



Bowling Green State University

Institutional

Animal

Care and

Use

Committee

**Policy/Procedure
Manual**

IACUC Policy/Procedure Manual

Table of Contents

Page	Title	Policy ID
3	Introduction	
4	Definitions	05-02-001
6	Eligibility to Submit IACUC Protocols	00-12-001
7	Principal Investigator Responsibilities	04-03-001
8	Initial Review – Protocols	05-02-002
10	Designated Member Review	10-12-001
11	Overages in Animal Usage	04-04-001
12	“Not Yet Approved” Protocol Retention	04-06-001
13	Collaborative Research Performed at Other PHS Assured Institutions	04-04-002
15	Euthanasia Certification Procedures	08-12-001
16	Food/Fluid Restriction	08-02-001
19	Non-Traditional or Wild-Caught Animal Policy	04-04-003
21	Non-Approved Vendor Animal Transfer Policy	04-03-002
23	Surgical Procedures: Definitions and Criteria for Differentiation	11-05-001
26	Reporting and Investigating Protocol Deviations and Allegations of Animal Mistreatment	09-03-001
29	Transportation Policy	11-04-001
32	University Animal Facilities Security and Restricted Access	10-11-001

Introduction and Purpose

The Institutional Animal Care and Use Committee (IACUC) has taken the time to develop and produce these policy/procedure statements to better guide those wishing to conduct animal research at Bowling Green State University. Reading over the first three policies will provide valuable information to the first-time protocol submitter will potentially result in a reduction in the number of clarifications/modifications the Committee requests upon initial review of the protocol application. The remaining policy/procedure statements apply to specific situations. A familiarity with this subject matter can assist in guiding future protocol development.

IACUC policies and procedures, as well as other valuable information, can be found on the IACUC website: <http://www.bgsu.edu/offices/orc/iacuc>.

IACUC POLICY AND PROCEDURE STATEMENT

Policy/Procedure: Definitions

Policy/Procedure ID: 05-02-001 **Effective:** February 18, 2005

A. Background

A Committee functions more effectively when everyone (members, researchers and administrators) “speaks the same language”. Therefore, definitions of specific, commonly used terms are provided in order to create consistency and common understanding.

B. Policy

Clarification / Modification – A change to, or provision of additional information for, a submission that is required before final approval can be granted. The Committee determines at their discretion whether the requested items can be reviewed by designated review or requires review by the full committee.

Designated Review – Review of a protocol or proposed change to an approved protocol by less than the full IACUC in a convened meeting. In accordance with PHS Policy (IV.C.2) and the Animal Welfare Regulations (9 CFR 2.31(d)(2)), the review may only be done after each Committee member has been given a list of proposed activities to be reviewed and had opportunity to request full Committee review. In the absence of such a request, at least one member, designated by the Chair and qualified to perform the review, reviews the proposed activities and has authority to approve, require modifications (to secure approval), or request full Committee review. Often erroneously called “Expedited Review”.

Primary Reviewer(s) – The Committee member(s) responsible for thoroughly reviewing a submission in advance of the convened meeting and “presenting” the submission at the convened meeting. The Primary Reviewer is responsible for identifying areas of potential confusion or insufficient information in the submission and contacting the PI for clarification/additional information. No Committee member is allowed to serve as the Primary Reviewer of a protocol for which s/he is the PI or a member of the research team.

Significant Changes – Changes to approved protocols that require IACUC review and approval before they are implemented. As a result of the great diversity of research performed at assured institutions, the Office of Laboratory Animal Welfare (OLAW) has not provided a general definition of what constitutes a significant change. OLAW has, however, identified several kinds of significant changes to serve as examples. They are:

- Changes in the objectives of a study
- Proposals to switch from non-survival to survival surgery
- Changes in the degree of invasiveness of a procedure or discomfort to an animal

- Changes in species or in the approximate number (greater than 5%) of animals used
- Changes in the Principal Investigator (see below for information regarding other personnel changes)
- The addition of hazardous agents in animal procedures
- Changes in anesthetic agent(s), the use or withholding of analgesics, and methods of euthanasia

Changes in the duration, frequency, or number of procedures performed on an animal may be considered significant depending upon the nature of the change. Certain personnel additions may require IACUC review depending upon the nature of the work the individual is to perform and the level of training required in order to perform the work.

Minor Changes – Minor changes are changes that are not deemed significant and do not require IACUC review. Implementation of these changes should be accompanied by notification to the Office of Research Compliance in order for ORC to keep the protocol file up to date.

IACUC POLICY AND PROCEDURE STATEMENT

Policy/Procedure: Eligibility to Submit IACUC Protocols

Policy/Procedure ID: 00-12-001

Effective: December 15, 2000

A. Background

Any proposed use of vertebrate animals in research or teaching requires IACUC review and approval.

B. Policy

Any BGSU employee planning to conduct animal research or teaching that involves the use of vertebrate animals must submit IACUC protocols. Graduate student and undergraduate student research must be submitted for IACUC review and approval by the faculty advisor with the faculty advisor listed as the Principal Investigator. If the research to be conducted under a given protocol is to further the pursuit of a graduate student's higher degree under the faculty member's supervision, the graduate student is encouraged to write the protocol, but the faculty member will be the Principal Investigator. At the discretion of the PI, student researchers or staff may be designated as the project coordinator. In all cases the PI assumes primary responsibility for the ethical conduct of the research. No research may be initiated without prior IACUC approval. These projects will be viable for three years from the approval date with interim annual renewals after the first and second year.

Classroom independent projects using vertebrate animals are restricted to USDA Category C activities – involving teaching, research, experiments or tests conducted involving no pain, distress, or use of pain relieving drugs. These projects will be viable for no more than one year after the approval date, and are to have the instructor listed as the Principal Investigator with the student listed as project coordinator. The instructor retains final responsibility for the activity carried out. Independent project protocols must be submitted to the IACUC for final review and approval prior to the start of their project.

IACUC POLICY AND PROCEDURE STATEMENT

Policy/Procedure: Principal Investigator Responsibilities

Policy/Procedure ID: 04-03-001

Effective: March 18, 2004

A. Background

The Principal Investigator (PI) is the individual who officially signs and submits an IACUC protocol and oversees the research project described thereon.

B. Policy

The PI is responsible for:

1. All individuals, with the exception of University Animal Facilities staff, (graduate students, undergraduate students, volunteers and any visitors they might bring into the facility to see or assist with the animals) who come into contact with the animals that are on the protocol.
2. Appropriate training of all personal working with the animals and documentation of that training.
3. All appropriate records and logs associated with the animals on the protocol. Records and logs must be kept in a location easily accessible by the UAF staff and the Attending Veterinarian. If the records are not kept in the room with the animals the location of the records must be posted in the room with the animals and communicated to the UAF Director.
4. Notifying University Animal Facilities of any personnel changes in the protocol, following approval of those personal changes.
5. Maintaining current approved IACUC paperwork related to the protocol.

IACUC POLICY AND PROCEDURE STATEMENT

Policy/Procedure: Initial Review of IACUC Protocols

Policy/Procedure ID: 05-02-002 **Effective:** February 18, 2005

A. Background

BGSU policy requires IACUC review of all research, research training, experimentation, biological testing, and related activities, involving live, vertebrate animals. The review is guided by the ethical principles regarding all research involving vertebrate animals, as set forth by the Animal Welfare Act and the PHS Policy.

Review and approval must occur before any animals can be used and includes the following considerations from the federal regulations (9 CFR 2.31d):

- Procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals.
- The PI has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals.
- The PI has provided written assurance that the activities do not unnecessarily duplicate previous experiments.
- Procedures that require more than momentary pain and distress to the animals will be performed with appropriate sedatives, analgesics or anesthetics, involve consultation with the attending veterinarian, and not include the use of paralytics without anesthesia.
- Animals that would otherwise experience severe or chronic pain or distress that can not be relieved will be painlessly euthanized at the end of the procedure.
- The animals' living conditions will be appropriate for their species.
- Medical care will be available for all animals by a qualified veterinarian.
- Personnel conducting procedures will be appropriately qualified and trained in those procedures.
- Activities that involve surgery must include appropriate provision for pre-operative and post-operative care of the animals. All survival surgery will be performed using aseptic procedures.
- No animal will be used in more than one major operative procedure from which it is allowed to recover unless justified by scientific reasons, required as routine veterinary procedure, or in special circumstances as determined on an individual basis.
- Methods of euthanasia must be acceptable, recommended methods (e.g., included in the most current version of the AVMA Euthanasia Report).

B. Procedure

1. The researcher completes an IACUC protocol form and submits a copy to the Attending Veterinarian and the Office of Research Compliance (ORC) by the appropriate deadlines (the IACUC meeting calendar and associated deadlines can be found at <http://www.bgsu.edu/offices/spar/orc/iacuc/MeetingCalendar.html>).
2. The ORC reviews the application for completeness and checks to make sure the principal investigator (P.I.) and all participants listed on the protocol have completed the appropriate level of animal training based upon their proposed roles on the protocol. If training is required or the application is incomplete (e.g., signatures, incomplete answers or missing literature search information) the P.I. will be contacted, and the application held from the review process until training has been acquired and/or required materials/information is provided.
3. The ORC assigns a protocol number and logs the protocol information into the active protocol database.
4. The ORC designates an appropriately qualified primary presenter.
5. If the protocol is complete it is included in the IACUC meeting packets, with all of the relevant materials. IACUC meeting packets are assembled and distributed to IACUC members seven days prior to the monthly meeting.
6. The Committee meets, discusses the protocol within the context of the review considerations identified above, and determines a review outcome. Possible outcomes are:
 - a. Approved
 - b. Clarifications / Modifications Required - researcher must provide clarification or make changes before final approval can be given
 - c. Deferred - the Committee does not have sufficient information to make a decision. Additional information is required from the researcher before the Committee will review the application.
 - d. Approval Withheld - the project cannot be conducted as proposed. Substantial changes must be made before the project can be re-submitted for review by the Committee.
7. The ORC notifies the P.I., in writing, of the Committee's decision and the PI is provided the opportunity, if the protocol review result is not "approved", to address the Committee's concerns.

IACUC POLICY AND PROCEDURE STATEMENT

Policy/Procedure: Designated Member Review

Policy/Procedure ID: 10-12-001

Effective: 12/15/10

Designated Member Review

A. Background

The Bowling Green State University PHS assurance recognizes that the IACUC may use Designated Member Review (DMR) subsequent to Full Committee Review (FCR). OLAW guidance states the following:

When substantive information is lacking from a protocol, the committee may have questions requiring a response from the PI. In such situations, the IACUC may take the following actions:

1. If all members of the IACUC are present at a meeting, the Committee may vote to require modifications to secure approval and have the revised research protocol reviewed and approved by DMR, or returned for FCR at a convened meeting.
2. If all members of the IACUC are not present at a meeting, the committee may use DMR subsequent to FCR according to the following stipulation:
 - a. All members agree in writing that the quorum of the members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.

B. Policy

In the event that all members of the IACUC are not present at a meeting, this policy serves as written documentation that all members have agreed that a quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. All appointed voting members will sign the following page(s) of this policy to indicate their agreement. Subsequently appointed members will also sign the policy to indicate that they have been informed of the policy and are in agreement with the policy.

IACUC POLICY AND PROCEDURE STATEMENT

Policy/Procedure: Overages in Animal Usage

Policy/Procedure ID: 04-04-001

Effective: April 15, 2004

A. Background

The number of animals shipped by the vendor may exceed the number of animals requested by an Investigator on a Vertebrate Animal Order Form. Vendors typically over-ship large or sensitive strain orders in anticipated compensation of loss due to the shipping process. This may result in providing more animals than are approved on a given protocol.

B. Policy

The number of animals approved in a protocol is considered to be an approximate number. An overrun of up to 10% is allowed. Overruns beyond 10% are allowed only with the approval by the full IACUC of an addendum to the protocol.

Numbers approved by addendum are not considered approximate and further overruns are not allowed without further addenda approved by the full IACUC.

Animals shipped in excess of the order may also be placed on other suitable protocols provided that the animals meet the requirements and are not in excess of an approved number.

IACUC POLICY AND PROCEDURE STATEMENT

Policy/Procedure: “Not Yet Approved” Protocol Retention

Policy/Procedure ID: 04-06-001

Effective: June 17, 2004

A. Background

When a new protocol submission is reviewed by the IACUC it may not be approved at the meeting (the IACUC may require clarifications or modifications, approval may be withheld or a decision on the protocol deferred). Normally the PI will submit responses to the conditions for review at the next IACUC meeting, but there are times that the PI does not respond to the conditions in a timely manner. There is the need to have a time limit within which PIs can respond to conditions and for the Office of Research Compliance to retain the “not yet approved” protocols.

B. Policy

When a new protocol is not approved at the IACUC meeting at which it is initially reviewed, the PI has 90 days to submit responses to conditions, comments or concerns. If responses are not received within 90 days a new protocol will need to be submitted to the IACUC for review, even if the research objectives have not changed. The initial review outcome notification sent to the PI by the Office of Research Compliance will indicate the date by which responses are due.

IACUC POLICY AND PROCEDURE STATEMENT

Policy/Procedure: Collaborative Research Performed at Other PHS Assured Institutions

Policy/Procedure ID: 04-04-002

Effective: April 15, 2004

A. Background

There are situations in which a Principal Investigator receives grant funding wherein BGSU is listed as the primary institution but the research with animals will be performed at a different assured institution.

NIH guidance (notice NOT-OD-01-017) to PHS awardee institutions and Institutional Animal Care and Use Committees indicates that to reduce regulatory burden there is no requirement for duplicate review of protocols if the performance site (the site which the animal related work is to be done) holds a PHS approved animal welfare assurance. If both institutions have full PHS Assurances, they may exercise discretion in determining which IACUC will review the research protocol. The guidance recommends that if an IACUC defers protocol review to another IACUC, then documentation of the review should be maintained by both committees and that the deferring IACUC should request to be informed of any significant questions or issues raised during a semiannual program inspection, by the performance site's IACUC, of a facility housing a research activity for which the deferring IACUC bears some responsibility or exposure.

Reference: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-017.html>

B. Policy

If a Bowling Green State University researcher is the Principal Investigator for a research project in which all animal-related research activities will be performed at another PHS assured institution, the BGSU IACUC will defer protocol review to the PHS assured performance site, with the following stipulations:

- The PI will submit documentation of the review and approval of the research activity by the performance site's IACUC to the BGSU IACUC, attached to a completed Inter-institutional Review Cover Sheet. The Office of Research Compliance will assign a BGSU protocol number to the project and will establish a protocol file for tracking purposes.
- The PI will provide, to the BGSU IACUC in a timely fashion, copies of performance site IACUC approval notifications relative to addenda and annual renewals for the research activity, to be maintained in the protocol file

Collaborative Research

- The PI will provide, to the BGSU IACUC in a timely fashion, documentation of significant questions or issues raised by the performance site's IACUC during its semiannual program inspection of a facility housing the research activity in question, to be maintained in the protocol file.

IACUC POLICY AND PROCEDURE STATEMENT

Policy/Procedure: Euthanasia Certification Procedures

Policy/Procedure ID: 08-12-001

Effective: December 11, 2008

Investigators or their designee must be certified in the euthanasia method approved in the protocol. Investigators or designee of active protocols are considered to be certified. Those submitting new protocols require training by the AF Director to become certified (previous experience is not grounds for exemption). Investigators are responsible for assuring that all their personnel carrying out euthanasia are properly trained in the method approved in the protocol.

IACUC POLICY AND PROCEDURE STATEMENT

Policy/Procedure: Food/Fluid Restriction

Policy/Procedure ID: 08-02-001

Effective: February 15, 2008

A. Background

It is the responsibility of the Bowling Green State University (BGSU) Institutional Animal Care and Use Committee (IACUC) to ensure judicious and humane use of animals in its teaching and research programs, consistent with federal requirements and BGSU's ethical standards.

The *Guide for the Care and Use of Laboratory Animals* (p. 38) states "animals should be fed palatable, non-contaminated, and nutritionally adequate foods daily or according to their particular requirements." Both the *Guide* and the United States Department of Agriculture Animal Care Policy #11 recognize that restriction of food and/or fluid intake beyond that necessary for normal pre-surgical preparation has the potential to cause unrelieved pain and distress in animals. The *Guide* (p. 12) requires that "at least minimal quantities of food and fluid be available to provide for the development of young animals and to maintain long term well-being of all animals." The *Guide* specifically requires that food and/or fluid restriction for research purposes must be "scientifically justified and that a program be established to monitor physiologic or behavioral indices with criteria (such as weight loss or state of hydration) to temporarily or permanently remove an animal from the experimental protocol." The Animal Welfare Act and Regulations (AWAR) §2.38 (f)(2)(ii) prohibit deprivation of food or water to train, work, or otherwise handle animals unless short-term withholding of food or water from animals is allowed in an IACUC-approved activity that includes a description of monitoring procedures. Public Health Service Policy (PHS Policy) (II; IV (A)(1)) requires that institutions comply with the AWAR and the *Guide*.

B. Definitions

1. Ad-lib food/water – (ad libitum – Without restraint) Food/water available at all times with the quantity and frequency of consumption being the free choice of the animal.
2. Pre-restriction or baseline weight
Weight of the animals before beginning food restriction. In adults this may be calculated by averaging the body weights recorded for at least 3 consecutive days immediately preceding the restriction period. In growing animals this weight may need to be periodically recalculated based on standard growth curves for the species and strain of animal (Figure 1).

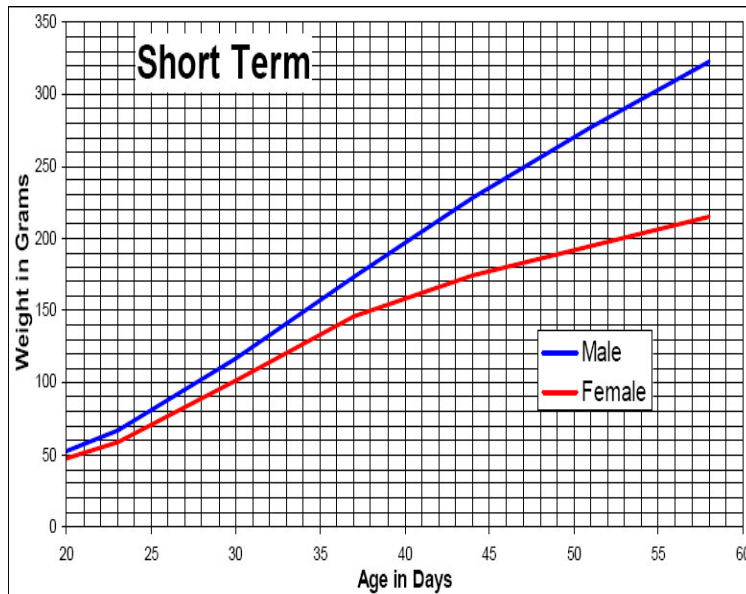


Figure 1. Growth curve for SD Rat - HLA®(SD)CVF®

3. Target (restricted) weight

The minimum weight for any animal after food restriction. This is typically limited to a minimum of 85% of the baseline weight. For example, a rat with a baseline weight of 500 grams may have a target weight of 425 grams.

4. Dehydration

Excessive loss of water from the body, as from illness or fluid deprivation. Signs may include dry mucous membranes, decreased urination, decreased elasticity to the skin or sunken eyes. Severe dehydration, i.e. greater than 10% of body fluid, may lead to shock and death.

C. Policy

Restriction of food and/or fluids must be scientifically justified in an IACUC protocol and approved by the IACUC prior to initiation of the associated research. Because food/fluid deprivation is carried out for many reasons, the IACUC will consider the maximum duration and degree of deprivation on a case-by-case basis with reference to the welfare of the animals (including consideration of the species and normal biology of the animal) and the goals of the particular study. The proposal should include the minimum duration and degree of food/water deprivation believed to be necessary to achieve the stated study objectives. In the case of conditioned-response protocols, a positive reinforcement, such as a preferred food or fluid, is recommended instead of a diet restriction.

D. Procedures

The weights of all animals approved for food restriction must be measured and recorded daily unless otherwise justified and approved by the IACUC. If the weight of an animal under food and/or fluid restriction falls below its target weight, its food and/or fluid intake must be increased immediately as appropriate until the animal regains at least its target weight. In this situation, the animal's body weight must be measured daily to ensure that body weight does not continue to decline.

For animals on food and/or fluid restriction, weight measurements and daily food and fluid intake of each animal must be recorded in relevant weight/feeding log records. The record must also include the target weight of the animal as well as the pre-restriction weight upon which the target weight is calculated (Note – in the case of young, growing animals, the target weight should be specified on a weekly or other interval dependent upon the species and normal biology of the animal-see Figure 1). The weight/feeding records must indicate that the restriction has been approved by the IACUC and include the IACUC protocol number. The records must also be readily available for inspection by the AV, UAF staff, IACUC, and any appropriate regulatory agencies or accrediting organization. If the records are not maintained in the same location in which the animals are housed, they must be maintained as close as possible to the housing area and notation regarding their location is required (Contact the UAF staff for assistance in this regard.).

Any animal under fluid restriction must be observed daily by trained animal care staff. If the animal appears to be dehydrated, the staff must contact the AV immediately for a consultation. If the AV determines that an animal is dehydrated, he/she will recommend a course of action that must be followed immediately.

The procedure/protocol for target weight determination (including the manner in which the pre-restriction weight will be determined) and ongoing monitoring/recording must be posted in/on the room/enclosure in which the animals are housed so as to be readily available for inspection by researchers, UAF staff, IACUC, AV, and any appropriate regulatory agencies or accrediting organizations. In addition, cages housing the animals in question must be clearly labeled to indicate that the animal is being food and/or fluid restricted. Contact the UAF staff to obtain appropriate cage labeling.

IACUC POLICY AND PROCEDURE STATEMENT

Policy/Procedure: Non-Traditional or Wild-Caught Animal Policy

Policy/Procedure ID: 04-04-003

Effective: April 15, 2004

A. Background

Non-Traditional species are defined as animals not commonly used as research subjects. These include fish, frogs, birds that are not obtained from an approved vendor, snakes, etc. They may be acquired through pet or other supply sources or are acquired from independent individuals.

Wild-Caught species are defined as animals that are acquired by the investigator directly from the wild through some form of trapping.

Quarantine for animals not acquired through an approved vendor is required. Additional tests may be necessary as determined by the Director or Consulting Veterinarian if the species is known to be a carrier for a transmittable pathogen (i.e. Hanta virus in Peromyscus). These tests can include blood sampling as well as fecal and dermal examination. The investigator will cover all costs. Environmental Health and Safety will be contacted where applicable.

B. Policy

Investigators using Non-traditional or wild-caught animals will provide/assure the University Animal Facilities Office before any animals are brought in:

1. Any information available on the potential health hazards these animals may present to the staff or other animals of the Animal Facility. This includes temperament (activity level, biting response, handling ease) and pathogens.
2. A report to the Animal Facilities office on any husbandry concern specific to the animals that will be brought in.
3. A current IACUC approved protocol that covers the new animals. The investigator should also provide assurances to the University Animal Facility Office that the newly arriving animals can be supported through either grant or departmental funds.
4. Any special considerations (i.e., specific caging that the University Animal Facility does not possess, custom food items or diets, special husbandry care or extra record keeping) will have to be supplied by the individual requesting to house the animals through funding and/or staffing.

The University Animal Facility Director is required to assess the risk to the general research animal (and human) population of Bowling Green State University before any new research animal can be brought into any animal facility site.

5. Any permits required by Federal, State or local veterinary or wildlife control agencies must be on file in the Office of Research Compliance prior to the arrival of any animals into the University Animal Facility.

IACUC POLICY AND PROCEDURE STATEMENT

Policy/Procedure: Non-Approved Vendor Animal Transfer Policy

Policy/Procedure ID: 04-03-002

Effective: March 18, 2004

Revised: April 18, 2011

A. Background

A “**Vendor**” is defined as a company with appropriate USDA licensing (where applicable) that sells animals commercially to Universities or other commercial or non-profit research institutions. This definition is based on the Animal Welfare Act regulations for warm-blooded animals.

A “**Non-Approved Vendor**” is defined as an academic institution, research enterprise, or individual, that does not sell animals commercially but that is willing to transfer animals in their possession to another institution for the purposes of research or teaching.

B. Policy

Prior to transfer of animals, Non-Approved Vendor suppliers of animals must provide the following to BGSU:

1. A current statement of examination with pathogen screening information ^{**} signed by the veterinarian at the originating facility. In the case of academic institutions or research enterprises this must be the attending veterinarian. In the case of individuals, this may be either the veterinarian used by the individual to provide primary care for the animals, or the BGSU Attending Veterinarian.
2. A report to the Director of the University Animal Facilities on any husbandry concern specific to the animals that are to be transferred.
3. If the animals to be transferred have an Intellectual Property value to the supplying institution (transgenic or otherwise uniquely altered species created at the Non-Approved Vendor institution), a Materials Transfer Agreement (MTA) must be executed by both parties (Non-Approved Vendor and BGSU) prior to transfer of animals. MTAs are developed in conjunction with the Office of Sponsored Programs and Research (SPAR) and should be sent directly to SPAR. Since MTAs are contracts that are legally binding, they may take several weeks to negotiate.

The Principle Investigator (PI) requesting the transfer of animals from a Non-Approved Vendor understands the following:

1. The PI must have an active IACUC-approved protocol that covers the animals to be transferred. The PI should also provide assurances to the University Animal Facility Director that the transferred animals will be supported through either grant or departmental funds.
2. The PI must notify the University Animal Facilities Director of the transfer of Non-Approved Vendor animals at least three (3) business days in advance of the arrival of transferred animals.
3. The PI must make acceptable arrangements for transfer of animals from the Non-Approved Vendor facility directly to the BGSU University Animal Facilities in a manner that complies with the BGSU IACUC Policy and Procedure Statement on Transportation of Animals.
4. University Animal Facilities is **NOT** obligated to accept any animals transferred from a Non-Approved Vendor source in the absence of a current statement of examination with pathogen screening information signed by the veterinarian at the originating facility or by the BGSU Attending Veterinarian. In addition, University Animal Facilities is **NOT** obligated to accept animals transferred without notification of the UAF Director or UAF Animal Care Staff three (3) business days in advance of the arrival of the transferred animals[†].

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In the case of animals with known pathogen contamination, acceptance of contaminated animals will be a joint decision between the BGSU Attending Veterinarian, the University Animal Facilities Director, and the Principal Investigator. The principle investigator will assume ALL FINANCIAL RESPONSIBILITY for treatment of medical conditions (such as pathogen contamination) that exist at the time of transfer to BGSU. All new animals will be quarantined as a safety precaution based on recommendations of the BGSU Attending Veterinarian.

†

In the event that animals are transferred in the absence of health certification or without 3 business days prior notification, as described above, depending on the method of shipping and the condition of animals at the time of receipt, animals may either be returned to the place of origin or euthanized on site at the discretion of the BGSU Attending Veterinarian and the University Animal Facilities Director.

IACUC POLICY AND PROCEDURE STATEMENT

Policy/Procedure: Surgical Procedures: Definitions and Criteria for Differentiation

Policy/Procedure ID: 11-5-001

Effective: May 5, 2011

Background

Definition of the term “**surgery**” and classification of surgical procedures as “**minor**” or “**major**” can be ambiguous and a source of confusion for researchers and animal care personnel. In order to alleviate confusion and minimize ambiguity, this Policy and Procedure Statement establishes a working system for classification of various types of surgery, and criteria for differentiation of surgical procedures. The purpose of this statement is to serve as a classification and terminology guide for investigators when preparing Animal Care and Use Protocols, and to assist investigators, the IACUC, and animal care personnel in the process of post-approval monitoring.

Several types of surgical procedures are defined and described in this Policy and Procedure Statement. These definitions are based on definitions and descriptions found in the Animal Welfare Act, the Animal Welfare Regulations, the Merck Veterinary Manual (10th Ed; Kahn, CM and Line, S, Eds), the Textbook of Small Animal Surgery (3rd Ed; Slatter D), the *Guide for the Care and Use of Laboratory Animals*, and the *Guidelines for the Care and Use of Mammals in Neuroscience and Behavioral Research*.

A. Policy

- 1) The BGSU IACUC defines as “**surgery**” any procedure outside of routine non-invasive animal husbandry procedures, performed by investigators or animal care staff under controlled conditions, that involves physical manipulation of an external or internal anatomical feature and that results in alteration (minor or major, either temporarily or permanently) of that anatomical feature.
- 2) The BGSU IACUC adheres to the classification system outlined in the Animal Welfare Act (Section 13(a)(3)(D,E)), which categorizes surgical procedures into three subtypes, as follows:

Non-survival surgery: any surgical procedure in which the animal is anesthetized but is not allowed to regain consciousness prior to euthanasia. This includes any procedure in which surgical manipulations are performed after administration of a lethal dose of anesthetic but prior to death of the animal (as determined by cessation of respiration and cardiac function).

Survival surgery: any surgical procedure in which an animal is expected to fully recover from anesthesia (local or general) following a major or minor surgical procedures. In the case of general anesthesia, any surgical procedure in which the animal is anesthetized, and is then allowed to regain consciousness following the procedure and is expected to fully recover, is considered a survival surgery.

Multiple survival surgeries: this classification applies to any situation in which an animal will be subjected to two (or more) distinct **survival surgery** procedures, as defined above. Bowling Green State University has no written policy regarding multiple survival surgical procedures. The Animal Welfare Act Regulations (9 CFR, Part 2, Section 2.31 (d)(1)(x)) specifically discourage multiple major survival surgeries. However, provisions for conducting multiple survival surgeries may be made on a case by case basis. The BGSU IACUC requires that any protocol in which multiple survival surgical procedures will be conducted provide extensive justification based upon scientific requirements, as specified in the Animal Welfare Act Regulations (9CFR, 2.31). Financial considerations (cost savings) and convenience for the investigator may **NOT** be used as justification for multiple survival surgeries.

3) Classification of surgical procedures as “**minor**” and “**major**” surgery, and criteria for differentiation:

Minor surgery is typically a *minimally invasive* surgical procedure involving manipulation of superficial structures of the body, with no incision or a very small incision relative to the size of the animal on which the procedure is performed.

Criteria for categorization of a surgical procedure as “**minor surgery**” are:

- 1) The procedure does not involve opening of the cranium, thoracic cavity, abdominal cavity, or pelvic cavity to expose organs or tissues for surgical manipulation
- 2) The procedure does not include extensive tissue dissection or transection
- 3) Under normal circumstances the procedure does not result in substantial temporary or permanent alteration or impairment of anatomic structure or physiological function of the organ or tissue being surgically manipulated
- 4) The procedure requires only local anesthesia, or short (<15 minutes) general anesthesia with no respiratory assistance.

Examples of minor surgery may include, but are not limited to:

- Epidermal or percutaneous biopsy
- Insertion of subcutaneous implants
- Abscess drainage
- Incision followed by wound closure without tissue or organ manipulation, as might occur in a control or “sham” surgical procedure, given the incision is small relative to the size of the animal as described above

Major surgery is typically regarded as a substantially invasive procedure that will substantially alter (either temporarily or permanently) an anatomical feature (whether internal or external) or physiological function, and may involve opening of body cavities, manipulation of organs, or significant dissection or transection of tissues:

Criteria for categorization of a surgical procedure as “**major surgery**” include, but are not limited to:

- 1) any procedure that requires opening of the cranium, thoracic cavity, abdominal cavity or pelvic cavity to expose organs to surgical manipulation
- 2) any procedure associated with extensive vascular or connective tissue dissection or transection
- 3) any procedure that will result in substantial (either temporary or permanent) alteration or impairment of the anatomic structure or physiological function of the organ or tissue being surgically manipulated
- 4) any procedure performed under general anesthesia that requires respiratory assistance (such as intubation).

Examples of major surgery include, but are not limited to:

- Brain surgery
- Resection or transection of regions of the digestive tract
- Ovariectomy
- Liver cannulation
- Extensive surgical modification of major vascular elements, such as the vena cava, femoral arteries, carotid arteries, jugular veins, etc.
- Organ removal – e.g. unilateral nephrectomy
- Amputation

IACUC POLICY AND PROCEDURE STATEMENT

Policy/Procedure: Reporting and Investigating Protocol Deviations and Allegations of Animal Mistreatment

Policy/Procedure ID: 09-03-001

Effective: March 20, 2009

PURPOSE:

It is the policy of Bowling Green State University that the care, use, and treatment of University-owned laboratory animals be of high quality and in compliance with all federal, state, and local regulations. The law requires that all persons involved or in any way associated with the use of animals in research know how to report animal mistreatment and/or protocol deviations (Animal Welfare Act, Title 7). There are no restrictions on who can report a noncompliance. Anyone who has knowledge of such noncompliance is obligated to report it to the proper Bowling Green State University official immediately.

This policy will be distributed to all personnel involved in animal research at BGSU during annual investigator training sessions. Personnel attending these sessions will be required to sign a document indicating that they have received and understand this information. Principal investigators are responsible for insuring that all personnel involved in research activities under their direction are aware of the above procedures.

DEFINITIONS:

Animal Mistreatment: The wrongful, abusive physical or psychological treatment of an animal that does not comply with established procedures or policies.

Noncompliance: Activities or failure to act such that either an IACUC approved protocol, local, state and/or federal law is violated.

Protocol Deviations: Actions involving animals which were not approved by the IACUC at a convened meeting.

REPORTING:

In accordance with the public law [9 CFR, Part 2, Subpart C 2.32(c) (4)], under no circumstances will reporting such incidences be detrimental to an individual's standing within the organization. All reports will be considered privileged information by the Committee. Instruction regarding the methods by which allegations may be made to

the IACUC and whistle-blower protection will be outlined in mandatory investigator training sessions. In addition, these instructions will be posted on bulletin boards in each building where research animals are used. Timely reporting is essential to protect the animals involved and to aid the investigation of warranted allegations.

PROCEDURES FOR REPORTING:

- a. If a person actually witnesses mistreatment or abuse, the witness will immediately notify the Animal Facilities Director (419-372-8753) or the IACUC Chairperson through the Compliance Officer (419-372-7716) so that the animal(s) involved can be evaluated and receive medical treatment if necessary.
- b. Reports of suspected protocol deviations should be made in writing whenever possible and should include, but need not be limited to, the nature place date and time of the occurrence, the person or persons alleged to be delinquent, and any additional supporting facts. Reports can be sent anonymously to the IACUC Chair at hsrb@bgsu.edu (201 South Hall), the UAF Director at uaf@bgsu.edu (102 Life Sciences), the Institutional Official (Graduate College, 120 McFall Center), or any member of the IACUC.

IACUC PROCEDURES FOR THE INVESTIGATION OF A COMPLAINT:

The IACUC Chair is responsible for the receipt and disposition of all complaints. All allegations will remain confidential to the extent possible until proven or disproven. When the complainant wishes to be openly identified, the IACUC Chair will acknowledge receipt of the allegation to the complainant in writing. The IACUC Chair will present all allegations to the IACUC during its next meeting. The IACUC will then determine if the complaint has sufficient substance to warrant a full investigation. The IACUC will determine the procedures by which it will carry out an investigation. All persons involved in the investigation will be informed in writing of the purpose of the investigation and the manner in which it will be conducted.

If there is indication of serious noncompliance, the IACUC may suspend activity under an approved protocol. Animals will be maintained during the investigation using the same approved procedures described in the protocol so that the animals can be used pending the outcome of a full investigation. The IACUC will examine all pertinent documents, animals, procedures, and interview involved personnel during its investigation. Persons against whom the complaint is made will be given the opportunity to appear before the committee. The final results of the investigation will be presented during a formal meeting of the IACUC and all committee members will

be given the opportunity to present minority views. The IACUC will inform all parties involved, including the complainant (if identified), of the committee's findings.

The results will be forwarded to the Institutional Official with appropriate recommendations.

- a. If following an investigation of the alleged incident the IACUC finds no evidence of animal mistreatment or noncompliance, the report of the investigation will be forwarded to the Institutional Official with the recommendation that no further action be taken.
- b. If allegations of animal mistreatment are substantiated, the Institutional Official will be advised of the committee's findings and recommendations. The Institutional Official will then take appropriate action after consulting with the IACUC and reviewing the results of the IACUC investigation. The Institutional Official has the authority to impose sanctions on an investigator found responsible for mistreatment or noncompliance. The decision of the Institutional Official is final.
- c. IACUC is empowered by USDA Regulation and PHS policy to suspend a previously approved project pending review by the Institutional Official. In this case, and whenever IACUC suspends an activity involving animals (for example when activities are suspended pending the outcome of an investigation), the Institutional Official must report the action with a full explanation to APHIS and any Federal funding agency including OLAW.

IACUC POLICY AND PROCEDURE STATEMENT

Policy/Procedure: Transportation Policy

Policy/Procedure ID: 11-04-001

Effective: April 14, 2011

A. Background

The *Guide for the Care and Use of Laboratory Animals* (the *Guide*) states that “All transportation of animals, including intra-institutional transportation, should be planned to minimize transit time and the risk of zoonoses, protect against environmental extremes, avoid overcrowding, provide food and water when indicated, and protect against physical trauma. Coordination of ordering and receiving with animal-care personnel is important to ensure that animals are received properly and that appropriate facilities are available for housing”.

B. Policy

Transporting animals within a building

- Animal Welfare Regulations (AWR) shall be followed in transporting regulated animals.
- When transporting animals, the most direct route should be taken in order to minimize the time spent in common hallways or lobbies where the public may be present.
- When transporting animals within campus buildings, cages and carts must be draped with cloth or other covering to ensure animals and cages are completely shielded from public view.
- All animals must be transported in a species-appropriate container. The container must be sanitizable or disposable and must have no floor openings that may injure the animal. It must provide a secure environment that is escape proof, has a solid floor, and be free of sharp edges that could possibly injure the animal.
- Animals must be transferred into a clean cage, even if they are to be used in a terminal procedure. This will greatly reduce the concentration of allergens in the cage, to which people may be exposed.
- Up to 2 standard rodent cages may be carried by hand. If 3 or more cages are to be transported, a cart is required. In all cases, cage lids must be secured to the cages with a clip, tie, or residue-free tape to prevent escape of the animal.
- Empty cages should not be placed in the hallways outside of laboratories. This practice may result in spread of disease to the healthy rodent populations and to

staff. Return all empty cages to the animal facility washroom. Note that empty cages should also be covered when they are being returned to the animal facility.

- Only investigative staff listed by name on the associated protocol may perform the transport.
- Investigators may transport their animals to and from their laboratory or specialized equipment facilities, if approved in their protocol.

Transporting animals outside of a building*

- Animal Welfare Regulations (AWR) shall be followed in transporting regulated animals.
- Transportation of animals is to be done in a direct and timely manner.
- Rodents should not be transported at a cage density of more than two times the standard housing density.
- Cages must not be stacked on top of each other if it interferes with ventilation.
- Unoccupied, dirty cages must be bagged in a plastic sealed bag during transportation.
- Special precautions or postponements are required when temperatures are below 50F or above 85F. Depending upon weather conditions, such as humidity and wind speed, special precautions may also be required when temperatures are between 50F – 85F.
- When the outside temperature is between 50F and 85F, the animals may be transported in a vehicle that is not climate-controlled. Animals must be transported within climate-controlled vehicles when the outside temperature is below 50F or above 85F. The heating/cooling system of the vehicle must maintain the inside temperature of the vehicle within this range (50F to 85F).
- Cargo areas used to transport animals must be cleaned and decontaminated.
- The use of private vehicles to transport laboratory animals presents a risk of contamination due to exposure to allergens, zoonoses, and other hazards associated with animal exposure and, is therefore, strongly discouraged.
- Personal vehicles may be used to transport animals if the following additional conditions are met:
 - The use of personal vehicles for transport of animals must be specified in the protocol and approved by the IACUC.
 - The container used to transport the cages must be secured to the inside of the vehicle to prevent spillage (e.g., using bungee cords or other suitable restraint).
 - Animals should be protected from direct sunlight and public view.
 - Under no circumstances should non-research personnel be present in a private vehicle when it is used for transporting laboratory animals.

- Each transport vehicle must undergo semi-annual inspections by the IACUC. The vehicle must have undergone at least one inspection before use.

*For non-commercial sources of animals, in particular, it is important for the Attending Veterinarian or the Veterinarian's designee to review the health status and other housing and husbandry requirements prior to authorizing shipment of animals. This will ensure that effective quarantine practices are implemented for incoming animals as well as addressing any special requirements needed to ensure animal well-being.

Any exceptions to this policy must be pre-approved by the IACUC.

UNIVERSITY ANIMAL FACILITIES POLICY AND PROCEDURE STATEMENT

University Animal Facilities Security and Restricted Access

Policy: Access to secure areas of the University Animal Facilities (UAF) is restricted to individuals listed as personnel on an IACUC-approved, active animal use protocol only. Exceptions to this policy may be granted on a case-by-case basis with prior notification and approval by the UAF Director **and** the IACUC Chair. In the case of such an exception, individuals entering secure areas who are not listed on an active animal care and use protocol must be accompanied by the principal investigator (PI) on an IACUC-approved active protocol **and** either the UAF Director, a member of the UAF Animal Care Staff, the IACUC Chair, or the Research Compliance Officer.
NO DEVIATIONS FROM THIS POLICY WILL BE PERMITTED.

Procedure:

Personnel requiring routine access to secure areas of the UAF must first be added to an IACUC-approved animal use protocol. The complete procedure for personnel to acquire routine access to secure areas of the UAF is as follows:

- 1) **Tetanus Immunization.** All individuals must provide proof of a current tetanus immunization at the time access codes to the UAF security system are issued. **No one will be issued secure access without proof of a current tetanus vaccination.** You will be required to receive a new tetanus vaccination, at University expense, if you cannot provide proof of a tetanus immunization within the previous five years.
- 2) **Individuals must complete animal user training.** To be added to an active protocol, individuals must first complete the on-line animal user training appropriate to the animal-related work they will perform. These requirements are as follows:
BGSU's Animal User Training Session I must be successfully completed by all researchers;
BGSU's Animal User Training Session II must be successfully completed by all researchers performing more than behavioral observations in naturalistic settings;
BGSU's Animal User Training Session III must be successfully completed by all researchers who will be performing surgery;
Individuals who will be performing euthanasia must also complete euthanasia training with Dr. David Clark, the Attending Veterinarian or Dr. Matthew Cannon, the UAF Director.
Information on completion of training sessions is available at <http://www.bgsu.edu/offices/orc/iacuc/page45036.html>.
- 3) **The PI on the protocol must complete and sign a BGSU Animal Research and Teaching Protocol Personnel Addition Request.** The Personnel Addition Request can be found at <http://www.bgsu.edu/downloads/gradcol/file44963.doc>. The PI must provide the name, phone number and email address of each individual to be added to the active

protocol, and must identify the procedures each individual will perform. The PI must sign the completed Personnel Addition Request form and deliver the signed form to the Institutional Animal Care and Use Committee Chairperson (currently Dr. Lee Meserve, Dept. of Biological Sciences). See Personnel Addition Form FAQs at the above link for information about completing the Personnel Addition form.

- 4) **Approval by the IACUC Chair.** The IACUC Chairperson signs the completed Personnel Addition Request previously completed by the PI, and forwards the completed signed form to the Office of Research Compliance for verification and processing.
- 5) **Verification of training.** Following receipt of the completed, signed Personnel Addition Request, the Office of Research Compliance will verify completion of training by all individuals to be added to the protocol. If training has not been completed, addition of the individual to the desired protocol will be delayed until appropriate training is completed. Individuals **must** complete the appropriate training **prior** to addition to an IACUC-approved protocol.
- 6) **Addition of personnel to an active protocol.** Following verification of training, the Research Compliance Officer adds the name(s) of the requested individual(s) to the database record for the active protocol.
- 7) **Notification.** The Office of Research Compliance will notify the PI via email after the requested individuals have been added to the desired animal use protocol.
- 8) **Contact University Animal Facilities to setup access.** After the PI has been notified of addition of personnel to an animal use protocol, the PI must contact the UAF Director or UAF Animal Care staff to schedule a time to set up access for newly-added personnel. At this time the PI should also indicate the type of access to be granted (e.g. business hours only, daylight hours only, 24-hour access, etc). PI's can contact the UAF via phone at (419) 372-8753 or (419) 372-3240, or via email to UAF@bgsu.edu .

It is very helpful if the PI can accompany new personnel, especially students, to the UAF at the time secure access is granted.

Establishing secure access takes approximately 15 minutes, during which time the individual must complete the University Animal Facilities Personnel Access form, provide proof of a current tetanus vaccination, and select a personal security code specific to the individual, which will be stored in the security system.

Once secure access has been granted, the individual's identity and access status will remain in the security system until that individual is removed from an active protocol, is no longer employed by BGSU, or (in the case of students) until the student is no longer enrolled at BGSU.

Removal of any individual from an active animal care and use protocol, either at the request of the PI or as a result of actions taken by the IACUC, will also result in removal from the security system. See the Personnel Addition Form FAQs for information about removing individuals from an active animal care and use protocol.

Contact the Director of University Animal Facilities at (419) 372-8753 or via email at UAF@bgsu.edu with questions or for further information.