When does ‘animal involvement’ become ‘animal use’?

As a curious six year old child, Michelle Montfort found a deer tick climbing up her leg and asked her mother if she could keep it as a pet. Her mother screamed and removed the scurrying arthropod, but Montfort never lost her fascination with ticks. Now, as Dr. Michelle Montfort, an associate professor at Great Eastern University, she submitted a grant to the NIH for a tick-related study to be performed in collaboration with a large number of local private animal hospitals. The hospitals’ role in the study would be to remove attached ticks that were found during a general examination of privately owned pet dogs. The ticks would be placed in a preservative solution and Montfort would be informed that the ticks were ready for her study. The species of tick was immaterial as was the reason for the dog being brought to the hospital. The dogs were simply a convenient way for Montfort to gather ticks that had recently been attached to an animal.

In her previous research Montfort did not need an IACUC protocol because she gathered ticks by dragging a white sheet across grassy areas near the school. She used those ticks immediately after they were picked off the sheet. Therefore, when she was informed that her new grant application received a very favorable priority score, she was surprised that the school’s grants management office requested that she obtain IACUC approval before her potential funding could be finalized. She maintained that she wasn’t studying dogs at all; she was studying ticks and the veterinarians at the hospitals would have removed the ticks whether or not they were to be used for her research. But the grants office said that she mentioned the role of the dogs on the Vertebrate Animals Section of her grant application and she should have realized that she would need IACUC approval.

Who is right, Montfort or the grants management office? If IACUC approval is needed would the participating animal hospitals have to be inspected semiannually by the IACUC? What additional considerations might there be for Great Eastern University or the participating animal hospitals?

RESPONSE

The IACUC should not be involved

Sara Tobias Savage, DVM, DACLAM

Montfort is not using vertebrate animals in her research and does not have a regulatory requirement for IACUC review. Ticks are arachnid arthropods and therefore, under the PHS Policy on Humane Care and Use of Laboratory Animals, are not animals and are not subject to regulatory oversight. No animals are ‘used’ in this research, either directly as subjects or indirectly by being obtained for the purpose of this research. The Great Eastern University IACUC has no authority under the Animal Welfare Act regulations to oversee any activities related to the dogs from which the ticks are collected. Removal of the ticks is not a research procedure but rather an independent clinical procedure. Were the hospitals considered satellite facilities, where animals were brought in for research activities, then semiannual inspections would be required, as per the regulatory guidelines and definitions in the Guide for the Care and Use of Laboratory Animals, the PHS Policy on Humane Care and Use of Laboratory Animals, and the Animal Welfare Act regulations1–3. Given the scenario described, the research that Montfort carries out does not direct or influence the activities of the individual veterinary hospitals or the owners of the dogs from which ticks are collected. No methods are described for manipulating vertebrate animals, no description is given of the requirements of participating hospitals, and no remunerative methods are discussed. The collection of ticks is simply incidental to the examination of dogs at veterinary hospitals. Interestingly, the protocol does not indicate that the collecting hospitals communicate to the dog owners any information regarding disposition of the ticks after removal from their dogs. The ticks would presumably be discarded as trash—or, possibly, as medical waste, depending upon each individual hospital’s practice—if they were not being collected for Montfort’s research. Additionally, it is unclear what Montfort’s research actually involves: evaluation of only the ticks, or evaluation of materials ingested by the ticks. The latter represent canine clinical samples, whereas the former do not. While the IACUC should decline to review the protocol, as the IACUC has no authority to oversee this research, a strong argument could be made that there is an ethical obligation to inform the dog owners of the final disposition of the ticks collected. The scenario presented does not describe Montfort’s tick research in detail, but if testing is done to evaluate the status of the ticks as potential vectors of disease or to analyze the blood that the tick consumed, dog owners or hospital representatives might have questions about the information that such analyses could reveal about the health profile of their animals. Montfort and the participating hospitals should establish a method of communicating with owners and veterinarians, and should make a clear statement of understanding regarding the impacts of their research results. As research is not being carried out on human subjects, evaluation by the institutional review board of Great Eastern University is not necessarily required. Legal ownership of the canine blood samples gathered from the ticks is one issue, and legal ownership of the ticks themselves...
is another—outside the scope ofthis column, 
but still worth considering to avoid potential 
legal entanglement in the future. The grants 
management office may consider legal review 
by the Great Eastern University team to avoid 
potential future liability.

1. Public Health Service. Policy on Humane Care 
and Use of Laboratory Animals (US Department 
of Health and Human Services, Washington, DC, 
1986; revised 2015).
2. Animal Welfare Act regulations. CFR 9, Chapter 
1, Subchapter A.
3. Institute for Laboratory Animal Research. Guide 
for the Care and Use of Laboratory Animals 8th 
edn. (National Academies Press, Washington, 
DC, 2011).

Savage is the Attending Veterinarian and Head of In 
vertebrate Professional inclusion of invertebrates1. However, 
ventions, which specifically addresses this occa-
sion involving vertebrates, they can fall under the IACUC’s 
purview. AAALAC International has pub-
lished a webpage of frequently asked ques-
tions, which specifically addresses this occa-
sional inclusion of invertebrates1. However, 
they make a point of only including inver-
tebates when colonies are housed within 
animal facilities, when higher level inver-
tebates are used, or when invertebrates make up 
a major portion of a unit’s research mis-
tion. The described scenario does not seem 
to be on the scale that AAALAC implies.

The scenario, as presented, lacks some 
information that is relevant to the question 
of how to proceed. Why does Montfort 
need ticks that have recently been attached 
at to animals? The answer to this question 
could determine the need for IACUC overs-
sight of the work. If the goal is a general sur-
vey of active tick populations that affect the 
local pet and human populations, then this 
could be set up as a simple case of profes-
sional collaboration. If the goal is to obtain 
the blood meal from the tick, the study 
could be interpreted as tissue collection and 
thus fall under IACUC policy.

If Montfort’s work triggers the Great 
Eastern University IACUC’s policy on tis-
sue collection, a simple protocol would 
suffice, serving to document appropriate 
practices of acquisition, use and disposal of vertebrate tissue and addressing occupa-
tional health and safety issues. This type of 
protocol would stand as a matter of record 
and would not require inspection of the 
premises of private veterinary practices.

If the research focuses on the tick itself, 
then a memorandum of understanding 
to the collaborating veterinarians and 
Great Eastern University would pro-
vide safeguards for all parties without 
increasing the administrative burden on 
the project’s participants. Since all handling 
will occur off-site by licensed veterinarians 
or veterinary technicians working in pri-
ate practice on privately owned pets, and 
since the pets will not be housed at Great 
Eastern University or handled by univer-
sity personnel, the institutional collabora-
tion policy would cover this research. A 
memorandum of understanding should be 
drafted between the private practice vet-
ernarians and Great Eastern University 
outlining the responsibilities of all par-
ties, particularly in relation to establishing 
requirements for notifying pet own-
ers or obtaining their consent, approving 
humane methods of removing ticks from 
the dogs, and upholding appropriate prac-
tices of acquiring and handling ticks with 
due consideration of occupational health 
and safety concerns.
The University should work with Montfort to draft a memorandum of understanding between the private practice veterinarians and Great Eastern University. This solution ensures the humane treatment of the privately owned pet dogs, the safe handling of the ticks and the appropriate notification or consent of the dogs’ owners while reducing the administrative burden on the researcher and her collaborating veterinarians.

RESPONSE

Legal requirements and ethical duties

John P. Gluck, PhD

The issues raised in this case bring to mind the lecture by the Russian émigré Alexandr Solzhenitsyn, given to the Graduating class of Harvard University in 1978, entitled *A World Split Apart*1. In his controversial critique of Western society, Solzhenitsyn expressed concern that the moral life was being crushed by a developing insistence that the detailed meaning of relevant black letter law was the only proper guide to right conduct. In other words, he saw the West as having conflated general ethical responsibilities to reduce harm and advance beneficence with the much more limited scope of the legal dictate. In the present case, if the relevant standards are interpreted narrowly, the removal of the tick is a purely clinical act taking place independently of Montfort’s PHS-supported research. Montfort has simply provided the means of containment and preservation of the specimen, which is then available for research at some other time and venue. Therefore the protocol is not required to undergo IACUC review, and the veterinary facilities involved are not subject to semiannual inspections2.

However, if the methods used in the tick collection need to be standardized and are not left to the case-by-case clinical discretion of the clinician in order to ensure the specimen’s usefulness to the research, the regulatory picture changes significantly. That situation would seem to require IACUC review because the tick extraction is not being carried out independently of the needs of the research. It also appears that, in order for this relationship with the veterinary hospitals to continue as the grant proceeds, the hospitals would need to be included in the semiannual inspections if the dogs from whom the ticks were or will be extracted remain for over 12 hours.

In either case, the question remains: are there other ethical duties that this research situation invites for expression? As the research is supported by public funds, Montfort may look for ways to reciprocate the courtesy and cooperation of the pet owners and veterinary staff, who have facilitated access to the dogs and tick collection, as a way for her to show respect, reduce harm and improve animal welfare. For example, she could show respect to the dog’s human family or guardians by providing a form that both describes the research and its goals and provides a place for formal authorization of the tick collection for the stated purpose—this would constitute informed consent. The form might also provide helpful information, such as the importance of checking family members for ticks in order to avoid any human medical morbidities. Perhaps Montfort could offer to provide some up-to-date continuing education about tick-borne diseases, about which she is likely an expert, to the veterinary staff as a way of improving the value of their future interactions with clients and patients. Perhaps she could discuss the data relevant to determining whether ticks cause pain upon removal and whether that should lead to modification of procedure. How far should Montfort go with these efforts? The answer is not in the Animal Welfare Act, Regulations, or PHS policy but in her own ethical commitments.


Gluck is Professor Emeritus at the Department of Psychology, University of New Mexico, Albuquerque, NM, and Faculty Affiliate of the Kennedy Institute of Ethics, Georgetown University, Washington, DC.