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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*¹, 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 collected². 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 semi-annual 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 of this 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).

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RESPONSE

Memorandum of understanding

Liesl Wiesen, MS, CMAR, ILAM

Invertebrates are not generally covered by IACUC policy and oversight. There are cases wherein, if used in conjunction with vertebrates, they can fall under the IACUC’s purview. AAALAC International has published a webpage of frequently asked questions, which specifically addresses this occasional inclusion of invertebrates¹. However, they make a point of only including invertebrates when colonies are housed within animal facilities, when higher level invertebrates are used, or when invertebrates make up a major portion of a unit’s research mission. 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 to animal? The answer to this question could determine the need for IACUC oversight of the work. If the goal is a general survey of active tick populations that affect the local pet and human populations, then this could be set up as a simple case of professional 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.

A word from USDA and OLAW

In response to the questions posed in this scenario, the United States Department of Agriculture, Animal and Plant Health Inspection Service, Animal Care (USDA, APHIS, AC) and the Office of Laboratory Animal Welfare (OLAW) offer the following guidance:

In this scenario, the dogs are under the care of a private practice veterinarian. State veterinary practice acts require a valid Veterinarian-Client-Patient Relationship (VCPR) under which the veterinarian is held responsible for the health and well-being of the client’s animal¹. A pet that receives care pursuant to a valid VCPR is not considered an animal² used or intended to be used for research, testing and experimentation. Such care includes but is not limited to routine vaccinations, surgery and medical treatment. The collection of samples and data under these circumstances does not make the activity subject to oversight under the Animal Welfare Act.

The PHS *Policy on Humane Care and Use of Laboratory Animals* covers live vertebrate animals used or intended for use in research, research training and biological testing activities conducted or supported by the PHS³. Veterinary clinical care of a privately owned animal is not a research activity and does not require IACUC approval⁴. In the scenario, the investigator’s research involves the ticks collected during routine veterinary clinical care, and the dogs are not being handled in response to the requirements of the NIH grant. The investigator has mistakenly indicated on the application that the activities involve research with live vertebrate animals and has completed the Vertebrate Animals Section. To rectify the situation, the investigator should contact the NIH extramural program official and grants management specialist managing the grant and inform them of the error. The program official and grants specialist will consult with OLAW and change the coding of the application to reflect no use of vertebrate animals. Verification of IACUC approval is not required.

1. American Veterinary Medical Association. Veterinarian-Client-Patient Relationship (VCPR) FAQ. <https://www.avma.org/public/PetCare/Pages/VCPR-FAQs.aspx> (accessed 1 June 2016).
2. Animal Welfare Act Regulations. 9 CFR, Chapter 1, Subchapter A, Part 1, Section 1.1
3. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals*. (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
4. Public Health Service. Frequently Asked Questions – Policy on Humane Care and Use of Laboratory Animals. Applicability of the PHS Policy, Question A8. *Office of Laboratory Animal Welfare, US Department of Health and Human Services* <http://grants.nih.gov/grants/olaw/faqs.htm#528> (2006; revised 2016).

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If Montfort’s work triggers the Great Eastern University IACUC’s policy on tissue collection, a simple protocol would suffice, serving to document appropriate practices of acquisition, use and disposal of vertebrate tissue and addressing occupational 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 between the collaborating veterinarians and Great Eastern University would provide 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 private practice on privately owned pets, and since the pets will not be housed at Great Eastern University or handled by university personnel, the institutional collaboration policy would cover this research. A memorandum of understanding should be drafted between the private practice veterinarians and Great Eastern University outlining the responsibilities of all parties, particularly in relation to establishing requirements for notifying pet owners or obtaining their consent, approving humane methods of removing ticks from the dogs, and upholding appropriate practices 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.

1. AAALAC International. AAALAC Accreditation: Frequently Asked Questions (2015). https://www.aaalac.org/accreditation/faq_landing.cfm#A2

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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 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.

1. Solzhenitsyn, A.I. *A World Split Apart*. (Harper and Row, New York, 1978).
2. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).

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