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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

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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