



Florida Institute of Technology
High Tech with a Human Touch

Institutional Animal Care and Use Committee

Florida Institute of Technology

Standard Operating Procedures

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TITLE: “Guide for the Care and Use of Laboratory Animals” and “Guidelines for the Use of Fishes in Research”, and “Guidelines for Use of Live Amphibians and Reptiles in Field and Laboratory Research” as Adopted Standards

Purpose: The purpose of the *Guide for the Care and Use of Laboratory Animals* (Guide), the *AVMA Guidelines on Euthanasia* (formerly “Report of the AVMA Panel on Euthanasia”), the *Guidelines for the Use of Fishes in Research*, and *Guidelines for the Use of Live Amphibians and Reptiles in Field and Laboratory Research* is to help institutions care for and use animals in ways judged to be scientifically, technically, and humanely appropriate. Further, the Guide and taxa-specific guides are intended to help investigators fulfill their obligations to plan and conduct animal experiments in accord with the highest scientific, humane, and ethical principles. The Guide and taxa-specific guides define the minimum standards for appropriate care and use of animals that FIT assures many of the funding sources, including the National Institutes of Health (NIH) - Public Health Service (PHS) and National Science Foundation (NSF), that we follow. Without such an assurance, those funding sources cannot provide research dollars.

PROCEDURE: The FIT Animal Care and Use Committee uses the current "Guide" and taxa-specific guides (fish, amphibians, reptiles) as the minimal standards of care for all laboratory and other research animals under the jurisdiction of FIT. Investigators should seek additional guidance from either a research animal veterinarian, the Animal Compliance Officer, and/or the IACUC.

[Guide for the Care and Use of Laboratory Animals 8th Ed. \(2011\). National Academies Press: Washington DC.](#)

[Guidelines for the Use of Fishes in Research \(2014\). American Fisheries Society: Bethesda, MD.](#)

[Guidelines for Use of Live Amphibians and Reptiles in Field and Laboratory Research 2nd Ed. \(2004\). American Society of Ichthyologists and Herpetologists \(online only\).](#)

Approved by the IACUC 29 June 2015

Author(s): S. Emer, C. Bashur



TITLE: Principal Investigator Status for Animal Care and Use Protocols

Purpose: The purpose of this procedure is to define the minimum requirements for an individual to hold PI status for a FIT Animal Care and Use Protocol. Such status carries with it final responsibility for any and all activities related to the work carried out under the protocol. This includes, but is not limited to, the completion of annual continuing reviews, the submission of renewals and amendments, and ultimate responsibility for the actions and safety of all personnel who use and care for animals in research, teaching, and outreach activities under an approved protocol. PI designation on a FIT Animal Care and Use Protocol does not assure or imply any guarantee of PI status in any other FIT context, office or laboratory space, personnel and fiscal management, or other department, school, college, or unit support, including employment.

PROCEDURE: A PI identified on a grant must also be identified as the PI on an animal protocol. To be identified as a PI on a FIT Animal Care and Use Protocol, an individual must hold a current appointment that provides 1 of the following:

- University PI status (currently this includes assistant/associate/full professors)
- Independent position status (which includes emeritus faculty, academic staff with the title Research Associate, Associate Research Professor, Instructor, Research Professional, Researcher, Research Scientist, Adjunct Faculty)

It is the IACUC's responsibility to determine if the individual identified on a protocol application as the PI is qualified to assume animal protocol PI status responsibilities. External personnel may be identified as a PI with review and approval by the IACUC. Persons denied PI status on animal protocols may appeal the IACUC's decision, but the IACUC shall have final authority for such decisions.

References:

Animal Welfare Act Regulations sec. 1.1 "Definitions": Principal Investigator means an employee of a research facility, or other person associated with a research facility, responsible for a proposal to conduct research and for the design and implementation of research involving animals.

Approved by the IACUC 29 June 2015

Author(s): S. Emer, C. Bashur



TITLE: Complete Protocol Submission

Purpose: This procedure describes the requirements for animal use protocol submission, approval, and maintenance for all FIT PIs.

PROCEDURE:

1. A FIT animal care and use protocol that has been reviewed and approved by at the IACUC and is in active status is required before any research, teaching, or outreach activity can be performed with the exception of noncontact observation of wild animals in their natural habitat that does not materially affect the animals.
2. Public Health Service Policy requires annual reviews and 3-year renewals to maintain active status of animal protocols. FIT PIs are required to abide by these regulations and follow established administrative processes for compliance. See procedure for “Annual Review and Protocol Renewal.”
3. Only 1 individual may be named as PI on an FIT animal care and use protocol. That individual must meet the criteria stipulated in the IACUC procedure “Principal Investigator Status.”
4. FIT animal care and use protocols must be submitted by the PI to the Animal Program Compliance Officer for processing.
5. Only the PI may submit amendments to approved protocols and rewritten protocols responding to IACUC review questions.
6. PIs are required to submit responses to committee questions, requests for additional information, or modifications to the protocol in a finalized version of the protocol. This finalized version shall contain all changes to the protocol with such information incorporated into the appropriate question(s). Such submission shall be considered a requirement for protocol approval.

For procedures on protocol maintenance, see procedure for “Annual Review and Protocol Renewal.”

Approved by the IACUC 29 June 2015

Author(s): S. Emer, C. Bashur



TITLE: Protocol Review

Purpose: In compliance with PHS Policy and the Guide for the Care and Use for Laboratory Animals, the IACUC must review and approve all proposed components of a protocol involving the care and use of vertebrate animals or significant changes to previously approved protocols either through Full Committee Review (FCR) or Designated Member Review (DMR). This policy describes these procedures. The IACUC must also review annual reviews of protocols.

PROCEDURE: Most protocols and renewals go through FCR and most amendments to protocols go through DMR. The IACUC can send any protocol to DMR unless a member specifically requests FCR. All IACUC members, including those absent, must be notified that DMR will be used. Otherwise the protocol or amendment will be sent to another IACUC meeting. Administrative changes do not need to be reviewed by the IACUC and can be verified as complete by the Animal Compliance Officer or designee but significant changes must be reviewed and approved by the IACUC.

PROCEDURES FOR FCR

1. The FCR method is a review at a convened meeting of a quorum present (i.e., a majority of the IACUC voting members at a convened meeting) and is generally used for new protocols and renewals. Approval of those protocols may be granted only after review and vote by a majority of the quorum present at a convened meeting.
2. If a FCR is requested by an IACUC member before approval of a DMR, the protocol or amendment must be reviewed at a convened meeting and approved by a majority of a quorum present.
3. The protocol or amendment will be distributed to all IACUC members before the meeting to allow for careful consideration of the project.
4. The IACUC has the authority to:
 - Approve
 - Require modifications to secure approval. The IACUC may also use DMR subsequent to FCR (see for procedure below).
 - The IACUC may "Defer" or "Table" a protocol if substantial modifications are required but these motions are not officially recognized by the PHS or Animal Welfare Regulations.
 - Withhold approval

PROCEDURES FOR DMR

1. Protocol submissions to the IACUC (including new protocols, renewals, and proposed significant changes to approved protocols) are initially routed by the IACUC Chair (or designee) to the full IACUC. These protocols are available to all IACUC members for review and comment over the course of two business days. If any committee member requests full committee review of the protocol, the protocol will be scheduled for review by a quorum of the IACUC. If no member requests full committee review, then the Designated Member Review (DMR) process will be used.



2. In the DMR process, the IACUC Chair delegates (or designee; i.e., Animal Compliance Officer or Research Office Reporter) primary review authority to a member of the IACUC. If the designated member is not a veterinarian, s/he may request veterinary review as part of the designated member review process.
3. The designated reviewer may
 - Approve a protocol as submitted,
 - Require modification to the protocol in order to secure approval, or
 - Recommend the protocol for full committee review. A designated reviewer may not unilaterally disapprove a protocol.
4. Complex protocols may be exchanged between the designated reviewer and the investigator multiple times for changes and clarifications prior to approval.

If a protocol is assigned to multiple designated reviewers, approval must be a consensus decision. If designated reviewers cannot reach a consensus decision on a given protocol, then that protocol is sent for full committee review.

Approved by the IACUC 19 May 2015

Author(s): S. Emer, C. Bashur



TITLE: IACUC Confidentiality

Purpose: The purpose of this procedure is to ensure confidentiality of IACUC deliberations and protocol information.

PROCEDURE:

- IACUC meetings will be closed to the public. Non-members may be invited to attend the meeting to provide information to the IACUC but they will not be present during deliberation and voting.
- In reviewing a protocol, an IACUC member may wish to seek additional information from professional experts either within FIT or external to FIT. Prior to seeking this information, the IACUC member **MUST** gain written approval from the PI in order not to divulge any confidential or proprietary information.
- No IACUC business will be conducted and no information about the proceedings and deliberations of the IACUC may be discussed in a location that allows the inadvertent release of verbal information.
- All members of the IACUC will be provided with a confidentiality agreement to sign.
- FIT does not currently use animals regulated by the USDA, therefore does not fall under USDA regulations. However, if FIT animal use changes or USDA regulations change such that the regulations apply to FIT, USDA regulations specific to confidentiality and penalties for the disclosure of confidential information will apply (7 U.S.C. 2157 Section 27).

Approved by the IACUC 17 December 2015

Author(s): S. Emer, C. Bashur



TITLE: Animal Contact Program Enrollment

Purpose: A fundamental responsibility of occupational health at FIT is to reduce the health and safety risks and hazards associated with animal contact. For individuals who have regular exposure to animals and/or animal facilities, risk is assessed by enrollment in University's Animal Contact Program (ACP), through the completion of an Animal Contact Risk Questionnaire. The information obtained in the questionnaire is connected with other campus hazard identification data and animal use materials. This information is used to determine required immunizations, use of personal protective equipment, hygiene practices, medical surveillance, and training. The information provided will be confidential (protected by Health Insurance Portability and Accountability Act) and only reviewed by FIT Health Services medical staff. The level of occupational health and safety practices required will be determined by the hazards and risks imposed by the environment, the degree of contact with animal species, and the length of the contact.

Definition:

- **Animal Use Area.** Established animal facilities (vivaria), procedure areas, and PI laboratories where animals are housed and or used/studied and conveyances in which animals are transported between animal use areas.

PROCEDURE : This procedure identifies 4 groups of employees, students, and visitors and outlines when enrollment in the ACP is required:

Group 1: Anyone who through their employment, training or service at FIT has regular contact with animals and/or animal use areas must enroll in the ACP. This includes:

- Faculty, staff, and students named in an approved animal care and use protocol for teaching, research, or outreach must enroll in the ACP. In cases where an individual is the Principal Investigator on a FIT protocol but is employed by a different institution (e.g., FWC) while holding a zero-dollar appointment at FIT, a risk assessment from their home institution may suffice. This requires approval by the Environmental Regulatory and Compliance (ERC) Office.
- Researchers, and any staff working within animal facilities. Staff who work outside animal facilities and have no animal contact are not required to enroll in the ACP. In cases where staff work in an animal facility but do not come into direct contact with animals and have minimal exposure to animal associated risks, it may not be necessary to enroll in the ACP. The ERC Office will determine the level of risk and the need for enrollment on a facility basis
- Animal care staff. This includes individuals who work or volunteer in animal facilities.
- IACUC members, including lay members and ex-officio.

Group 2: Students. There are 3 categories of students relevant to this procedure. This includes:

- Students working in a PI's laboratory fall into the Group 1 category. As such, these students will be listed on a research protocol and will therefore be required to complete the ACP enrollment.
- Students working for an animal facility. The majority will have regular contact with animals and/or animal facilities. These students must enroll in the ACP.
- If a student's role in a facility is associated with minimal animal handling and animal-associated risk (e.g., feeding fish in a pond), a position description will be reviewed for risk and if deemed



appropriately low, the student does not need to enroll in the ACP. This decision is made by the ERC Office.

- Students enrolled in a class that involves animals. There are 2 categories:
 - a. A course associated with minimal exposure to animals is associated with a small risk. In this case, the instructor(s) will make an announcement and there will be signage/documentation of the potential risks. Enrollment in the ACP is not required. The designation of a course not warranting enrollment will be made by the ERC Office.
 - b. For a class with more than minimal animal contact and/or exposure (e.g., a class that involves taking care of animals) the instructor(s) and students must enroll in the ACP.

Group 3: Visitors. A visitor is defined as any individual who is not authorized to normally be in an animal use area. All visitors to animal areas must be trained in the proper use of and wear the same personal protective equipment required of all other University personnel in the same animal area on campus. This includes compliance with all OSHA standards including the respirator use standard (29 CFR 1910.134). There are 2 categories of visitors relevant to this procedure:

1. Visitors to areas where the risk of illness or injury is low and where there will not be more than very casual, short-term direct animal contact. In this case, the visitor needs supervision, and there will be signage/documentation of the potential risks (e.g., Contractor, inspector).
2. Visitors who will experience more than minimal exposure will be required to have either:
 - a. prior risk assessment from a different institution: Communication of prior assessment and acceptance to FIT Health Services. This communication will be facilitated by supervisor of the animal facility.
 - b. enrolled in the FIT ACP.

Group 4: FIT Service Personnel (nonanimal facility employee, e.g., physical plant personnel).

All service personnel need to communicate with a facility employee point-of-contact prior to entering the facility. For service personnel who will not come in direct contact with an animal and thus the overall risk is deemed minimal, clear signage and PPE are sufficient.

Additional requirements for all 4 groups defined above:

- **Training Documentation.** All required training provided to the above groups must be documented. A copy of this documentation will be retained.

See also IACUC Procedures “Animal Area Security and Access Control”; and “Photography and Videography in FIT Animal Use Areas.”

Approved by the IACUC 29 June 2015

Author(s): S. Emer, C. Bashur



TITLE: Annual Review and Protocol Renewal

Purpose: The purpose of this procedure is to provide guidelines for the IACUC and investigators to efficiently carry out protocol renewals. This procedure will provide a uniform process for renewals and make it clear that protocols must be renewed prior to their expiration in order for research under that protocol to continue.

PROCEDURE: Public Health Service regulation mandates that the IACUC conduct 1) continuous review of each previously approved, Animal Care and Use Protocol and associated ongoing activity, and 2) a complete review of approved protocols once every 3 years. To accomplish this requirement, PIs will be notified by the IACUC email system at least 3 months before each protocol is scheduled to expire. This correspondence will advise them that they must submit 1) an **Annual Report** or 2) a renewal **Animal Care and Use Protocol** so that it can be approved prior to the expiration date. If a PI does not respond to the first notification, a second notification will be sent at least 2 months before each protocol is scheduled to expire. If a PI still does not respond, the system will notify the PI 30 days before the protocol expiration date that the protocol will expire. This will be the final notice to submit renewal documents. To guard against the chance a PI does not receive the notification due to extended absence from their office (e.g., illness, sabbatical, etc.), the Chairperson of the PI's department will be copied on this final notification.

1. The **Annual Report** form can be found on the IACUC website. Submission of the annual report requires report of the number of animals used to date, unexpected outcomes, and modifications to the approved protocol (amendment submission required). Required on or before the first and second year anniversaries of the approved protocol.
 - a) Submitted renewal reports that are received by the deadline(s) identified in the above notifications will be scheduled for review at the committee's next convened IACUC meeting or for Designated Review. Results of the IACUC review will be communicated to the PI in a timely manner to avoid protocol expiration.
 - b) If necessary, amendment(s) to approved protocols must be finalized before the annual report due date. The Protocol Modification form is available on the IACUC website.
 - c) If a PI fails to respond to amend the protocol, the protocol will be suspended. Upon suspension, the IACUC will within 24 business hours notify the PI, the responsible attending veterinarian, the Animal Facility Manager, and Department Chair. The Protocol Modification form must be submitted and approved if the investigator wishes to restart the research.
2. A 3-year renewal **Animal Care and Use Protocol** form can be found on the IACUC website. Required on or before the third year anniversary of the approved protocol.
 - a) If modifications are required by the IACUC for approval, the PI will have a maximum of 2 weeks to respond. Such response will be in the form of a protocol rewrite which incorporates and highlights (bold) the response(s).
 - b) If a PI fails to respond to the IACUC's questions within the required time frame, the protocol will expire on its expiration date. Upon expiration, the IACUC will within 24



business hours notify the PI, the responsible attending veterinarian, the Animal Facility Manager, and Department Chair. An investigator wishing to restart the research will have to submit a new protocol, which will undergo the IACUC review and approval process.

Approved by the IACUC 29 June 2015

Author(s): S. Emer, C. Bashur



TITLE: Animal Care and Use Authorization and Mandatory Training

Purpose: This procedure defines the minimum training requirements for individuals who use or care for animals in teaching, research, and outreach at FIT.

Definitions:

- Animal users include: (i) all animal care staff/personnel responsible for routine animal care, including husbandry personnel, facility managers; (ii) faculty, staff, students, and volunteers involved in vertebrate animal-based research, teaching, or outreach (e.g., principal investigators, staff, students, volunteers involved in research or animal care, and students in courses requiring risk assessment); (iii) visitors to the University (e.g., visiting scientists, investigators, faculty, students, volunteers) who use vertebrate animals; (iv) all appointed IACUC members, including IACUC members meeting the federal regulatory definitions of unaffiliated and nonscientist members.

Affiliation status involves 2 categories: (i) FIT affiliated, which applies to those eligible for a FIT ID, and (ii) non-FIT affiliated, which applies to those not eligible for a FIT ID.*

PROCEDURE: The FIT IACUC requires all animal users at FIT and associated facilities to successfully complete the training requirements described in this procedure.

1. Required of ALL FIT animal users (as defined above):
 - a. Animal Contact Program risk assessment, which must be completed and evaluated before animal contact (Risk Questionnaire). “Animal Contact Program Enrollment” procedures describe who must complete this assessment.
 - b. All applicable, species-specific online CITI Program animal research courses: Working with the IACUC; and Wildlife Research, Working with Fish, Working with Mice, Working with Rats, Working with Amphibians, and/or Working with Reptiles depending on research area. (Note: animal care personnel that maintain exhibits are exempt from the Working with the IACUC course.)
 - c. Occupational health and safety modules for all applicable CITI animal research courses. (e.g., Working with Reptiles: Background, Research Mandates, Zoonotic Diseases, Occupational Health Considerations)
 - d. Training for animal users reauthorization is required every 3 years. Animal contact health risk assessments must occur every 3 years or when an individual experiences a change in health status or in the type of animal research performed.
 - e. Individuals who request to use a new species for which they have not been trained must complete species-specific course(s) administered by the online CITI Program for the species with which the individual will work.
2. Deadlines
 - a. Animal Contact Program risk assessment must be completed before animal contact and renewed every 3 years. See the “Animal Contact Program Enrollment” procedures regarding whether enrollment in the occupational health program enrollment is necessary.
 - b. Animal use training needs to be completed before animal contact.



- c. FIT-affiliated animal users not listed on protocols must complete the requirements described in section 1 of these procedures within 30 days of appointment to perform animal activities.
- d. FIT-affiliated animal users listed on protocols must complete the requirements described in section 1 of this procedure within 30 days of being added to an IACUC-approved protocol. Extensions for individuals named on protocols beyond 30 days must be requested through the Animal Compliance Officer. If individuals use or care for animals before completing the required training, they must work under the direct supervision of a supervisor who has completed the required training described in section 1 of this procedure.
- e. Non-FIT-affiliated animal users who have not received FIT training (e.g., visiting scientists, investigators, faculty, or students) must work under the direct supervision of the host Principal Investigator or a designee who has completed the required training. Non-FIT-affiliated individuals who intend to spend more than 30 days working with live vertebrate animals during that time must be listed on a FIT IACUC-approved animal care and use protocol and complete the required training described in section 1 of this procedure.

3. Consequences

Failure to fulfill the training requirements described in section 1 of this procedure and proceeding to perform hands-on work with vertebrate animals not under direct supervision of a qualified individual will be considered a protocol violation and treated as such (see procedure for “Protocol Non-Compliance”).

See also Animal Contact Program Enrollment.

*Affiliation status DOES NOT affect the ability to register within the free online training program (CITI). To register, visit www.citiprogram.org; enter Florida Institute of Technology for affiliation.

Approved by the IACUC 17 December 2015

Author(s): S. Emer, C. Bashur



TITLE: Animal Area Security and Access Control

Purpose: Access to FIT animal use areas must be strictly controlled to minimize health risks to both humans and animals. The following procedure is intended to ensure a minimally disruptive environment for FIT animals, to protect the health of persons and animals, to protect the confidentiality and integrity of FIT research, to prevent interruptions to research, and to ensure respect for the privacy and safety interests of FIT staff and students.

In compliance with the *Guide for the Care and Use of Laboratory Animals*, all animal use areas must have policies or standard operating procedures (SOPs) pertaining to animal contact, protective clothing/equipment, and conduct.

PROCEDURE: Access to animal use areas is limited according to levels of access described below as zone 1, zone 2 or zone 3. All individuals granted access to animal use areas must abide by the individual animal use area policies and SOPs pertaining to animal contact, protective clothing/equipment, and conduct.

1. Levels of Access

Zone 1 – Animal display areas (Panther Dining, President’s Office, DMES-Link, Commons); **public access**

Zone 2 – Teaching and research labs, and prep areas where animal activities occur;

Unescorted access during non-animal activities by those assigned to an active approved animal care and use protocol, departmental administration, and authorized staff members whose access is necessary for performance of job duties

Unescorted access during animal activities by those assigned to an active approved animal care and use protocol

Escorted access during animal activities by course roster students assigned to an active approved animal care and use protocol, departmental administration, and authorized staff members whose access is necessary for performance of job duties

Zone 3 – Long term animal housing areas (OLS rodent housing, Harris aquaculture project rooms, OLS snake housing, ARL snake housing);

Unescorted access by those assigned to an active approved animal care and use protocol, or those on a staff roster that indicates that they work, provide care or oversight in the animal use area



Escorted access by those needing infrequent or ancillary access to animal quarters, those not assigned to care for the animals in the area, and those not assigned to a protocol or those that have not completed the animal use training to safely access an animal area (visitors, volunteers, non-animal care workers, researchers observing procedures, facility maintenance personnel); *not to preclude emergency responses in animal areas*

2. For visits to animal areas, the host must inform the area manager of the visit and receive affirmation from the manager prior to the visitor's arrival. For visits to PI laboratories, no such notification is required.
3. For visits to animal areas, visitors must be accompanied by their FIT host (e.g., PI or designee, authorized Animal Compliance inspection team) at all times. For visits to PI laboratories, visitors must be accompanied by their FIT host when animals are present.
4. The visitor agrees to abide by the individual area SOPs pertaining to animal contact, protective clothing/equipment, and conduct. The host is responsible for ensuring compliance with applicable SOPs by all invited visitors.
5. All visitor activities must be consistent with campus Occupational Health and Safety rules as applicable. The host is responsible for ensuring such consistency for all activities undertaken by invited visitors.
6. The use of any recording device (e.g., film camera, digital camera, camera phones, digital recorder, sound recorder) is prohibited except as allowed by the IACUC, and animal compliance inspectors (FIT and government). See "Photography and Videography in FIT Animal Use Areas."
7. Access to FIT animal use areas may not be denied to government inspectors (e.g., OLAW, USDA, FWC). Such inspectors must abide by items 2-5 of this procedure.

Approved by the IACUC 14 July 2015

Author(s): S. Emer, C. Bashur



TITLE: Animal Acclimation

Purpose: Transportation unavoidably causes stress in animals. Utilizing animals for research prior to their stabilization from transport stress may have unintended or detrimental effects on research results. The Guide for the Care and Use of Laboratory Animals strongly recommends that newly received animals be given a period for physiologic, behavioral, and nutritional acclimation before their use. This policy sets forth the required minimal time that animals should be allowed to acclimate prior to research use. For some species or strains of animals longer times may be required to allow for return to normal parameters.

Definitions:

- **Acclimation:** physiological and psychological adaptation to a novel environment or procedure.
- **Acclimation Period:** [species-specific] pre-determined period of time during which animals undergo no experimental manipulations in order to adequately recover from the stress of transport and acclimate to the new housing environment.
- **Transportation:** movement of animals from a vendor or other off-campus location, including intra- and inter-city, intra- and inter-state and international transport involving land, sea and/or air transport.

PROCEDURE:

This procedure applies to all experimental animals that arrive at a FIT animal facility following transportation as defined above. This policy does not address room-to-room or building-to-building transport of animals within the same campus.

No experimental manipulations may be performed during acclimation periods. Only routine husbandry-related interactions, health-assessments and medically necessary treatments may occur during the acclimation period.

Listed below are the minimum acclimation periods for animals newly received at FIT. Investigators are strongly encouraged to allow additional time for animals to stabilize to their new environment and to consider longer periods of acclimation if indicated for the specific type of study being performed. Exceptions to this procedure must be described and justified in the animal use approval form and approved by the IACUC. Failure to allow animals to acclimatize properly could adversely impact animal health and research data.

Rodents: minimum 48 hours; 1 week is standard and recommended. It is in the Principal Investigator's best interest to ascertain how the studies undertaken are confounded by transportation stress. For example, it has been reported in rodents that subsequent to transportation:

- Reproduction including reproductive hormones and behavior are affected (larger effect in adolescent rodents) [1, 2, 3]
- Immunologic functions are inhibited [4]
- Corticosterone levels are elevated [5]
- Serum chemistry parameters are affected [5]
- Fetal brain development and response to toxins are affected [6]
- Heart rate, body temperature and activity are affected [7]



Fish: Species specific and must be described in approved protocol. Fish should be given time to acclimate to new environments, feeds, and routine activities before being used in studies. Slow acclimation to change often is critical [8]. It is not uncommon for fish to exhibit acute health problems 48 to 72 hours following transfer. The time used for acclimation within and between experiments should be standard and specific for a species. A commonly used acclimation period is 2–4 weeks. However, investigators should note that laboratory holding conditions may cause physiological changes in wild animals brought into the laboratory, such as immunosuppression, or loss of tidal or diel rhythmicity, even though no visual signs of stress are present. (See also *Guidelines for the Use of Fishes in Research.*)

Reptiles: Species specific and must be described in approved protocol. Upon receipt of commercial specimens, and prior to introduction to any existing laboratory colonies, commercial specimens should be subjected to careful inspection for potential health problems or known pathogens. If feasible, a quarantine period may be advisable. If not euthanized upon procurement, wild-caught reptiles must be quarantined for a minimum of 30 days. Exceptions to this requirement, including captive animals purchased from commercial suppliers, will be dependent on the source and/or justifications described in the protocol. (See also *Guidelines for Use of Live Amphibians and Reptiles in Field and Laboratory Research.*)

References:

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Approved by the IACUC 17 December 2015

Author(s): S. Emer, C. Bashur



TITLE: Animal Transport

Purpose: The purpose of this procedure is to ensure that any transportation of animals outside of animal facilities is conducted in an appropriate manner, safe for the animals and the public. All transportation of animals outside an animal facility, including building to building, must be described in an approved protocol. It is the responsibility of the PI to ensure that there is protocol and facility manager approval prior to moving animals between facilities. The IACUC must approve any exemption to this procedure, prior to its application.

PROCEDURE:

General considerations:

- All transportation must be in accordance with the Guide for the Care and Use of Laboratory Animals, and facility-specific standard operating procedures.
- Containment used for transport must:
 - limit exposure to allergens, waste products or odors (e.g., filter top cages for rodents).
 - provide sufficient air for normal respiration.
 - prevent escape of the animal if an accident occurs.
 - be safe for the animal and species-appropriate (e.g., coolers for fish).
 - be sanitizable or disposable.
 - ideally be the animal's home containment to limit stress.
- Live animals should not remain outside of approved housing facilities for more than 12 hours unless specifically approved in the animal protocol.
- Following transportation, animals should have access to food and water unless restriction is stipulated and approved in the animal use protocol.

Pedestrian transportation between buildings:

- Small animals may be manually transported from the housing facility to a laboratory in secured containment.
- Containment must be protected from temperature extremes, sunlight, car lights, or visual observation by use of opaque plastic bags or boxes, opaque fabric, or other opaque covering.
- To prevent escape of animals or spillage of contents, containment should be secured with nonresidue tape, bungee cords, rubber bands, etc. during transport.

Vehicular transportation:

- **Under no circumstances shall animals be transported by public transportation such as campus or city buses or shuttles.**
- Transport of animals between University facilities must be performed in a University vehicle, and animals must be in appropriate containment (see above). It is the responsibility of the PI, lab manager or other animal care personnel to acquire clearance, approvals and reservations for the vehicle obtained through Campus Security.
- Exceptions, (e.g., transportation of fish in non-University owned vehicles), must be included in an IACUC-approved animal protocol and must be approved by all applicable University departments.



- General criteria for an approved vehicle include:
 - adequate heating/cooling to keep animal ambient temperature between 45-85 degrees F (7-30 degrees C), which may involve preheating or precooling the vehicle used for transport.
 - protection from direct sun.
 - protection from public view.
 - method to contain waste.
 - method to discourage allergens.
 - method to secure containment inside the vehicle (e.g., bungee cords).
- separation of animal and personnel spaces.

Approved by the IACUC 17 December 2015

Author(s): S. Emer, C. Bashur



TITLE: Animal Care

Purpose: Animal care staff and/or researchers assume full or partial responsibility for animal husbandry activities. Animals may require standard care or be on a special diet, a regulated watering schedule, an extended cage-cleaning cycle, or animals may require specialized husbandry because of protocol-driven reasons. FIT must assure that all personnel who provide care for animals are appropriately trained and that animal care activity is sufficiently documented.

PROCEDURE: Animal care provided by animal care staff and/or researchers within dedicated vivarium space must be justified in an animal-use protocol and be approved by the Animal Care and Use Committee. Animal care staff and/or researchers must receive training to properly care for animals to meet the following standards, and this training must be documented:

- Staff that perform any type of husbandry procedures, standard (e.g., feeding, cleaning, water quality measurements, etc.) or otherwise (e.g., restrictions), must document them. Documentation must include, but not be limited to:
 - Description of task
 - Time and date performed
 - Initialing of completed activity by individual performing the task
- Documentation of husbandry tasks must be kept in animal housing room(s), e.g., contained within a binder, and be readily accessible to all animal care personnel, PIs, IACUC members, and inspectors.
- Emergency contact numbers for reaching the PI, laboratory manager, other animal care staff must be available, including contact information for nonbusiness hours.
- Animal facility lab managers must check animal records or log sheets daily to confirm that required animal care tasks performed by staff are complete.
- It is the responsibility of the animal facility lab manager to contact the PI if critical animal care duties (e.g., feeding, watering, cleaning) have not been performed or documented. The PI must respond within 4 hours. Animal facility lab managers must document each and every attempt to contact the PI.
- If there is no response from the PI within 4 hours, animal facility lab managers must contact the Animal Program Compliance Officer. The Compliance Officer will determine the course of action.
- If there is no response from the PI within 24 hours, animal facility lab manager must provide care to the animals. Depending on health status of the animals, the lab manager in consultation with the IACUC, IO, and/or veterinarian will determine the disposition of the animals (e.g., euthanasia, transfer to holding protocol).
- Husbandry procedures that differ from standard husbandry practices must be described in detail in an approved animal use protocol. Such procedures could include, but are not limited to:
 - Restricted feeding
 - Regulated watering
 - Provision of special diets (e.g., powdered diet, agar diet)
 - Specialized environmental enrichment

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Author(s): S. Emer, C. Bashur



TITLE: Primary Enclosure Labeling Requirements

Purpose: To allow for timely and unambiguous identification of research animals, cage/tank cards are used to convey important information amongst researcher, veterinary, and animal care staff. The FIT IACUC follows the recommendations as outlined in the 8th ed. of the *Guide for the Care and Use of Laboratory Animals* in regard to what information is to be included on the ID cards.

PROCEDURE: To ensure that communication is open and that animals receive appropriate and timely care, the following information is **required** on an animal ID card:

- Name of the responsible investigator
- Current name(s) and contact information for research personnel in case of emergency
- Approved protocol number

The following additional information is **strongly recommended** to be included on the cage card:

- Pertinent dates (date of birth, date of arrival)
- Source of the animal (e.g., name of commercial vendor or institution, capture location)
- Species, strain or stock of animal (if known and applicable)
- Health/behavioral status of the animal
- Treatments an animal received
- Any biohazards, toxic substances, or radioactivity the animal has been exposed to

A card must be placed on all primary enclosures, including tanks housing fish groups, cages housing rodent groups, and cages/tanks housing individuals.

For animals lacking a permanent physical identification (i.e., tattoo), a method must be in place and readily accessible to vets and husbandry staff for linking these animals to their identifying information and records (e.g., description of individual animals). Investigators/animal managers may develop any style of ID card as long as the above information is provided on the card. Card templates are available from the Animal Compliance Officer.

Unidentified animals will be transferred to an established holding protocol.

Reference: *Guide for the Care and Use of Laboratory Animals*, 8th ed.

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Author(s): S. Emer, C. Bashur



TITLE: Laboratory Housing of Animals

Purpose: For experimental reasons, research animals are sometimes housed outside of dedicated animal housing space within a vivarium, within a researcher's laboratory or a teaching laboratory. For example, animals may need to be exposed to certain environmental conditions that cannot be provided within the vivarium, such as warm or cool temperatures. This procedure addresses requirements for nonvivarium housing of animals, for which investigative TAs or students provide some or all husbandry.

PROCEDURE: Housing of animals outside a dedicated vivarium for greater than 12 hours requires IACUC approval. Such housing cannot exceed 24 hours, must be based on clearly defined needs, and must be described in an IACUC-approved animal care and use protocol. Such housing will be approved only for scientific reasons, or urgent and/or intensive medical needs of the animals that cannot be accommodated within dedicated animal facilities. The protocol must also contain details of husbandry practices and the suitability of the laboratory environment for housing animals (e.g., adequate ventilation, light-dark cycle).

Requirements for housing animals in a laboratory include:

- Minimum of semiannual Inspections of facilities by the IACUC or its designee before animals are housed there.
- Training of laboratory TAs or students by the Animal Compliance Officer in appropriate husbandry practices for the species being housed, including proper documentation of husbandry procedures.
- Proper storage of feed and water.
- Weekend and holiday care plans (unless protocol states that laboratory animal housing will not be used during these times), including familiarity with sick animal reporting methods.
- Waste management procedures, especially if animals are exposed to potentially dangerous chemicals.
- Notification to animal care staff when animals are moved to laboratory housing.
- Lab manager monitoring of husbandry documentation and health of animals at least monthly for laboratories that house animals for more than 48 consecutive hours.

Approved by the IACUC 17 December 2015

Author(s): S. Emer, C. Bashur



TITLE: Genotyping of Mice and Rats

Purpose: To establish consistent standards for genotyping of mice and rats in the FIT animal program.

PROCEDURE: The proper genetic identification of genetically engineered animals in a litter is critical to the efficient pursuit of research and in reducing the number of animals involved in a research project. Most often the genotype is determined by analysis of DNA extracted from tissues of young rodents. Analysis by the Polymerase Chain Reaction (PCR) requires the least amount of DNA. DNA for PCR analysis can be obtained from ear punches, hair, fecal samples, oral or rectal swabs [1-9]. Depending on the requirements of the study, investigators are urged to consider these noninvasive alternatives. Larger amounts of DNA are required for Southern Blot determination of the genotype. Obtaining tissue from a mouse or rat for DNA analysis via tail biopsy is a safe, effective, and humane procedure that causes minimal or transient pain and distress when performed properly. An alternative method is removal of 1 of the distal phalanges of a foot (“toe clipping”), which has the added advantage of permanently identifying the animal. DNA prepared from tail biopsies or toe clips is suitable for analysis by either Southern Blot or PCR. PIs are encouraged to use the least invasive alternative possible. If animals are genotyped, they must be accounted for in the animal numbers.

Tail biopsy:

1. Procedures for tail biopsy for DNA analysis and/or genotyping must be described in an approved Animal Care and Use Protocol. If animals are genotyped, they must be accounted for in the animal numbers.
2. Mice and rats must be 28 days old or less at the time of tail biopsy if no anesthesia is used. The optimal time is age 12-14 days. At this age the yield of DNA is highest [8,10,11]. In addition, the prompt analysis of tail tissue allows the genetically desirable animals to be identified prior to weaning which will facilitate more efficient use of cage space.
3. For animals more than 28 days old, local or general anesthesia is required prior to collection of tissue as well as perioperative analgesia as recommended by a laboratory animal veterinarian. This must be described in the approved Animal Care and Use Protocol.
4. Samples between 2 and 5 mm may be taken. The yield of DNA does not proportionally increase as tail fragments larger than 5 mm are used due to the presence of cartilage and bone that are not as rich in DNA as the more metabolically active distal end [14]. Requests to sample greater amounts must be requested in the context of an animal use protocol and approved by the IACUC.
5. All animals must be monitored to assure effective hemostasis. Hemostasis can be achieved by methods such as digital pressure, cautery, or the use of silver nitrate.
6. Repeat tail biopsies on animals older than 24 days require anesthesia and analgesia and must be justified in the Animal Care and Use Protocol and approved by the IACUC.

Toe clipping:



1. Procedures for toe clipping for DNA analysis and/or genotyping must be described in an approved Animal Care and Use Protocol. Toe clipping may only be used when no other method of individual identification is feasible [12].
2. Mice and rats must be less than 14 days old at the time of toe clipping. Performing the procedure at day 7-10 is technically easier than earlier when toes have not completely separated [13]. In addition, the prompt analysis of toe tissue allows the genetically desirable animals to be identified prior to weaning which will facilitate more efficient use of cage space.
3. Toe clipping is not permitted in animals >14 days of age.
4. No more than 1 toe per foot may be sampled; the front feet should not be sampled if future experimental use could include tests of grip strength.
5. All animals must be monitored to assure effective hemostasis. Hemostasis can be achieved by methods such as digital pressure, cautery, or the use of silver nitrate.
6. If repeat genotyping is necessary, another method must be utilized for DNA collection.

Ear punching:

1. Procedures for ear punching for DNA analysis and/or genotyping must be described in and approved Animal Care and Use Protocol.
2. Mice and rats can be ear punched at any age after the ears have separated from the head during neonatal development. The prompt analysis of ear tissue allows genetically desirable animals to be identified prior to weaning.
3. Ear punching can be used as both a method of identification and of tissue collection for genotyping.
4. It is recommended to use a 2 mm ear punch, since 1 mm punches do not provide enough tissue for DNA analysis.
5. No anesthesia or analgesia is required for ear punching.
6. If additional genotyping is necessary, ear punching can be repeated.

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(http://oacu.od.nih.gov/arac/documents/Rodent_Genotyping.pdf)

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Author(s): S. Emer, C. Bashur



TITLE: Animal Transfer and Reassignment

PROCEDURE: An animal may be transferred when the following conditions are met:

- Transfers within the University must be documented (see below).
- The designee at the receiving location has given permission.
- For external transfers, agreements with outside institutions must contain language allowing for the transfer of animals.

A record of the Transfer Form and any supporting documentation must be maintained by the IACUC. This should include:

- Date of transfer
- Original protocol number (PI) or external responsible party
- Receiving protocol number (PI) or external responsible party
- Signature of transferring party, receiving party, and designee approving the transfer
- For external transfers, agreement/contract with outside institution

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Author(s): S. Emer, C. Bashur



TITLE: Laboratory and Teaching Animal Adoption

Purpose: Any animal purchased or bred for use in research or teaching by, or donated to, FIT is considered the property of FIT. Occasionally, surplus healthy animals are no longer needed for the research or teaching program. This procedure is to provide guidance to University administration, researchers, animal care staff, and other interested parties for the potential adoption of surplus animals outside the University.

PROCEDURE: As a humane and ethical user of animals, FIT encourages adoption of healthy surplus research and teaching animals, with the following stipulations:

- The animal must no longer be needed by the University as a research or teaching animal.
- The animal must be healthy and not genetically modified.
- The animal must never have been exposed to an infectious disease that is potentially zoonotic, or have been exposed to recombinant organisms.
- Adoption must be listed as a potential method of disposal in the approved animal use protocol that covers the animal.
- Animals must have a suitable temperament to be a pet, as determined by animal personnel.
- Prospective adoptions must be approved in advance by the IACUC Chair or designee.
- The Animal Adoption Memorandum of Understanding must be completed before the adoption will be considered.
- Some research animal vendors will not permit animals that originated with them to be adopted; FIT will respect their policies.

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Author(s): S. Emer, C. Bashur



TITLE: Photography and Videography in FIT Animal Use Areas

Purpose: The following procedure describes the allowable use of visual recording in FIT animal use areas. This procedure is intended to protect the confidentiality and integrity of FIT research, to assure respect for the privacy and safety interests of staff and students, and to prevent misleading representation of FIT animal use and related procedures.

Definition:

- animal use area - established animal facilities, and PI laboratories where animals are housed, tested, or used, and conveyances in which animals are transported between animal use areas

PROCEDURE: The use of any recording device (e.g., film camera, digital camera, camera phones, digital recorder, sound recorder) is prohibited in animal use areas (including research and teaching labs) with the following exceptions:

1. When performed by government inspectors (e.g. NIH/OLAW Officers);
2. When performed by an authorized PI or designee when required for scientific reasons described in an approved animal protocol (e.g., publications, laboratory documentation);
3. When performed by an authorized PI or designee for the purpose of recording instructional activities covered by an IACUC-approved protocol;
4. When performed by personnel authorized by veterinarian when required to assist in clinical diagnosis;
5. When performed by authorized personnel when required to document condition of facilities, or compliance or animal handling issues at the direction of University officials, IACUC, veterinarian, or representatives of federal agencies;
6. When reporting concerns related to animal welfare.

See the FIT IACUC “Animal Area Security and Access Control” procedure for rules regarding access to animal use areas, including visitor access. PIs who wish to allow filming in animal use areas for reasons not described above must involve facility managers in planning these activities prior to filming. This includes photography or filming by outside interests, e.g., journalists. PIs must work with the FIT Marketing and Communication Office; designated FIT press officers are available to work with investigators who might have photographers or videographers in their labs.

Guidance for implementing this procedure:

Rights of Individuals:

- Student/staff/faculty who may be photographed in the course of their work should be informed when such activity is imminent.



- Any individual may decline being photographed, filmed, or recorded and is not required to be subject to recording.

Unintended Distribution of Images:

- Consideration should be given to the secure processing, transport, and storage of negatives, disks, tapes, media cards, etc. taken by PIs or lab personnel in the course of their work.
- Every effort should be made to show appropriate and accurate context when audio or visual recordings are made (e.g., if an animal is anesthetized or sedated, include the associated equipment; have personnel wearing required personal protective equipment appropriate for the work appear in the image).
- Every effort should be made to avoid showing identifying landmarks for security purposes (e.g., room numbers, workers' name badges/IDs).
- FIT faculty and staff should be mindful of the potential for photographs and video images of animals used in teaching and research to be the target of public records requests. In some circumstances, such photographs or video images may be accessible to members of the public under Public Records Law. Faculty and staff are encouraged to consult with Legal Services prior to creating such photographs or video images.

Careless or casual use of recorded images or sounds from a facility could unintentionally expose students, staff, and faculty to unwanted attention and harassment or misrepresent the nature of animal activities occurring at FIT. Facility managers/PIs may wish to consider asking visitors to read this procedure prior to entering animal facilities or taking photography or other recordings, or adding this procedure to facility-specific SOPs.

Approved by the IACUC 29 June 2015

Author(s): S. Emer, C. Bashur



TITLE: Animal Facilities Hurricane Disaster Plans

Purpose: The purpose of this document is to provide a plan of action for responding to hurricane-related emergencies that may impact teaching and research animals housed at Florida Tech properties. The goal is to plan for humane handling, treatment, housing and care of animals during a hurricane such that employee safety, health and welfare, animal safety, health and welfare, and continuous animal care are ensured. The plan covers animal facilities located at Olin Life Sciences, Harris (Life Sciences Annex), Applied Research Laboratory (ARL) and Vero Beach Marine Laboratory (VBML).

Emergency response and recovery plans are required by PHS Policy, the Guide for the Care and Use of Laboratory Animals, and Animal Welfare Act Regulations.

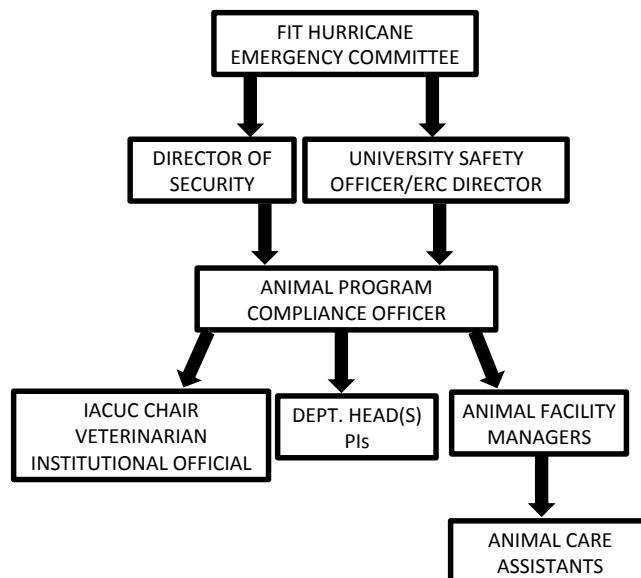
The following steps address the most likely emergencies related to hurricanes, including sustained power outage, loss of water supply, sustained HVAC failures and flooding.

Procedure:

I. Action Plans

A. Communication

Emergency contact information will be updated regularly and will remain corporate private.





B. Steps to Be Followed

1. Maintain emergency supplies at all times (see Sec. III Supplies).
2. Ensure that personnel have necessary access (card, key).
3. Prepare the facilities and animals as described below.
4. If the disaster results in unsuitable environmental conditions for a sustained amount of time, animals should be evacuated.
5. **NEVER ENDANGER YOUR PERSONAL SAFETY**
6. Check animals as soon as safely possible. Provide food, water and clean housing, assess animal health, and dispose of deceased animals as soon as possible.

Olin Life Sciences		
5-7 Days Out	2-3 Days Out	Final Hours
Change bedding in all rodent cages	Separate female rodents w/litters	Relocate rodents and log book to OLS 141 prep area
Feed all snakes as normal	Conduct animal inventory	Open fume hood
Clean all snake cages	Fill 30-gallon drum with water	Fill rodent water and food
Replace batteries in CO ₂ meter	Properly store equipment and items off of floor	Check snake water dishes
Check pressure in CO ₂ tank	Fill extra rodent water bottles	Unplug heater and store off of floor (snake room)
Confirm emergency contact numbers	Fill clean cages with bedding	Relocate digital thermometer and hygrometer with rodents
Confirm inventory of emergency supplies		Double check that facility is secure

Applied Research Laboratory		
5-7 Days Out	2-3 Days Out	Final Hours
Feed all snakes	Conduct animal inventory	Check water dishes
Clean all snake cages	Fill 30-gallon drum with water	Unplug heaters and store off of floor
Confirm emergency contact numbers	Properly store equipment and items off of floor	Double check that facility is secure
Confirm inventory of emergency supplies		



Harris Aquaculture		
5-7 Days Out	2-3 Days Out	Final Hours
Confirm emergency contact numbers	Fill additional tanks with water	Prepare buckets with clean nets
Confirm inventory of emergency supplies	Bring inside nets and other equipment	Place air stones in all tanks w/out sumps
Make sure all tanks w/air delivery have functioning air stones	Properly store equipment and items off of floor	Check that all air stones are functioning
Connect tubing and air stones to air supplies in all tank areas	Outdoor Aquaculture Area - Secure all loose items in shed	Double check that facility is secure
Prepare MS-222 instructions for euthanasia	Fill 30-gallon drum w/RO water	
Request /fill sea water supply	Inform research personnel of emergency procedure initiation	

Vero Beach Marine Laboratory		
<p>All laboratories in the main building and hex building (both are hurricane category 4 resistant) will be checked and all active experiments will be shut down. Running water and seawater pumps will be turned off. All the animals in the facility will be moved to the main building and hex building, or transported to facility that is not affected by the disaster alert.</p>		
<p>General steps:</p> <ul style="list-style-type: none"> Clean up debris and tanks on sand dune line Pick up and store misc. pipe sections @ North Side – store with pipe behind South West systems Pick up debris between all North side tanks Secure any loose shade cloth on North side framework – flapping in wind now Have Ameri-Gas top of propane tank Give a maintenance overlook to stationary generator Have portable generator ready to go with extension cords Make sure all tanks with O2 delivery have O2 diffuser stones Secure egg collectors with rope and anchor augers that are currently being utilized Clean up stuff on West side of Main buildings Secure troughs and any unused equipment Clean up pipe debris from back of Growout building Remove cinder blocks from tanks (North side) and replace with pie wedges 		
5-7 Days Out	2-3 Days Out	Final Hours
Fill all vacant North side tanks with water to secure	Remove shade cloths from smaller tanks and store	Double check that all tanks have proper O2 flow



5-7 Days Out	2-3 Days Out	Final Hours
Double check proper O2 delivery to all North tanks that are populated	Remove shade cloth from South West tanks, re-secure with fiberglass covers	Shut off any unnecessary power to equipment (i.e. chillers)
Fill all vacant biofilters with water to secure	Try to secure all dome tank covers the best we can	Re-locate Ornamental Broodstock
Order O2 tanks for each South West system tank (4), make sure large O2 tank is filled (North side)	Have a plan finalized for Ornamental Broodstock re-location	Secure any last minute loose items (ie. nets, trash cans)
Ensure all airstones are in place and working properly to all tanks	Have a plan as to where employees will be located and assign duties for final preparation	All equipment will be checked and shut down
Ensure all O2 diffuser stones are working properly	Make sure containment nets are secure on Cobia Broodstock tanks	All facilities will be checked to see that everything is secure
If Ornamental Broodstock is staying @ beach, have tanks filled and ready to stock	Secure or remove covers over South West system sumps	All the laboratories, including the chemical storage areas, will be locked
Store and secure all vacuum hoses and equipment (nets, ladders, etc.)	Have O2 bottles rigged and ready to go on the 4 South West system tanks	All records in the offices will be secured and locked. Unplug telephone, computer, network, and fax/copy machine
Fill gasoline jugs for generator operation		Personnel will be evacuated
Secure all racks of pipe with rope, bundle all together		
Secure loose equipment on South side of Growout building		
Secure any equipment on floors that could be damaged by flood		

All of these activities will be coordinated with the companies located at the Vero Beach Marine Lab.

Indian River Shores Public Safety Office (police and fire dept.): 772-231-2451



II. Supplies (All facilities, unless otherwise indicated)

Flashlights/headlamps	First aid kit	Newspapers (OLS, ARL)
Batteries	Buckets	Nets (Harris)
Duct tape	Carcass disposal containment	Bedding (OLS)
Trash bags	30-gallon drum for water	Rodent chow (OLS)
Latex gloves	Pillowcases (OLS, ARL)	5% Hydrogen peroxide
Knife	Rubbermaid containers (OLS, ARL)	MS-222 (Harris, VBML)
Towels	Aquarium tubing (Harris, VBML)	Air stones (Harris, VBML)

III. Recovery

- A. Assess environmental conditions (temperature, humidity).
- B. Locate hazards, stabilize these first.
- C. Assess animal health. Triage animals if needed and notate observations. Remove animal carcasses.
- D. Transfer animals to clean enclosures. Clean home/primary enclosures if power is restored.
- E. Conduct animal inventory to assess for escapes.
- F. Euthanasia: determine if distressed animal(s) are beyond rescue, euthanasia completed by trained personnel:

	Agent	Method
Fish	MS-222	Immersion in 250-500 mg/L
Reptiles	Sodium pentobarbital	Intra -cardiac or -coelomic injection of 1 mL per 10 lbs body weight
Mammals (rodents)	CO2	Inhalation at 10-30% displacement of chamber volume/min

IV. Training

Essential personnel must be trained on their roles and responsibilities with respect to this plan (within 30 days of hire). Updates to the plan must be communicated to personnel (within 30 days).

Approved by the IACUC 17 December 2015

Author(s): S. Emer, C. Bashur



TITLE: Adverse Event Reporting

Purpose: This procedure provides a definition of “Adverse Events” and identifies the minimum reporting and reviewing responsibilities for both protocol-related and non-protocol-related adverse events. The purpose of the reporting system is to improve monitoring for problematic trends, focus scarce time and resources on problem areas, help ensure appropriate follow-up when problem areas are identified, and clarify and harmonize expectations between the IACUC, PIs, and animal care staff, with the ultimate goal of improving animal welfare.

Definition: An adverse event is defined for the purposes of these procedures as any event that harmed or posed a threat of harm to a vertebrate animal and that meets either of the following conditions:

- The event is research-related but is not identified in the approved protocol or occurring at a rate or severity higher than is indicated in the approved protocol; or
- The event is not research-related but is unanticipated or due to a facility, physical plant, equipment, or personnel failure, malfunction, or mistake.

Examples of events that count as adverse events under this procedure include:

- Failures in HVAC systems, automatic feeders, or water systems.
- Adverse experimental treatment outcomes that were not anticipated in the protocol.
- Adverse outcome related to animal housing procedures.
- High levels of “cluster” morbidity or mortality, a grouping of animal illnesses or deaths occurring closely together, significantly above anticipated incidence.

Examples of events that do not count as adverse events under this procedure include:

- Breeding animals without an approved protocol. (The breeding would still need to be reported to the IACUC as noncompliance).
- Mortality resulting from treatment complications anticipated in the approved protocol at or below the rate anticipated in the approved protocol.

PROCEDURE: Email reporting and reviewing responsibilities for adverse events are as follows:

The PI is responsible for filing with the Animal Compliance Officer or IACUC via email, within 3 business days, an “Adverse Event Report” for any research-related adverse events [(1) in the definition].

The Animal Facility Lab Manager is responsible for filing with the Animal Compliance Officer or IACUC via email, within 3 business days, an “Adverse Event Report” for any nonresearch-related adverse events [(2) in the definition].

The IACUC is responsible for reviewing Adverse Event Reports routinely to identify potential problem areas or trends that merit attention. The IACUC maintains the right of approval of proposed corrective plans and may require further actions it deems necessary such as additional formal follow-up reporting, mandating protocol amendments, or even ordering a temporary cessation of animal use pending further review and information. Any actions taken or requirements made regarding a research-related adverse event will be reported to the PI by representatives of the IACUC.

Approved by the IACUC 14 July 2015 Author(s): S. Emer, C. Bashur



TITLE: IACUC Animal Facility Inspections

Purpose:

The purpose of IACUC animal facility inspections is to ensure that all animal housing facilities are managed and maintained according to PHS, FWC, and FIT policies.

Procedure:

All facilities housing live, vertebrate animals for research or teaching purposes must be inspected semi-annually by the IACUC (PHS Policy IV.B.2.), but inspections can occur more frequently.

Inspection teams include IACUC staff and/or members of the IACUC. No IACUC member may be excluded from an inspection in which they wish to participate, unless there is a conflict of interest.

A full copy of each inspection report will be submitted to the IACUC for review/approval and will be included in the semi-annual report to the Institutional Official (IO).

The animal facility manager will be notified by IACUC staff to schedule inspections. However, some inspections may be conducted “unannounced”, in which case the managers will not be notified of the inspection.

The inspection will be conducted using the OLAW Facility Inspection Checklist and the standards set forth in the *Guide for the Care and Use of Laboratory Animals*, *Guidelines for the Use of Fishes in Research*, *Guidelines for Use of Live Amphibians and Reptiles in Field and Laboratory Research* and Florida Fish and Wildlife regulations. A quick reference guide, which includes the areas the IACUC is inspecting, may also be sent to the facility managers prior to a scheduled inspection. Examples of inspected areas include documentation (training, daily logs, protocols, SOPs, animal contact, permits, etc.), personal protection methods, animal housing, space requirements, environment (temperature, ventilation, illumination, noise, etc.), behavioral management, food/water availability, sanitation, emergency/holiday/weekend care, population management, and veterinary care.

Deficiencies will be characterized as either minor or significant*, and correction plans will be discussed with the appropriate personnel in charge of the facility. A report describing each observation/deficiency, including required correction dates, will be sent to the manager. The report will also include the required response due dates for any deficiency noted. The manager must respond by the due date and list the reasons for the deficiencies occurred and provide a corrective action plan for each deficiency. It is the responsibility of the manager to ensure that all deficiencies identified during the inspection are corrected.

The IACUC and the IO will be notified of all significant deficiencies and take appropriate actions, as needed. Any deficiency that is not corrected by the specified date will be reviewed by the IACUC, and necessary action will be determined on a case-by-case basis.

The completed inspection report will be submitted for review and approval by the IACUC. The manager will be provided access to the IACUC approved inspection report. A final copy of the report will be included in the Semi-Annual Program Evaluation to OLAW.



* Nearly identical definitions of a **significant deficiency** are found in the *USDA AWA Regulations and PHS Policy*. The two definitions are below:

- USDA Animal Welfare Act Regulations, 9 CFR Part 2, Subpart C, Section 2.31, par. (c)(3): “A **significant deficiency** is one which, with reference to Subchapter A, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals.”
- Public Health Service Policy on Humane Care and Use of Laboratory Animals, IV. Implementation by Institutions, paragraph B.3: “...A **significant deficiency** is one which, consistent with this Policy, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule for correcting each deficiency...”

References

- Public Health Service Policy IV. B. 1-3
USDA CFR 9. 2.31(c) (1-3)

Approved by the IACUC 17 December 2015

Author(s): S. Emer, C. Bashur



TITLE: Protocol Non-compliance

Purpose: This procedure establishes guidelines for addressing instances of regulatory or procedure non-compliance by all individuals at FIT who are engaged in the care or use of animals for teaching, research, or outreach. Such noncompliance issues would include, but not be limited to: conducting research with animals without an approved protocol in place; violation of the methodologies, procedures, numbers, and conditions of the approved protocol; violation of requirements of the Public Health Service Policy on Humane Care and Use of Laboratory Animals; disregard of instructions of an attending veterinarian; or violation of FIT IACUC procedures. Documentation of the source of authority for these activities is found in the References.

PROCEDURE:

1. FIT upholds the fundamental principle that using animals is a privilege and not a right. As per the 8th edition of the NRC Guide for the Care and Use of Laboratory Animals (2011), using animals is a privilege granted by society to the research community with the expectation that such use will provide either significant new knowledge or lead to improvement in human and/or animal well-being.
2. It is recognized that isolated instances of noncompliance can occur as the result of simple and minor error with no intent to circumvent applicable requirements. As such, IACUCs have the discretion to determine that a full investigative process and formal corrective measures are not required in particular circumstances. Thus, this procedure is not intended to eliminate the ability of an investigator to immediately correct a simple and minor oversight or error in conjunction with the pertinent IACUC. Rather, this procedure is intended to address a serious compliance issue that, in the determination of an IACUC and in specific cases the Institutional Official (IO), go beyond a simple and minor oversight. It is important to note that all protocol errors regardless of magnitude must be self-reported as soon as they are identified (see point 4 below for information regarding to whom reports must be made), even though no formal investigation or corrective measures by the IACUC may be deemed appropriate.
3. An allegation of noncompliance is typically reviewed and resolved by the IACUC. In exceptional instances relative to animal welfare, an allegation of noncompliance may be reviewed and resolved by the IO.
4. When an incident of noncompliance becomes suspected or known, it shall be reported to the Chair of the IACUC or the Animal Program Compliance Officer. Instances of suspected noncompliance may alternatively be reported to the veterinarian, the Principal Investigator, or a Facility Manager, who in turn will inform the Chair or Compliance Officer. Instances of suspected noncompliance may also be reported as provided in the Whistleblower Procedure. If the noncompliance issue presents a potential immediate animal health or welfare risk, the Attending Veterinarian must be immediately contacted in order to assess the situation and take any action determined to be appropriate to alleviate risk to the animals.



5. The IACUC Chair will advise the individual(s) involved that an instance of noncompliance has been alleged, as provided by Standard Operating Procedures for Suspension or Termination and Reinstatement of Animal Use Privileges and/or Protocols. The Chair will also promptly inform the IO, and the Attending Veterinarian of the alleged instance of noncompliance.
6. The IO possesses independent authority to investigate alleged instances of noncompliance relative to animal welfare and to implement corrective measures (including imposing additional corrective measures to those imposed by the IACUC), if in his/her judgment the IACUC has not sufficiently investigated or addressed the instance of noncompliance or the allegation involves a matter of critical importance to FIT's animal care and use program. However, in no event may the IO weaken any corrective measure imposed by the IACUC.
7. The investigation of an allegation of noncompliance and the imposition of any corrective measures by an IACUC or in cases related to animal welfare by the IO, and the process for seeking reconsideration of the findings of an investigation and any corrective measures imposed, shall be in accordance with the pertinent Standard Operating Procedures for Suspension or Termination and Reinstatement of Animal Use Privileges and/or Protocols or Standard Operating Procedures for Suspension or Termination and Reinstatement of Animal Use Privileges by the IO. The noncompliance must be corrected within 7 days of notification from the IACUC.
8. All IACUC actions regarding allegations of noncompliance will be reported to the Animal Compliance Officer and the IO by the IACUC Chair or designee.

References:

The following summarization is intended to provide the IACUCs and the IO with a synopsis of the sources which provide the committee and/or the IO with the authority to suspend or terminate animal use and related activities.

Relevant Authority: Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) charge IACUCs with the responsibility and authority to:

- Review, and, if warranted, investigate concerns involving the care and use of animals at the research facility resulting from public complaints received and from reports of noncompliance received from laboratory or research facility personnel or employees. PHS Policy sec. IV.B.4.
- Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities. PHS Policy sec. IV.B.7.
- Suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the approved protocol, the Guide for the Care and Use of Laboratory Animals, the institution's PHS Assurance, or the PHS Policy. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present. PHS Policy ss. IV.B.8, IV.C.6.

The PHS Policy further provides that:



- 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 any Federal agency funding that activity. PHS Policy sec. IV.C.7.
- The IACUC shall notify principal investigators in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval. If the IACUC decides to withhold approval of an activity, it shall include in its written notification a statement of the reasons for its decision and give the principal investigator an opportunity to respond in person or in writing. PHS Policy sec. IV.C.4.
- Proposed activities and proposed significant changes in ongoing activities that have been approved by the IACUC may be subject to further appropriate review and approval by officials of the research facility. However, those officials may not approve an activity involving the care and use of animals if it has not been approved by the IACUC. PHS Policy IV.C.8.

Further amplifying PHS Policy are various federal and university guides and policies. These include:

- The Guide for the Care and Use of Laboratory Animals, 8th Edition, which confirms that using animals in research is a privilege granted by society to the research community. The Guide is formally established as IACUC research procedure by FIT.

Approved by the IACUC 29 June 2015

Author(s): S. Emer, C. Bashur



TITLE: Suspension or Termination and Reinstatement of Animal Use Privileges and/or Protocols by the IACUC

Purpose: FIT considers the humane and ethical use of animals in research, teaching, and outreach activities a privilege, not a right. This privilege is extended to faculty, scientists, students, and staff when a PI obtains approval of a protocol by the FIT IACUC. A PI maintains this privilege by adhering to all relevant animal program rules and requirements and by demonstrating a continuous commitment to animal welfare. The USDA Animal Welfare Act Regulations and the Public Health Service Policy on the Humane Care and Use of Laboratory Animals empower IACUCs to protect animals and institutional principles of ethical animal use by suspending or terminating an individual's privilege to use live, vertebrate animals. Documentation of the source of authority for these activities is found in Appendix 1. Suspension or termination of animal activities and/or protocols are infrequent but significant events. The following are guidelines regarding IACUC activity leading to, and following, suspension or termination.

Definitions:

1. **Suspension of previously approved animal use privileges:** An action initiated by the attending veterinarian or IACUC to temporarily stop specified animal activities pending future review and action by the IACUC.
2. **Suspension of a previously approved protocol for cause:** An action initiated by the attending veterinarian or IACUC to temporarily stop some or all protocol-related animal activities pending future review and action by the IACUC.
3. **Termination of previously approved animal use privileges:** An action initiated by the attending veterinarian or IACUC to permanently stop specified animal activities based on a review of the facts and majority vote by the IACUC.
4. **Termination of a previously approved protocol for cause:** An action initiated by the attending veterinarian or IACUC to permanently stop some or all protocol-related animal activities based on a review of the facts and majority vote by the IACUC.
5. **Transfer of animals to husbandry protocols:** Animals assigned to a suspended or terminated protocol must be reassigned immediately to the holding protocol maintained by the academic unit in which the animals are housed or to another IACUC-approved protocol. If corrective actions are made within 7 days of notification of noncompliance, associated animals may be retained without transfer to the holding protocol with IACUC approval. Failure to correct noncompliance within 7 days of notification will result in the transfer of animals to the holding protocol.
6. References to communications made in writing are understood to include email correspondence.

PROCEDURE:

When considering suspension or termination:

1. IACUC closed session discussion regarding alleged inappropriate behavior or noncompliance by a PI/student/staff/instructor (the "individual concerned") will be held within 7 days from the date of allegation and will begin with a description of the alleged infraction(s). If possible, the



individual concerned should be allowed to address the committee during the discussion, although immediate animal welfare concerns must take precedence. It may be prudent to call the University's Office of Human Resources and request that a representative from OHR be present for the IACUC's discussion.

2. If the IACUC believes that an infraction has occurred, it may develop a motion to suspend or terminate animal use privileges and/or a protocol. The motion should cite specific grounds for the action and conditions under which suspended or terminated privileges and/or protocols might be reinstated. It also must include the time at which the action takes effect and the duration of the action if applicable. The motion should be read to the IACUC prior to a vote.
3. During discussion of protocol suspension or termination, IACUC members are directed to consider the following:
 - a. The disposition of animals assigned to that protocol, in the case of protocol suspension.
 - b. Whether the protocol can be assigned to a different PI in good standing, in the case of revocation of privileges.
 - c. Conditions under which individuals associated with the protocol but not under investigation could continue animal work, in the case of termination of animal use privileges.
4. All discussion must be documented in approved IACUC minutes.

Following a vote to suspend or terminate animal use privileges and/or a protocol:

1. IACUC action, including grounds for that action and any conditions for reinstatement, must be described in an official letter from the IACUC Chair to the individual concerned. A copy of the letter will be sent to the relevant supervisor (e.g. PI and/or Department Chair), Dean, and IO.
2. As required by law or regulation, OLAW, USDA, or other agency must be notified of the action taken.
3. Requests for clarification or reconsideration of the action from the individual concerned must be made in writing to the IACUC Chair. The individual concerned may ask to address the committee in person, in which case this item will be added to the agenda for the next IACUC meeting's closed session.
4. If a PI's animal use privileges are suspended, the PI's protocol could be maintained by identification of a replacement PI. This action requires a protocol amendment and IACUC consideration and approval.
5. If a protocol is suspended, its animals must be reassigned (such as to an appropriate holding protocol or another PI's protocol) or euthanized. The IACUC Chair and Attending Veterinarian will consult with animal program staff to identify appropriate assignment.

Reinstatement of animal use privileges and protocols:

1. The individual concerned must request reinstatement in writing to the IACUC Chair. He/she must provide written evidence that all requirements for reinstatement have been met. The individual concerned also must provide a written plan that describes how the activities that led to the suspension or termination will not be repeated. The committee must respond to the request at the next IACUC meeting.
2. A motion to reinstate suspended or terminated privileges and/or protocols, which should include additional IACUC recommendations such as extended oversight, must be made by a



voting member of the IACUC. The reinstatement motion must include the time at which the reinstatement takes effect. The motion should be read to the IACUC prior to a vote. The motion, discussion, and vote must be documented in approved minutes.

Appendix 1

The following summarization is intended to provide the Animal Care and Use Committees (ACUCs) with a synopsis of the sources which provide the committee with the authority to suspend or terminate the animal use related activities covered in this SOP.

Relevant Authorities: The USDA Animal Welfare Act Regulations (AWARs) and the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) charge Institutional Animal Care and Use Committees (IACUCs) with the responsibility and authority to:

- Suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the approved protocol, the AWARs, the Guide for the Care and Use of Laboratory Animals, the institution's PHS Assurance, or the PHS Policy. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present. AWAR ss. 2.31(c)(6) and (d)(6); PHS Policy ss. IV.B.8., IV.C.6.
- Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes in an approved protocol regarding the care and use of animals in ongoing activities. AWAR sec. 2.31(c)(7); PHS Policy sec. IV.B.7.
- Review, and, if warranted, investigate concerns involving the care and use of animals in teaching, research or outreach resulting from public complaints received and from reports of noncompliance received from laboratory or research facility personnel or employees. AWAR sec. 2.31(c)(4); PHS Policy sec. IV.B.4.

The AWARs and PHS Policy further provide that:

1. An institution's attending veterinarian shall have appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and to suspend an activity utilizing animals immediately based on analysis of the situation. AWAR sec. 2.33(a)(2).
2. If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to APHIS and any Federal agency funding that activity. AWAR sec. 2.31(c)(7); PHS Policy sec. IV.C.7.
3. The IACUC shall notify principal investigators in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval. If the IACUC decides to withhold approval of an activity, it shall include in its written notification a statement of the reasons for its decision and give the principal investigator an opportunity to respond in person or in writing. AWAR sec. 2.31(d)(4); PHS Policy IV.C.4.
4. The IACUC may reconsider its decision, with documentation in Committee minutes, in light of the information provided by the principal investigator. AWAR sec. 2.31(d)(4).
5. Proposed activities and proposed significant changes in ongoing activities that have been approved by the IACUC may be subject to further appropriate review and approval by officials of the research facility. However, those officials may not approve an activity involving the care and use of animals if it has not been approved by the IACUC. AWAR sec. 2.31(c)(8); PHS Policy IV.C.8.

Further amplifying and clarifying the AWARs and PHS Policy is the federal and university guides and policies. This includes: The Guide for the Care and Use of Laboratory Animals, 8th Edition, which confirms that using animals in research is a privilege granted by society to the research community.

Approved by the IACUC 29 July 2015

Author(s): S. Emer, C. Bashur



TITLE: Suspension or Termination and Reinstatement of Activities Using Animals by the Institutional Official (IO)

Purpose: The USDA Animal Welfare Act Regulations (AWARs) and the Public Health Service Policy on the Humane Care and Use of Laboratory Animals (PHS Policy) define the role of the Institutional Official (IO) as the individual who is authorized to commit on behalf of the research facility that animal welfare regulations will be met. The AWARs and PHS Policy do not preclude any IO or institutional sanctions. Therefore, although action to suspend or terminate activities will normally be handled by the IACUC, the IO also has the authority to suspend activities using animals (see definition below). Documentation of the source of authority for these activities is found in the Appendix.

Suspension or termination of activities using animals

It is the expectation that at such time that the IO considers taking action to suspend or terminate activities using animals, or impose sanctions to address misconduct that does not affect animal welfare but those sanctions will impact activities using animals, the IO will follow this Procedure to ensure animals are protected and all matters of due process are honored, including defining a path to reinstatement of activities using animals. This document is designed to facilitate implementation of Non-Compliance procedures.

Definitions:

1. Activities using animals are understood to mean any circumstance in which an animal is handled, manipulated, maintained, or observed directly or indirectly within the FIT animal program as described in an IACUC-approved protocol, Standard Operating Procedure, or veterinary standard for the purposes of research, teaching, or outreach. These activities can be a specific manipulation(s) in a protocol, all manipulations in a protocol (the entire protocol), or an individual's overall ability to work with animals in any capacity (privilege to use animals).
2. Attending Veterinarian (AV): The veterinarian employed by FIT.
3. Suspension of activities using animals: An action to stop temporarily specified activities using animals. Such action may be taken by the IACUC, AV, or IO.
4. Termination of activities using animals: An action to stop permanently specified activities using animals taken by the IO in his/her institutional role. The IACUC may take action to terminate activities with animals. The AV cannot independently take action to terminate activities using animals.
5. References to communications made in writing are understood to include email correspondence.

PROCEDURE: When considering suspension or termination:

1. Discussions regarding alleged inappropriate behavior or non-compliance by a principal investigator/student/staff/instructor (the "individual concerned") must be in consultation with the IACUC.
2. Such discussions should begin with a description of the alleged infraction(s). The individual concerned should be solicited for information, however, immediate animal welfare concerns and institutional integrity must be priorities.



3. If the IO believes there is reason to suspend or terminate activities using animals, the following should be considered and planned for with input from the AV and IACUC prior to action:

- a. The disposition of animals assigned to protocols, in cases of suspension or termination of all activities using animals (e.g., an entire protocol or protocols).
- b. If there are students who could be disadvantaged by such action.
- c. Whether the protocol can be assigned to a different PI that is in good standing, in the case when suspended or terminated activities using animals includes the removal of an individual's ability to use animals in any capacity, rendering that individual ineligible to be PI on a protocol.
- d. Conditions under which individuals associated with protocol(s) but not under investigation could continue animal work, in the case of suspension or termination of all activities using animals (e.g., an entire protocol or protocols).
- e. Effective date and duration of the suspension of privileges.
- f. Terms of reinstatement of activities using animals if applicable.

4. All discussion must be documented.

Following IO action to suspend or terminate activities using animals:

Action to suspend or terminate, including grounds for that action and any conditions for reinstatement of activities using animals as decided in conjunction with the IACUC, must be described in an official letter from the IO to the individual(s) concerned. The IO may draw from any institutional resources available to facilitate reinstatement to ensure animals are protected and all matters of due process are honored. Reinstatement of activities using animals must be coordinated with and facilitated by the IACUC.

Approved by the IACUC 14 July 2015; Author(s): S. Emer, C. Bashur

Appendix

Relevant Authorities: The USDA Animal Welfare Act Regulations (AWARs) and the Public Health Service Policy on the Humane Care and Use of Laboratory Animals (PHS Policy) charge the Institutional Official (IO) with the responsibility and authority to:

1. Legally commit on behalf of the research facility that animal welfare regulations will be met. AWAR sec. 1.1.
2. Sign, and have authority to sign the institution's Assurance, making a commitment on behalf of the institution that the requirements of the PHS policy will be met. PHS Policy sec. III.G.
3. Receive recommendations from the Institutional Animal Care and Use Committee (IACUC) regarding any aspect of the research facility's animal program, facilities, or personnel training. AWAR sec.2.31(c)(5); PHS Policy IV.B.4.
4. Review the reasons for suspension, take appropriate corrective action in consultation with the IACUC, and report the suspension and corrective action to appropriate federal agencies, when the IACUC suspends an activity involving animals. AWAR sec. 2.31(c)(7); PHS Policy sec. IV.B.7.
5. Subject activities approved by the IACUC to further review and approval. AWAR sec. 2.31(c)(8); PHS Policy sec. IV.B.8. Further amplifying and clarifying the AWARs and PHS Policy are various federal and university guides and policies. These include: The Guide for the Care and Use of Laboratory Animals, 8th Edition, which confirms that using animals in research is a privilege granted by society to the research community. The adoption of the Guide as standard is an established FIT IACUC procedure.



TITLE: Animal Holding Protocol

Purpose: Federal regulations require the IACUC to review and approve all activities involving the use of live vertebrate animals; all animals intended for use in research, testing, and teaching or for related purposes must be housed under an active and approved IACUC protocol at all times. Occasionally, situations occur where protocols become inactive (e.g., protocol expiration, suspension, termination; permit expiration), but animals remain in the institutional animal facilities. In order to avoid euthanasia of valuable research animals, and to remain in compliance with regulatory requirements, the IACUC allows transfer of animals to the so-called Holding Protocol for a maximum of 30 days.

PROCEDURE: During the 30 days, investigators must take the necessary actions to gain re-approval of their Animal Use Protocol in order to avoid forfeiture of their animals. The IACUC will consider other circumstances for the housing animals on the Holding Protocol on a case-by-case basis (e.g., transfer of new FIT faculty from other institutions). Requests to use the Holding Protocol must be reviewed by the Animal Program Compliance Officer and routed to the IACUC for final approval.

While animals are housed on the Holding Protocol, the following conditions apply:

Housing Only: The use of the Holding Protocol is limited to animal housing. No experimental manipulations or harvest of tissue are allowed.

Restricted Access: Animals housed under the Holding Protocol are completely off limits to investigators. The IACUC notifies the Primary Investigator and all research personnel on the protocol (via e-mail) when animals are transferred to the Holding Protocol. Any use of animals housed under the Holding Protocol will be treated as serious regulatory non-compliance.

Cage/tank Labeling: Animal cage cards are clearly marked with a Holding Protocol number.

Animal Care: Animal facility managers and their assistants will assume responsibility for the animals and will provide routine husbandry and veterinary care as needed. *NOTE: Federal funds (e.g. NSF grant funds) may not be used to pay for costs associated with animal research in the absence of an approved IACUC protocol.*

Animal Welfare: Medical treatment and/or euthanasia will be performed by, and at the discretion of, animal facility managers, Animal Compliance Officer, and the attending veterinarian.

Reinstatement: When protocols are reinstated or approved, animals will be transferred from the Holding Protocol to the approved protocol.

30 Day Limit: At the end of 1 month, the IACUC in consultation with the Institutional Official (IO) will determine the disposition of the animals. Animals remaining at the end of 30 days will be euthanized, made available for approved adoption, or transferred to another approved protocol unless an extension is granted. When applicable, failure to correct noncompliance at the end of the 30 days will result in protocol termination.

Approved by the IACUC 29 June 2015 Author(s): S. Emer, C. Bashur



TITLE: Collaborative Research Projects, Sub-grants, and Subcontracts Taking Place at Non-FIT Facilities

Purpose: Prior to use of animals by FIT faculty or staff in teaching, research, or outreach, an approved protocol must be in place. This includes animal-based teaching, research, and outreach occurring at facilities not owned or controlled by FIT. This procedure covers such use in 2 instances: when the work is supported by funds administered through FIT and/or when the FIT investigator(s) will utilize their affiliation with the University in publications and presentations. This procedure further defines the responsibilities of investigators in these instances and outlines the options and obligations of the IACUC. Because the animal program at another institution is beyond the direct control of FIT, it is imperative that animal-based teaching, research, and outreach only be conducted at well-managed locations that comply with applicable regulatory requirements.

PROCEDURE:

1. Any FIT investigator conducting collaborative animal-based teaching, research, and outreach and/or entering into sub-grants or subcontracts at facilities not owned or controlled by FIT must have an IACUC-approved protocol from the institution where the animal work occurs. Once approval is granted, the investigator must provide a copy of 1) an approval letter from that institution's IACUC to the Office of Sponsored Programs (OSP) and 2) the approved protocol to the FIT IACUC. Principal Investigators are responsible for reporting any change in approval status to OSP.
2. While federal regulatory agencies do not require duplicative review by both institutions, FIT will not relinquish its right to review any animal use protocol. Determination of the need for duplicative review shall be made by the IACUC using established FIT protocol review processes.
3. If the research, teaching, or outreach involves animals covered under the Animal Welfare Act (USDA), the non-FIT facility must provide evidence that it is registered as a "Research Facility" with the USDA. If PHS funding supports the activity, the non-FIT facility must provide evidence to the FIT Investigator of current PHS Assurance. Research, teaching, or outreach using live vertebrate animals at non-USDA registered or non-PHS assured institutions will adhere to OLAW's guidance and will be reviewed by FIT institutional representatives on a case-by-case basis.
4. If an investigator conducts collaborative animal-based teaching, research, and outreach at both FIT and non-FIT facilities and the activity for both locations is described in the other institution's protocol, the IACUC may, at their discretion, accept the other institution's protocol for their review.

An approved Animal Care and Use Protocol shall be required for any research involving University faculty, staff, students, or funding that utilizes privately owned animals and that involves practices beyond those associated with normal husbandry. Inspection of privately owned animal facilities may or may not be required as determined by the IACUC.

Approved by the IACUC 14 July 2015

Author(s): S. Emer, C. Bashur



TITLE: Whistle Blower Procedure and Posting

Purpose: FIT encourages the reporting of concerns related to animal welfare. This procedure provides the mechanism to report concerns regarding animal welfare, and provides assurance that persons may express those concerns.

PROCEDURE: Any individual who has concerns related to the use of animals in teaching, research, or outreach at FIT may express those concerns without fear of reprisal. To that end, FIT will not tolerate any reprisal against an individual who has come forward with concerns or allegations of wrong-doing involving the care and use of animals. Any such reprisal is prohibited by state law and University procedure, and perpetrators are subject to sanctions.

This procedure provides 3 separate avenues for individuals to express concerns relating to the use of animals in teaching, research, or outreach.

1. Any individual may report concerns anonymously to the Environmental and Regulatory Compliance Office (321-674-8493).
2. Any individual may report concerns to persons with authority over FIT's animal care and use program, which includes the chair of the IACUC, the Animal Compliance Officer, the Attending Veterinarian, and the University's Institutional Official.
3. FIT employees may report concerns under the procedures of the Florida Whistleblower's Act. In order to receive legal protection against reprisal by the Florida Whistleblower's Act, employees should direct their concerns in writing to anyone in their supervisory chain of command for animal care and use purposes before disclosing the concerns to anyone other than their attorney, collective bargaining representative, or legislator. The supervisory chain of command for animal care and use purposes includes their immediate supervisor, their Dean's or Director's Office, or any of the persons with authority over the FIT animal care and use program listed above. Employees who feel that a personnel action has been taken against them in reprisal for reporting a potential violation of animal care and use requirements should contact their supervisor, their Dean's or Director's Office, the chair of the IACUC, the Animal Compliance Officer, or the University's Institutional Official. The contact should be made within sixty (60) days of the personnel action in order to receive protection under the Whistleblower's Act.

Each facility is responsible for posting this procedure in sufficient numbers and locations to assure employees' awareness. Facilities wishing to modify the posting to include additional College/School contacts may do so as long as, at a minimum, the following are included (see example below):

- Chair of the IACUC Committee
- Animal Program Compliance Officer

Approved by the IACUC 14 July 2015

Author(s): S. Emer, C. Bashur