TITLE: IACUC Oversight of Animal Activities

PURPOSE: To provide guidance on how different animal activities are overseen by the IACUC.

REVIEW/REVISIONS: Permanent amendment/revisions to this policy must be presented to the Institutional Animal Care and Use Committee (IACUC) for review before implementation, with the exception of updating internet URLs, if required. Continuing review of this policy by the IACUC will occur at least every three years.

EFFECTIVE DATE: 11/19/2012; Revised/Re-Approved: 12/10/2012, 11/9/2015, 2/8/2016, 9/12/2016, 8/14/2017, 1/8/2018

PERSON(S) RESPONSIBLE: IACUC Membership and Office, University Animal Care Veterinarians, everyone that interacts with animals

POLICY/PROCEDURES:

The IACUC expects that for all animal activities at the University of Arizona, animal welfare is a primary focus. In addition, the impact to human health must be considered when interacting with animals. However, not all animal activities are regulated in the same manner. Accordingly, this policy outlines different animal activity and the process by which the IACUC oversees these activities.

Full protocol:

A full protocol is required for any teaching, testing or research performed on animals at the University of Arizona. Any changes to the approved animal activities must be addressed by submitting a protocol amendment for review and approval before the new activity occurs. Full protocols are subject to the requirement for certification of participating personnel, semi-annual inspections, continuing review at years one and two for protocols following USDA regulations (species or funding) and de novo review after three years, among other requirements.

Abbreviated protocol:

Not all animal activities require a full protocol. If the animal activity falls under one of the categories listed below, only an abbreviated protocol is required. The individual responsible for the activity must submit the abbreviated protocol as the Principal Investigator (PI). The IACUC Office will review the abbreviated protocol to determine whether the activity falls into one of the categories listed below, or whether the activity must be submitted as a full protocol. The PI is responsible for notifying the IACUC Office if the animal activity changes in a substantive way. This type of protocol may require certification of participating personnel, depending on the activities performed. Abbreviated protocols may be reviewed by the IACUC for reapproval every three years.

General:

- Non-research, non-teaching or non-testing activities involving non-USDA regulated species (see below for definition), such as animals that participate in club activities (e.g., mascots, 4-H, FFA), sports, recreation (e.g., fish ponds or aquaria) or are service animals (Note 1)
  - Non-research, non-teaching or non-testing activities involving USDA regulated species may require a full protocol depending on the type of activity (Note 2)
Veterinary Care:
- Activities ordered and/or performed by the Attending Veterinarian or designee that involve only standard veterinary or emergency procedures necessary to ensure animal welfare (e.g., vaccinations, blood collection for serology for health status determination, animal holding, emergency surgery) (Note 3)

Food Products and Safety Laboratory:
- Activities that occur as part of the USDA inspected procedures at the Food Products and Safety Laboratory (Note 4)
  - Does not include any research, teaching or testing activities with live animals which may occur at this location

Wildlife:
- Activities where free-living wild vertebrates are subjected to field study or wildlife management activities, as described in the appropriate wildlife permit (Note 5), includes:
  - Observation and/or recording (video/sound)
  - Use of bait stations
  - Use of field vocalizations
  - Capture/handling/release with/without relocation
    - Handling includes identification (branding, tagging, tattooing, toe clipping), collection of blood by peripheral venipuncture, swabbing (e.g., skin, saliva), tissue biopsy, collection of hair/fur/feathers
    - Animals must be released < 12 hours of capture (USDA regulated species only)
  - Capture with humane euthanasia, including for collection of samples and/or museum specimens
- Activities involving specimens that can be collected without handling or otherwise interfering with an animal or its environment such as scat, discarded feathers, hair or fur (Note 5)
- Removal of nuisance wildlife under an AZGF permit (Notes 1, 2, 5)

Eggs:
- Activities with terrestrial vertebrate embryos before 80% of their mean incubation period. Note that if live animals are used to produce the eggs, the activity must be covered under an IACUC protocol (Note 6).
- Activities with aquatic vertebrate embryos before hatching. For zebrafish, this specifically refers to less than 3 days post-fertilization. Note that if live animals are used to produce the eggs, the activity must be covered under an IACUC protocol (Note 6).

No live animals:
- Research, teaching or testing activities involving carcasses, tissues, cells or fluids. Note that live animals may not be manipulated expressly for the purpose of obtaining the material (Note 7). Material can be obtained from:
  - An animal that is euthanized as part of another approved IACUC protocol
  - Another research institution
  - Commercial sources, including scientific suppliers, tissue or blood banks, supermarkets, abattoirs or the Food Products and Safety Laboratory
    - Does not include custom antibodies or other bio-products produced specifically for the investigator using live animals in any way
  - Samples used for diagnostic tests performed by private veterinarians or diagnostic laboratories
  - Salvaged animals (e.g., road kill, euthanized by private veterinarians or animal shelters)
    - Salvaged wildlife requires appropriate permits to be obtained by the PI
Exempt from an IACUC protocol:

Certain activities are always exempt from an IACUC protocol:

- Non-research, non-teaching or non-testing activities involving privately owned animals, where the activity is not an official University of Arizona activity, e.g., walking a dog across campus
- Activities involving retrieval or use of animal-related data from records
- Any activity involving invertebrate species
- Removal of vertebrate vermin

Definitions:

- **Animal**: Animal Welfare Act Regulation (AWAR) §1.1 defines an animals as “any live or dead dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or any other warm blooded animal, which is being used, or is intended for use for research, teaching, testing, experimentation, or exhibition purposes, or as a pet. With respect to a dog, the term means all dogs, including those used for hunting, security, or breeding purposes”. PHS Policy defines an animal as a “live, vertebrate animal”, and does not include unhatched eggs or dead animals.
- **Exhibitor**: Any person (public or private) exhibiting any animals, which were purchased in commerce or the intended distribution of which affects commerce, or will affect commerce, to the public for compensation. The definition excludes retail pet stores, horse and dog races, organizations sponsoring and all persons participating in State and county fairs, livestock shows, rodeos, field trials, coursing events, purebred dog and cat shows and any other fairs or exhibitions intended to advance agricultural arts and sciences.
- **Field studies**: AWAR §1.1 defines a field study as a “study conducted on free-living wild animals in their natural habitat”. However, this term excludes any study that involves an invasive procedure, harms, or materially alters the behavior of an animal under study.” Furthermore, AWAR §2.31,d,1 states that field studies are exempt from IACUC review. Note that “invasive procedure”, “harms”, or “materially alters” are undefined and an assessment of this must be made by the IACUC on a case-by-case basis.
- **Non-USDA regulated species**: AWAR does not cover “birds, rats of the genus Rattus, and mice of the genus Mus, bred for use in research; horses not used for research purposes; and other farm animals, such as, but not limited to, livestock or poultry used or intended for use as food or fiber, or livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber”. There is debate about the intent of the AWAR with respect to birds. As written, all birds are excluded, but the intent was to exclude only birds bred for research, instead of all birds. Cold-blooded animals, including lizards, snakes, turtles, fish, frogs or other amphibians, are also non-USDA regulated species.
- **Research facility**: As defined by AWAR §1.1, a research facility is any school (except elementary or secondary schools) or institution that uses or intends to use live animals in research, tests, or experiments, and that purchases or transports live animals, or receives funds for the purpose of carrying out research, tests, or experiments.

Notes:

1. The use of non-USDA regulated species is exempt under AWAR. In addition, the PHS Assurance for the University of Arizona only covers activities involving live vertebrate animals supported by PHS funds, which excludes most non-research and non-teaching activities.
2. Technically, institutions using USDA regulated species fall under the description of exhibitor. However, the University of Arizona is defined as a “research facility”, rather than licensed as an “exhibitor”. As such, one common interpretation is that non-research or non-teaching use of USDA-regulated species is not explicitly covered by AWAR at research facilities. However, the IACUC must review all uses of USDA-regulated species, including non-research
and non-teaching activities to ensure that these animals are cared for and used in a manner consistent with AWAR. Depending on the type and duration of the activity, the IACUC may exempt the activity from the protocol process.

3. Standard veterinary care, as performed by UAC veterinarians and staff, does not constitute research, teaching or testing. Rather, these activities are part of the animal care program, which is reviewed by the IACUC during the semi-annual program review.

4. USDA inspected activities at the Food Products and Safety Laboratory do not constitute research, teaching or testing. The animal activities that are part of the normal operations of the Food Products and Safety Laboratory are already under USDA regulation and inspection.

5. AWAR §2.31,d,1 states that field studies (defined above) are exempt from IACUC review. PHS-funded field studies are not exempt. However, the IACUC must review field studies to determine whether the proposed activities involve an invasive procedure or harm or materially alter the behavior of the animals under study. Appropriate permits are required for all activities involving wildlife. Guidance from the USDA has clarified the definition of field study/wildlife management.

6. AWAR does not regulate birds or cold-blood animals such as lizards, snakes or frogs. Therefore, there are no AWAR requirements for the IACUC to review the use of eggs from these species. OLAW has interpreted “live vertebrate animals” to apply to egg-laying vertebrate species only after hatching (ILAR News, 1991 33:68-70). Based on this interpretation, the same stage of development in fish is considered to be when the embryo has absorbed the yolk-sac or begins to forage on its own (ILAR Journal, 2003 44:286-294). Note that the IACUC has stipulated a cut-off of 80% of the mean incubation period for terrestrial vertebrate (bird) eggs to reduce the chance that the eggs will hatch before use. In addition, OLAW expects assured institutions to have policies and procedures in place that address the care or euthanasia of animals that hatch unexpectedly.

7. Although AWAR §1.1, §2.31 define regulated animals as “live or dead”, a “research facility” is defined as one using or intending to use only live animals and there is no reference to the use of dead animals. Therefore, the usual interpretation of AWAR §1.1 and §2.31 is that IACUC review is not required for activities involving dead animals. Similarly, only live animals are referenced in PHS Policy III,A. Therefore, PHS Policy does not require IACUC review and approval of the use of dead animals that are not specifically manipulated or euthanized for that activity. Also see: http://grants1.nih.gov/grants/olaw/references/lab97v26n3p21.htm.

PROVISOS:

All animal activities are subject to IACUC guidelines, policies and procedures, in addition to all regulations imposed by any local, state or federal agency (e.g., wildlife permits). If IACUC approval of a study is required by a regulatory or funding agency (including USDA or Hatch funded projects), a full protocol must be submitted.

The PI must ensure that all personnel are appropriately enrolled in the Medical Surveillance Program and ensure that they receive proper/adequate training appropriate to the scope and nature of the activities.

Abbreviated protocols may be subject to reevaluation by the IACUC for conditions including, but not limited to, changes in federal, state, local, or institutional policy and/or changes in funding source.

If the study activities change in any way, the IACUC must be immediately notified in writing of the changes. Continuing oversight by use of an abbreviated protocol will depend on the type of the new activities. If the activities no longer meet these criteria, a full protocol must be submitted to IACUC for review and approval before commencing any work.

JUSTIFICATION:

The University of Arizona is registered as an animal research facility with NIH and USDA. In addition, the University of Arizona is accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International
(AAALAC). The University of Arizona Animal Welfare Assurance (A3248-01-2015) states that “This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS and/or NSF.”