## protocol review

# **Research Gone A-Fowl**

r. Thomas Lauke, Great Eastern University's (GEUs) field and wildlife researcher, received a National Science Foundation (NSF) grant to determine if guinea fowl can successfully survive as wild populations in various suburban areas. Guinea fowl are known for eating deer ticks and there are areas, such as in Maine, that have high rates of Lyme disease. The goal is to establish a wild population of guinea fowl to reduce the incidence of Lyme.

Lauke submitted the IACUC protocol and was asked to join an IACUC meeting to help the IACUC understand certain details of the project. Lauke described his research, including:

- 1. Guinea fowl would be purchased from a vendor and released into the wild to establish colonies (i.e., the animals would live, breed and hatch as wild animals).
- Because the birds start laying eggs in the spring (March/April), the birds would be released in late November so they can acclimate to the area.
- 3. Starting in May, keets will be captured on a weekly basis and a microchip will be subcutaneously implanted into

each animal, ensuring that the animals' movement and social structure can be recorded. T e keets will then be released back into the wild.

4. T e chip is meant to track the survival of the keets but it has limited capabilities; the birds will need to be recaptured every 6 months so the recorded data can be downloaded.

Ultimately the protocol was approved by the IACUC.

A year or so later, Lauke filed an amendment to increase the number of animals, indicating, as the justification,

## A WORD FROM OLAW AND USDA

## A Word from OLAW

Institutional Animal Care and Use Committees are tasked with a variety of responsibilities to ensure the welfare of animals used in research. Although this study was supported by the National Science Foundation, the requirements of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) and supplemental documents are applicable as established via Memorandum of Understanding1 with this agency. The birds in this scenario are live, vertebrate animals funded by an entity for which OLAW provides oversight. Further, the animal activities are subject to the PHS Policy because they influence the biology, behavior, and ecology of the study animals and other species, regardless of whether the study animals were hatched in captivity or in the wild. Not only do the proximate factors of the guinea fowl flock's welfare need to be considered but also the ultimate considerations of environmental impact. As noted, factors to evaluate include appropriate containment, shelter, predation, clean water supply, supplemental feed, investigator ability to locate and track the animals, and investigator surgical competence and successful application of this procedure. The ability to fulfill the aims of the research must be addressed considering the difficulties with recapture and whether the proposed amendments successfully address this issue. The increase in animals numbers should be justified in relation to achieving the study

aims and any potential impacts to the ecosystem. Purposeful or accidental release of non-native species has often resulted in negative environmental outcomes. Considering the variety of factors involved, the IACUC may invite consultants to assist in the review of complex issues<sup>2</sup>.

## A Word from USDA

In 2002, Congress limited the exclusion of birds from the Animal Welfare Act's definition of *animal* to only those birds bred for use in research<sup>3</sup>. By doing so, Congress explicitly placed birds not bred for research and not otherwise excluded from regulation under the protection of the AWA. Thus, wild birds used for research are generally regulated. In the Final Rule that established standards for birds, APHIS defined *bred for* 

use in research to mean an animal bred in captivity and used for research<sup>4</sup>. In this scenario, the birds bred in captivity and used for the research project are not regulated, while the wild-hatched offspring may be regulated depending on the activity. Field studies remain exempt from the AWA and AWR. In the AWR, field studies are defined as studies "conducted on free-living wild animals in their natural habitat," but "any study that involves an invasive procedure, harms, or materially alters the behavior of an animal under study" is excluded<sup>5</sup>. The IACUC must determine whether proposed activities are consistent with this definition and exempt from the AWR. To make this determination, IACUCs are encouraged

to refer to the Animal Care Tech Note Research with Free-Living Wild Animals in Their Natural Habitat and the Animal Welfare Act<sup>6</sup>. IACUCs may also consult the relevant scientific literature or guidelines from professional organizations<sup>7</sup>. If the IACUC determines the activities are invasive, harm, or materially alter the behavior of the birds, the activities, and thus the wild-hatched birds, are regulated

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## protocol review

a failure to recapture all the animals (and therefore collect data). The IACUC ended up reviewing the amendment via Full Committee Review due to concerns about Lauke's inability to recapture animals.

How would you and/or your IACUC handle this situation, considering, for example:

- 1. T e USDA Bird Rule
- 2. T e PHS Policy and US Government Principles

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## COMPLIANCE CONSIDERATIONS

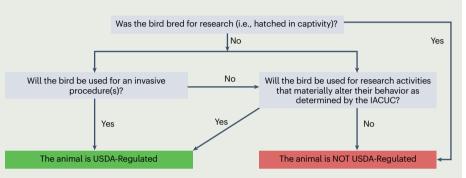
*The Protocol Review coordinators offer the following compliance considerations:* 

#### 1) Are the guinea fowl USDA-regulated?

In February 2023, the USDA released new welfare standards for birds (a.k.a. the new bird rule). Per the new regulation, birds that are hatched in captivity and used for research are not considered a regulated/ covered species. A simple flowchart (Fig. 1) can be used as a starting point to determine whether birds under a research registration are covered (note that the IACUC must still make the determination of whether activities qualify as a Field Study or require IACUC oversight and, then, to what degree).

In this scenario:

- T e original guinea fowl that were purchased from a vendor were hatched in captivity and not used for research; therefore, they are not USDA-regulated.
- T e ofs pring of these purchased animals were then hatched in the wild to establish a wild colony; these animals were not used in research and are thus not covered.
- However, the guinea fowl that were captured for tracker implant were not hatched in captivity and were used for research; therefore they are USDA-regulated.



**Fig. 1** A simple flowchart that can be used as a starting point to determine whether birds under a research registration are covered. Note that the IACUC must still make the determination of whether activities qualify as a Field Study or require IACUC oversight and, then, to what degree.

The PHS Policy and the *Guide* apply to all species when supported by PHS funds.

## 2) What about the failure to recapture?

There are no federal mandates specifically addressing the failure to recapture animals; however, the fundamental ethical obligation to ensure the humane and judicious use of animals dictates that IACUC re-review of the activities is needed to determine whether the research can (should) continue. Additional considerations include whether there are welfare concerns for the animals with embedded microchips that could not be recaptured. It is the authors' opinion that this scenario does not constitute non-compliance or "off-protocol work", but, rather, an unexpected challenge to the approved activities (i.e., not an adverse event or unexpected consequence) that requires IACUC consideration and, potentially, consultation with outside entities (e.g., local wildlife departments). Ultimately, it is up to the IACUC to determine how to proceed.

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## Foul Experiences

r. Thomas Lauke's NSF funded grant involves work with guinea fowl, a species native to Africa and considered poultry by the United States Department of Agriculture (USDA)<sup>1</sup>. All animal activities conducted under this grant are subject to the provisions of the PHS Policy<sup>2</sup>, and the Guide for the Care and Use

of Laboratory Animals (The *Guide*)<sup>3</sup>. Since the birds were bred in captivity and used for research, the USDA Bird Rule<sup>4</sup> does not apply.

Dr. Lauke has requested an increase in animal numbers from the Great Eastern University (GEU)'s IACUC due to a failure to recapture all the animals and to collect data. There are critical issues that GEU's IACUC needs to consider during the review. First, were the birds allowed to acclimatize to the local environment before being released? Second, how are the guinea fowl contained in the study area? Are they protected from depredation, diseases, and adverse weather conditions? Is shelter provided? Are they on GEU property, public (federal, state, local), or private property? How easily can the researchers access the area to observe the birds? Third, are the birds checked according to the Guide; if not, what is the frequency and why? How is routine monitoring of the birds accomplished? Any technological issue affecting tracking of the birds needs to be addressed. Fourth, keets tend to have low survival rates in the wild. Was this a factor in the failure to capture that the Principal Investigator did not envisage? Is it possible that some keets did not survive, and therefore could not be caught? Regardless, the cause of any losses needs to be resolved. Fifth, guinea fowl while considered poultry<sup>1</sup>, are a non-native species. Were other federal, state, and local government agencies contacted to confirm that guinea fowl can be released into a potentially non-confined area? Are all required permits in place? Sixth, why was the investigator unable to recapture the guinea fowl? Did the team

have the necessary skills to accomplish the task? How can the capture of these birds be improved without compromising their welfare? Seventh, the IACUC needs to revisit the chip implantation procedure to make sure there is no adverse impact on the keets and that they recover from it properly. Eighth, the IACUC must address the final disposition of the birds. What will happen to the birds when Lauke has completed the study? Final disposition was not mentioned in the scenario.

GEU's IACUC should thoroughly examine the issues raised above while reviewing Dr. Lauke's request, including adequate numbers justification, and revisit the previously approved procedures before making a final decision.

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