

How do you Zoo?

Dr. Thomas Lauke, a Great Eastern University (GEU) professor, has a National Science Foundation (NSF) grant to develop effective therapies to treat ectoparasites in elephants. Lauke contacted veterinarians who care for elephants at various zoos with Safari Parks across the USA. After he explained his research, they affirmed that they would be willing to assist as collaborators.

Lauke's research first required analysis of the quantity and type of ectoparasites present on the elephants' skin, which could be determined from five swabs taken at different locations on each elephant. The zoo veterinarians agreed to collect these samples during routine clinical exams (which occurred at least weekly) and send the swabs to Lauke. Further, although IACUC-approved protocols weren't required for clinical exams, each of the participating zoo had IACUC-approved standard operating procedures (SOPs) for the clinical activities, which clearly separated clinical care from research activities.

Even though each zoo agreed that the swabs were not invasive and were not considered field research, they all wanted a memorandum of Understanding (MOU) to ensure that the activities were considered by an IACUC and that the data would

only be used for Lauke's ectoparasite project.

Lauke called the GEU IACUC Chair, Dr. Crick, to determine if an approved IACUC protocol was needed for the samples collection. Crick arranged for Lauke to meet with the IACUC to discuss the matter. During the meeting, Lauke summarized his research and indicated that the swabs would be collected by colleague veterinarian and provided to him for analysis, and that he would not have any contact with the animals. Lauke explained the swabs would be collected non-invasively and that the collection process would not alter the behavior of any animals. He therefore concluded that the proposed activities would qualify as a field study and that IACUC oversight was unneeded. In fact, Lauke explained, the swabs would be collected under the IACUC-approved clinical care SOPs maintained at each zoo.

After Lauke completed his summary, Mrs. Maith Coinsias, the community member of the GEU IACUC expressed one primary concern. Coinsias said that since the swabs were being collected for research purposes,

they could not be collected under the zoos' clinical care protocols and could not be considered a field study. Lauke reminded the IACUC that IACUC-approved SOPs for the clinical activities were in place at the participating zoos and that each zoo agreed the samples could be collected by the zoo veterinarians. In addition, Lauke mentioned that samples collected would be considered a part of clinical care since it behooves the acting zoo veterinarians to know the types of ectoparasites that may be found on their Safari roaming elephants.

Should the GEU IACUC require an IACUC submission for the review and approval of the sample collections conducted by non-GEU personnel and covered under veterinarian clinical care? If not, does the GEU IACUC need to acquire supporting information from participating zoos?

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Compliance Considerations

The Protocol Review coordinators offer the following compliance considerations:

1. Can the swabs obtained for Dr. Lauke be considered clinical care?

The fact that the samples are collected “opportunistically”, i.e. during veterinary examinations that are required to maintain the health and wellbeing of the animals, does not make the sample collection part of the clinical care provided (even if the outcome is interesting to the zoo veterinarian). If, however, the zoo veterinarians collected skin swabs themselves, for their own analysis, and simply collected a few more for Dr. Lauke, then the swabs could be considered part of the clinical care of the elephants.

2. Do the samples collected, non-invasively, during routine clinical exams qualify as a field study?

While the sample collection process in and of itself meets the criteria to qualify as a field study, i.e. it is non-invasive and does not materially alter the behavior of the animals, the zoo elephants are captive animals, and the definition of a field study does not apply (e.g., their behavior is already materially altered by virtue of being in the zoo).

However, if the animals were in the wild, the IACUC must make the determination if activities qualify as a field study (possibly on a case-by-case basis), as has previously been established by GEU (i.e., the “USDA has explicitly placed the authority to make these decisions with the IACUC, as the subject matter experts.”^{1*})

3. Should the GEU IACUC require an IACUC submission for the review and approval of the sample collections conducted by non-GEU personnel and covered under veterinarian clinical care?

Yes; because the sample collection is a research activity, IACUC review and approval of the proposed activities involving vertebrate animals is required. That being said, the IACUC protocol is a conventional method of obtaining a description of proposed animal activities but need not be the only method. The method of information acquisition and dissemination is up to each individual institution.

4. Does the GEU IACUC need to acquire supporting information from participating zoos?

In this scenario, because the activities are considered research and IACUC review

and approval is required, it behooves the institution (as noted in the *Guide*) to execute a memorandum of understanding (MOU) to establish animal ownership, veterinary oversight, etc. GEU could require a contract or MOU of some sort to establish legal or financial responsibilities (e.g., liability, intellectual property), but this is outside of the scope of the IACUC.

*Note: “The Animal Welfare Act (AWA) and Animal Welfare Regulations (AWR) establish the legal standards facilities must follow. A Tech Note is not legally binding on the facilities; rather, it restates, summarizes and provides interpretative guidance on the law.”²

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2. USDA, APHIS (Tech Note, 2021) *Research Involving Free-living Wild Animals in Their Natural Habitat*. https://www.aphis.usda.gov/animal_welfare/downloads/tech-note-free-living-wild-animals.pdf

Do the right thing for the Elephants and require the PI to submit a protocol

According to the Animal Welfare Act (AWA), field studies are defined as: “any study conducted on free living animals in their natural habitat, which does not involve an invasive procedure and does not materially alter the behavior of the animal under study”¹.

According to this definition, the elephants in the Safari Parks are not free living in their natural habitat, so despite Dr. Lauke’s argument, this project fails to meet USDA criteria for a field study. Indeed, zoos and safari parks are animal exhibits that are overseen by the USDA. Although a skin swab is relatively non-invasive, it is not a routine part of a standard veterinary clinical exam as performed by the zoo veterinarians. Ms. Coinsias was spot-on when she pointed out that the skin swab is being collected for research purposes (we love our Great Eastern Community members). While the clinical care of the elephants may ultimately benefit from the identification of ectoparasites, these samples are

being collected specifically for Dr. Lauke’s project. This is where Great Eastern should draw the line. Both OLAW and USDA permit the use of excess tissue or blood without the need for a separate protocol, but only if animals are euthanized or blood drawn for purposes unrelated to the research project.

The Great Eastern IACUC should require Dr. Lauke to submit a protocol for the project. As this project is funded by NSF, a grant/protocol congruence verification will also be needed. The protocol should specify that these are not Great Eastern-owned animals and that their housing and care will be provided by their owners, and also that Dr. Lauke will not have any direct animal contact.

In addition to ensuring that the project is being performed in accordance with all regulatory requirements, Dr. Lauke will benefit from having an IACUC-approved protocol in place for the following additional reasons:

- It will facilitate the approval of the Memorandum of Understanding (MOU) with the collaborating zoos. Note that

the MOUs should also specify how the data will be used.

- The project will eventually include treatment of the animals for ectoparasites since development of effective therapies is the ultimate goal of the funded research project. Having an established protocol in place will ease the transition since the protocol can then be amended to add treatment of the animals.
- It will also facilitate the publication of this important study. Most journals now require a statement of IACUC approval for any manuscript including animal use.

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1. Title 9 CFR, Chapter 1, Subchapter A - Animal Welfare, Section 1.1.

A Word from OLAW and USDA

In this scenario, questions are asked about IACUC review and approval for data collected in the context of veterinary clinical care for an NSF-funded activity.

Response from OLAW

A researcher at Great Eastern University is using zoo animals for data collection for an NSF-funded project. The biological sampling and data collection is added to routine veterinary care and is performed by the zoo's clinical veterinarians. The NSF has a memorandum of understanding with OLAW that stipulates Animal Welfare Assurances for NSF-affiliated institutions¹. Therefore, the requirements of the PHS Policy apply to NSF-funded vertebrate animal use². Because the animals are held in captivity, cared for regularly by veterinary staff and are not living under field conditions, the activity cannot be considered a field study. The *Guide for the Care and Use of Laboratory Animals* describes field studies as use of non-domesticated vertebrate species living under natural conditions³. When data are collected for the advancement of animal or human health, the activity is considered research rather than veterinary patient care⁴. Such animals are subject to IACUC oversight⁵, even if housed in zoological collections at domestic or foreign locations⁶, and Assurances are required to cover the performance sites^{5,7}. The university should have written agreements with the participating zoos that address the responsibilities for animal

care and IACUC oversight^{3,8}. If the samples were routinely collected as part of the zoos' standard operating procedures, providing the samples to the Principal Investigator would not require Assurances for the performance sites or IACUC approval. In such a case, the sample collections would be listed on the grant application as not involving vertebrate animals.

Response from USDA

This scenario describes the intent of a university researcher to utilize data collected during routine examinations of animals kept at zoos and safari parks. Specifically, skin swabs taken from elephants by attending veterinarians at these facilities with the aim of developing effective ectoparasite treatments. The central question is whether or not IACUC approval and oversight is required for these activities, i.e., can this work be classified as a "field study"? As was well fleshed out by both Respondents and Drs. Danridge and Greer, the answer to that question is no. Animals maintained in captivity in a zoo or safari park are not "free-living wild animals in their natural habitat" and, therefore, this proposed activity does not meet the definition of a field study under the AWA regulations⁹. As such, IACUC approval and oversight of the protocol are required for this project.

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- Public Health Service Policy on Humane Care and Use of Laboratory Animals – Frequently Asked Questions. Applicability of the PHS Policy, Question No. A.7. *Does the IACUC need to approve research studies that use privately owned animals, such as pets?* (US Department of Health and Human Services, Bethesda, MD, USA). <https://olaw.nih.gov/faqs#/guidance/faqs?anchor=question50226>
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- 9 CFR, Chapter 1, Subchapter A, Part 1, § 1.1 – Definitions.

“Grey” areas of research in a Zoo setting

Research or Field Study: Is a protocol required or not?

This scenario discusses a few key topics commonly encountered in collaborative research with zoos that is typically non-invasive and could be deemed standard medical or management activities.

The community member of the GEU IACUC raises a good question about whether or not the sample collection can be considered a field study. The USDA defines a field study as “any study conducted on free-living wild animals in their natural habitat, which does not involve an invasive procedure, and which does not harm or materially alter the behavior of the animals under study.”¹ Because these animals are no longer free-living wild animals in their natural habitats, our institution would not consider this a true field study. We would require our IACUC to review the details surrounding the sample collection and animal handling procedures. To address this, we have created a blanket opportunistic sampling IACUC protocol that clearly outlines these procedures and functions as a standard operating procedure (SOP) for all sample collections to be used in research projects that are taken opportunistically during a routine veterinary or husbandry procedure.

The value of SOPs

Because the partners have these SOPs in place and can share them with the GEU IACUC,

these documents can be reviewed in place of an IACUC protocol. PHS policy states that the IACUC must review and approve activities on a project-specific basis, taking into account a number of factors, e.g., the aims of the study, consideration of alternatives, minimization of pain and distress². Reviewing the SOPs would satisfy that requirement.

Strengthen collaboration with a MOU

When working with collaborators at multiple locations in a scenario similar to this one proposed at GEU, it is also a best practice for institutions to define their respective responsibilities. Multi-institutional collaborations have the potential to create ambiguities. Memorandums of understanding (MOUs) can help clarify each party’s responsibilities for the various aspects of animal care and use associated with samples from zoo-owned animals being collected at partner zoos by non-GEU veterinarians².

Consideration for research funding sources

Another consideration to make is that this study is being funded by the NSF, so GEU’s IACUC must also make sure to adhere to the PHS policy on use of animals in research. According to PHS policy, the IACUC is responsible for oversight of vertebrate animal activities supported by

the PHS and those supported by NSF and Veterans Affairs (VA) in accord with PHS Policy³. If the IACUC determines that the proposed activity is likely to alter or influence the activity of the study animals or other species found in the study area, then protocol review and approval is required. However, if the IACUC determines that the proposed activity will not alter or influence the activity of the study animals, IACUC review and approval is not needed. Because the GEU IACUC has confirmed the sample collection will be non-invasive and not alter the behavior of the animals, this would not require IACUC review.

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2. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. (National Academies Press, Washington DC, 2011) p 15.
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