Guidance for Determining USDA "Field Study" Exemptions

Guidance from USDA

The USDA Animal Welfare Act (AWA) states that field studies are exempt from the USDA requirement for IACUC review (section 2.31. d.1). It 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" (section 1.1).

This AWA definition of field study is relatively general in that it does not define key words including "invasive," "harm," or "materially alter." Instead, the USDA allows individual IACUCs the latitude to define these terms and then use their definitions to determine whether a particular study qualifies as a USDA field study and, thus, would be exempt from reporting. The USDA may review the IACUC's rationale behind their determination of whether proposed work falls under the USDA definition of a field study. Therefore, these guidelines have been developed to provide the ASU IACUC rationale behind decisions of whether work performed in the field qualifies as a USDA field study.

Additionally, the *USDA APHIS Animal Care Inspection Guide* states that "[a]nimals euthanized, killed, or trapped, and collected, such as for study or museum samples, from their natural habitat via humane euthanasia" are not to be included on the USDA annual report. The Animal Welfare Act states "*Euthanasia* means the humane destruction of an animal accomplished by a method that produces rapid unconsciousness and subsequent death without evidence of pain or distress, or a method that utilizes anesthesia produced by an agent that causes painless loss of consciousness and subsequent death." Accordingly, both chemical agents and commercially available kill traps are considered euthanasia, and, therefore, the killing of animals in the field by these methods does not exempt a study from being considered a "field study" for USDA purposes. Furthermore, a rare accidental death that occurs during the use of live traps does not prohibit the study being classified as a field study.

ASU Definitions Pertaining to Field Studies

Invasive procedure: Any procedure, other than that associated with an approved euthanasia method, that exposes underlying tissues or enters a body cavity other than the mouth, nostrils, or a short distance into the rectum.

Harm: More than momentary pain or distress. Does not include confinement without injury in a live trap that allows the captured animal some free movement.

Materially altered behavior: Behavior that, upon the release of the animal, is functionally different than its pre-capture behavior beyond that which relates to the likelihood of the animal being captured again using the same trapping method (i.e., the development of trap avoidance or trap-happiness). "Functionally different" is defined in terms of reproductive and survival success.

Examples

Determination of whether proposed field work qualifies as a USDA field study is made on a case-by-case basis by the IACUC based on the above definitions. However, below are examples of procedures that would result in the proposed work being suitable or not for classification as a USDA field study.

A USDA field study may include the following procedures:

- Live-trapping animals in traps that are designed not to injure the animal and allow for some free movement
- Short-term handling of animals at the site of capture or a nearby field processing location
- Collection of external morphometric data
- Marking the external surface of the animal via hair clipping or visible marking techniques (e.g., Sharpie pen)
- Swabbing of the mouth, nostrils, or rectum
- Injection of sterile liquids or materials (e.g., transponder tags) that are not expected to materially alter an animal's activity or behavior
- Ear punching or clipping in rodents
- Blood collection through a needle or by way of a skin nick
- Attaching external bands or tags to limbs or ears
- Sedation or anesthesia used to immobilize an animal rather than to provide analgesia
- Euthanasia by inhalation, chemical injection, or commercially available kill trap

A USDA field study may **not** include any of the following procedures:

- Surgical procedures that expose underlying tissues
- Endoscopic procedures
- Stomach or colonic gavage
- Toe-clipping of a digit used for digging or climbing
- Delivery of chemicals (e.g., glucocorticoids, sex steroids) via injection, patch, or implant that may alter an animal's activity or behavior
- Transport of animals away from the area of capture beyond that required to get the animal to the field processing location.
- Release of an animal away from its site of capture
- Repeated disturbance during breeding and rearing of young
- Any other procedure that would reasonably be expected to cause more than slight or momentary pain or distress in a human being to which that procedure is applied

Non-research animal management programs

Animal, pest, and population management programs (e.g., culling, relocation, and non-surgical sterilization) for the purpose of limiting wildlife damage and human interaction are activities not

covered by the AWA if they are not performed for the purpose of research, teaching, testing, or experimentation.

Studies conducted in the wild outside the Unites States

In addition, field research, even if it includes invasive procedures, harm, or material alteration of behavior, that is conducted outside the United Sates is exempt from USDA reporting since it is not within the jurisdiction of the USDA.

ASU IACUC oversight of studies conducted in the wild

While field studies, as defined in the AWA, and foreign field research are exempt from USDA animal welfare regulations, AAALAC International makes no distinction between laboratory and field studies, and thus requires all research and teaching conducted by AAALAC-accredited institutions in the field, regardless of the location, to have some degree of IACUC oversight based on risk assessment, harm:benefit analysis, and hazard identification. Furthermore, the Office of Laboratory Animal Welfare (OLAW) requires IACUC review and approval if the fieldwork alters or influences the activity of the study animal, regardless of whether the animal is handled or where the work is being conducted.

Accordingly, independent of the determination of whether a study qualifies for a USDA exemption as a field study, any activity conducted in the wild regardless of location that requires the handling of a vertebrate animal or significantly disturbs their normal behavior must receive ASU IACUC approval prior to being conducted. Determination of whether a study will significantly disturb normal behavior is decided on a case-by-case basis by the IACUC Chair and Attending Veterinarian, who may seek guidance from subject experts within and outside ASU.

Thus, rather than influencing what field work requires IACUC review and approval, the USDA definition of field study mainly influences which free-ranging animals used in research and teaching need to be reported to the USDA.