizers used for each species			
- special precautions for the use of paralytics			
<u>4. Euthanasia</u>			
- compliance with current <u>AVMA Panel on Euthanasia</u> unless approved by IACUC			
- guidance provided on appropriate methods for each species			
- training available for personnel in humane methods of euthanasia			
<u>5. Drug Storage and Control</u>			
- safe, secure, storage arrangement			
- record keeping meets regulations			
- procedures exist for ensuring drugs are within expiration date			

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APPENDIX R

Lines of Authority & Responsibility for Animal Care & Use Programs

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APPENDIX S

NDSU GUIDELINES FOR OCCUPATIONAL HEALTH & SAFETY IN THE CARE & USE OF VERTEBRATE ANIMALS

(*The Guidelines can be found at the following website: <http://facilities-mgmt.ndsu.nodak.edu/oseh/OccupationalSafetyandEnvironmentalHealth2005.pdf>.)*

NDSU IACUC oversees the entire animal use program and evaluates it on behalf of the university. Some aspects of the overall program are administered through departments other than where the IACUC office is administered. NDSU promotes an inter-departmental cooperation in order to maintain the highest quality animal use and care program.

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APPENDIX T

2006 NDSU PHS-OLAW ANIMAL WELFARE ASSURANCE STATEMENT

[NOTE: The 2006 Assurance has been approved, it will be provided to the committee members and members of the research faculty who request a copy]

(The 2006 Assurance may be requested through the IACUC Office.)

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Institutional Animal Care and Use Committee (IACUC)

For the protection of animal subjects



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Animal Health and Illness Report

Date Observed

Building/Room #

Species

Animal ID #

(Shoebox number if applicable)

Investigator

Observer

(Print Name)

Veterinarian

Neil Dyer, signature

Animal Observation

Emergency Only: **Attending Veterinarian – Neil Dyer, 1-7521, 1-8307, or Cell (218) 233-9278, Alternate Attending Veterinarian – Sarah Wagner, 1-5393, 701-232-5687**

NOTES:

Please submit this report to the Attending Veterinarian in Van Es Hall at the Vet. Diagnostic Lab. You can do this through campus mail or submit electronically via email at: [mailto:neil.dyer@ndsu.edu?subject=Health and Illness report](mailto:neil.dyer@ndsu.edu?subject=Health%20and%20Illness%20report)

Office use only:

NOTES:

Appendix V

SAMPLE IACUC DECISION LETTER TO PI

July 6, 2005

Dr. Principal Investigator
Animal Department
Animal Hall,

Re: IACUC Approval of New Protocol, #A0199, "Protocol Title," Category B-E

Approval Date:	July 6, 2005
Current Approval Period:	July 6, 2005– July 6, 2008
Annual Update Due:	June 1, 2006

Dear Dr. Principal Investigator:

The referenced project has been reviewed by the NDSU Institutional Animal Care and Use Committee and has IACUC approval as of the date indicated above. A copy of the New Protocol Form with IACUC approval signatures is enclosed for your records.

The IACUC requests that you keep a copy of this protocol on file at the location or facility where the animals will be housed. During the course of this project, if you plan any significant changes in the protocol, a Change in Protocol Form outlining the proposed changes must be submitted to the IACUC, and IACUC approval granted, before implementation of the changes. A report and renewal of the project is also required on an annual basis. A reminder will be sent to you about a month before the report due date.

Please feel free to consult with Dr. Neil Dyer, NDSU's Attending Veterinarian (231-7521 or neil_dyer@ndsu.edu), to ask questions or discuss any animal-related needs or concerns throughout the duration your project. The IACUC Chair is also available if you have questions regarding animal welfare or university requirements.

NDSU has an Animal Welfare Assurance on file with the Public Health Service's Office of Laboratory Animal Welfare (OLAW). The assurance number is **A3244-01**, last renewed on July 2001. NDSU is also registered with the U.S. Department of Agriculture as an Animal Research Facility under the registration number **45-R-002**.

Thank you for your cooperation with NDSU IACUC procedures.

Sincerely,


Pierre A. Freeman
IACUC Director

enclosure

APPENDIX W

Annual Update Form

Institutional Animal and Use Committee (IACUC) For the protection of animal subject



Office Use Only
Date Received:

Department of Sponsored Programs Administration
Office of the Vice President for Research, Creative Activities and Technology Transfer
1735 NDSU Research Park Drive, P.O. Box 5756
Fargo, ND 58105-5756, Phone (701) 231-8114, Fax (701) 231-8089

Annual Update

Today's date:

Please return update by:

Federal regulations require continual monitoring of animal use protocols.

Please write in any changes or missing information and return this form to keep IACUC records on this project updated.

Investigator(s): Unknown, Person

Department: Unknown

Title:

Campus Address

Protocol #: A9999

Animal Model(s): All

Original Approval Date:

Expected Project End Date:

Animal Source/Vendor:

Number of animals approved for use:

Indicate number of animals used to date: 0

Animals are housed at:

Room:

Funding Source:

Pain Category:

Other animal detail:

Euthanasia Method:

Disposal Method:

Please add or delete names here to accurately indicate any personnel / staff changes since the last IACUC approval was granted. All faculty, staff, or students who handle animals must complete all applicable training for animal use.

Position/Project Personnel:

Project Type:

(Check [X] all that apply)

- Nature of the Study:**
- Survival (Chronic) Study
 - Inducement of a Disease State
 - Transgenic Breeding
 - Antibody Production
 - Terminal (Acute) Study
 - Inducement of Behavioral Stress
 - Multiple Surgeries
 - Neuromuscular Blockers
 - Blood/Tissue Collection
 - Prolonged Restraint

Project Status: (Check [X] below to indicate the status of this project)

REQUEST FOR PROTOCOL CONTINUANCE:

- Active - project ongoing

REQUEST FOR PROTOCOL TERMINATION

- Inactive - Completed
 - Inactive - Not Funded
 - Inactive - Never Initiated
- Date project was completed or inactivated _____

Project Progress:

(Please describe in the space provided; attach additional pages, if necessary)
Please provide a brief update on the progress made in achieving the specific aims of the protocol.

Project Problems / Adverse Events: (Please describe in the space provided; attach additional pages, if necessary.)

Please describe any unanticipated adverse events, morbidity or mortality, the cause(s), if known, and how these problems were resolved. If NONE, this should also be indicated. (Use back of sheet or attach separate sheet if needed.)

Future plans: (Check [X] all that apply)

- No changes are planned and the project will continue as previously approved by the IACUC.
- Changes are planned which affect the number of animals utilized, methods used, or the amount of animal pain, discomfort, and distress. A full description and justification for the proposed changes will be submitted, following the instructions on the IACUC Change in Protocol Form. (Please note that if the modifications are significant, you may be required to complete a new protocol application. If you have questions or require assistance in making this determination, please contact the IACUC Office.)
- Other. Provide a brief explanation in the space below.

Certifications of the Principal Investigator

Note: Please certify by checking the boxes below

Alternatives to Animal Use:

Alternatives to the use of animals should be considered and used when possible. By checking here, the PI assures that literature searches for alternatives have been conducted (documentation of such searches may be requested by the IACUC), that alternatives to the use of animals have been and continue to be considered for this project, and will be substituted whenever possible to achieve the specific project aims.

Alternatives to Potentially Painful Procedures:

By checking here, the PI assures that procedures which cause the least amount of pain or distress to the animals are considered and used whenever possible. Since the last IACUC approval, the PI has and will continue to consider alternatives which are potentially less painful or distressful to the animals while still achieving the specific project aims.

Duplication:

Activities involving animals must not unnecessarily duplicate previous experiments. By checking here, the PI provides documented assurance that the activities of this project remain in compliance with the requirement that there must be no unnecessary duplication.

The signature below certifies that the Principal Investigator understands the requirements of the PHS Policy on Humane Care and Use of Laboratory Animals, applicable USDA regulations, and NDSU IACUC Policies governing the use of vertebrate animals for research, testing, teaching or demonstration purposes. Signature further certifies that the information provided above is accurate and that the investigator will continue to conduct the project in full compliance with the aforementioned requirements.

PI signature: _____ **Date:** _____

(IACUC Office Use Only)

IACUC Chair signature: _____ **Date:** _____

IACUC Attending Veterinarian signature: _____ **Date:** _____

Comments:

This form may be updated as needed but will remain in similar format.