

Is 'saving money' a valid justification?

One of the guiding principles of using animals for biomedical research is to use the smallest number of animals that may lead to statistically or biologically significant results. Supporting this concept, both the NIH and USDA state that “investigators may use fewer animals than approved. This does not require IACUC approval, notification, consultation, or administrative handling.”¹

Dr. Ed Stark was an established researcher with a propensity for doing things in a way that just skirted the line between right and wrong. This tendency often caused problems for the school's IACUC, as exemplified by an incident when Stark decided to reduce the number of animals in one of his IACUC approved experiments. He did this by euthanizing an entire group of negative (untreated) control mice without informing the IACUC. When the IACUC office finally found out what Stark had done, the committee chairman asked him for an

explanation because Stark had argued during the initial review of his protocol that the untreated controls were scientifically necessary. But now he said that the findings to date with his experimental groups were trending toward strong statistical significance and the vehicle control mice (those having corn oil mixed in their diet) were adequate controls to complete the study. He added that he wanted to avoid some of his per diem charges, so eliminating an unnecessary group of animals made good sense, and in any case the IACUC had no authority to even question him about how he conducted his experiment as long as there was no protocol noncompliance or animal welfare issues.

Stark's response did not sit well with the IACUC chairman who discussed the incident at the next full committee meeting. The chair's position was that there was nothing in the protocol that gave

Stark the authority to euthanize an entire experimental group of healthy animals that he originally stated were important to his study. On the other hand, he was aware of the NIH guidance about an investigator being allowed to use fewer animals without informing the IACUC¹ but he did not interpret that guidance as sanctioning the euthanasia of an entire experimental group just to save money.

How do you think the IACUC should resolve the issues raised by its chairman?

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References

1. Public Health Service. *Guidance on significant changes to animal activities*. Notice NOT-OD-14-126. (National Institutes of Health, Washington, D.C. 26 Aug. 2014.)

Unnecessary tension

In this scenario, there appears to be ongoing tension between Dr. Stark and the IACUC. However, it is unclear whether the tension exists with the IACUC as a whole or specifically with the IACUC chair. Regardless of the cause or nature of any underlying tension, both the IACUC and Dr. Stark have responded inappropriately in this scenario. With respect to Dr. Stark's actions, he was within his right to not use the control group as originally requested and justified during the initial protocol review. The justification was based on the knowledge and data he had at the time; results obtained during the course of his experiments showed that the untreated controls were no longer needed. Unless the IACUC or animal facility has a specific policy requiring notification of the IACUC of the euthanasia of experimental groups, no regulatory requirements exists for an investigator to notify the IACUC in this particular case. On the other hand, Dr. Stark could have investigated other options for the untreated controls prior to euthanasia.

For example, he could have reached out to the animal facility to determine if the mice could be used for training or transferred to another protocol where they could be used.

The quantity of mice euthanized is not indicated in the scenario, so it is difficult to determine if the response by the IACUC Chair is warranted. The IACUC has a responsibility to develop policies and procedures to assist researchers in making ethical decisions and to ensure researchers are aware of and understand those policies and procedures. This responsibility could include providing a process or resources for donating unused animals for training or to other researchers if animals are no longer needed for a particular study. Researchers should also be informed that decisions on use (or in this case, euthanasia) of animals should be based on balancing the research objectives with the health and welfare of the animals and should not be based on cost savings.

Researchers and the IACUC should work together to balance the health and

welfare of animals used in research and the scientific objectives of the studies where animals are needed. Recently, there has been a dramatic increase in regulatory burden for researchers and studies have shown that the burden is often self-imposed. As there are no specific policies dictating reporting of this kind of event to the IACUC, the response by the IACUC Chair is bordering on self-imposed regulatory burden. The IACUC has responsibility to oversee the responsible use of animals in research at the institution. As such, the committee should be working collaboratively with researchers to maintain the balance described above while affording the research an appropriate amount of flexibility to carry out their studies.

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