Boise State University

Institutional Animal Care and Use Program Guide

February 2013

Table of Contents:

Section VIII -- Occupational Health and Safety Program	Section VIII provides information on the Occupational Health and Safety program as a part of the overall animal care and use program.
Section IX – Veterinary & Veterinary Care Program	Section IX discusses responsibilities of the IACUC Veterinarian and what is adequate veterinary care.
Appendix I -- Forms	Appendix I provides links to regulatory guides and samples of forms used by IACUC to perform and support its functions.
Appendix II -- Definitions	Appendix II provides definitions.

Section I -- Regulatory Authority

Boise State University has determined any activity involving animals for research, testing and training, is subject to the authority of the PHS Animal Welfare Assurance and the Federal Animal Welfare Act (AWA) and its amendments 7 U.S.C. 2131, et seq.

Boise State University also accepts obligations and standards that apply to academic and research institutions that are enforced by the United States Department of Agriculture (USDA) through on-site inspections to ensure proper animal care and use. The PHS Policy also requires institutions to follow the recommendations of the Guide for the Care and Use of Laboratory Animals (GUIDE).

A. INSTITUTION: Boise State University is responsible for the review of all activities involving animal use and the procurement, handling, and care of animals used of research, training, or testing if:
   1) the research, training, and testing is conducted under the auspices of the university, no matter of funding sources, or
   2) the research, training, and testing is conducted under the direction of any faculty, student, staff, or agent of the university in connection with his/her university responsibilities, or
   3) the research, training, and testing is conducted under the direction of any faculty, student, staff, or agent of the university using any property or facility of the university.

Institutional Principles for the Utilization and Care of Laboratory Animals.

Boise State University concurs with the U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in testing, research and training.

The University adopts and ensures that the following principles are adhered to:

I. The transportation, care, and use of animals shall be in accordance with the Animal Welfare Act (AWA) and other applicable laws, guidelines, and policies.

II. Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.

III. The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and *in vitro* biological systems should be considered.

IV. Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.

V. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents.

VI. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure.

VII. The living conditions of animals should be appropriate for the species and contribute to their health and comfort. Normally, the housing, feeding, and care of all animals used for biomedical purposed must be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied. In any case, veterinary care shall be provided as indicated.

VIII. Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals.

IX. Where exceptions are required in relation to the provision of these Principles, the decisions should not rest with the investigators directly concerned but should be made, with due regard to Principle II, by an appropriate review group such as an institutional animal care and use committee. Such exceptions should not be made solely for the purposed of teaching or demonstration.

B. PRESIDENT: The responsibility for compliance with federal, state or University regulations concerning activities involving the care and use of animals rests with the President of Boise State University. The President has delegated this authority to the Vice President for Research as the Institutional Official (IO).

C. VICE PRESIDENT FOR RESEARCH: The Vice President for Research is the authorized Institutional Official (IO), delegated by the President, for animal research, training, testing, use and care.

The Vice President for Research shall:
(a) ensure compliance with all applicable laws and policies; (b) appoint an institutional animal care and use committee (IACUC) with appropriate administrative support; (c) develop administrative procedures necessary to implement the BSU Institutional Animal Care and Use Program Guide; (d) with consultation from the IACUC Chairperson and the Coordinator for Research Compliance will annually review the composition of the IACUC membership to ensure efficiency and a balance of interests in regard to animal research; (e) perform all necessary reporting requirements; (f) report to the appropriate officials any noncompliance with laws and policies, as well as, any corrective or remedial action taken; (g) give proper administrative and operational authority to commit institutional resources to ensure compliance with the PHS Policy and other requirements; (h) ensure that all personnel involved in animal care, treatment, and use are qualified to perform duties, and that training and instruction in specific areas are provided to those personnel; (i) review qualifications of personnel to ensure they can fulfill their responsibilities; and (j) ensure that the University maintains records for the specific time period as required.

Section II -- IACUC Composition, Purpose, Requirements, Membership and Quorum

A. PURPOSE and Legal Requirements:

Contemporary laws and guidelines require that animal experimentation precede human application of new medical procedures, drugs, and devices and that sound animal care and use programs be implemented by institutions using laboratory animals. The U.S. Government Principles provide an ethical framework within which Federal agencies and institutions that receive Federal support are to operate when dealing with issues pertaining to the use of laboratory animals. The Federal Animal Welfare Act, along with its implementing regulations, mandates minimal standards of laboratory animal care and use. These standards apply to nearly all academic and research institutions and are enforced by the United States Department of Agriculture (USDA) through on-site inspections to ensure proper animal care and use. The PHS Policy also requires institutions to follow the recommendations of the GUIDE to conduct activities involving animals.

There are other Federal laws which may pertain to specific research and academic programs, depending upon the type of work being done and the species being used. In addition to Federal laws, regulations, and guidelines there are an increasing number of state and local statutes which affect an institution's research and academic programs involving the use of animals. Institutional administrators should ensure that procedures are in place to enable them to remain cognizant of and compliant with state and local laws and regulations that may affect their institution's programs.

B. AUTHORITY:

The President of Boise State University has delegated the authority to the Vice President for Research, who also serves as the IO, to appoint all IACUC members to a four (4) year term, appropriately staggered, in order to ensure continuity. At the discretion of the IO, members may be reappointed also to further terms or appointed for a shorter term. The IO in consultation with the IACUC Chairperson and the Director for Research Compliance will annually review the IACUC membership. The review may include but not limited to, the attendance, timely submission of comments and participation in scheduled meetings. Members may be terminated prior to the end of their four (4) year term if deemed necessary. The IO shall appoint one member of the IACUC to serve as Chairperson for a term of four years and is responsible for appointing new members to the IACUC by issuing an appointment letter. The Vice President for Research shall delegate the responsibility to the IACUC to make appropriate updates, changes and modifications to the program and the program guide manual as necessary.

C. MEMBERSHIP AND COMPOSITION:

Membership shall consist of no fewer than five members with varying backgrounds. At least one member shall be a licensed Doctor of Veterinary Medicine; one member shall be a practicing scientist; at least one member shall be a person whose primary vocation is in a nonscientific area; and one person shall be unaffiliated with the University. An individual, who meets the requirements of more than one of these categories, may fulfill more than one requirement. Members appointed to the IACUC must: (1) be active in attendance (due to requirements for a quorum to approve and/or suspend); (2) must be timely in their responses to pending concerns in order to quickly facilitate protocol; (3) must be active in discussions and

deliberations; and (4) must represent themselves as a benefit to the committee and ensure continuity.

Committee members will receive the assigned proposed proposal to be reviewed for the next monthly meeting. The committee members are responsible for full review of the Animal Use Protocol or Field Study Protocol form/proposals assigned to him/her. The members are responsible for contacting the Office of Research Compliance (ORC) at AnimalCare@boisestate.edu for further clarification of procedures or additional information that is considered important for proper review of the protocol prior to the monthly meetings.

The IACUC recognizes that university research scientists must conduct their research in a timely and responsible fashion. Therefore, to facilitate research while assuring animal welfare, the IACUC must conduct its business as efficiently as possible. This can only be accomplished if all committee members fully participate in IACUC activities.

IACUC members should make every effort to attend and actively participate in all regularly scheduled meetings, promptly conduct complete reviews of protocol, and participate in facility and program reviews. Committee members must also recognize the sensitive nature of the IACUC activities and maintain confidentially (AWA, Section 2157).

(1) Chairperson: A knowledgeable and effective leader is crucial to an effective IACUC. The Chairperson will be responsible for all activities of the IACUC including, but not limited to: (a) schedule meetings; (b) set the agenda for meetings; (c) ensure that a quorum of the IACUC is present and declare the loss of a quorum resulting in the end of official business; (d) ensure all members have a copy of the protocol to be reviewed; (e) moderates the meetings; (f) keep records of activity; (g) by written letter of acknowledgment, inform the principle investigator of the IACUC's decisions regarding his/her protocol; (h) sign, approve, and send the required reports to the IO; (i) report to the IO any activities that been suspended by the IACUC for noncompliance; (j) approve the minutes of meetings, (k) keep abreast of new regulations and trends; (l) evaluates and champions policy and practices to improve the animal care program; and (m) call emergency meetings when necessary.

Note: the Chairperson may delegate, in writing, one or more of these activities to other members or staff.

(2) Veterinarian: At least one member must be a 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 University, PHS Policy IV.A.1.c.. They must be able to provide critical review of the protocol for veterinary care issues. For additional information on the role and responsibilities of the Veterinarian, see the Office of Laboratory Animal Welfare (OLAW) Guidebook, B.3.53-57

(3) Nonaffiliated member: The nonaffiliated member is intended to represent general community interests. An informed nonaffiliated member can bring significant value to the committee by bringing a non-institutional perspective to the research endeavor. This member has equal status to every other committee member, and should be provided the opportunity to participate in all aspects of the IACUC functions. This member shall not be: (a) a member of the immediate family of a person who is affiliated with the University; (b) a laboratory animal user; or (c) a person with financial interest in the facility, such as an animal supplier.

(4) Scientist: The IACUC must include a practicing scientist experienced in research involving animals, whose primary concerns are in a scientific area. The principle role

of the scientist is to ensure that the interests of scientific colleagues are being fairly represented in the review process, and to aid in the IACUC's assessment of relevance, validity, and technical aspects of the protocol submitted for approval. This individual can also bring to the IACUC a better understanding of the selection, use, and limitations of animal models, and certain aspects of experimental design. The scientist can also bring perspectives on how to best launch new initiatives to engender the support of the scientific community and others involved in the care and use of animals.

(5) Nonscientist: Individuals serving in this capacity should be in a nonscientific area (e.g., ethicist, lawyer, member of clergy, health and safety, human resources) and have no obvious connections to any area of science. This role is to further the diversity of the IACUC and add to the balance of foils for the scientist members who may have a vested interest in the promotion of animal studies.

(6) Vice Chairperson: The IACUC will designate a current member to serve as Vice Chair, who will serve in the absence of the Chairperson at a convened meeting.

(7) Non-voting members: Participants, whose roles are administrative and operational to support the IACUC, are identified by the ORC. These non-voting members include: (1) the animal facility staff, (2) the Coordinator for Research Compliance and other ORC staff serving as advisory, and (3) consultants or individuals with expertise in specific areas, when requested by the IACUC to attend a meeting. The following duties have been delegated as responsibilities for the ORC staff: (1) take minutes of the meetings and maintain appropriate records; (2) ensure each member receives agenda and protocol information prior to meetings; (3) schedule conference calls; (4) serve as the point of contact to receive protocol; (5) prepare inspection and evaluation reports; (6) maintain a database of IACUC approved protocols, annual reviews and disapproved protocols; and (7) maintain the IACUC membership roster.

D. QUORUM REQUIREMENT:

Certain official IACUC actions require a quorum: (1) full committee review of a research project, PHS Policy IV.C and Animal Welfare Regulations (AWR) 2.31(d) (2)d; and (2) suspension of an activity PHS Policy IV.C.6 and AWR 2.31(d)(6).

A Quorum is defined as a majority (greater than 50%) of the voting members of the IACUC. Therefore, a protocol is approved only if a quorum is present AND if more than 50% of the quorum votes in favor. PHS policy and AWR require that in order to suspend an activity, the IACUC must review the matter at a convened meeting of a quorum, and the suspension must be approved by a majority vote of the quorum present. For reasons other than conflict of interest, an abstention from voting does not alter the quorum or change the number of votes required.

(1) Electronic Quorum: Guidance on Use of Telecommunication for IACUC Meetings (NOT-OD-06-052) Methods of telecommunications (e.g., telephone or video conferencing) are acceptable for the conduct of official IACUC business requiring a quorum, provided the following criteria are met:

- All members are given notice of the meeting.
- Documents normally provided during a physically convened meeting are provided to all members in advance of the meeting.
- All members have access to the documents and the technology necessary to fully participate.
- A quorum of voting members is convened when required by PHS Policy.

- The forum allows for real time verbal interaction equivalent to that occurring in a physically convened meeting (i.e., members can actively and equally participate and there is simultaneous communication).
- If a vote is called for, the vote occurs during the meeting and is taken in a manner that ensures an accurate count of the vote. A mail ballot or individual telephone polling cannot substitute for a convened meeting.
- Opinions of absent members that are transmitted by mail, telephone, fax or e-mail may be considered by the convened IACUC members, but may not be counted as votes or considered part of the quorum.
- Written minutes of the meeting are maintained in accordance with the PHS Policy, IV.E.1.b.

The USDA Animal and Plant Health Inspection Service Animal Care, which is responsible for the USDA Animal Welfare Regulations that contain identical provisions regarding convened IACUC meetings, concurs with this notice and will publish consistent guidance in its Research Facility Inspection Guide.

(2) Polling Electronic or Teleconference: "Polling" is defined as sequential, one-on-one communication, either in person or via telephone, email, or U.S. mail. Polling is an appropriate mechanism for providing all committee members with the opportunity to call for full board review of a protocol. It may also be appropriate as a mechanism for distributing and reviewing drafts of meeting minutes, reports, and other administrative business, including the request and clarification for additional information from the PI/researcher. Polling of IACUC members does NOT, however, satisfy the definition of a meeting of a convened quorum and should NOT be used for conducting IACUC business that requires the "vote" for the committee.

Modifications to existing protocols that are considered minor (change in lab personnel, change in funding source, and change in transporting animals for field studies) and continuing review/annual renewals that do not indicate major changes or modifications are eligible for designated member review. Designated member review (DMR) consists of review of the renewal and/or modification by at least one member of the IACUC, designated by the Chairperson and qualified to conduct the review. The designated member reviewer(s) have the authority to approve, require modifications in (to secure approval) or request full committee review (FCR). Prior to DMR, the renewal and/or modification are sent electronically to all committee members for review for a designated period of time. For all designated member reviews, any committee member has the authority to request the protocol go before the full committee for review. DMR approval can be obtained via email, telephone, or fax, with proper records maintained in the protocol files.

E. PROTOCOL REVIEW CRITERIA:

In order to approve new protocols or proposed significant changes for ongoing projects, the IACUC shall conduct a review of those components related to the care and use of animals and determine that the proposed protocol is in accordance with mandated requirements. In making this determination, the IACUC shall confirm that the protocol will be conducted in accordance with the Animal Welfare Act insofar as it applies to the project, and that the protocol is consistent with the *Guide*, unless acceptable justification for a departure is presented. Further, the IACUC shall determine that the protocol conforms and meets the university's requirements.

a. Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.

b. Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.

c. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure.

d. The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding, and non-medical care of the animals will be directed by facilities staff experienced in the proper care, handling, and use of the species being maintained or studied.

e. Medical care for animals will be available and provided as necessary by a qualified veterinarian.

f. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.

g. Methods of euthanasia used will be consistent with the recommendations of the AVMA Guidelines on Euthanasia unless a deviation is justified for scientific reasons in writing by the investigator.

Section III – Function and Management of the IACUC

The University and other regulatory agencies have delineated the following areas, in order for the IACUC to fulfill its requirements and obligations properly.

FUNCTION, MANAGEMENT AND OPERATIONS: As an agent of the University, the IACUC shall:

(A) With consultation of the IO, establish and/or modify procedures to implement and maintain BSU's Institutional Animal Care and Use Program and the Program Guide Manual.

(B) Review, approve, require modifications in order to secure approval, or withhold approval activity related to the care and use of animals. This authority 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 University is not required nor obligated to conduct the research activity.

(C) Review, approve, require modifications in order to secure approval, or withhold approval of proposed significant changes regarding the use of animals for ongoing activities.

NOTE: SIGNIGICANT CHANGES: The following are considered significant changes: (a) change in the objectives of the protocol or research; (b) change in the degree of invasiveness; (c) change in species; (d) change in anesthetic agents or methods of euthanasia; (e) change in investigator or other personnel involved with animal use or care; (f) change in facility for housing or care of animals; and (g) change in number of animals to be used of greater than 10% .

(D) 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.

(E) Inspect at least once every six months the University's animal facilities satellite facilities, field sites, affiliated and nonaffiliated sites, using the GUIDE as a basis for evaluation.

(F) Prepare the IACUC evaluation and inspection of facilities report as set for in the PHS Policy at IV.B.1-8., OLAW Guidebook A-2 table B , and submit reports to the IO. These reports must: (1) indicate whether or not any minority views filed and must be included in report; (2) be signed by a majority of the IACUC involved in the inspection; (3) identify deficiencies as either minor or significant. ***Note: a significant deficiency is one that is or may be a threat to the health and safety of the animals;*** (4) include a reasonable and specific plan with a schedule of dates for correcting each deficiency, must be included in the report; and (5) be kept on file for a minimum of three years.

(G) Conduct continuing review of previously approved ongoing protocols at least annually. Thirty (30) days prior to end of the third year, a new protocol will need to be

submitted for the project. The submission of a new protocol for projects continuing beyond three years will include class projects.

(H) Review any allegations and concerns of noncompliance or concerns brought to the IACUC's attention involving the care and use of animals.

(I) Whenever necessary, obtain records and other relevant information related to the use of animals, in order to approve proposed protocols.

(J) At any time, make written recommendations to the IO regarding any aspects of the University's animal use and care program, facilities, or personnel training.

(K) Notify the Investigator, in writing, of its decision to approve or disapprove/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 at IV.C.4 If the IACUC decides to disapprove/withhold approval of a protocol, it shall include in its written notification a statement of the reason(s) for its decision, and give the Investigator an opportunity to respond.

(L) Report any noncompliance with federal, state, and university laws, policies, or procedures to the IO.

(M) Provide accurate record keeping of the committee meetings and results of deliberations.

(N) Hold and conduct meetings with a quorum present as frequent as necessary to fulfill its responsibilities, but at least once every six (6) months. A quorum is defined as a majority (greater than 50%) of the voting members of the IACUC. Therefore, a protocol is approved only if a quorum is present AND if more than 50% of the quorum votes in favor. A motion may be passed only at a convened meeting of a quorum of the IACUC if it receives the affirmative vote of the majority of the quorum present. A tally of the numbers of members who vote for, against, or abstain from voting shall be recorded in the minutes. Any minority views shall also be recorded in the minutes.

(O) Maintain communication with other university units and committees that have related responsibilities, i.e., bio-safety, occupational health and safety, university counsel, and risk management.

(P) The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the protocol or provisions of the Animal Welfare Act (AWA) and the GUIDE.

(Q) The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum and with the suspension vote of a majority of the quorum present.

1. If the IACUC suspends an activity involving animals, the IO, in consultation with the IACUC, shall review the reasons for suspension, take appropriate

corrective action, and report that action with a full explanation to the Office of Laboratory Animal Welfare (OLAW).

2. Protocol that has been approved by the IACUC may be subject to further appropriate review and approval by other officials of the University. However, those officials may not approve sections of a protocol related to the care and use of animals if they have not been approved by the IACUC.

3. If a serious violation of harm or a threat to the health and wellbeing of the animal is involved, immediate action will be taken by the Chairperson or the Attending Veterinarian. The Chairperson or the Attending Veterinarian has the authority to stop or terminate the activity directly involved. When this happens, they will notify the IO and the ORC Director as soon as possible to determine if an investigation is necessary. A special session may be called for the IACUC to convene and take over the jurisdiction of the research. The IO, in consultation with the IACUC and ORC Director, shall review the reason for the suspension, take corrective actions and provide a written report of the action to OLAW, appropriate sponsored agency, Dean, Chairperson and PI.

(R) The IACUC Chairperson may appoint subcommittees, as deemed appropriate, to facilitate the business of the IACUC. All members of subcommittees shall consist of members in good standing. Subcommittees shall report directly to the IACUC with recommendations or reports. No actions may be taken by the subcommittee without prior approval of a majority of the quorum at a convened IACUC meeting.

Section IV — IACUC Review and Approval

Who Must Submit an Animal Use Protocol:
Any testing, research, or instructional use of live vertebrates by BSU faculty, researchers, affiliates, staff, or students requires the submission of an Animal Use Protocol to the IACUC. The protocol must be fully approved before an animal user may acquire, house, or manipulate animals.
http://web1.boisestate.edu/research/compliance/animal.shtml

Who Must Submit a Field Study Protocol:
Any observation only field study conducted on free-living wild animals in their natural habitat by BSU faculty, researchers, affiliates, staff, or students does not require the submission of a Field Study Protocol to the IACUC. To determine if your study meets the definition of observation only, please consult the Observation Only Study Guidelines.

Any field study that will disturb or increase the stress level of the animal; involves an invasive procedure; materially alters the behavior of the animal; or has the potential to cause harm or accidental injury to the animal will require the submission of a Field Study Protocol. Protocols must be fully approved before a field investigation may begin. Protocol forms can be found on the IACUC website at: http://web1.boisestate.edu/research/compliance/iacuc-forms.shtml

THE PROTOCOL REVIEW AND APPROVAL PROCESS: A period of four to six weeks should be allowed for a protocol to be reviewed. The IACUC's regular meetings are scheduled for once a month. The IACUC meeting schedule is posted on the IACUC website. Review of a proposed protocol by the full committee invokes a deliberative process. PHS Policy, the GUIDE and Animal Welfare Regulations (AWR) require that minutes of the IACUC meetings reflect committee attendance and deliberations.

The Office of Research Compliance (ORC) receives all proposed research projects submitted for IACUC review electronically or in hard copy. ORC performs initial review for completeness, assigns a protocol number, and enters project information into a database. ORC and an assigned IACUC member if appropriate, works with the PI to address any issues found in the initial review. ORC distributes the project protocol electronically, or by hard copy if requested, to all IACUC members for review.

If full committee review is requested by any member, approval of those research projects may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present. Through full committee review, IACUC members have the authority to table the review or call for a motion for the protocol to be approved, require modification (to secure approval), or withhold approval. The purpose of a full committee is to have all IACUC members involved in the review and decision-making on the disposition of protocols during an interactive meeting. This in turn allows the IACUC to utilize the expertise of its members in a discussion-based format.

The IACUC may use electronic telecommunications to conduct business at convened meetings as per the *Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals* (NOT-OD-06-052).

Protocols are approved for a maximum of one (1) year, with annual review/renewals for the next two (2) years. After year three (3), the Principal Investigator (PI) will need to rewrite and submit the protocol to be reviewed as a new protocol.

(A). Prior to the formal review process, each IACUC member shall be provided with a copy of the protocol via email, fax or US surface mail. Within two weeks of receiving the protocol, the IACUC members will review the protocol and return their comments to ORC. The comments will be emailed or via campus mail in order to ensure the review process is conducted in a timely manner. The Principal Investigator may be contacted by the ORC to respond to questions and/or make modifications to the protocol. The protocol is then placed on the agenda for the regular convened monthly meeting of the IACUC. A summary of all comments will be presented at the meeting for review and discussion.

(B). If full committee review is requested by any member, approval of those research projects may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present.

(C). Designated member review consists of review by at least one member of the IACUC designated by the IACUC Chairperson and qualified to conduct the review. The designated member reviewer(s) have the authority to approve, require modifications in (to secure approval) or request full committee review. Prior to designated member review, research project information is sent electronically, or by hard copy if requested, to all committee members for review for a designated period of time. Any committee member has the authority to request the protocol be reviewed by the full committee.

Designated member review is used subsequent to full committee review when there are outstanding concerns with a protocol, modification, and/or annual renewal after full committee review. Investigator responses and modifications to secure approval are reviewed by designated member review if included in the motion to require modifications (to secure approval). The motion must pass unanimously as any member can request the modifications to secure approval be reviewed by the full committee at the next meeting.

If there are significant changes to a protocol, the protocol must be modified by the submission of a modification form that specifically identifies all changes and justifies the reasons for the changes *(see Section III for Significant Changes).* All modifications to current approved protocols are subject to the review and approval requirements of protocols as described above.

At least sixty (60) days prior to the anniversary date of an approved protocol, the ORC will send a renewal notice to the Principal Investigator (PI). The PI has the primary responsibility to ensure the annual review is submitted in a timely manner. **If the renewal form is not received in time to be placed on the agenda for the next scheduled IACUC meeting, and the anniversary date has past, prior to IACUC review and approval – <u>the protocol will be considered concluded</u> and a final report will need to be submitted to the ORC. The PI will need to submit a NEW protocol for IACUC review and approval to continue the research project**.

(D). Notification: Following each monthly meeting, the Chairperson notifies ORC to electronically distribute an Official Letter of Notification to the PI regarding the IACUC's determination of their protocol indicating its approval status, duration of approval, and if applicable, requirements to secure approval. If the IACUC withholds approval of a protocol, ORC

immediately notifies the IO. The IACUC Chairperson and Research Compliance Director meet with the IO as necessary.

Categories of Action: These actions are recorded in the minutes of each convened meeting.

(1) Full approval (approval as read) of the protocol. The IACUC has determined that all review criteria, based on the PHS Policy, the GUIDE, and AWRs, has been adequately addressed by the Principal Investigator, thus providing the PI permission to perform the protocol and procedures as described.

(2) Modifications to secure approval: If the IACUC has outstanding concerns with the protocol, modification, and/or renewal after full committee review, the IACUC can move to send the submission back to the PI for modification to secure approval. The IACUC can include in its motion whether the modifications are to come back to the full committee for review (FCR) or to be sent for designated member review (DMR).

(3) Defer or table a vote: If the protocol requires: clarification in order for the IACUC to make judgment; or if certain expertise is not present; or if the IACUC wishes to seek outside consultation; or until additional information can be obtained, then the protocol may be deferred or tabled.

(4) Disapprove or withhold approval: The IACUC can determine that a protocol may be disapproved if it has not adequately addressed all the requirements set forth by University, state, or federal requirements, as applicable. An individual IACUC member may not withhold or disapprove a protocol; this action may only be taken if the review is conducted using FCR and a quorum is present for the vote. If the IACUC decides to withhold approval of an activity, it shall include in its written notification, a statement of the reason(s) for its decision and give the investigator an opportunity to respond in person or in writing (PHS Policy IV. C.4.).

(5) Suspension of active protocol: If the IACUC suspends an approved protocol involving animals, the IO, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW or other appropriate agencies.

For Modification, Deferred, Withheld or Suspension action, the ORC acts as the liaison and communicates with the Principal Investigator to resolve all concerns brought forward by the IACUC. Once the PI has clearly answered each issue, the ORC will communicate the responses to all members of the IACUC and await their action. This communication and clarification of issues is considered an administrative function.

During an IACUC meeting, no member may participate in the IACUC review or approval of a research project, in which the member has a financial conflicting interest or is personally involved in the project, except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum (PHS Policy IV. C. 2.).

The IACUC may invite consultants to assist in the review of complex issues. Consultants may not approve or withhold approval of an activity or vote with the IACUC unless they are also a current member of the IACUC.

Protocols that have been approved by the IACUC may be subject to further appropriate review and approval by officials of the institution. However, those officials may not approve an activity involving the care and use of animals if it has not been approved by the IACUC. Any IACUC

protocol submission involving biohazardous agents or materials, DNA, tissue, blood products collection, or radioisotopes will require prior approval by the University's Biosafety Committee (IBC) or the University's Radiation Safety Officer. Other committee approvals are the responsibility of the Investigator.

CRITERIA FOR REVIEW AND APPROVAL FOR PROTOCOL.

There are many criteria that need to be taken into account with each protocol. The following are not intended to be all inclusive nor limited to, but are presented as 'standard general guides' that the IACUC will take into consideration for their review:

(1) Justification for (a) using animals and (b) rationale for the number and selection of species; (2) Identify the procedures that will be conducted on animals; (3) Animal housing, location, and conditions; (4) Consideration and adoption of applicable alternatives to animal use where appropriate; (5) Replacement or utilizing non-animal models or different species; (6) Assurance that studies or research is not duplicated; (7) Refinement, elimination or reduction of unnecessary pain and distress in animals; (8) Treatment of pain and discomfort; (9) Post-procedure care and monitoring; (10) Restraint; (11) Method of euthanasia and carcass disposal; (12) Identification and qualifications of research personnel; (13) Occupational Health and Safety issues are addressed for safe working environment; and (14) Proposed study written in a language understandable by the lay public as to purpose and relevance of project.

Using the above as 'standard general guides', some of these areas are mandated and considered essential in the review process. You may need to refer to specific regulations or requirements as follows:

(1) Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society. The US Government Principles for the Utilization and Care of Vertebrate Animals in Testing, Research, and Training

(2) Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design. PHS Policy IV.C.1.a

(3) A proposal ….must contain a rationale for involving animals…. 9 CFR 2.31.e.2

(4) A proposal … must contain a description of procedures designed…..for the conduct of scientifically valuable research… 9 CFR 2.31.e

(5) Statements on protocol application must be written in language understandable to the lay public about the purpose and relevance of the proposed study. The US Government Principles, Part II and PHS Policy IV.D.1.d

APPLICATIONS:

Lab Animal Care & Use Protocol Application

http://web1.boisestate.edu/research/compliance/iacuc-forms.shtml

Field Study Protocol Application

Testing, research, or teaching activities that involve the care and use of animals, need to submit a proposed protocol application for approval by the IACUC. The application shall contain the following information:

(1). Administrative Data: protocol title, investigator, contact information, funding source, status for application form, and permits if applicable.

(2). Alternatives Literature Search: The AWRs require principal investigators to consider alternatives to procedures that may cause more than momentary or slight pain or distress to the animals and provide a written narrative of the methods used and sources consulted to determine the availability of alternatives, including refinements, reductions, and replacements. The written narrative must include: the data base(s) searched or other sources consulted, the date of the search, the years covered by the search, and the key words or strategy. The principal investigator must also consider whether or not their proposed research unnecessarily duplicates previous studies.

(3.) Justification for the Use of Animals: Federal Regulations require that all investigators provide a narrative describing the rational for using animals and the appropriateness of the species. The animal model selected should be the most appropriate species for the project based upon the anatomical, physiological, or other characteristics in consideration of the scientific objectives, 9 CFR 2.31.

(4). Animal Model: The Animal Model must identify the species to be used and the approximate number of animals to be used. Protocols involving animals should have a sound research design for the animals selected. To justify the number of animals to be used, a power analysis may be required. The protocol must include a description of procedures designed to assure that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals. Consultation with the IACUC Attending Veterinarian may be necessary. The use of pharmaceutical-grade chemicals and other substances ensures that toxic or unwanted side effects are not introduced into studies conducted with experimental animals. They should therefore be used, when available, for all animal-related procedures. The use of non-pharmaceutical-grade chemicals or substances should be described and justified in the animal use protocol and must be approved by the IACUC (*Guide*, p 31).

(5). Animal Housing: Description of the living conditions and housing location of the animals. The living conditions of animals must be appropriate for the species and contribute to their health and comfort. Any deviation from standards set forth by the GUIDE and AWR must be scientifically justified and approved by the IACUC, PHS Policy IV.C.d, 9 CFR 2.31.

(6). Project Overview: Provide a complete description of the project, the significance of the project, and the proposed use, procedures, and experiments involving animals. Consultation with the IACUC Veterinarian may be necessary in order to complete.

(7). Description of actual surgical procedures to be used, if applicable. Include: (a) duties of all personnel who will be handling animals; (b) describe pre-operative procedures; (c) describe any potential post-operative complications and procedures to manage problems; (d) describe long-term care of chronic survival procedures; (e) describe post-operative care; (f) identify who will be responsible for the observation of animals until appropriate reflexes have returned.

Note: Records of individual surgical procedures must be kept; documenting procedures used and animal's responses from pre to post-operative period. Medical progress records during wound healing, suture removal, and the final disposition of animals are also necessary. A surgical log must be kept and made available for audit by the USDA, AAALAC, NIH, BSU and the IACUC members. These records must be kept for a period of three (3) years after protocol has ended or expired.

(7). Description of any drugs and euthanasia methods to be used, and disposal of animals, PHS Policy IV.C.1.g, the GUIDE and 9 CFR 2.31. Unless a deviation is justified for scientific or medical reasons, euthanasia methods should be consistent with the AVMA Guidelines on Euthanasia

(8). Personnel Statement: A statement must be provided by the PI indicating that all personnel involved with the research protocol have read and understand the protocol and will be appropriately trained in order to adequately perform their responsibilities related to the research project.

PROGRAM AND FACILITIES REVIEW

A. Program Review and Site Inspection

The IACUC must fulfill its regulatory responsibilities to inspect animal housing areas (facility) at least once every six months to evaluate compliance with applicable guidelines, AWR 2.31,c.2; PHS Policy IV, B.2. The facility inspection is performed with at least two members, and no member may be excluded should he/she wish to participate.

The IACUC must also review its animal care and use program every six months. The program reviews are scheduled to occur at a convened monthly meeting. The program review is conducted with a quorum of members, one of which must be the Chairperson or the Co-Chairperson.

A copy of the prior program report is provided to each member prior to the current review and inspection. For the program review, the Chairperson goes over each item on the checklist and asks for comments or questions from other members.

The IACUC Chairperson provides written comments and concerns that are noted while conducting the facilities inspection.

B. Reporting Requirements

The results of the program review and the facilities inspection are reflected in a report. The Office of Research Compliance (ORC) prepares a draft of each semiannual report using OLAW's semiannual report template with findings from the recent program review and facilities inspection. The IACUC Chairperson reviews, edits as needed, and signs the final version. ORC sends the report electronically to the IO.

The semiannual report to the IO includes: Dates of the program review and facility inspections, locations of the facilities, a description of the University's adherence to the PHS Policy and the Guide, approved departures, significant and minor deficiencies with associated corrective actions and schedules, and minority views.

A copy of this report is on file in the ORC office.

C. Responsibilities of IACUC

The IACUC has the responsibility and authority to halt and/or suspend any animal research if it is determined the physical or psychological well-being of the animal is improper and/or in violation of University, state or federal requirements. The IACUC will review the activity warranting suspension at a convened meeting of the IACUC with a quorum present. The principal investigator (PI) may be invited to attend to participate in the deliberation and answer questions. The IACUC may suspend activity involving animals by a majority vote of the quorum present.

After the IACUC has voted to suspend an animal activity, the PI is notified in writing by the IACUC Chairperson of this action. The IACUC will also initiate appropriate corrective actions, which must be met prior to resuming animal activity.

If a serious violation of harm or a threat to the health and wellbeing of the animal is involved, immediate action will be taken by the Chairperson or the Attending Veterinarian. The Chairperson or the Attending Veterinarian has the authority to halt or terminate the activity directly involved. When this happens, they will notify the IO and the ORC Director as soon as possible to determine if an investigation is necessary. A special session may be called for the IACUC to convene and take over the jurisdiction of the research. The IO, in consultation with the IACUC and ORC Director, shall review the reason for the suspension, take corrective actions and provide a written report of the action to OLAW, appropriate sponsored agency, Dean, Chairperson and PI.

Section V – Reporting and Recordkeeping

REQUIREMENTS FOR REPORTING AND RECORDKEEPING

All administrative (semi-annual reports, teleconferences, minutes, and administrative correspondence) records are to be kept for a minimum of three years. The **exception** is records that relate directly to federal grant funded research, then original protocols, modifications, annual reviews, and approval letters, must be kept for the duration of the grant award and for an additional three years, after completion. For federally funded IACUC protocols, there may be additional record retention requirements. Please contact the Office of Research Compliance (ORC) before discarding files. IACUC protocols that were not approved will be kept for one (1) year after submission and ORC will be the official repository for those records.

Records documenting such activities as the provision of adequate veterinary care, training, and occupational safety, are expected to conform with the recommendations of the *Guide* and with commonly accepted professional standards. Examples of records retained until no longer needed would be records for food and water schedules for animals being housed once they leave lab facility and training records for individuals once they leave BSU.

(A). Minutes of the IACUC meetings mandates the following: the PHS Policy, the GUIDE and USDA Office of Animal and Plant Health Inspection Services subpart C, 2.35 (APHIS) *http://www.aphis.usda.gov/ac/index.html*

(1) The minutes must include records of attendance. Although members may arrive late or leave during a meeting, a member is generally marked as either present or absent. An exception would be when a member leaves the meeting room during discussion of a protocol on which that member is a participant. If an IACUC member steps outside during a vote of their protocol, this does not reduce the quorum nor change the number of votes required – this member's vote is an automatic abstention.

(2) Records of IACUC activities: Activities would include corrections or approval of previous minutes, presentations of programs, policy facility and compliance reports; and outcome and decisions on policies, protocols and amendments. Deliberations need to, as a minimum, summarize the key points discussed prior to a committee decision

(B). Records of semiannual IACUC reports and recommendations as forwarded to the IO, in regard to the evaluation and inspection of program and facility.

(1) These records will include the deficiencies and plans for correction.

(2) The report must contain a description of the nature and extent of the University's compliance with the PHS Policy GUIDE and USDA Office of Animal and Plant Health Inspection Services (APHIS) *http://www.aphis.usda.gov/ac/index.html.* Any departures must be identified and modifications proposed, with a plan and timetable for correction.

(3) Any minority views of IACUC members must be included.

(4) Minor and significant deficiencies must be distinguished. A significant deficiency is defined as one that "is or may be a threat to the health or safety of animals". Program or facility deficiencies, including accidents or natural disasters, which cause injury, death, or severe distress in animals, are, by definition, 'significant'. Examples of minor deficiencies include chipped paint and burnt-out light bulbs.

(5) The report must also identify any facility that is American Association for Accreditation of Laboratory Animal Care (AAALAC) *http://www.aaalac.org* accredited.

(C) Other Reporting

The Principal Investigator must provide a copy of the Unanticipated Events/Incident Report to the IACUC, who shall promptly report to IO a full explanation of the circumstances and actions taken with respect to: (1) any serious or continuing non compliance; or (2) any serious deviation from the provisions of the *GUIDE* *http://www.nap.edu/readingroom/books/labrats* *or AWA* *http://www.nal.usda.gov/awic/legislat/awa.htm*; or (3) any suspension of an activity by the IACUC.

Alternative 1

(C) Other Reporting

The Principal Investigator must provide a copy of the Unanticipated Events/Incident Report to the IACUC Administrator

Section VI – Investigator Responsibilities

Principal Investigators have the primary responsibility for the care, use, and welfare of animals.

Minimum qualifications required to submit a protocol: The Principal Investigator conducting the procedures on the species being maintained or studied will be appropriately trained and qualified in those procedures. Outside investigators and BSU students must have a BSU faculty "sponsor". The faculty "sponsor" will be the Principal Investigator held responsible for the conduct of the study. Vice President for Research may grant exceptions as he/she sees fit (see BSU Policy 5020).

A. Who Must Submit an Animal Use Protocol.
Any testing, research or instructional use of live vertebrates by BSU faculty, researchers, staff, or students requires the submission of an Animal Use Protocol to the Animal Care and Use Committee (IACUC). The protocol must be fully approved before an animal user may acquire, house, or use animals. IACUC applications and forms can be found on the IACUC website.

(1). Information Required for Animal Use Protocol: The protocol form requires a non-technical description of the research project, a justification for the use of animals, a description of all procedures to be performed on animals (in detail), and precautions to be taken to guarantee humane care and treatment of the animals. In addition, the protocol must include a justification concerning the numbers of animals to be used, information on care and housing, and information of anesthesia and/or euthanasia, if applicable. Investigators with questions regarding protocol preparation are encouraged to contact the Office of Research Compliance (ORC) at *AnimalCare@boisestate.edu* to facilitate the review process and reduce the chance of delay in the approval process.

B. Who Must Submit a Field Study Protocol.
Any observation only field study conducted on free-living wild animals in their natural habitat by BSU faculty, researchers, affiliates, staff, or students does not require the submission of a Field Study Protocol to the IACUC. To determine if your study meets the definition of observation only, please consult the Observation Only Study Guidelines.

Any field study that will disturb or increase the stress level of the animal; involves an invasive procedure; materially alters the behavior of the animal; or has the potential to cause harm or accidental injury to the animal will require the submission of a Field Study Protocol. Protocols must be fully approved before a field investigation may begin. Protocol forms can be found on the IACUC website at: http://web1.boisestate.edu/research/compliance/iacuc-forms.shtml

(1). The protocol form requires a non-technical description of the research project, a justification for using a particular animal species, a description of all procedures to be performed (in detail), and precautions to be taken to guarantee humane care and treatment of the animals. In addition, the investigator should indicate if permission has been obtained from appropriate landowners or public land managers to conduct the research at the site indicated. The investigator must be able to assure the IACUC that necessary permits have been obtained. Investigators with questions regarding protocol preparation are encouraged to contact the Office of Research Compliance (ORC) at *AnimalCare@boisestate.edu* to facilitate the review process and reduce the chance of delay in the approval process.

C. General Guidance for Principal Investigator working with the IACUC:

Before preparing the proposed protocol for submission to the IACUC, the Principal Investigator is advised to read and have a clear understanding of:

(1) The BSU Institutional Animal Use and Care Program Guide
http://www.boisestate.edu/research/compliance/animal.shtml
(2) The PHS Policy on Humane Care and Use of Laboratory Animals
(3) The Animal Welfare Act (AWA) and the Animal Welfare Regulations (AWR)
(4) The Guide for the Care and Use of Laboratory Animals (GUIDE)

IACUC applications and forms can be found on the IACUC website, or can be received by contacting *AnimalCare@boisestate.edu* or ORC at x65404. Completed forms can be submitted electronically or by mail. If submitted electronically, **the signed, signature page(s) must be submitted to the Office of Research Compliance, before protocol is placed on agenda for review and approval.**

(1) Administrative functions:
(a) When preparing a protocol for the IACUC, investigators should approach this process with the same care they use in submitting grant applications to funding agencies.
(b) Use the current form, completing it on-line, then send electronic version to *AnimalCare@boisestae.edu* and mail a hard copy of the signature page to Office of Research Compliance (ORC) Simplot/Micron Bldg. 216, MS1138. IACUC approval can not be granted until the signature page is on file in the ORC.
(c) Answer all questions – if you don't know what the question means or need clarification, contact the IACUC Chairperson or ORC for assistance.
(d) Be sure the contact information is complete with a phone number and an email address, where you can actually be reached.

(2) Investigator Responsibilities in regard to animal care:
(a) Supervise animal care in all areas under his/her jurisdiction.
(b) Ensure that all experimental animals are procured in a proper and legal manner.
(c) Maintain current information on costs and supplies of laboratory animal and equipment.
(d) Ensure that all animals are checked daily for health status.
(e) Ensure that all animals are fed daily with foods that exceed standards for good nutrition for laboratory animals.
(f) Ensure all animals are given fresh water daily.
(g) Ensure all feeding and water devices are cleaned as needed (minimum once a week).
(h) Ensure that cages are cleaned as often as needed.
(i) Ensure all animals leaving the facility, for use in other areas, are properly housed in cleaned cages.

(3) Investigator Responsibilities in regard to personnel/staff/students handling animals.
(a) Ensure all personnel have been informed of potential hazards and risk involving handling or capture of specific species.
(b) Ensure personnel have been properly trained for safety procedures if bitten, scratched, and skin or eye exposure to urine or feces.
(c) If an Unanticipated Event or an Incident occurs (bitten, scratched, lung exposure, chemical exposure), the incident must be reported to the supervisor

and an incident report must be completed. Please use the link Report an Incident to notify campus personnel of incidents as they occur. This link is also available on the following websites: IACUC, EH&S, Risk Management, Security, and Emergency Management.

(d) Ensure personnel are wearing appropriate protective clothing, shoes and gloves.

(e) Ensue appropriate clothing and personal protective equipment will be used if personnel will be exposed to containment airborne particulate material or vapor, i.e. respiratory protection, masks, eye covering, face shields.

Section VII—Training
1

Training Requirements

NIH Policy Manual 3040-2, Animal Care and Use in the Intramural Program, requires that all personnel who work with animals be adequately trained to perform the tasks that are required by their job. The manual identifies Principal Investigators and Animal Users as two categories of personnel for whom specific training courses are provided. Each course consists of a discussion of the following subjects:

- The organizational structure of the NIH Intramural Animal Care and Use Program;
- Current laws, regulations and guidelines for the care and use of animals in research;
- Responsibilities to use animals humanely;
- Alternatives to the use of animals and alternatives for painful procedures;
- The prevention and/or alleviation of pain and distress;
- Proper use of anesthetics and/or analgesics;
- Requirements for properly performing survival surgery;
- Issues related to animal euthanasia;
- Appropriate methods for resolving concerns about the care and use of animals;
- Additional educational and training opportunities that are available through the Office of Animal Care and Use.

The Office of Animal Care and Use (OACU), Office of the Director offers a variety of training courses for NIH intramural personnel who work with animals. These courses are provided free to participants and fulfill federal training requirements for working with animals, *http://oacu.od.nih.gov/training/index.htm*.

Principal Investigator = Senior Scientist in charge of an animal research project

- Initial Course
- Refresher Course

Animal User = Working with animals under the direction of a senior scientist (Co-Investigator)

- Initial Course
- Refresher Course

Section VIII – Occupational Health & Safety Program (OCHS)

An occupational health and safety program must be part of the overall animal care and use program. The OCHS program, in coordination with the Attending Veterinarian, will provide the overview for Animal Welfare Act compliance, inspection of animal facilities, animal and human health surveillance, and in-service training for animal care personnel. The basic elements of a program includes hazard identification and risk assessment, personnel training and protection, written procedures and policies regarding hazard use and monitoring, and medical evaluation and preventive medicine.

The extent and level of participation of personnel in the program should be based on the hazards posed by the animals and materials used, the exposure intensity, duration, and frequency, the susceptibility of the personnel, and the history of occupational illness and injury in the particular workplace. A health history evaluation is advisable before work assignment to assess potential risks for individual employees. Periodic medical evaluations and appropriate immunization schedules are advisable for some risk categories. Immunization of animal care personnel against tetanus is important.

In accordance with the *Guide*, *http://www.nap.edu/readingroom/books/labrats*, assurance must be provided by an organization that all personnel at risk are appropriately considered under the occupational health and safety program.

All University personnel having contact with laboratory animals and field study animals, or their soiled bedding, are required to wear appropriate personal protective clothing (PPC). For any animal facility, outer garments (clothes and footwear) that are worn while handling animals or cleaning their environment must not be worn away from that facility unless it has been suitably cleaned and sanitized. For field studies, clean PPC should be worn that is appropriate to accomplish the desired activity in the given environmental conditions and to minimize potential health risks.

The purpose of this policy is to identify a minimum standard of attire for personnel who are handling animals, investigator laboratories, and teaching laboratories.

1. The attire should provide a minimum level of protection for animal workers and their clothing form contamination with animal materials such as excretions, dander and body fluids.

2. Attire should also minimize the exposure of animals to contaminants carried on the clothing and footwear of personnel working with the animals.

3. Certain animal facilities have strict entry requirements for either BioSafety or BioSecurity purposes and should be clearly posted at entry points.

    a. Foot cover is required for entry into all animal rooms. Rooms housing fish and or amphibians are exempt from this requirement.
    b. Dedicated outer ware (lab coat or disposable gown) and gloves are required for animal handlers.

c. All personnel will wash their hands after handling animals.

These policies apply to animal rooms, procedure rooms, investigator laboratories, and teaching laboratories. These policies also apply to both live and dead animals.

West Niles Awareness for Field Studies

People and animals are infected with the West Nile Virus through the bite of an infected mosquito, and cannot contract the virus from contact with an infected animal or person. The virus is spread by migrating infected birds, which are bitten by mosquitoes. The infected mosquitoes can then pass the virus on to people and other animals.

Most people infected with the West Nile Virus have no symptoms, or will only have a mild flu-like illness. Common symptoms of infection include fever, headache, muscle aches, tiredness, nausea and vomiting, eye pain, skin rash, and enlarged lymph nodes. But in a small percentage of the population, the virus can lead to serious illness requiring hospitalization, especially in people over the age of 50.

To protect themselves, people are advised to:

(a) Be aware of standing water which provides a mosquito breeding habitat, such as ponds, overflow and water collection pools in fields and pastures, and shallow slow water flow streams;
(b) Cover up exposed skin when performing field studies outdoors by wearing, gloves, a hat, long sleeve shirt, long pants, and shoes that provide foot coverage;
(c) Apply insect repellent approved by the EPA to exposed skin and clothing. Follow instructions on the product label;
(d) Avoid mosquitoes when they are most active – between dusk and dawn;
(e) Report dead birds to your local Fish and Game Office.

Section IX – Veterinary and Veterinary Care Program

The Attending Veterinarian of record for the IACUC, and as per the Federal Welfare Act, has final authority and responsibility to insure that the IACUC program of veterinary care is adequate.

The Boise State University IACUC provides the Attending Veterinarian the authority to oversee the adequacy of all aspects of animal care and use of animals used in research, training and teaching, the authority to oversee the adequacy of all aspects of animal care and use of animals, and the authority to ensure that adequate veterinary care including pre and post procedural or surgical care, in accordance with current established practices, is provided at all times. The Attending Veterinarian has the responsibility of providing guidance to Principal Investigators, as well as, guidance and support to the IACUC.

The Attending Veterinarian retains the authority to immediately access the medical records of animals used for research, training and teaching, and access to care given to animals.

Adequate veterinary care consists of appropriate method to: identify possible disease or disease control methods for animals being housed in facility; manage protocol-associated potential disease; provide consultation for anesthesia and analgesia; observe and/or consult with surgery, including pre and post surgical care; assess animal well-being by observation and/or communication with animal facility staff if warranted, for signs of illness, injury or abnormal behavior; and oversee aspects of sanitation practices, zoonosis control, and hazard containments.

At least one veterinarian must be a full member of the Institutional Animal Care and Use Committee (IACUC) and actively involved in the review of all protocols and projects, and in the inspection of facilities and review of institutional programs involving animals in research, testing and teaching. For the veterinary care program to be judged "adequate," there is a continuing institutional responsibility to foster and support enhancement of the program through the identification and adoption of techniques, procedures, and policies that improve laboratory animal health and well-being.

The provision of adequate veterinary care involves the following primary areas of responsibility:

A. Disease Detection and Surveillance, Prevention, Diagnosis, Treatment and Resolution

(1). The isolation, quarantine and stabilization programs for newly arrived animals are necessary to provide time to assess their health status, allow them to recover from the stress of shipment, and an opportunity to adapt to their new environment. The extent of these programs depends on several factors, including species and source of the animals, as well as their intended use. For some animals, such as rodents obtained from

reliable sources for which health status is known, visual inspection on arrival may suffice. For species such as nonhuman primates, farm animals, wild animals, random source dogs and cats, and non-specific pathogen free rabbits and rodents, appropriate quarantine and isolation procedures must be employed.

(2). Preventive medicine programs such as vaccinations, ecto- and endoparasite treatments and other disease control measures should be initiated according to currently acceptable veterinary medical practices appropriate to the particular species and source. Only animals of defined health status should be used in research and testing, unless a specific, naturally occurring or induced disease state is being studied. Systems should be established to protect animals within the institution from exposure to diseases. Transgenic and mutant animals may be particularly susceptible to diseases and may require special protection to ensure their health. Systems to prevent the spread of disease may include facility design features, containment/isolation equipment, and use of standard operating procedures. Training of animal care and research staff is essential to prevent the spread of animal diseases.

(3). Daily observation of all animals by a person or persons qualified to verify their well-being is required. It is not necessary for a veterinarian to personally make this assessment each day. However, at a minimum, a trained paraprofessional or technician must observe each animal every day, and there must be a timely and accurate method for conveying information regarding animal health, behavior, and well-being to the veterinarian.

(4). Disease surveillance is a major responsibility of the veterinarian and should include routine monitoring of colony animals for the presence of parasitic, bacterial, and viral agents that may cause overt or inapparent disease. Additionally, cells, tissues, fluids, and transplantable tumors that are to be used in animals should be monitored for infectious or parasitic agents that may cause disease in animals. The type and intensity of monitoring necessary will depend upon professional veterinary judgment and the species, source, use, and number of animals housed and used in the facility.

(5). Diagnostic laboratory services must be available and used as appropriate. Laboratory services should include necropsy, histopathology, microbiology, clinical pathology, serology, and parasitology, as well as other routine or specialized laboratory procedures as needed. It is not necessary that all of these services be available within the animal facility if other laboratories with appropriate capabilities are available and used.

(6). Animals with infectious disease must be isolated from others by placing them in isolation units or separate rooms appropriate for the containment of the agents of concern. In certain circumstances, when an entire group of animals is known, or thought to be exposed or infected, it may be appropriate to keep the group intact during the time necessary for diagnosis and treatment, for taking other control measures, or for completion of a project.

(7). The veterinarian must have authority to use appropriate treatment or control measures, including euthanasia if indicated, following diagnosis of an animal disease or injury. If possible, the veterinarian should discuss the situation with the principal investigator to determine a course of action consistent with experimental goals. However, if the principal investigator is not available, or if agreement cannot be reached, the veterinarian must have authority to act in order to protect the health and well-being of the institutional animal colony. The veterinarian's authority should be exercised with the concurrence of the IACUC and the Institutional Official (IO).

B. Handling and Restraint: Anesthetics, Analgesics and Tranquilizer Drugs, and Methods of Euthanasia

Adequate veterinary care includes providing guidance to animal users and monitoring animal use to assure that appropriate methods of handling and restraint are being used and to ensure proper use of anesthetics, analgesics, tranquilizers, and methods of euthanasia. Written guidelines regarding the selection and use of anesthetics, analgesics and tranquilizing drugs and euthanasia practices for all species used must be provided and periodically reviewed by the veterinarian. Guidelines may be developed in-house or provided by specific references to the current veterinary literature. In addition, the veterinarian or trained paraprofessionals should provide formal or informal instruction in the proper use of such agents and euthanasia procedures.

The veterinarian must have the responsibility and authority to assure that handling, restraint, anesthesia, analgesia, and euthanasia are administered as required to relieve pain and such suffering in research animals, provided such intervention is not specifically precluded in protocols reviewed and approved by the IACUC. The veterinarian must exercise good professional judgment to select the most appropriate pharmacologic agent(s) and methods to relieve animal pain or distress in order to assure humane treatment of animals, while avoiding undue interference with goals of the experiment.

C. Surgical and Postsurgical Care

A program of adequate veterinary care includes the review and approval of all preoperative, surgical, and postoperative procedures by a qualified veterinarian. The institution bears responsibility and must assure, through authority explicitly delegated to the veterinarian or to the IACUC, that only facilities with programs appropriate for the intended surgical procedures are utilized, and that personnel are adequately trained and competent to perform the procedures. The veterinarian's inherent responsibility includes monitoring and providing recommendations concerning preoperative procedures, surgical techniques, the qualifications of institutional staff to perform surgery, and the provision of postoperative care.

D. Animal Well-Being

Adequate veterinary care includes responsibility for the promotion and monitoring of an animal's well-being before, during, and after experimentation or testing. Animal well-

being includes both physical and psychological aspects of an animal's condition evaluated in terms of environmental comfort, freedom from pain, and distress and appropriate social interactions, both with conspecifics and with man. The veterinarian must have the authority and responsibility for making determinations concerning animal well-being and assuring that animal well-being is adequately monitored and promoted. The veterinarian must exercise this responsibility in review of animal care and use protocols, and must have the authority to remove an animal from an experiment which is adversely affecting its well-being beyond a level reviewed and approved by the IACUC. The following examples represent how this responsibility can be met:

(1). Ensuring the adequacy of the physical plant, caging, and ancillary equipment.

(2). Developing, implementing, and monitoring sound animal care (husbandry) programs including such areas as sanitation, nutrition, genetics and breeding and vermin control.

(3). Establishing an acclimatization program to adapt animals to either short-term or long-term restraint procedures.

(4). Improving and enriching an animal's environment to minimize the development of physical or behavioral abnormalities.

(5). Providing appropriate opportunities for human-animal socialization and acclimatization to the research environment or procedures.

(6). Performing periodic physical and clinical evaluations appropriate for the species and the experimental situation.

(7). Providing pre-procedural and post-procedural care in accordance with current established veterinary procedures.

E. Appropriate Use of Animals in Research and Testing

The veterinarian must be involved in the review and approval of all animal care and use in the institutional program. This includes advising on the design and performance of experiments using animals as related to model selection, collection and analysis of samples and data from animals, and methods and techniques proposed or in use. This responsibility is usually shared with investigators, the IACUC, and external peer reviewers.

BSU Animal Care and Use Program Guide Manual

BSU Animal Care and Use Policy

FORMS

- BSU Animal Use Protocol Application
- BSU Field Study Protocol Application
- BSU Request for IACUC Changes/Modifications
- BSU Renewal and/or Final Report

Animal Welfare Act (AWA)

Animal Welfare Regulations (AWR)

PHS Policy Humane Care and Use of Laboratory Animals

Office of Laboratory Animal Welfare (OLAW)

The Guide for the Care and Use of Laboratory Animals (GUIDE)

Institutional Animal Care and Use Committee – Guidebook

The Zebrafish Book

Guidelines for the Use of Fishes in Research

Guidelines for the Use of Wild Birds in Research

Guidelines of the American Society of Mammalogists for the Use of Wild Mammals in Research

Guidelines for the Use of Live Amphibians and Reptiles in Field and Laboratory Research

Animal
Any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes.

Animal Facility
Any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities, used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation. A satellite facility is any containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 24 hours.

Animal Welfare Act
Public Law 89-544, 1966, as amended, (P.L. 91-579, P.L. 94-279 and P.L. 99-198) 7 U.S.C. 2131 et. seq. Implementing regulations are published in the Code of Federal Regulations (CFR), Title 9, Chapter 1, Subchapter A, Parts 1, 2, and 3, and are administered by the U.S. Department of Agriculture. http://www.aphis.usda.gov/ac/publications/AWA/AWAINDEX.HTML

Animal Welfare Assurance or Assurance
The documentation from an institution assuring institutional compliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals http://grants.nih.gov/grants/olaw/references/phspol.htm and must be on file with the Office of Laboratory Animal Welfare http://grants.nih.gov/grants/olaw/olaw.htm

Change in Scope or Modification
An alteration made by the Principal Investigator that constitutes a change (significant or minor) from the aims, objectives, or purposes of the approved project. The following are examples of changes or modifications, that need to be approved by the IACUC: changing the specific aims; changing to a different animal model; using research animals in a way other than approved; shifting the research emphasis from one disease area to another; using a new technology; transferring the research project to another organization; changing the principal investigator.

Guide
Guide for the Care and Use of Laboratory Animals, http://www.researchtraining.org/referencedocuments/animalrefs/phs/uselaban.html HHS, NIH Pub. No. 86-23, 1985 edition or succeeding revised editions.

Institutional Animal Care & Use Committee (IACUC)
Committee established by a research institution to ensure that the care and use of animals in research is appropriate and humane. IACUCs independently determine that an institution is meeting requirements to ensure humane care and use of animals and is complying with regulations. They also review and approve protocols.

Institutional Official
An individual who signs and has the authority to sign the institution's Assurance, making a commitment on behalf of the institution that the requirements of this Policy will be met.

Inquiry is defined as information-gathering and preliminary fact-finding to determine whether the potential noncompliance warrants an investigation.

Investigation is defined as a formal examination and evaluation of relevant facts to determine whether noncompliance has taken place or, if noncompliance has already been confirmed, to assess its extent and consequences and determine appropriate action.

Investigator
Same as Principal Investigator

Minor and significant deficiencies (in regard to program and facilities):
A significant deficiency is defined as one that "is or may be a threat to the health or safety of animals". Program or facility deficiencies, including accidents or natural disasters, which cause injury, death, or severe distress in animals, are, by definition, 'significant'. Examples of minor deficiencies include chipped paint and burnt-out light bulbs.

Office of Laboratory Animal Welfare (OLAW)
NIH office that oversees compliance with the PHS Policy on Humane Care and Use of Laboratory Animals.

Protocol
A formal design describing the methods for research involving animal use or care, in which the Principal Investigator submits to the IACUC for review and approval. A protocol generally has an objective, rationale, design, eligibility requirements, treatment regimen, and a description of research and data analysis methods.

Principal Investigator (PI)
Individual identified as BSU's qualified person designated on the application to direct a research project or program. This person oversees the scientific and technical aspects of a research project, the day-to-day management of the research, and serves as the 'point-of-contact' for the research project. Same as Researcher or Investigator.

Public Health Service
The Public Health Service or PHS currently includes the Agency for Health Care Policy Research, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Health Resources and Services Administration, the Indian Health Service, the National Institutes of Health, and the Substance Abuse and Mental Health Services Administration.

Quorum
A majority of the membership of the Institutional Animal Care and Use Committee (IACUC).

Research
Systematic investigation, including research development, testing, and evaluation, to develop generalizable knowledge. Go to 45 CFR 46.102 definitions; go to full 45 CFR 46.

Researcher
Same as Principal Investigator or Investigator.