Institutional Animal Care and Use Committee
Policies and Procedures Manual

Office of Research and Economic Development
University of Wyoming

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This Policies and Procedures Manual was adapted from the University of Texas at Austin Institutional Animal Care and Use Committee Handbook of Policies and Procedures

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Section 1: Introduction

1.0 Purpose and scope of manual

It is the responsibility of the University of Wyoming (University) to provide suitable orientation, appropriate materials, adequate resources and training to enable faculty, staff, and Institutional Animal Care and Use (IACUC) members to carry out their respective duties consistent with the *Guide for the Care and Use of Laboratory Animals* (the *Guide*), the *Public Health Service Policy on Humane Care and Use of Laboratory Animals* (PHS Policy), and the *Animal Welfare Act and Animal Welfare Regulations* (AWRs).

1.1 Mission statement

The University recognizes the importance of animals in research and the scientific and ethical responsibility for their humane care and use. All those involved with the use of laboratory animals are responsible for insuring the health and well-being of the animals used in research and education at the University. The IACUC is responsible for overseeing the care and well-being of animals used for research and educational purposes at the University and serves the public by ensuring compliance with all legal and ethical standards regarding the use of vertebrate animals in research and teaching at the University.

1.2 Office for Laboratory Animal Welfare (OLAW)

The Office of Laboratory Animal Welfare (OLAW) implements PHS Policy. OLAW's responsibility for laboratory animal welfare extends to all PHS-supported activities involving animals. From time to time, OLAW issues policy guidance, interpretation, or general notices regarding PHS Policy and co-sponsors animal welfare workshops that are held in different locations across the country.

Specific OLAW responsibilities include:

- Implementation of the PHS Policy;
- Interpretation of the PHS Policy;
- Negotiation of Animal Welfare Assurances;
- Evaluation of compliance with the PHS Policy; and
- Education of institutions and investigators receiving PHS support.

Office for Laboratory Animal Welfare
National Institutes of Health
RKL 1, Suite 360, MSC 7982
6705 Rockledge Dr., Bethesda, MD
20892-7982 zip code for US Mail 20817 zip code for delivery service or hand delivery
Telephone: (301) 496-7163 Fax: (301) 915-9481
e-mail: olaw@od.nih.gov
http://grants.nih.gov/grants/olaw/olaw.htm

1.3 Animal Welfare Assurance

Before the PHS may award a grant or contract that involves the use of animals, the recipient institution and all performance sites involving or using animals must have on file with OLAW an approved Animal Welfare

Assurance (Assurance). The Assurance is the cornerstone of a trust relationship between the institution and the PHS. Included in the Assurance are:

- The designation of the Institutional Official (IO) responsible for compliance;
- A commitment that the institution will comply with the PHS Policy, with the *Guide*, and with the Animal Welfare Act (AWA) and the Animal Welfare Regulations; and
- A description of the institution's program for animal care and use.

The PHS Policy applies to the use of live, vertebrate animals in any activity supported or conducted by the Public Health Service (PHS). PHS agencies include:

- Agency for Healthcare Research and Quality;
- Agency for Toxic Substances and Disease Registry;
- Centers for Disease Control and Prevention;
- Food and Drug Administration;
- Health Resources and Services Administration;
- Indian Health Service;
- National Institutes of Health;
- Office of Public Health and Safety;
- Office of the Secretary;
- Program Support Center;
- Substance Abuse and Mental Health Services Administration; and
- Office of the Assistant Secretary for Preparedness and Response.

The University of Wyoming has an AWA Assurance on file. The AWA Assurance number is A3216-01.

1.4 United States Department of Agriculture (USDA)

In 1966, Congress passed the Laboratory Animal Welfare Act (PL 89-544) and the United States Department of Agriculture (USDA) was named the responsible agency for the enforcement of the AWA. Congress passed the AWA in 1966 and strengthened the law through amendments in 1970, 1976, 1985, and 1990. The USDA's Animal and Plant Health Inspection Service (APHIS) administers the AWA, its standards, and its regulations. The University of Wyoming is a registered Class R Research Facility with the USDA (customer number 16 under certificate number 83-R-0001).

The Animal Welfare Act

The AWA requires that minimum standards of care and treatment be provided for certain animals bred for commercial sale, used in research, transported commercially, or exhibited to the public. Individuals who operate facilities in these categories must provide their animals with adequate care and treatment in the areas of housing, handling, sanitation, nutrition, water, veterinary care, and protection from extreme weather and temperatures.

Inclusions

The AWA (Title 7, Chapter 54, Section 2132(g)) defines the term “animal” to mean any live or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or such other warm-blooded animal that is

being used, or is intended for use, for research, testing, experimentation, or exhibition purposes, or as a pet. With respect to a dog, the term means all dogs including those used for hunting, security, or breeding purposes.

Exemptions

The AWA (Title 7, Chapter 54, Section 2132(g)) excludes birds, rats of the genus Rattus, and mice of the genus Mus, bred for use in research, 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 use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber.

Research facilities

In addition to providing the required standards of veterinary care and animal husbandry, regulated research facilities must provide dogs with the opportunity for exercise and promote the psychological well-being of primates used in laboratories. Researchers must also give regulated animals anesthesia or pain-relieving medication to minimize the pain or distress caused by research if the experiment allows. The AWA also forbids the unnecessary duplication of a specific experiment using regulated animals.

Research facilities must establish an IACUC to oversee the use of animals in experiments. The IACUC is responsible for ensuring that the facility remains in compliance with the AWA and for providing documentation of all areas of compliance to the USDA/APHIS. The AWA does not permit APHIS to interfere with research procedures or experimentation. To ensure that all licensed and registered facilities continue to comply with the AWA, APHIS inspectors make unannounced inspections at least once annually.

If an inspection reveals deficiencies in meeting the AWA standards and regulations, the inspector instructs the facility to correct the problems within a given timeframe. If deficiencies remain uncorrected at the unannounced follow-up inspection, APHIS documents the facility's deficiencies and considers possible legal action.

APHIS also conducts reviews and investigates alleged violations. Some cases are resolved with Official Notices of Warning or agency stipulation letters, which set civil penalties for the infractions. Civil penalties include cease-and-desist orders, fines, and license suspensions or revocations.

In addition to conducting regular inspections, APHIS performs inspections in response to public input about the conditions of regulated facilities. Concerned individuals are encouraged to inform APHIS about facilities that should be licensed or registered.

1.5 Administration of research ethics at the University of Wyoming

The Office of Research and Economic Development is responsible for the functioning of the IACUC. If you have questions about the rules or procedures or the applicability of the information in this manual to your research, contact:

Office of Research and Economic Development
Old Main 308
Phone: (307) 766-5320 Fax: (307) 766-2608
e-mail: IACUC@uwyo.edu
http://www.uwyo.edu/research/animal-care/index.html

Section 2: The Institutional Animal Care and Use Committee

2.0 Authority

IACUCs derive their authority from the Health Research Extension Act (HREA) of 1985 and the Animal Welfare Act. These laws require the Chief Executive Officer (CEO), or designee to appoint the IACUC, whose responsibilities are delineated in the law and federal policy and regulations. The Office of Laboratory Animal Welfare (OLAW) considers the CEO to be the highest operating official of the organization. The President of the University of Wyoming delegates authority through the Institutional Official (IO) to appoint the membership of the IACUC on an annual basis.

Once appointed, the IACUC reports to a senior administrator known as the Institutional Official (IO). The Vice President for Research and Economic Development is the appointed IO at the University of Wyoming. The IO is given the administrative and operational authority to commit institutional resources to ensure compliance with the PHS Policy and other requirements.

The IACUC's mandate to perform semiannual program evaluations as a means of overseeing the animal care and use program puts the IACUC in an advisory role to the IO. In its semiannual reports the IACUC advises the IO of the status of the Institution's compliance, establishes plans and schedules for correcting deficiencies necessary to either maintain or achieve compliance, and makes recommendations to the IO regarding any aspect of the Institution's animal program, facilities, or personnel training.

The IACUC's authority to review and approve protocols is independent of the IO, who may not overrule an IACUC decision to withhold approval of a protocol. If the IACUC approves a protocol, the Institution is not required or obligated to conduct the research activity. The Institution may also subject protocols to additional institutional review (e.g., department head, the Department of Environmental Health and Safety, the Radiation Safety Committee, etc.).

The University of Wyoming has established an IACUC, which is qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and procedures.

2.1 Committee composition

The IACUC is composed of regular voting members and non-voting members. The IACUC may use, as necessary, non-voting members and consultants during review discussions. Some IACUC members fulfill specific regulatory requirements (e.g., veterinarian with program responsibility, an individual nonaffiliated with the Institution); others have unique roles by virtue of their position (e.g., Chair, Veterinarian, etc.).

There are no specific prohibitions regarding individuals filling more than one role on the IACUC, but OLAW strongly recommends against the same person serving multiple roles.

Required categories of membership include:

- **Veterinarian.** The PHS Policy and AWRs mandate the appointment of a veterinarian with direct or delegated program responsibility to the IACUC. The IO may appoint more than one veterinarian to the IACUC, but the veterinarian with direct or delegated program responsibility must be designated as such. The veterinarian with program responsibility, called the Attending Veterinarian, must have training or experience in laboratory animal science and medicine or in the care of the species being used.

- **Chair.** The Chair is appointed annually and is a faculty member of the University with research experience.
- **Nonaffiliated.** The nonaffiliated member(s) represent general community interests. Neither they, nor their immediate family, have an affiliation with the University. These members are voting members, have equal status to every other committee member, and are provided the opportunity to participate in all aspects of IACUC functions.
- **Scientist.** PHS Policy requires that the IACUC include a practicing scientist experienced in research involving animals.
- **Nonscientist.** PHS Policy requires that the IACUC include a member whose primary concerns are in a nonscientific area. Examples include, but are not limited to, ethicist, lawyer, member of the clergy, librarian, etc.

The Institution considers persons with expertise in the disciplines involved in institutional research and teaching programs for service on the IACUC.

There is no requirement that any particular member or category of members be present at all IACUC meetings. The institution, however, must have a properly constituted IACUC in order for the IACUC to conduct valid official business.

Alternate members may be appointed to the IACUC as long as they are appointed by the IO or other official with authority to appoint members and there is a specific one-to-one designation of IACUC members and alternates. An IACUC member and his or her alternate may not count toward a quorum at the same time or act in an official member capacity at the same time. Alternates should receive training identical to the training provided to regular IACUC members.

The University of Wyoming IACUC meets the compositional requirements set forth in section of IV.A.3.b. of PHS Policy.

Comparison of IACUC membership requirements

PHS Policy **PHS Policy IV.A.3.a-b**	**USDA Regulations** **9 CFR, 2.31(a)(b)**
Appointed by the IO	Appointed by the IO
Minimum of five members: • 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. • One practicing scientist experienced in research involving animals.	Minimum of three members: • At least one Doctor of Veterinary Medicine with training or experience in laboratory animal science and medicine, and who has direct or delegated program responsibility for activities involving animals at the institution. • One member not affiliated in any way with the institution and not a member of the immediate family of a person who is affiliated with the institution;

• One member whose primary concerns are in a nonscientific area (for example, ethicist, lawyer, clergy). • One member not affiliated in any way with the institution and not a member of the immediate family of a person who is affiliated with the institution.	person who represents the general community interests in the proper care and treatment of animals and is not a laboratory animal user (USDA Policy 15). • Not more than three members from the same administrative unit of the institution.
The PHS Policy requires institutions to follow the *Guide*, which states that committee membership should include at least one public member to represent general community interests in proper care and use of animals and that public members should not be laboratory animal users.	

2.2 Conflict of interest

Both the AWRs and PHS Policy state that no IACUC member "may participate in the IACUC review or approval of an activity in which that member has a conflicting interest, (e.g. is personally involved in the activity) except to provide information requested by the IACUC."

All investigators, consultants, and IACUC members are required to disclose any conflicts of interest. Please review the University's Policy on Conflict of Interest and Commitment in Research for information regarding what is a conflict and how to disclose the conflict. The University's Policy on Conflict of Interest and Commitment in Research can be found at: http://www.uwyo.edu/research/compliance/conflict%20of%20interest/index.html .

An investigator or IACUC member is said to have a conflict of interest whenever that person, his or her spouse, or dependent child falls under any of the following conditions:

- Is an investigator or sub-investigator on the protocol (IACUC members only, not applicable to principal investigators).
- Has entered into a financial arrangement with the sponsor or agent of the sponsor, and the outcome of the study could influence the value of the economic interest.
- Acts as an officer or a director of the sponsor or an agent of the sponsor.
- Has an equity interest in the sponsor of $5,000 or greater
- Has received payments or other incentives from any sponsor that when aggregated for the investigator or member, spouse and dependent children, total $5,000 or greater.
- Has identified him or herself for any other reason as having a conflict of interest.

Other possible examples of conflict of interest include cases where:

- A member is involved in a potentially competing research program;
- Access to funding or intellectual information may provide an unfair competitive advantage; or

- A member's personal biases may interfere with his or her impartial judgment.

If the investigator submitting a protocol believes that an IACUC member has a potential conflict, the investigator may request that the member be excluded. The Chair (or in his or her absence, another designated member of the IACUC) will present the declared conflict and the Committee will determine whether a conflict exists. Should an IACUC member declare involvement in any way in a research protocol under review by the IACUC, or state a conflict of interest with the research protocol, then the member(s):

- May remain in the meeting room to provide information requested by the IACUC;
- Shall leave the meeting room for discussion and voting; and
- Are not counted towards quorum.

2.3 Confidentiality

During the process of initial or continuing review of an activity (including, but not limited to, any annual reviews or protocol amendments), material provided to the IACUC and the Office of Research and Economic Development shall be considered privileged information and the IACUC shall assure the confidentiality of the data contained therein to the extent allowed by law.

2.4 Quorum requirements

Certain IACUC actions require a quorum: full committee review of a research project (Policy IV.C.2. and AWR §2.31(d)(2)) and suspension of an activity (Policy IV.C.6. and AWR §2.31(d)(6)).

The University defines a "quorum" as more than half of the regular IACUC voting members. A protocol is approved only if a quorum is present and if more than fifty percent of the quorum votes in favor of protocol approval. For reasons other than conflict of interest, abstentions from voting do not alter the quorum or change the number of votes required.

2.5 Functions of the Institutional Animal Care and Use Committee (IACUC)

The Institutional Animal Care and Use Committee (IACUC) will:

- Review at least once every six months the University's program for humane care and use of animals, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are described in Section 7.1.
- Inspect at least once every six months all of the University's facilities, including satellite facilities, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are described in Section 7.2.
- Prepare reports of the IACUC evaluations as set forth in the PHS Policy IV.B.3 and submit reports to the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official are described in Section 7.4.
- Review concerns involving the care and use of animals at the University. The IACUC procedures for reviewing concerns are described in Section 8.
- Make written recommendations to the IO regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the IO are described in Section 2.8.

- In accord with PHS Policy IV.C.1-3, the IACUC shall review and approve, require modifications in (to secure approval), or withhold approval of activities related to the care and use of animals. The IACUC procedures for protocol review are described in Section 3.
- Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in PHS Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research or educational projects are described in Section 3.9.
- Notify investigators and the IO in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy IV.C.4. The IACUC procedures to notify investigators and the IO of its decisions regarding protocol review are described in Section 3.6.
- Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy IV.C.1-4 at least once every three years. The IACUC procedures for conducting continuing reviews are described in Section 4.
- Suspend an activity involving animals as set forth in the PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are described in Section 8.4.

2.6 Liability

Under PHS Policy, the primary responsibility for meeting applicable Federal and state rules rests with the institution. Failure to comply with PHS Policy could result in OLAW's withdrawal of approval of the institution's Animal Welfare Assurance, thereby making the institution ineligible to receive Federal funds for activities involving animals. Failure to comply with the Animal Welfare Act could result in the USDA's withdrawal of Certification and assessment of monetary fines. The Institutional Official (IO) is the individual held responsible on behalf of the institution for ensuring compliance. The University of Wyoming Vice President for Research and Economic Development is the IO.

2.7 Use of electronic mail (email) for official correspondence

Electronic mail (email), like postal mail, is a mechanism for official University communication. The IACUC will exercise the right to send email communications to all laboratory animal users and the IACUC will expect that email communications will be received and read in a timely manner. This policy applies to all faculty, staff, students, or any other person listed on a protocol submitted to the IACUC for review and approval. Official communications using email can include email to a group, or an email message to only one person.

2.8 Making recommendations to the institutional official

The IACUC will make written recommendations to the IO regarding any aspect of the Institution's animal care and use program. The procedures for making recommendations to the IO are as follows:

- Recommendations are formulated at convened meetings of the IACUC.
- Recommendations are prepared in writing by the Attending Veterinarian, the IACUC Chair (or designee), and/or any IACUC member. A copy of these recommendations are reviewed and approved at a convened meeting of the IACUC. Any minority views are noted and included in the final report.
- The IACUC Chair or his or her designee submits recommendations, including minority views that are approved by the IACUC, to the IO.

Section 3: IACUC Research Proposals

3.0 Protocol review

The IACUC is responsible for overseeing and evaluating all aspects of animal care and use and is charged with reviewing proposals that involve animals to ensure that the criteria established in the PHS Policy and the Animal Welfare Regulations (AWRs) are implemented. In its review of proposals, the IACUC's primary goal is to facilitate compliance with applicable laws, regulations and policies consistent with the performance of appropriate and productive scientific endeavors.

3.1 General scope of review

The following kinds of activities involving animals are subject to review by the IACUC prior to initiation:

- Activities conducted by University faculty, staff, or students;
- Activities performed on the premises of the University;
- Activities performed with or involving the use of facilities or equipment belonging to the University;
- Activities satisfying a requirement imposed by the University for a degree program or completion of a course of study; and/or
- Activities certified by a dean or department head to satisfy an obligation of a faculty appointment at the University, including requirements for clinical or adjunct appointments.

3.2 UPDATED Specific types of activities

Research

Many of the animals covered under IACUC review are used in research, including medical, biological, and behavioral research as well as agricultural research (such as the study of food and fiber production or diet manipulation). Any research project that is conducted by any employee (or under the direction of) or student of the University, in connection with his or her University responsibilities, requires IACUC approval. A PI conducting research must submit the applicable protocol form. A copy of the applicable form can be found at: http://www.uwyo.edu/research/compliance/animal-care/index.html .

Teaching

The use of animals in educational research settings is subject to IACUC review. Examples include using animals to teach agricultural techniques, animal husbandry, and medical or veterinary procedures in a research setting. An individual using animals for observational and/or non-invasive teaching, must submit the teaching protocol form. A copy of this form can be found at: http://www.uwyo.edu/research/compliance/animal-care/index.html . For all other types of teaching, please use the standard protocol form.

Breeding Colonies

Maintaining a breeding colony is subject to IACUC review. If the animals are being maintained as part of a breeding colony and are not associated with any research or teaching, the PI must submit a breeding colony protocol form which can be found at http://www.uwyo.edu/research/compliance/animal-care/index.html . If the

animals in the breeding colony are being used for research or teaching purposes, discussed above, then the applicable protocol form should be completed (see above).

Research projects in which the investigator is a consultant

In some instances, University faculty or staff may serve in an advisory capacity for a research project conducted outside the University community. IACUC review is required unless the investigator has a consulting relationship in which:

- The investigator is hired on his or her own time;
- The investigator holds no rights in the work; and
- Neither the investigator nor the University retains any data.

Note: This section does not apply when University faculty or staff are collaborating with other institutions, just when they serve in an advisory capacity.

Research in foreign countries

Research conducted by the University's investigators in foreign countries falls under the University's purview and guidelines. Regardless of the setting, the standards for ethical and responsible use of animals in research will not be relaxed even if different customs prevail.

All animal-based research conducted in foreign countries is subject to IACUC review. This includes the use of animals in foreign research institutions. This also includes animals involved in fieldwork if the research involves an invasive procedure, harms, or materially alters the behavior of an animal being researched. The IACUC requires documentation of local approval, as well as documentation of any necessary permits, before granting final approval for the project. With regard to activities supported by PHS funds, foreign institutions that serve as performance sites must also have Assurances on file with OLAW.

3.3 Exemptions

The following are exempt from IACUC review:

- Activities involving animals that perform tasks or participate in club activities (e.g., animals that participate in University Rodeo);
- Use of tissues, organs or other parts of dead animals if received as such; and
- Noninvasive observation of wild animals in their natural habitat. Field studies that involve killing, trapping, banding, darting, implantation of telemetry devices, or any other invasive manipulation require IACUC approval.

3.4 UPDATED Who can be a principal investigator?

All animal research that is conducted by or under the direction of any employee, faculty, staff, student or agent of the University in connection with his or her responsibilities must be under the direct supervision of a member of the faculty of the University. Generally, faculty are considered to be sufficiently knowledgeable to supervise and/or conduct research as determined by their appointment. The IACUC may at its discretion, determine that a faculty member lacks sufficient expertise to carry out any particular research project based on their relevant training and experience.

Research conducted by non-faculty, academic support staff, post-doctoral fellows, staff appointments, graduate students, or undergraduate students must be under the direction of a faculty member, as defined above. In such cases, the faculty member shall be considered the Principal Investigator (PI). The PI may delegate the performance of any or all components of the research to non-faculty if they certify to the IACUC that the individuals are sufficiently trained to perform the functions assigned.

Individuals that do not meet any of the above criteria may, by demonstrating sufficient cause and necessary expertise, petition the Associate Vice President for Research and Economic Development for permission to submit an application for approval of an IACUC protocol. Such agreement shall be in writing and require the individual to comply with all relevant IACUC and University policies for the conduct of research involving animal subjects. Whether to make an exception to the above requirements is at the sole discretion of the Associate Vice President and his/her decision shall be final.

3.5 Protocol review criteria

In order to approve proposed research projects or proposed significant changes in ongoing research projects, the IACUC shall conduct a review of those components related to the care and use of animals and determine that the proposed research projects are in accordance with PHS Policy, AWRs, and the applicable US Government Principles. Since the PHS Policy further requires that the provisions of the *Guide* apply, there are many other aspects of research that an IACUC should review, such as food and water deprivation, use of noxious stimuli, and physical restraint. The *Guide* provides useful guidance on these and other practices.

If the IACUC does not have the scientific and technical expertise to evaluate all aspects of a proposal, it may bring in outside expert consultants to provide information. Such consultants shall not have a conflict of interest with the research activity and shall not vote on any matters pertaining to the protocol. In all cases, the investigator must justify and explain his or her proposed experiments to the satisfaction of the IACUC.

3.6 Protocol review procedures

The procedural review requirements of the PHS Policy or the AWRs take precedence even though they may differ from some commonly used parliamentary procedures. The Institution may develop its own meeting procedures as long as the procedures do not contradict or are not inconsistent with the requirements of the PHS Policy or the AWRs.

If a proposed activity may cause more than momentary or slight pain or distress to animals, the AWRs specifically require investigators to consult with the Attending Veterinarian (AV) or his or her designee during protocol development.

The PHS Policy and AWRs recognize two methods of protocol review: full committee review (FCR) and designated member review (DMR). The following pertains to review of initial protocols as well as to review of proposed significant changes in previously approved protocols.

Full committee review (FCR)

Full committee review of protocols requires a convened meeting of a quorum of the IACUC members. The PHS Policy and AWRs are explicit that proposals reviewed by the full committee must receive the approval vote of a majority of the quorum present in order receive approval.

If a protocol will be reviewed by the full committee, at least three (3) business days prior to a meeting, the Office of Research and Economic Development will electronically distribute copies of the protocols being presented or any other items of discussion to each IACUC member, including non-voting member(s). At the meeting, the Committee has the authority to approve, require modifications in (to secure approval), disapprove, or table (defer until future meeting) any proposed activity. The Committee may find the protocol is approvable on certain conditions and votes to allow the protocol to be reviewed, and approved, using the Designated Member Review (DMR) process, as described below. Approval of the change from FCR to DMR must be unanimous of a quorum of members and is recorded in the minutes. Committee members are given the opportunity to require that the requested modification(s) be brought before the next committee meeting. Under no circumstances will animal work be permitted to resume or begin until final approval is granted.

IACUC members can take the initiative to contact the investigator prior to the meeting for clarifications, additional information, or in anticipation of questions the IACUC may raise. Full committee review differs from designated member review, which delegates authority to approve a proposal to one or more members.

Designated member review (DMR)
To utilize designated member review (DMR), each IACUC member is provided a copy of the protocol document from the Office of Research and Economic Development. Committee members are given a ten (10)-calendar day consideration period to review the protocol document and (1) respond with comments or questions for the PI, (2) allow the DMR to review the protocol, or (3) to hold the protocol for the next FCR. The responses are sent to the Office of Research and Economic Development via email. The Office of Research and Economic Development tallies the votes to ensure that more than half of the voting members respond, and at the end of the member consideration period sends the protocol to DMR for review. If any member votes to hold the protocol until the next IACUC meeting, then the protocol is placed on the agenda for the next IACUC meeting.

The designated reviewers are the Attending Veterinarian and the IACUC Chair (or his or her designee). These designated members have authority to approve, require modifications in (to secure approval), or request full committee review. The designated reviewers may not withhold approval; this action may only be taken if the review is conducted using FCR.

Notification of review outcome

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

- Upon completion of the review process, each PI receives a scanned signed copy of the approved protocol, an email granted approval, and whether any special monitoring provisions will be required. Records of communication are maintained within the IACUC protocol files.
- Upon completion of the review process, a copy of the meeting minutes is provided to the IO. This informs the IO of all actions taken by the IACUC.

3.7 Required principal investigator certifications

In order to submit a protocol to the IACUC for review, the PI must certify the following:

I have read the University of Wyoming's IACUC Policies and Procedures Manual found at http://www.uwyo.edu/research/animal-care/index.html. I have received a copy of the NIH Guide for the Care and Use of Laboratory Animals and/or The Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching and will provide for the care, use and treatment of the animals used for the purpose described above accordingly. I will use procedures which will avoid or minimize discomfort, distress and pain to animals used in my research. I have considered alternatives to procedures that may cause more than momentary slight pain or distress to the animals. These studies do not unnecessarily duplicate previous experiments. I HAVE CONSULTED AS NEEDED WITH ATTENDING VETERINARIAN (David Evertson, 745-7341), OR BACKUP VETERINARIAN ON STAFF AT ALPINE ANIMAL HOSPITAL, DURING THE PLANNING OF THIS PROJECT AND WILL CONSULT WITH THE VETERINARIAN DURING THE PROJECT. I will inform the attending veterinarian immediately if any problems occur, including unanticipated pain or distress, injury, morbidity or mortality. I will submit an amendment request for IACUC approval if there are any significant changes from the approved project. I will submit an annual update for IACUC approval for continuation if this project extends beyond one year. I assure the IACUC that all persons involved in the care and use of animals used to conduct this protocol have received the appropriate training and are qualified to perform the procedures described above.

It is implicit upon submission of the protocol that the PI has read and agrees to abide by the above obligations.

3.8 Range of IACUC actions

Upon review of protocols, the IACUC may take one of several different actions depending upon the findings of the committee: approval, modifications required in (to secure approval), and withhold approval. An IACUC may also defer or table review of a protocol. The PHS Policy and AWRs require the IACUC to notify investigators and the institution in writing of its decision to approve or withhold approval, or require modifications in (to secure approval) of a protocol. If approval is withheld the IACUC must provide the reasons for its decision and give the investigator an opportunity to respond.

Approval

When the IACUC has determined that all review criteria, based on the PHS Policy and AWRs, have been adequately addressed by the investigator, the IACUC may approve the project, thus granting the investigator permission to perform the experiments or procedures as described.

The IACUC-approved proposal may be subject to further appropriate review and approval by institutional officials due to financial, policy, facility, or other institutional or administrative considerations. Those officials, however, may not approve an activity if it has not been approved by the IACUC.

Modifications required in (to secure approval)

The IACUC may require modifications to the protocol before granting approval. If the IACUC determines that a protocol is approvable contingent upon receipt of a specific modification (e.g., receipt of assurance that the procedure will be conducted in a fume hood), or clarification of a specific point, the IACUC may handle these modifications or clarifications as administrative details that any member, such as the Chair, could verify prior to granting approval.

If a study is unusually complex or involves untried or controversial procedures the IACUC may wish to impose restrictions (e.g., approval for the use of a limited number of animals as a pilot study with a written report of interim results, or close monitoring by veterinary or other qualified personnel). If such modifications represent significant departures, the IACUC can ask the investigator to revise the protocol to reflect the modifications imposed by the IACUC.

If the protocol is missing substantive information necessary for the IACUC to make a judgment, or the IACUC requires extensive or multiple modifications, then the IACUC can require that the protocol be revised and resubmitted. If the IACUC wishes to shift to the designated member reviewer mode for the approval of the modified protocol, that shift should be explicitly noted in the meeting minutes and the requirements for designated review must be met.

Withhold approval

When the IACUC determines that a proposal has not adequately addressed all of the requirements of the PHS Policy and AWRs, as applicable, or the described activities represent inappropriate or unethical use of animals, the Committee may withhold approval. A designated reviewer may not withhold approval; this action may only be taken if the review is conducted using the full committee method of review. As indicated above, a higher institutional authority may not administratively overrule an IACUC decision to withhold approval of a proposal.

Defer or table review

If the protocol requires significant clarification in order for the IACUC to make a judgment, Committee members with certain expertise are not present, the IACUC wishes to seek external consultation, or any of a number of other reasons prevent the IACUC from conducting its review, then the IACUC may wish to defer or table review until a future FCR.

3.9 UPDATED Review of modifications to approved protocols

Significant changes

The Protocol Update form must be completed if the PI is proposing significant changes regarding the use of animals in any ongoing approved protocol. Significant changes include the following:

- Changes in animal species
- Changes in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC
- Changes in experimental agents or procedures
- Changes in clinical signs and morbidity criteria
- Changes in pain or distress
- Changes in principal investigator
- Changes in study objectives
- Changes that impact personnel safety.

The Protocol Update form, found at http://www.uwyo.edu/research/compliance/animal-care/index.html , must be submitted electronically to the IACUC at IACUC@uwyo.edu. **The Changes shall not be implemented until this form is approved.**

The IACUC has made the determination that the following significant changes may be handled administratively by the Office of Research in consultation with the veterinarian:

- Changes in anesthesia, analgesia, sedation, or experimental substances
- Changes in euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals
- Changes in duration, frequency, type, or number of procedures performed on an animal.

The IACUC has made the determination that the following changes may be handled administratively by the Office of Research:

- Change in personnel, other than the PI. (**Note:** An administrative review will still be conducted to ensure that all personnel are identified, adequately trained/qualified, provided the opportunity to enroll in University Occupational Health and Safety Program, and meet other criteria as required by the IACUC).

3.10 Processing of protocols through DMR

The goal of the IACUC and Office of Research and Economic Development is to rapidly process protocols in an effort to provide faculty with the maximum amount of time possible to address Committee concerns and clarifications. In order to maintain an expeditious review process, proposed protocol modifications and annual renewal forms will be circulated to Committee members for ten (10) calendar days and only those items that are specifically asked to be reviewed at the FCR will be assigned to a meeting agenda.

3.11 Minimization of pain and distress

In design of the research, training or educational activities, it is the responsibility of the PI to consider and include procedures that minimize animal pain or distress.

As required by the PHS Policy and the AWRs, and as reiterated in the *Guide*, the IACUC is mandated to critically evaluate research protocols to ensure that pain and distress are minimized in laboratory animals and assure that appropriate steps will be taken to enhance animal well-being. The AWRs stipulate that the IACUC determine that the PI has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animal and has provided a written narrative description of the methods and sources used to determine that alternatives were not available.

The *Guide* states that the IACUC should ensure that the protocol addresses:

- Appropriate sedation, analgesia, and anesthesia;
- Criteria for timely intervention, removal of animals from study, or euthanasia if painful or stressful outcomes are anticipated; and
- Details of post-procedural care.

The protocol must provide adequate information for the IACUC to assess the potential animal pain and/or distress resulting from the study and the effectiveness of the pain- and distress-relieving agents proposed for use. Criteria for re-dosing the animal should also be established. The Attending Veterinarian must be consulted for any procedure that has the potential to cause more than momentary pain or distress.

Examples of procedures which the *Guide* suggests may have the potential to cause pain or distress include, but are not limited to:

- Physical restraint,
- Survival surgeries,
- Food or water restriction,
- Death as an endpoint,
- Noxious stimuli,
- Skin or corneal irritancy testing,
- Tumor burdens,
- Intra-cardiac or orbital sinus blood sampling, and
- Abnormal environmental conditions.

Assessing pain and distress

Numerous references indicate that both laboratory animals and humans receive and process noxious stimuli using similar mechanisms. An animal's response to pain is often adaptive to reduce movement to minimize re-injury and aid recuperation. This response, however, may lead to physiological and behavioral changes which impact negatively on both the animal's well-being and the research results.

Fundamental to the relief of pain is the ability to recognize its clinical signs in various species of animals. Due to the inability of animals to verbalize, it is essential that animal care staff and researchers receive adequate training on how to recognize clinical signs of pain and distress. It is often useful to start with a general set of observations for assessing pain and distress such as change in body weight, physical appearance/posture, or changes in unprovoked and provoked behavior. The assessment system should then be modified on a case-by-case basis using specific changes that may be anticipated in a particular study.

Alleviation of pain and distress

Accepted best practices for dealing with the possibility of unrelieved pain and distress should be considered and incorporated into protocols unless there is sound scientific rationale for deviation from those practices. The investigator must also provide an assurance that unrelieved pain will continue for only the minimum period of time necessary to attain the study objectives.

Protocol methodology should be considered that decreases the potential for pain or distress. In addition to thorough searches of the literature, this can be done through the careful use of pilot studies to determine earlier endpoints or less invasive alternatives.

Pharmacologic treatment of pain or distress should be given as consistent with the type of pain/distress and the needs of the research question. The Attending Veterinarian must be consulted for all such protocols and should provide guidance to investigators and the IACUC. Non-pharmacologic treatments should also be employed. This may include special housing considerations, dietary and other environmental enrichments, adjustments, and careful supportive care.

It is the responsibility of the investigator to show that he or she has considered all the options for minimizing pain and distress that do not compromise the scientific validity of the experiment. The IACUC's deliberations regarding the management of potential pain and distress in a protocol will be documented. Personnel should be trained in pain and distress management. The IACUC should ensure that there is a mechanism in place for prompt reporting of sick animals to the veterinary staff.

3.12 Use of Expired Drugs and Materials in Laboratory Animals

The USDA's Animal Care Policy #3 outlines the use of expired drugs and materials in laboratory animals:

> The use of expired medical materials such as drugs, fluids, or sutures on regulated animals is not considered to be acceptable veterinary practice and is not consistent with adequate veterinary care as required by the regulations promulgated under the AWA. The facility should either dispose of all such materials or segregate them in an appropriately labeled, physically separate location from non-expired medical materials. APHIS has no jurisdiction over facilities using expired medical materials for non-regulated animals or non-regulated activities.
>
> For acute terminal procedures, where an animal is put under anesthesia, the research is carried out (surgery or testing of a compound) and the animal is euthanized without ever waking up, medical materials may be used beyond their "to be used by" date if such materials use does not adversely affect the animal's wellbeing or compromise the validity of the scientific study. Anesthesia, analgesia, emergency drugs and euthanasia drugs that are within their expiration dates are required for all such procedures. Facilities allowing the use of expired medical materials in acute terminal procedures should have a policy covering the use of such materials and/or require investigators to describe in their animal activity proposals the intended use of expired materials. The attending veterinarian and the Institutional Animal Care and Use Committee (IACUC) are responsible for ensuring that proposed animal activities avoid or minimize discomfort, distress, and pain to the animal. APHIS has determined that these responsibilities cannot be met unless the veterinarian and the IACUC maintain control over the use of expired medical materials.

The University of Wyoming IACUC's policy is that the use of expired drugs is not considered to be adequate veterinary care as the expected results cannot be guaranteed and the animals may experience unnecessary pain and distress due to unrelieved symptoms or side effects of expired drugs.

Section 4: Monitoring of Approved Protocols

4.0 Continuing review: The annual review

AWRs require an annual review of protocols. PHS Policy requires the IACUC to conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy IV.C.1-4 at least once every three years.

At the University of Wyoming, regardless of the species used and funding source, the IACUC requires an annual report on the status of each protocol. In doing so, the Investigator verifies that completed activities were conducted in accordance with the approved protocol, describes any proposed departures from the approved protocols, and solicits information about activities projected for the upcoming year. In addition, the number of animals used over the course of the previous protocol year needs to be provided.

When Annual Review Forms are submitted to the Office of Research and Economic Development prior to the protocol's expiration date, the protocol is considered active and experiments can continue to be conducted up until the protocol's expiration date if no changes or the approval of the Annual Review Form, whichever comes first. If there is a lag period between the protocol's expiration date and the approval of the Annual Review Form, the PI must cease all experiments until the Annual Review Form is approved.

Procedures for conducting annual reviews

If the research is still active, the PI must complete the Annual Review Form and return it to the Office of Research and Economic Development **before** the expiration of the protocol approval. **It is the responsibility of the investigator to submit the annual review form by the appropriate deadline date prior to protocol expiration.** Review of the Annual Review Form is conducted as described in Section 3. If a PI fails to submit the Annual Review Form **before** the expiration of the protocol approval, the following must occur:

1. The PI must cease all work under the animal protocol until further notice.

2. When the PI has successfully submitted and obtained approval of the annual review after an appropriate review method (as described in Section 3.6), animal work may continue.

3. If the PI fails to successfully renew the protocol by the expiration date, the protocol will be considered to be permanently expired and the PI will be required to resubmit a new protocol in order to restart work. Additionally, the IACUC may consider suspending (as described in Section 8.4) or terminating that PI's animal use privileges.

If a protocol is allowed to lapse while the associated vertebrate animals are still being housed on campus, the Associate Vice President for Research and Economic Development will make a determination, after consultation with the Attending Veterinarian and the IACUC Chair, if any threat to animal well-being is posed and if so will take the appropriate action. Action can include, but is not limited to, transferring the animals to another study, placing the animals with an outside agency, or euthanizing the animals.

If the animals have been used primarily for teaching or demonstration and were originally privately-held animals that were not purchased with University funds, they may be able to be returned back to the original

owners or another experienced individual. Requests for such transfers can be made to the Office of Research and Economic Development.

If the animals are part of a breeding protocol not currently associated with research or teaching, the PI must annually re-submit the Breeding Colony Approval Form for review. The Breeding Colony Approval Form can be found at http://www.uwyo.edu/research/compliance/animal-care/index.html .

The purpose and substance of continuing review

The purpose of continuing review is primarily threefold:

- To inform the IACUC of the current status of the project;
- To ensure continued compliance with PHS, USDA and institutional requirements; and
- To provide for re-evaluation of the animal activities at appropriate intervals.

Federal requirements, research ethics, and moral obligations of the scientific community to society demand that IACUCs conduct appropriate and meaningful reviews of ongoing animal protocols in the same responsible manner that initial reviews are done. This ensures that the IACUC will not "rubber stamp" a previously approved protocol during continuing review just because it has undergone a thorough initial review.

Ethical cost-benefit analysis

Animal activities are most frequently justified from an ethical cost-benefit perspective. This means that any animal pain, morbidity, and mortality must be outweighed or at least balanced by the potential benefits of the project in terms of its relevance to human or animal health or advancement of knowledge. Ethical cost-benefit assessment should be a major focus during initial and continuing review by the IACUC. This assessment should not, however, be misconstrued as the equivalent of an NIH study section review of scientific merit. Instead, it represents a threshold level of review that documents that the use of animals continues to be justified. Without such assessment, there is lack of accountability, which negates the purpose of continuing review, particularly for projects not funded by the PHS or other funding agencies with rigorous peer review.

The obvious question that arises is why an ethical cost-benefit relationship would change over time. After a protocol is initially approved by the IACUC it is possible that new information may have become available. For example, new in vitro techniques may be discovered that could reduce the number of animals required. Or an investigator may find that a lesser degree of morbidity can be used as an experimental end point. Conversely, in some situations, it may be necessary for scientific reasons to increase the number of animals or to allow animals to reach a more advanced stage of morbidity than originally specified in the protocol. In either case, the ethical cost-benefit ratio will be altered and the IACUC should re-evaluate this new relationship. Proposed changes in the protocol can be considered during continuing review and approved as warranted.

4.1 The third-year resubmission: *De novo* review

The PHS Policy requires that a complete IACUC review of PHS-supported protocols be conducted at least once every three years. The University of Wyoming requires that a complete IACUC review of **all** protocols, regardless of funding source, be conducted at least once every three years.

The three-year period begins on the actual date of IACUC approval; the IACUC may not administratively extend approval beyond the three years. Since the protocol approval period cannot be extended, investigators

must be cognizant of the protocol approval period. To aid investigators, the Office of Research and Economic Development shall attempt to provide adequate warning of pending protocol expiration. However, the warning system is not fail-safe. **It is the responsibility of the investigator to submit the third-year resubmission by the appropriate deadline date prior to protocol expiration.** The IACUC requires a third-year resubmission be submitted as a new proposal, using the most recent version of the application.

Procedures for conducting triennial reviews

The PI must resubmit the entire protocol to the Office of Research and Economic Development. A *de novo* review of the third-year resubmission is conducted per Section 3.6. If a PI fails to submit a third-year resubmission and receive approval by the expiration date of the protocol, the following action is taken:

1. On the third anniversary of the protocol approval, the Office of Research and Economic Development will notify the PI that the animal protocol has expired. The PI will be notified in writing that all activities under the protocol must cease and any ongoing work under the expired protocol is a serious and reportable violation of PHS Policy.

2. Any remaining animals under that protocol will be transferred to the department head. Per diems for animal care will continue to be charged. In the event that animal care charges are being charged to a sponsored project, an alternate account must be identified for such charges.

3. When the PI has successfully obtained approval of the protocol, animals will be transferred from the department head to the new approved protocol.

4. If the PI fails to successfully renew the protocol and continues to use animals, the IACUC may consider suspension or recommending to the IO that the PI's animal use privileges should be terminated.

4.2 Post-approval monitoring

Periodically, the IACUC will identify certain protocols (usually new or recently revised protocols) that it feels would benefit from close veterinary oversight. The requirement of specific monitoring can be a provision of protocol approval and is communicated to the PI, as described in Section 3.6. The Attending Veterinarian is notified of the need for monitoring and is provided with the pertinent details. The Attending Veterinarian periodically, and as necessary, provides updates to the IACUC. The Attending Veterinarian conducts random, but frequent, visits to high-use areas. It is important to note that maintaining a friendly and collaborative presence in the research lab areas is a proactive way to ensure that minor issues are identified rapidly for quick correction, and that major issues are prevented.

Section 5: Training in the Humane Care and Use of Laboratory Animals

5.0 Training

All personnel working with laboratory animals must be appropriately qualified to do so in order to ensure the humane treatment of animals. Although the PHS Policy and AWRs do not specify a particular program or the frequency with which a program should be offered, the requirement for competence is mandatory.

The AWRs, in Section 2.32(a) and (b), specify:

> It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal 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 qualifications of personnel reviewed, with sufficient frequency to fulfill the research facility's responsibilities.

The PHS Policy, Section IV.C.1.f. places responsibility specifically with the IACUC to ensure that personnel conducting procedures on research animals are appropriately qualified and trained in those procedures.

5.1 Who should receive training?

All personnel should receive training if they interact directly with or work with animals. Training should be specific to the animal species involved and to the kind of procedures to be performed or animal-related interactions. For training purposes, personnel can be grouped as researchers (including Principal Investigators) and animal care technicians. In some instances, personnel may not be clearly divisible into these groups if job responsibilities are more diversified than this classification suggests. For example, facility staff such as animal care technicians may have job functions that include both animal care and research procedures.

Training should also be made available to temporary staff, such as students. PIs are responsible for identifying these people and assuring that appropriate training is accomplished.

5.2 UPDATED Training requirements for University laboratory animal users

The IACUC requires all personnel that conduct any research and/or teaching that involves handling, manipulating, or performing procedures on live vertebrate animals, whether in the laboratory or in the field, to complete training. Protocols will not be approved until all personnel listed on a protocol are current with their training.

The majority of IACUC training conducted at the University is through the web-based Collaborative Institutional Training Initiative (CITI) found at https://www.citiprogram.org/. Instructions for first-time users can be found on the Office of Research and Economic Development webpage at http://www.uwyo.edu/research/animal-care/index.html.

The IACUC-required training is a three-fold process:

1. Completing the CITI Lab Animal Welfare Course for Researchers.

2. Completing any appropriate species specific courses offered by CITI (see list below). When a new species is requested, individuals are required to complete the new species modules. **Those performing survival animal surgery must take the CITI aseptic surgery course.**

Species specific courses include the following:

- Working with Amphibians in Research Settings
- Working with Mice in Research Settings
- Working with Hamsters in Research Settings
- Working with Gerbils in Research Settings
- Working with Guinea Pigs in Research Settings
- Working with Rabbits in Research Settings
- Working with Cats in Research Settings
- Working with Dogs in Research Settings
- Working with Swine in Research Settings
- Working with Nonhuman Primates in Research Settings
- Working with Wildlife

Additional optional courses include (1) reducing pain and distress in laboratory mice and rats and (2) antibody production.

Online refresher training for both principal investigators (PI) and animal users is required every **three** years.

5.3 Education and training for IACUC members

Member training

IACUC members must either complete the Lab Animal Welfare Course for IACUC Members or the Lab Animal Welfare Course for Researchers. The IACUC Member module consists of the following: an introduction to essentials for IACUC members; responsibilities of the IACUC and IACUC members; the members of the IACUC; the IACUC, the CEO, and the IO; authority of the IACUC; conducting IACUC business—the quorum; procedures for reviewing protocol forms; outcomes of animal protocol forms; the types of protocol reviews; documenting IACUC actions; the IACUC semi-annual evaluation; performing the facility inspection and the program review; identifying, documenting, and correcting deficiencies; investigating allegations of improper animal care or use; and maintaining the public trust.

Documentation of training is maintained through the Office of Research and Economic Development.

Continuing education

Continuing education for IACUC members usually occurs at each IACUC meeting. The objectives of providing ongoing training for IACUC members is to increase their knowledge, understanding, and awareness of current laws and regulations, new directives, best practice guidelines, and institutional policies. It also provides a regular forum for the IACUC to discuss concerns or questions. Information provided includes, questions and concerns brought to the attention of the IACUC, official directives, relevant publications, conference announcements, seminar proceedings, animal facility staff and/or veterinarian's observations/recommendations, and compliance issues.

Section 6: Occupational Health Program

6.0 The IACUC's responsibility for occupational health and safety

The PHS Policy places responsibility for ensuring a safe working environment for personnel involved in the animal care and use program with the institution. An effective Occupational Health Program works with many separate institutional components including animal care and use, research, environmental health and safety, occupational health, and administration and management. Assurance of a safe working environment is one of the topics the IACUC should consider in each animal use proposal and as part of the semiannual program evaluation.

6.1 Role of the IACUC in the occupational health program

Procedures are in place for conducting a health and safety review of research activities that present hazards. These procedures are incorporated into the IACUC protocol review process. Procedures to identify and address non-experimental hazards (e.g., during semiannual facility inspections and program reviews) are also in place. Communication and other procedural links between the IACUC and the environmental health and safety department are established, maintained, and documented. The IACUC has a role in ensuring that personnel comply with health and safety requirements.

6.2 UPDATED Elements of the occupational health program

The University's Occupational Health Program is facilitated by the Risk Management and Safety Department. This Department develops and maintains programs and policies to promote accident, injury and illness prevention. Services provided by this Department include training, technical advice, audits and consultation. This Department also provides guidance to researchers and departments in performing hazard assessments and producing safety procedures for hazardous jobs, tasks or research projects. This Department provides a vast assortment of training including Safety Orientation and Laboratory Safety, Chemical Hygiene, Hazard Communication, and Hazardous Waste Guidelines. Trainees are informed in class about allergies, pregnancy and reproductive hazards, illness, and immune suppression. Departments are responsible for training both their employees and students on department-specific occupational health procedures, including general personal hygiene and personal protective equipment.

New employees, including student employees, are required to take Safety Orientation and Laboratory Safety, which includes general personal hygiene and personal protective equipment (departments will address specifics to the job). Safety Orientation and Laboratory Safety covers the pervasive hazards that face all employees and introduces them to University resources and other available training. Laboratory Safety presents an overview of the University Occupational Safety and Health Administration (OSHA) Chemical Hygiene program covering chemical safety in the laboratory and general chemical safety and responsibilities. This class also covers personal protective equipment, fume hoods, and understanding Material Safety Data Sheets. Attendance is a requirement for all personnel who work in laboratories that use chemicals.

Hazard Communication class covers the hazards of materials or chemicals in the workplace and includes basic awareness of allergies, pregnancy and reproductive hazards, illness, and immune suppression.

Laboratory workers are exempted from the hazard communication requirements, but are required to attend Laboratory Safety (Chemical Hygiene) training and comply with the University Chemical Hygiene Plan requirements. If respiratory protection is requested, a hazard assessment is first completed by EHS to determine

the need for a respirator. Individuals who are provided respirators are covered under the University's Respiratory Protection Program, including hazard assessment, medical evaluation, training, and fit-testing.

All employees working with laboratory animals are required to have an up-to-date tetanus immunization. Immunization for specific diseases will be required when substantial opportunity for exposure exists (i.e., rabies vaccination for selected personnel at the Veterinary Sciences, Biological Sciences, or other departments). These employees will also be highly encouraged to obtain a health evaluation as part of the program of medical surveillance.

Individuals without direct animal contact such as housekeepers, security and other staff are required to take Hazard Communication class (see above). Depending on the their job, maintenance engineers, housekeepers, security and other staff without direct animal contact may be required to take additional training.

Personnel (including students) working with laboratory animals will be provided with an educational program early in their employment. Training will include techniques in laboratory animal care and handling, zoonotic diseases, personal hygiene and personal protective equipment, and methods for preventing and treating animal associated injuries. Periodic courses in safety will be conducted through EHS.

All on-the-job injuries, such as animal bites and scratches, must be reported to the appropriate department head. Injuries that may require treatment will be referred to the University Student Health Service if a student, or to the local hospital if an employee. The Institution will assume costs not covered by Wyoming Worker's Compensation.

Records of unusual illness, bite wounds, and work assignments will be kept by the department employing the individual. The Risk Management and Safety Department maintains an injury log for OSHA. Pre- and post-employment sera may be banked for future diagnostic purposes and titers are monitored for specific biological agents of concern.

Use of hazardous biological, chemical, and physical agents must be conducted in accordance with procedures developed by the Risk Management and Safety Department and the Centers for Disease Control/National Institutes of Health Biosafety in Microbiological and Biomedical Laboratories.

Section 7: Semiannual Program Review and Facility Inspections

7.0 Semiannual reviews

The PHS Policy and Animal Welfare Regulations (AWRs) stipulate that the IACUC must review the program for humane care and use of animals and inspect all institutional animal facilities at least once every six months, using the *Guide* as the basis for evaluation.

7.1 Program Review

At least once every six months, the IACUC will review the University's program for humane care and use of animals, using the *Guide* as a basis for evaluation. To facilitate the evaluations, the Committee uses the Sample OLAW Program and Facility Review Checklist.

The evaluation includes, but is not limited to, a review of (a) the IACUC membership and functions; (b) IACUC records and reporting requirements; (c) husbandry and veterinary care; (d) personnel qualifications; and (d) occupational health and safety.

In addition, the evaluation will include a review of the Institution's PHS Assurance. If program deficiencies are noted during the review, they will be categorized as significant or minor and the Committee will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of animals. No member will be involuntarily excluded from participation in any portion of the reviews.

7.2 Facility inspections

At least once every six months, the IACUC inspects all of the University's animal facilities, including satellite facilities, using the *Guide* as a basis for evaluation. Inspections will be performed by on-site visits by a sub-committee of the IACUC including either the Attending Veterinarian or the IACUC Chair.

A responsible party (e.g., Principal Investigator, animal care technician) is notified of any minor or significant deficiency identified in their laboratory, facility or designated space. Responsible parties are required to promptly provide a response to the deficiency notification with a description of how the deficiency has been corrected or to submit a written plan with a timeline outlining how the deficiency will be corrected.

Findings from the facility inspections are compiled by the Office of Research and Economic Development and prepared for IACUC review and discussion at a regular, convened IACUC meeting following the inspections.

7.3 Deficiency correction schedule

All deficiencies identified during the facility inspection and/or program review are designated by the IACUC as minor or significant. A significant deficiency is defined as a situation that is or may be a threat to animal health or safety. The IACUC, through the IO, is obligated to promptly report to OLAW any serious or continuing noncompliance with the PHS Policy or any serious deviation from the provisions of the *Guide.*

For both categories of deficiencies, a reasonable and specific plan and schedule with dates for correction must be included in the final report. All individuals to be involved in the corrections should be consulted to ensure that the plan is realistic. If the institution is unable to meet the plan, the IACUC, through the IO, will inform

APHIS within fifteen business days of the lapsed deadline. Federally funded projects will have their relevant funding agency informed.

7.4 Documentation

A written report of the semiannual program review and facility inspection is prepared by the Office of Research and Economic Development. The AWRs require the report to be signed by a majority of the IACUC members at a convened meeting. The report describes the institution's adherence to the AWRs, PHS Policy, and the *Guide* and identifies specifically any deviations from these documents.

The report will indicate whether or not any minority views were filed, and minority views will be included in the final document. A copy of the report is sent to the IO and is kept on file for a minimum of three years in the Office of Research and Economic Development. The University notifies OLAW of the dates of the semiannual program evaluations and facility inspections in the annual report to OLAW.

Section 8: Animal Welfare Concerns and Non-Compliance Situations

8.0 Evaluation of animal care and use concerns

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

8.1 Methods for reporting

To facilitate communication, there are a number of options available to communicate concerns about animal care and use at the University or to report instances of suspected non-compliance with laws, rules, regulations, and policies. The names and phone numbers of contact persons including the Attending Veterinarian and the Associate Vice President of Research and Economic Development are listed on the Office of Research and Economic Development website, readily available to institutional employees.

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

Requests for anonymity will be honored to the extent possible. This includes protecting the confidentiality of those who report concerns as well as anyone against whom allegations are directed, while allegations are under investigation. The policy of the University is to prohibit unlawful retaliation against employees as a consequence of good faith actions in the reporting of, or the participation in, an investigation pertaining to allegations of wrongdoing.

8.2 Procedures for the investigation of animal care and use concerns

Initial evaluation and actions

Concerns may include situations or activities ranging from those in which animals are reported to be in immediate, actual, or perceived jeopardy to those in which violations of the AWRs or institutional Animal Welfare Assurance are alleged to be occurring but animals are not in apparent danger. They may focus on allegations of past policy and procedure violations or protocol non-compliance.

The course of action taken by the IACUC should be driven by the potential significance of the alleged situation. For example, conditions that reportedly jeopardize the health or well-being of animals should be evaluated immediately. To cope promptly with such situations, the Attending Veterinarian is authorized to halt procedures which he or she believes do not comply with institutional policies until the IACUC can be convened and consider the matter formally. Similarly, situations that may involve potential criminal activity or human safety should be reported promptly to the University's Police Department or the Department of Environmental Health and Safety. Allegations of other ongoing policy or procedural matters may not require such same-day attention, but should not be deferred merely as a matter of convenience. Emergency meetings may be necessary in these cases to ensure prompt consideration of concerns. Depending on the concern, the Associate Vice President of Research and Economic Development, in consultation with the Attending Veterinarian, may make a determination of the appropriate corrective action and/or next steps.

Formation of a subcommittee

Upon receipt of a concern, the IACUC Chair should convene a meeting of a sub-committee of IACUC members. This subcommittee can either meet in person or via email discussion. After initial review of the complaint, the subcommittee will determine whether it requires further investigation and immediate action, further investigation but no immediate action, or no action. Once this decision has been made, the subcommittee should determine which individuals or other institutional or non-institutional offices may require notification.

If immediate action appears warranted because animal or human welfare may be compromised, the IACUC should notify the IO and proceed accordingly. Veterinary medical intervention, suspension of a research activity, and/or notification of appropriate safety, occupational health, or other officials are examples of actions that may be taken immediately to protect animal or human welfare. In accordance with the AWRs, if an activity is suspended, the IO shall report that action to APHIS and any federal agency funding that activity. If the PHS supports the activity in any way, the IACUC, through the IO, must promptly notify OLAW.

Investigation

Should the IACUC determine that further investigation is required, the subcommittee should conduct the investigation and report back to the IACUC. It is important to avoid actual or perceived conflicts of interest in this process. The nature of the investigation will vary depending on the circumstances, but often involves:

- Interviewing complainants (if known), any persons against whom allegations were directed, and pertinent program officials;
- Observing the animals in their environment; and
- Reviewing any pertinent records (e.g., animal health records, lab notebooks, protocols, and other documents).

The sub-committee will provide a report to the IACUC, which summarizes the results of the information-gathering. The report should also contain:

- The results of the investigation;
- Any supporting documentation such as correspondence, reports, and animal records;
- Conclusions regarding the substance of the concerns per requirements of the AWRs, the PHS Policy, the *Guide*, and institutional policies and procedures; and
- Recommended actions, if appropriate.

The report should then be provided to the IO, who can find that:

- There was no evidence to support the concern or complaint;
- The concern or complaint was not sustained, but related aspects of the animal care and use program requires further review; or
- The concern or complaint was valid.

8.3 Non-compliance with IACUC protocol, policies, procedures, or decisions

Protocol non-compliance occurs when procedures or policies approved by the IACUC are not being followed. Examples include, but are not limited to:

- Conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals;
- Conduct of animal-related activities without appropriate IACUC review and approval;
- Failure to adhere to IACUC-approved protocols;
- Implementation of any significant change to IACUC-approved protocols without prior IACUC approval;
- Conduct of animal-related activities beyond the expiration date established by the IACUC (note that a complete *de novo* review is required at least once every three years);
- Chronic failure to provide space for animals in accordance with recommendations of the *Guide* unless the IACUC has approved a protocol-specific deviation from the *Guide* based on written scientific justification;
- Participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained;
- Failure to monitor animals post-procedurally as necessary to ensure well-being (e.g., during recovery from anesthesia or during recuperation from invasive or debilitating procedures);
- Failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry);
- Failure to ensure death of animals after euthanasia procedures (e.g., failed euthanasia with CO_2); or
- Failure of animal care and use personnel to carry out veterinary orders or treatments.

8.4 Consequences of non-compliance

When faced with protocol noncompliance, the IACUC's first step, if possible, should be to find a way to bring the protocol into compliance. Subsequent actions of the IACUC may include:

- Implementing measures to prevent recurrence;
- Notifying the IO of its actions;
- Notifying funding or regulatory agencies, as required;
- Notifying the complainant, any persons against whom allegations were directed, and pertinent program officials (appropriate supervisory and management staff, the public affairs office, institutional attorneys, etc.); and/or
- Applying corrective actions.

Corrective action

If allegations of animal mistreatment or protocol non-compliance are verified, the IACUC can apply corrective actions. If, in the opinion of the IACUC, corrective actions are not appropriate, they need not be applied. A clearly minor and unintentional misinterpretation of an IACUC policy that has created no problem for an animal is an example of where a verified allegation of protocol non-compliance may lead to an explanation, not a corrective action.

Examples of corrective actions include, but are not limited to:

- Suspension of a specific protocol or parts of a specific protocol;
- Suspension of all of the investigator's protocols until problem is corrected;
- Required attendance at IACUC meetings;

- Retraining of personnel;
- Technical ability required to be approved by a veterinarian;
- Written reprimand;
- Written warning;
- Other research staff required to take over work temporarily or permanently;
- Denied access to animal facilities for a specific period of time; and
- Temporary or permanent suspension of animal use privileges.

Suspension of animal activities

The IACUC is authorized to suspend a project if it finds violations of University policy, PHS Policy, the *Guide*, the Animal Welfare Assurance, or Animal Welfare Regulations. Suspension may occur only after review of the matter at a convened meeting of a quorum of the IACUC and a vote for suspension by a majority of the quorum present. Further, the IACUC must consult with the IO regarding the reasons for the suspension. The IO is required to take appropriate corrective action, and report the action and the circumstances surrounding the suspension to OLAW. Because an IACUC action to suspend a project is a serious matter, the action must be reported to OLAW promptly.

8.5 Reporting requirements

Failure by research personnel to follow Federal and/or University regulations, guidelines, policies and/or procedures may require reporting to the appropriate institutional, local, state and/or Federal agencies.

Principal investigator reporting

The Principal Investigator and protocol personnel must report any serious or continuing non-compliance with an IACUC protocol, policies, procedures, decisions, or deviations from the *Guide*. The report should be on University/departmental letterhead, addressed to the Associate Vice President for Research and Economic Development, and emailed (preferred) to IACUC@uwyo.edu or mailed to the Office of Research and Economic Development. The self-report of non-compliance should include the following information:

- Relevant grant or contract number(s);
- Full explanation of the situation, including what happened, when and where, the species of animal(s) involved, and the category of individuals involved (e.g., principal or co-principal investigator, technician, animal caretaker, student, veterinarian, etc.);
- Description of actions taken by PI to address the situation; and
- Description of short- or long-term corrective plans and implementation schedule(s).

IACUC and IO reporting

The IACUC, through the IO, will submit an annual report to OLAW by January 31 of each year. The University's reporting period is January 1 – December 31. The report will include:

- Any change in the accreditation status of the University (e.g., if the University obtains accreditation by AAALAC or AAALAC accreditation is revoked), any change in the description of the University's program for animal care and use as described in the Assurance, or any change in the IACUC membership. If there are no changes to report, the University will provide written notification that there are no changes.

- Notification of the dates that the IACUC conducted its semiannual evaluations of the University's program and facilities (including satellite facilities) and submitted the evaluations to the IO.

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

- Any serious or continuing non-compliance with PHS Policy;
- Any serious deviations from the provisions of the *Guide*; and
- Any suspension of an activity by the IACUC.

All investigations by the IACUC will be reported internally to the Vice President for Research and Economic Development. The Vice President, will send a summary of the results of the investigation to the following individuals, as appropriate:

- Principal investigator (PI)
- PI's department chair
- PI's college dean
- Environmental Health and Safety Department

Section 9: Recordkeeping

9.0 Maintaining IACUC records

The institution is responsible for maintaining:

- The Animal Welfare Assurance approved by OLAW;
- Minutes of IACUC meetings;
- Records of IACUC activities and deliberations;
- Minority IACUC views;
- Documentation of protocols reviewed by the IACUC and proposed significant changes to protocols;
- IACUC semiannual program evaluations and facility inspections, including deficiencies identified and plans for correction; and
- Accrediting body determinations.

All records are to be kept for a minimum of three years, with the exception of records that relate directly to protocols, which must be kept for the duration of the activity and for an additional three years after completion of the activity.

9.1 Meeting minutes

Review of proposals by the IACUC invokes a deliberative process, and the PHS Policy and AWRs require that the institution maintain "minutes of IACUC meetings, including records of attendance, activities of the Committee, and Committee deliberations" (PHS Policy IV. E; 9 CFR Part 2 Subpart C 2.35 (a)(1)). The IACUC has some latitude in the degree of detail in these minutes.

Recorded minutes from IACUC full committee reviews are intended to reflect the substantive discussion of protocols. Minutes are intended to contain sufficient information that a reasonable person could understand the nature of the discussion. Meeting minutes are not intended to provide a verbatim transcript of discussion or to reiterate shared knowledge of the Committee such as recent discussions about a protocol in previous minutes. Minutes of each full committee review are recorded in writing and include records of attendance, a summary of the issues discussed and the resolution of issues, and the results of IACUC votes on protocols.

Records of attendance

Although members may arrive late or leave during a meeting, generally a member is marked as either present or absent. An exception would be when the IACUC member leaves the meeting room during discussion of a protocol on which that member is a participant. If the temporary absence of a member drops the number of members present below the quorum, no official action may take place, and this will be noted in the minutes.

Activities of the committee

Activities of the Committee include, but are not limited to, corrections or approval of previous minutes; presentation of program, policy, facility and compliance reports; and decisions on policies, protocols, and amendments.

Deliberations of the committee

A deliberation of the Committee refers to the discussion and reasons leading to particular IACUC decisions. Minutes should include as a minimum a summary of the key points discussed prior to a committee decision.

Completed minutes are distributed to all IACUC members. Minutes are discussed at a subsequent convened meeting of the IACUC and the committee votes on approval. A copy of the approved meeting minutes is then provided to the IO. This informs the IO of all actions taken by the IACUC.

9.2 Protocols

The PHS Policy and the AWRs require that animal applications and proposed significant changes be retained for the duration of the animal activity and for an additional three years after the end of the activity. Proposals submitted to the IACUC must be kept for three years even if approval was not granted or animals were not used. The records must show whether or not IACUC approval was given.

9.3 Other records

Both the PHS Policy and the AWRs require that the University retain the semiannual program review and facility inspections report and any recommendations of the IACUC. PHS Policy also requires that the OLAW Assurance and reports of accrediting agencies (e.g., AAALAC) be kept on file. USDA requires additional records on dogs and cats. Animal health records are not usually maintained by the IACUC, but are kept in the animal facility or in the research laboratory. All these records must be kept for at least three years and must be accessible to OLAW, USDA, and funding agencies for inspection or copying.

UPDATED APPENDIX A

Protocol Approval Form

DHHS/NIH/OLAW ASSURANCE #A-3216-01
EFFECTIVE: *04/25/14-03/31/18*

UNIVERSITY of WYOMING
INSTITUTIONAL ANIMAL CARE and USE COMMITTEE
PROTOCOL APPROVAL FORM

Submit completed form to the IACUC at IACUC@uwyo.edu or Office of Research, Room 308, Old Main.
RESEARCH SHALL NOT BEGIN UNTIL THIS FORM IS APPROVED.

New project _____ Revised protocol _____ Date_____
(Project will be approved for one year from date of IACUC approval. An annual update form must be submitted annually if project extends beyond one year.)

Title of project:
Project leader(s):
Department(s):
Phone:
Email:

Proposal Category (The PI may choose more than one category).

****Note:** If live animals will only be observed in their natural habitat and the study will not involve an invasive procedure, harm to the animal, or materially alter the behavior of the animal, **an IACUC protocol is not required**. If live animals will only be used for **observational and/or non-invasive teaching**, please stop and complete the University Teaching Protocol Form.

A _____ Live animals will be humanely killed without any treatments, manipulations, etc., but will be used to obtain tissue, cells, sera, etc.

B _____ Live animals will be bred or held for use in teaching, testing, experiments, research, or surgery, but not yet used for such purposes. **STOP**→ If this is all that is involved, please complete the University Breeding Colony Form.

C _____ Live animals will be involved in teaching, research, experiments, and/or tests, but the procedures will only involve minimal, momentary, or no pain/distress to the animals and pain relieving drugs will not be used.

D _____ Live animals will be involved in experiments, teaching, research, surgery or tests and either some or all of the procedures involve more than minimal and/or momentary pain or distress to the animal and appropriate anesthetics, analgesics, or tranquilizing drugs will be used.

E _____ Live animals will be involved in experiments, teaching, research, surgery or tests and either some or all of the procedures involve pain or distress to the animal and anesthetics, analgesics, and/or tranquilizing drugs will not be used because of the adverse impact on the affected procedures or results.

Species Information

Animal species (genus, species, common name) (one species per protocol form-unless procedures are identical):

Number to be used/year: Total animal days/year (# animals x #days):

Number to be used/project: Total animal days/project:

Source of animals:

Location Information

Location of animal room: Building/Room number

Location of animal care log book/medical records: Building/Room number

Duration of project: Begin End

Funding Information

Sponsoring agency (if applicable):

UW Budget ID/Project Grant number (if applicable):

Name person(s) and/or unit responsible for animal care:

Name: Phone: Email:

1) a. Purpose (*in lay terms*)

b. Scientific objective(s)

c. Potential for use of in vitro systems or computerized models instead of live animals

i. Elaborate on current availability of animal data that could be used to predict outcomes

ii. Elaborate on the uniqueness of the study such that the requirement for live animal research is necessary

2) Describe all procedures: *Description should allow the IACUC to understand the experimental course of an animal from its entry into the experiment to the endpoint of the study*.

a. Overview of procedures

(***Reference citations for b-e***)

b. Type and duration of restraint

c. Name and dose of anesthesia and/or tranquilizer (contact attending veterinarian)

d. Surgical procedures

i. pre-operative procedures

ii. aseptic methods to be used: surgical attire

iii. who will perform surgical procedures

iv. where will surgical procedures be performed

v. non-survival/survival surgery

vi. justification if more than one surgical procedure per animal

d. Post-surgical care

i. Recovery facility

ii. Name, dose, route of administration and regimen for analgesia; (investigate literature for pain management for species used; consult attending veterinarian)

3) Justification for species chosen (lowest possible species on phylogenetic scale)

4) ***Statistical*** justification for the specified number of animals (assistance to determine the appropriate number of animals per treatment)

a. Justification for number of animals per experiment

b. Justification for number of experiments per year (as stated on page 2)

c. Literature cited/reviewed for justification of number of animals proposed

5) Will animals be subjected to euthanasia?

   a. Method of euthanasia

   b. Drug and dosage

   c. If using drugs for euthanasia, describe disposal of animal remains.

   d. If animals will not be euthanized, describe plan for future use or other dispersal.

6) If the proposal category checked is D or E, then the experimental procedures may cause more than momentary or slight pain or distress and the PI must address the following: Provide a written narrative description, including methods and sources used in search, of how it was determined that alternatives to potentially painful or distressful procedures are not available. The Narrative should include at a minimum the following:

   a. A list of the databases (two or more) searched (see below);
   b. The terms used to search for alternatives to **each** painful or distressful procedure;
   c. Whether any alternatives were found and if so a description of each alternative; **and**
   d. If alternatives were found, an explanation of why the alternatives can't be used in this study.

Note: *The purpose of this search is NOT to explain why the research does not duplicate other work. The purpose of this search is to show that there are no alternative to the potentially painful or distressful procedures outlined in this protocol.*

Including i: Literature cited; database references must include name of databases searched, the date of the search, period covered, and keywords used. For assistance with literature searches please see: http://libguides.uwyo.edu/AWA (which includes a video from a representative of the USDA) or contact the following University of Wyoming Librarians: Jenny Garcia at: jgarcia@uwyo.edu or David Kruger at: tseliot@uwyo.edu .

And/Or ii: personal communications

   e. **A minimum of two databases must be searched.**

      i. Database 1:
      ii. Database 2:
      iii. Please add additional databases as necessary

Please refer to Animal Welfare Act 9CFR Section 2.31 (d) (1) (ii)

7) Explain why this research does not involve unnecessary duplication of previous research or experiments For assistance with literature searches please see: http://libguides.uwyo.edu/AWA (which includes a video from a representative of the USDA) or contact the following University of Wyoming Librarians: Jenny Garcia at: jgarcia@uwyo.edu or David Kruger at: tseliot@uwyo.edu .

   a. Please indicate date of search, name of databases, keywords used, and number of responses. **A minimum of two databases must be searched.**

      i. Database 1:
      ii. Database 2:
      iii. Please add additional databases as necessary

   b. Discuss relevant literature to justify why unnecessary duplication of previous research is not involved. The written narrative in this section should include at a minimum the following information:
      i. A list of the databases (two or more) searched (see above);
      ii. The terms used to search;
      iii. Whether any similar research was found and if so a description of that research; and
      iv. If similar research was found, an explanation of why this research is so different or why additional research is needed on the same topic that this research does not unnecessarily duplicate research that has already been done.

   Please refer to Animal Welfare Act 9CFR Section 2.31 (d) (1) (iii)

8) Training/experience documentation: Federal regulations require appropriate training and experience for all personnel involved in the care and use of animals. An up-to-date "Verification of Training for Animal Work" form must be on file in the Research Office for *each* person, including the P.I., involved in the care and use of animals to be used in this protocol.

   Verification of Training for Animal Work form: http://www.uwyo.edu/Research/forms.htm

   For PI(s) (name): attached ___ on file ___ date _____
   For animal care worker/lab technician (name): attached ___ on file ___ date _____
   Graduate student(s) (name): attached ___ on file ___ date _____
   Others (name): attached ___ on file ___ date _____

   Please list specific experience and/or qualifications of each animal care worker necessary to perform the specific techniques and procedures described in this protocol (such as surgery) if not included on the "Verification of Training for Animal Work" form attached or on file.

Principal Investigator Assurance**: "I have received a copy of the NIH Guide for the Care and Use of Laboratory Animals and/or The Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching and will provide for the care, use and treatment of the animals used for the purpose described above accordingly. I will use procedures which will avoid or minimize discomfort, distress and pain to animals used in my research. I have considered alternatives to procedures that may cause more than momentary slight pain or distress to the animals. These studies do not unnecessarily duplicate previous experiments. **I WILL INFORM THE ATTENDING VETERINARIAN (DAVID EVERTSON 745-7341) OR BACKUP VETERINARIAN ON STAFF AT ALPINE ANIMAL VETERINARY CLINIC IMMEDIATELY IF ANY

PROBLEMS OCCUR, INCLUDING UNANTICIPATED PAIN OR DISTRESS, INJURY, MORBIDITY OR MORTALITY. *I will submit a revised protocol for IACUC approval before making any significant deviations from the approved project procedures occurs. I will submit an annual update for IACUC approval for continuation if this project extends beyond one year. I assure the IACUC that all persons involved in the care and use of animals related to this protocol have received the appropriate training and are qualified to perform the procedures described above."*

REVIEWED AND APPROVED:

_____
Principal Investigator …….Date

_____ _____
Department Chairperson ……Date Veterinary Officer …… Date

ACTION BY THE ANIMAL CARE AND USE COMMITTEE: APPROVED ☐ DISAPPROVED ☐

_____ _____
Chairperson, IACUC Date Associate Vice President for Research Date

UPDATED-APPENDIX B

Teaching Protocol Form

Required informational sheet for instruction involving the use of animals. This form may only be used for observational and/or non-invasive instruction. For all other types of instruction involving animals, please complete the full IACUC Protocol Form.

The informational sheet must be filled out and submitted by the faculty member instructing the class using the animals before the first day of class during the semester in which the students will be using the animals.

This sheet should be used for class projects or assignments designed to provide students with an opportunity to work with animals as part of a class. If the animals will be used in research, research training, experimentation, biological testing, or exhibition purposes, the faculty member or student must submit a full IACUC protocol.

The informational sheet should be submitted to the IACUC in care of:

Institutional Animal Care and Use Committee	Phone: 307-766-5322
1000 East University Avenue, Dept. 3355	Fax: 307-766-2608
Room 308, Old Main	email: IACUC@uwyo.edu
Laramie, WY 82071	

The informational sheet must include the following information:

1)

Name:	**Phone:**
Title:	**Fax:**
Institution:	**Email:**
Department:	**Address:**

2) **Title, semester of class.**

3) **Purpose for the use of the animals (in lay terms).**

4) **Description of the procedures, including:**
- Overview of procedures
- Number of animals and species
- Type and duration of restraint
- Name and dose of anesthesia and/or tranquilizer (contact attending veterinarian)
- Surgical procedures and post-surgical care
- Justification for species chosen (lowest possible species on phylogenetic scale)
- If euthanasia will be used, include (1) the method, (2) the drug and dosage, and (3) the disposal of the animal remains. If animals will not be euthanized, describe plan for future use or other dispersal.

5) **Describe the training that will be provided to the students to ensure that they are appropriately qualified and trained to conduct the procedures.**

6) **Attach a copy of the course syllabus and any other relevant information (e.g., lab manual)**

APPENDIX C

Breeding Colony Protocol

DHHS/NIH/OLAW ASSURANCE #A-3216-01
EFFECTIVE: 04/25/14-03/31/18

UNIVERSITY of WYOMING
INSTITUTIONAL ANIMAL CARE and USE COMMITTEE
BREEDING COLONY APPROVAL FORM

Submit completed form **on February 1st of each year to the IACUC, Office of Research, Room 308, Old Main.

New Colony: _____ **Changed Colony: _____** **Updated Colony:_____**

INDIVIDUAL RESPONSIBLE FOR COLONY MAINTENANCE

Name: Department:

Work Phone #: Emergency Phone (after hours) #:

Email: Date:

LOCATION

Location of animal room: Building/Room number

Location of animal care log book/medical records: Building/Room number

FUNDING

Sponsoring agency (if applicable):

UW Budget ID/Project Grant number (if applicable):

Describe the responsible individual's training and experience as it relates colony maintenance and breeding of animals:

OTHER RESEARCH PERSONNEL INVOLVED IN MAINTAINING THE COLONY

Name:	Email Address:
Name:	Email Address:
Name:	Email Address:

Describe their training and experience as it relates colony maintenance and breeding of animals:

A. Please provide the following information about the breeding colony after you have reviewed the IACUC Policies and Procedure Manual:

1. Provide a scientific justification for establishing and maintaining a breeding colony of animals at the University: *NOTE: Cost savings alone is not a valid justification for maintaining a breeding colony.*
2. Describe any variations from standard husbandry, care or housing required by the breeding colony:
3. Describe the breeding scheme that will be used (monogamous pairs, harem, etc.):
4. Describe how overcrowding of breeding cages will be avoided, particularly when harem-breeding schemes are used (e.g., females are separated when visibly pregnant):
5. Indicate the age at which animals are weaned.
6. Indicate with an "**X**" in the bracket **[ ]** how the animals will be genotyped:
Sample type: **[ ]** Tail clip

[ ] Blood sample--Describe the collection procedure:
[ ] Other (describe):

Age of animals when sample is taken:
[ ] 0-14 days
[ ] 14 days – 20 days (pre-weaning)
[ ] 21 days (weaning)
[ ] 22 days and older (adult post-weaning)

Method of anesthesia (required for animals genotyped at or above weaning age):

Method of identification:
[ ] PCR
[ ] Southern
[ ] Coat color
[ ] Other (describe):

7. Describe how the health and maintenance of the colony is managed and recorded. Include a brief description of the record-keeping procedures that will be used to track pedigree, breeding performance, number of animals produced by the colony, etc.:

8. Describe any known or expected phenotypes (behavioral, anatomical or physiological) of animals produced in the colony. If the phenotype may adversely affect the health and welfare of the animals, describe how animals will be monitored and treated for pain, distress and discomfort:

9. Indicate with an "**X**" in the bracket **[ ]** how animals in the breeding colony will be individually identified:

[ ] Ear notch
[ ] Ear tag
[ ] Tattoo
[ ] Microchip implant
[ ] Cage card only
[ ] Other (describe):

NOTE: *Toe clipping as a method of identification requires a scientific justification; less invasive methods are strongly recommended.*

10. Indicate whether breeder animals will receive any experimental or therapeutic drugs, ovulation agents or in-utero therapies or therapeutics. List the agent, dosage and frequency of administration if applicable:
11. Indicate how excess or unused animals produced in the colony (i.e.: animals with the wrong genotype, retired breeders, animals not needed for the research) will be euthanized:

B. List in the table below the number of animals needed to establish the colony, including founder animals, wild-type strains needed for backcrossing, etc. Please be aware that only one species may be listed per breeding colony approval form. If multiples species are involved, please list each species on its own form.

NOTE: If this is a renewal application for an existing colony, please list the breeder animals that you currently have in your colony.

SPECIES AND STRAIN	TOTAL # OF ANIMALS
EXAMPLE: Mouse Balb/c	*EXAMPLE: 100*

C. Estimate the approximate number of animals that will be produced in the colony and retained as replacement breeding animals during the three-year protocol period. Please be aware that only one species may be listed per breeding colony approval form. If multiples species are involved, please list each species on its own form.

SPECIES AND STRAIN	TOTAL # OF ANIMALS

D. Estimate the approximate number of animals that will be produced in the colony but not used for research purposes or retained as breeders (e.g., culled littermates, wrong genotype). Provide a brief explanation of why they will not be used, and describe what will be done to minimize this number.

Approximate number not used:	

Explanation of why they will not be used:	
What will be done to minimize this number:	

Principal Investigator Assurance: *"I have received a copy of the NIH Guide for the Care and Use of Laboratory Animals and/or The Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching and will provide for the care, use and treatment of the animals used for the purpose described above accordingly..* ***I WILL INFORM THE ATTENDING VETERINARIAN (DAVID EVERTSON 745-7341) OR BACKUP VETERINARIAN ON STAFF AT ALPINE ANIMAL VETERINARY CLINIC IMMEDIATELY IF ANY PROBLEMS OCCUR, INCLUDING UNANTICIPATED PAIN OR DISTRESS, INJURY, MORBIDITY OR MORTALITY.*** *I will submit a revised protocol for IACUC approval before making any significant deviations from the approved colony discussed above. I will submit an annual update for IACUC approval for continuation of this colony if the colony extends beyond one year. I assure the IACUC that all persons involved in the care and use of animals related to this protocol have received the appropriate training and are qualified to perform the procedures described above."*

_____
Principal Investigator …….Date

REVIEWED AND APPROVED:

_____
Department Chairperson ……Date

_____
Veterinary Officer …… Date

ACTION BY THE ANIMAL CARE AND USE COMMITTEE: APPROVED ☐ DISAPPROVED ☐

_____
Chairperson, IACUC Date

_____
Associate Vice President for Research Date

UPDATED APPENDIX D

Annual Review Form

DHHS/NIH/OLAW *ASSURANCE #A-3216-01*
EFFECTIVE: 04/25/14-03/31/18

UNIVERSITY of WYOMING
INSTITUTIONAL ANIMAL CARE and USE COMMITTEE
ANNUAL REVIEW FORM

This form must be submitted annually for continuing projects. Submit completed form to the IACUC at IACUC@uwyo.edu or Office of Research, Room 308, Old Main.

Title of project :

Previously approved for the period:
Project leader(s):
Department(s):
Phone: Email:
Type: Research _____ Instruction _____
Sponsoring agency (if applicable):
UW Budget ID/Project Grant number (if applicable):

Describe any changes in the animal component of the project (e.g. change in anesthetic, species, pain category, surgical procedure, new techniques, changes in number of animals used.)

If significant changes are planned, a new animal protocol form may need to be submitted to the IACUC for review. Please consult with the attending veterinarian, your departmental IACUC member, or the Office of Research, 308 Old Main, 766-5320.

2) List the name, position, and telephone numbers of all personnel associated with this project.

Attach completed "Verification of Training for Animal Work" form for new personnel not listed on the original protocol.

3) Number of animals used in this project during the last year

Species	Number

4) Number of animals to be used for this project during the coming year (**Note:** if the number of animals to be used is increasing from the previous year and the rational for this increase is not covered in the original protocol, please explain why more animals are necessary for the upcoming year).

Species	Number

Principal Investigator Assurance: *"I have received a copy of the NIH Guide for the Care and Use of Laboratory Animals and/or The Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching and will provide for the care, use and treatment of the animals used for the purpose described above accordingly. I will use procedures which will avoid or minimize discomfort, distress and pain to animals used in my research. I have considered alternatives to procedures that may cause more than momentary slight pain or distress to the animals. These studies do not unnecessarily duplicate previous experiments.* ***I WILL INFORM THE ATTENDING VETERINARIAN (DAVID EVERTSON 745-7341) OR BACKUP***

VETERINARIAN ON STAFF AT ALPINE ANIMAL VETERINARY CLINIC IMMEDIATELY IF ANY PROBLEMS OCCUR, INCLUDING UNANTICIPATED PAIN OR DISTRESS, INJURY, MORBIDITY OR MORTALITY. *I will submit a revised protocol for IACUC approval before making any significant deviations from the approved project procedures occurs. I will submit an annual update for IACUC approval for continuation if this project extends beyond one year. I assure the IACUC that all persons involved in the care and use of animals related to this protocol have received the appropriate training and are qualified to perform the procedures described above."*

REVIEWED AND APPROVED:

_____ _____
Principal Investigator …….Date

_____ _____ _____ _____
Department Chairperson ……Date Veterinary Officer …… …… Date

ACTION BY THE ANIMAL CARE AND USE COMMITTEE: APPROVED / / DISAPPROVED / /

_____ _____ _____ _____
IACUC Chairperson Date Associate Vice President for Research Date

UPDATED APPENDIX E

Protocol Update Form

DHHS/NIH/OLAW *ASSURANCE #A-3216-01*
EFFECTIVE: 04/25/14-03/31/18

UNIVERSITY of WYOMING
INSTITUTIONAL ANIMAL CARE and USE COMMITTEE
ANNUAL PROTOCOL UPDATE FORM

This form must be submitted before implementing any modifications, for example increasing the number of animal, on an approved protocol. This form can be submitted at any time (i.e. you do not have to wait for your annual review). Submit completed form to the IACUC at IACUC@uwyo.edu or Office of Research, Room 308, Old Main.

Title of project :

Previously approved for the period:
Project leader(s):
Department(s):
Phone: Email:
Type: Research _____ Instruction _____
Sponsoring agency (if applicable):
UW Budget ID/Project Grant number (if applicable):

Describe any changes in the animal component of the project (e.g. change in anesthetic, species, pain category, surgical procedure, new techniques, changes in number of animals used.)

If significant changes are planned, a new animal protocol form may need to be submitted to the IACUC for review. Please consult with the attending veterinarian, your departmental IACUC member, or the Office of Research, 308 Old Main, 766-5320.

2) List the name, position, and telephone numbers of all personnel associated with this project.

Attach completed "Verification of Training for Animal Work" form for new personnel not listed on the original protocol.

3) Number of animals used in this project during the last year

Species	Number

4) Number of animals to be used for this project during the coming year (**Note:** if the number of animals to be used is increasing from the previous year and the rational for this increase is not covered in the original protocol, please explain why more animals are necessary for the upcoming year).

Species	Number

Principal Investigator Assurance: *"I have received a copy of the NIH Guide for the Care and Use of Laboratory Animals and/or The Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching and will provide for the care, use and treatment of the animals used for the purpose described above accordingly. I will use procedures which will avoid or minimize discomfort, distress and pain to animals used in my research. I have considered alternatives to procedures that may cause more than momentary slight*

pain or distress to the animals. These studies do not unnecessarily duplicate previous experiments. ***I WILL INFORM THE ATTENDING VETERINARIAN (DAVID EVERTSON 745-7341) OR BACKUP VETERINARIAN ON STAFF AT ALPINE ANIMAL VETERINARY CLINIC IMMEDIATELY IF ANY PROBLEMS OCCUR, INCLUDING UNANTICIPATED PAIN OR DISTRESS, INJURY, MORBIDITY OR MORTALITY.*** *I will submit a revised protocol for IACUC approval before making any significant deviations from the approved project procedures occurs. I will submit an annual update for IACUC approval for continuation if this project extends beyond one year. I assure the IACUC that all persons involved in the care and use of animals related to this protocol have received the appropriate training and are qualified to perform the procedures described above."*

REVIEWED AND APPROVED:

_____ _____
Principal Investigator …….Date

_____ _____ _____ _____
Department Chairperson ……Date Veterinary Officer …… …… Date

ACTION BY THE ANIMAL CARE AND USE COMMITTEE: APPROVED / / DISAPPROVED / /

_____ _____ _____ _____
IACUC Chairperson Date Associate Vice President for Research Date

APPENDIX F

Verification of Training For Animal Work

(Submit completed form to IACUC@uwyo.edu or the IACUC, Office of Research, Room 308, Old Main)

Date: _____

Name: _____

Position: _____

Department: _____ **Phone:** _____ **email:** _____

Supervisor: _____ **email:** _____

Date employed: _____

Species to be used: _____

Procedures conducted with animals (i.e. types of surgery, routine husbandry, feeding trials, euthanasia, etc.)

_____

_____

Formal training in animal care and management for species indicated: _____

_____

_____

Informal or on-the-job training in animal care and management for species indicated: _____

_____

_____

PLEASE attach copies, if any, of training certificates or other documentation of formal animal care training completed and forward copies of training certificates or documentation completed in the future.

I certify that animals under my care will be cared for according to applicable animal husbandry practices, the NIH Guide for Care and Uses of Laboratory Animals, and the Animal Welfare Act. Animals used for research and instruction will be cared for as dictated in the animal care and use protocol approved by the Institutional Animal Care and Use Committee and according to the Program of Veterinary Care on file. ***I WILL INFORM THE ATTENDING VETERINARIAN (DAVID EVERTSON 745-7341) OR BACKUP VETERINARIAN ON STAFF AT ALPINE ANIMAL VETERINARY CLINIC IMMEDIATELY IF ANY PROBLEMS OCCUR, INCLUDING UNANTICIPATED PAIN OR DISTRESS, INJURY, MORBIDITY OR MORTALITY.***

_____ _____

Signature of Employee Date Signature of Supervisor Date

_____

Signature of Department Head Date

UPDATED APPENDIX G

DHHS/NIH/OLAW Assurance Approval Letter

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DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
Division of Assurances
6705 Rockledge Drive
RKL 1, Suite 360, MSC 7982
Bethesda, Maryland 20892-7982
Home Page: http://grants.nih.gov/grants/olaw/olaw.htm

FOR EXPRESS MAIL:
Office of Laboratory Animal Welfare
Division of Assurances
6705 Rockledge Drive, Suite 360
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 451-5672

April 25, 2014

Reference: Renewal Assurance **#A3216-01**

William A. Gern, Ph.D.
Vice President for Research and Economic Development
University of Wyoming
1000 E. University Avenue
Department 3355
Laramie, Wyoming 82071

Dear Dr. Gern:

The Office of Laboratory Animal Welfare (OLAW) reviewed and approved the renewal of your institution's Animal Welfare Assurance (Assurance) that was submitted in compliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), as revised August 2002.

Your Assurance renewal, number **A3216-01**, became effective on **April 25, 2014** and expires on **March 31, 2018**. This Assurance supersedes all previously issued Assurances. Please include the Assurance number in all correspondence to OLAW. A copy of the Assurance signature page is enclosed.

The Assurance is a key document in defining the relationship of your Institution to the PHS. It sets forth the responsibilities and procedures of your Institution regarding the care and use of laboratory animals. Among the important elements of the Assurance, I would especially call your attention to the reporting requirements that are essential for continued compliance with the PHS Policy. Please note that a Report to OLAW is required at least once every 12 months. The reporting period, unless requested otherwise in writing, is the calendar year. Reports, for the previous calendar year, are due **January 31**.

If we may be of further assistance, please do not hesitate to contact me or Dr. Parlett.

Thank you for your attention in these matters.

Sincerely,

Eileen M. Morgan
Director, Division of Assurances
Office of Laboratory Animal Welfare, NIH

Enclosure

cc:
Dr. Robert Scott Seville

VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official

Name: William A. Gern

Title: Vice President for Research and Economic Development

Name of Institution: University of Wyoming

Address: *(street, city, state, country, postal code)*

1000 E. University Avenue
Department 3355
Laramie, WY 82071

Phone: (307) 766-5353	Fax: (307) 766-2608

E-mail: willger@uwyo.edu

Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure the humane care and use of animals as specified above.

Signature: William A. Gern Date: 4-23-14

B. PHS Approving Official *(to be completed by OLAW)*

Eileen M. Morgan-Director, Division of Assurances
Office of Laboratory Animal Welfare
National Institutes of Health
6705 Rockledge Drive
RKL1-Suite 360-MSC 7982
Bethesda,, MD 20892-7982

Signature: Eileen M Morgan Date: 4/25/14

Assurance Number: A3216-01

Effective Date: 4/25/14 Expiration Date: 3/31/18