



A. PURPOSE

Explain regulatory definitions behind IACUC oversight, how to determine if an IACUC protocol is needed, and how it will be classified.

B. RESPONSIBILITY

The Animal Welfare Program office staff will assist PIs in determining the type of protocol that is needed (abbreviated or full) and its USDA designation (USDA-regulated or non-USDA). The IACUC, through its normal protocol review process and with guidance from the AWP, AV, and IACUC Chair, will make the final determination.

C. PROCEDURE

Full protocol:

A full protocol is required for most teaching, testing, or research performed on live, vertebrate 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, and *de novo* review after three years, and may be subject to other state and/or UArizona requirements or regulations. Most federally funded work requires a full protocol.

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 may be required. The individual responsible for the activity must submit the abbreviated protocol as the Principal Investigator (PI) or Co-I. The PI must meet University of Arizona RII PI eligibility requirements. The AWP 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. This type of protocol may require certification of participating personnel, depending on the activities performed.

If the study activities change in any way, the IACUC must be immediately notified in writing, via the AWP office, 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.

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, *de novo* review every three years, and/or changes in funding source.

Categories for abbreviated protocol:

- **Wildlife:**

NOTE: Activities that require capture and handling of live animals may require a full protocol, to allow for accurate descriptions, counts, oversight, and protections for animals and handlers. Capture with humane euthanasia may require a full protocol.

- Activities where free-living wild vertebrates are subjected to field study or wildlife management activities that do not require handling, as described in the appropriate wildlife permit, includes:



- Observation and/or recording (video/sound)
- Use of bait stations
- Use of field vocalizations
- 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.
- Removal of nuisance wildlife under an AZGF permit as part of standard field activity (IE incidental trapping and removal of non-target, nuisance species).
- **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 a full IACUC protocol.
 - 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 a full IACUC protocol.
- **Animals for display/exhibition purposes:**
 - University-owned animals that are part of a display or exhibition with no handling other than standard husbandry may need an abbreviated protocol
- **Privately/client-owned animals:**
 - Privately owned animals being used for research, teaching, testing, or demonstration by University of Arizona representatives may or may not fall within IACUC and/or USDA regulatory oversight, and may require an abbreviated or full protocol, depending on the reason for the activity.
 - Observation and measurement of privately owned animals participating in their normal activities generally requires an abbreviated protocol
 - Demonstrations of husbandry or veterinary practices (IE removing pests from pets, fitting collars) generally require an abbreviated protocol
 - The owner should be present and/or consent, in the form of an owner consent document, should be recorded for work with privately owned animals.
- **No live animals:**
 - Research, teaching or testing activities involving carcasses, tissues, cells, or fluids. Note that USDA-regulated, PHS, NSF, HHS, and/or NASA-funded work, **live animals may not be manipulated** expressly for the purpose of obtaining the material. 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. An organization producing custom antibodies for a PI must have or obtain a PHS assurance, or be included under the UA assurance via an Interinstitutional Assurance [IIA]. Reach out to the AWP office for additional guidance on covering custom antibodies.
 - 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)
- D. Salvaged wildlife requires appropriate permits to be obtained by the PI.

E. REFERENCES, MATERIALS, AND/OR ADDITIONAL INFORMATION



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 [D16-00159 (A-32487-01)] 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, HHS, NSF, and/or NASA.**”

University of Arizona Animal Welfare Program website:

- Links to IACUC documents and program information as well as regulatory resources:
<https://research.arizona.edu/compliance/IACUC>
 - [Resources for Animal Users](#): including links to regulatory agencies

Notes and Examples: Examples are not exhaustive. Contact the AWP office with questions regarding specific situations.

- **Non-USDA regulated species and animals:** AWAR does not cover “rats of the genus *Rattus*, and mice of the genus *Mus*, birds 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”. Cold-blooded animals, including lizards, snakes, turtles, fish, frogs, or other amphibians, are not regulated by the USDA.
 - For practical purposes, the IACUC may differentiate between a USDA-regulated species (IE any warm-blooded animal other than birds, *Rattus*, and *Mus*) and USDA-regulated animals covered by AWAR. Not every protocol falls under USDA regulation, even if it includes work with an otherwise USDA-regulated species. The UAC veterinarians and IACUC office staff will assist with this determination.
- **Eggs:** 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.
- **Privately owned vs University owned animals:**
 - Receiving extra blood or tissue from a veterinary examination at a private clinic, to be used as part of a PI’s research, is not regulated and an abbreviated protocol for University tracking purposes may be required. However, blood drawn specifically for the PI’s use, even if during a private veterinary examination, would require IACUC approval, and, depending on the species, would be USDA-regulated.
 - Veterinary examinations or procedures performed on privately-owned animals, as part of a veterinary clinical skills course, performed as standard veterinary care (e.g. spays and neuters performed for a shelter and used to instruct a course), require a protocol to allow for IACUC and University oversight. The protocol may be full or abbreviated, depending on activity and IACUC determination.



- A standing teaching herd owned by the University of Arizona, kept for the purpose of providing teaching subjects, requires a full protocol and, depending on the species, may be USDA-regulated.
- Privately owned rangeland herds being observed and wearing radio collars for tracking would require an abbreviated protocol. A University owned herd would generally require a full protocol as husbandry activities would be the responsibility of the University.
- **Field studies:** AWAR §2.31,d,1 states that field studies are exempt from IACUC review. **PHS-, NSF-, HHS-, and NASA-funded** field studies are not exempt. The University of Arizona requires at least an abbreviated protocol for field studies.
 - 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.
 - The PI is expected to provide the appropriate permits required for all activities involving wildlife.
- **UAC Veterinary Care:** 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. UAC has specific protocols for animals that may need to be held or transferred.
- **Food Products and Safety Lab (FPSL):** 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. The IACUC has an MOU in place with the FPSL regarding reporting of animal welfare concerns.

Definitions: The following terms are specifically defined by regulatory agencies, and those definitions play a part in AWP and IACUC determinations.

- **Animal:** “Animal” is defined slightly differently by Animal Welfare Act Regulation (AWAR) and PHS Policy. 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, NSF, HHS, and/or NASA** funds, which excludes most non-research and non-teaching activities.
 - **AWAR §1.1** defines an animal 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.

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/laba97v26n3p21.htm>

- **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.
 - 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 (for example, wildlife management) to ensure that these animals are cared for and used in a manner consistent with AWAR. Rarely, depending on the type and duration of the activity, the IACUC may exempt the activity from the protocol process.

- **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. The University of Arizona is considered a research facility.
- **Field Study:** 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.” 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. See also “**Wildlife**.” Specific guidance from the USDA has clarified the definition of field study/wildlife management and studies originally designated as a field study may be updated to USDA-regulated and require a full protocol.
 - Activities which require capture/handling/release with and/or without relocation may need a full protocol to capture all the activities and risks associated with working with wildlife.
 - Handling includes identification (branding, tagging, tattooing, toe clipping), collection of blood by peripheral venipuncture, swabbing (e.g., skin, saliva), tissue biopsy, direct collection of hair/fur/feathers



F. HISTORY

To be removed prior to publication.

Effective Date	Version #	Authors	Description
04/11/2022	000	IACUC	New document
3/13/2023	001	IACUC	Updates to birds
11/12/2024	002	IACUC	Updates to abbreviated protocols, privately owned animals, birds, custom antibodies