

Never do anything against conscience, even if the state demands it

Academic research is a high stress environment, with pressure to meet deadlines, manage lab activity and personnel, and maintain regulatory compliance. As Dr. Martel, I would be very uncomfortable with actions of the dean and the external political demand placed on my research

If the dean is receptive, I would first voice my moral and ethical conflicts with moving to the nonhuman primate (NHP) model; however, if this argument fails, I would attempt to outline the additional risks and costs associated with NHP research (i.e., costs to renovate facilities and train care staff; costs of maintaining animals as well as rehoming or retirement costs for NHPs; and possible attention from activist groups). The dean should be aware that the IACUC will likely identify these same ethical and regulatory concerns and the final decision to approve the NHP research lies with the IACUC. Per the U.S. Animal Welfare Regulations¹, institutional officials “may not approve an activity involving the care and use of animals if it has not been approved by the IACUC.”

If this approach failed, my next step would be to contact my department head, institutional official, institutional legal office, faculty senate representative, or other relevant office to voice my concerns and to determine if the dean may have a conflict of interest. I would document all interactions so that if the dean’s actions violate any laws, including the Animal Welfare Act and Regulations, I would have records to report the violations. Fortunately, in case of attempted retaliation, I would be protected by the Animal Welfare Regulations², which states, “no facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting.”

As Martel, I would not submit an amendment to add NHPs to the study. This would be a significant change according to OLAW and must be reviewed by the IACUC. While no federal regulations prevent me from submitting an amendment, I have spoken with the IACUC chair, and we are hesitant to move forward until I am ready to conduct the NHP research. I don’t feel comfortable with assuring that the rhesus is an appropriate species, something I know the Animal Welfare Regulations requires me to include in my proposal. In

A WORD FROM OLAW AND APHIS

In this scenario, a researcher who developed a promising new treatment in mice and dogs for a genetically transmitted, fatal disease in humans is pressured by a U.S. senator to quickly conduct similar studies in rhesus monkeys. The researcher and the Institutional Animal Care and Use Committee (IACUC) must decide a course of action when faced with continuing pressure from the university dean and the senator amid concerns over mild toxicity seen in the dog study.

In response to the issues posed in this scenario, the National Institutes of Health – Office of Laboratory Animal Welfare (NIH-OLAW) and the U.S. Department of Agriculture – Animal and Plant Health Inspection Service (USDA-APHIS) provides the following clarification:

A Word from NIH-OLAW

The PHS Policy states that activities approved by the IACUC may be subject to further appropriate review and approval by officials of the institution. However, those officials may not approve an activity involving the care and use of animals if it has not been approved by the IACUC¹. To address the current situation, the IACUC chair and the researcher should consider educating the dean and the senator about the necessary legal safeguards that require a thorough review of the potential harms of the research balanced with the potential benefits. This is critical considering the unknown cause of the toxicity found in normal control dogs. In addition, the PHS Policy and the *Guide for the Care and Use of Laboratory Animals* require research personnel to have sufficient training or experience to conduct procedures on the species used^{1,2}. It is not clear if Martel or his staff have the requisite qualifications and expertise to work with monkeys. Lastly, for NIH-funded research, substitution of one animal model for another from what was identified in the approved project is a change in scope that requires prior approval from the NIH awarding Institute or Center³. If the researcher decides to begin work with monkeys and the change in scope is approved, conducting an IACUC-approved pilot study may delineate clinical signs useful for humane and scientific endpoints before proceeding with a full study.

A Word from the USDA-APHIS

The Animal Welfare Act regulations (AWAR) define the roles and responsibilities of the

IACUC, Principal Investigator (PI), and the Institutional Official (IO); and ensures a Federal funding agency receives information on the work it financially supports⁴. Under the AWAR, the IACUC is required to review and approve an animal activity or a significant change to an on-going activity before the work begins, but it is not permitted to describe methods or set standards for the design, performance, or conduct of actual experimentation conducted by a research facility^{5,6}. As a result, the PI in this scenario is permitted to decide whether or not to add nonhuman primates to the study as long as the work is in compliance with the requirements as set forth in the regulations and approved by the IACUC^{7,8}. The dean, who is serving as the IO, has the authority to conduct an additional review of an activity approved by the IACUC but no authority to request an activity that was not approved⁹. The senator in this scenario has no authority over the study because he is not a member of the IACUC or representing a funding Federal agency. In light of the requirements, it behooves all parties involved to work together within the context of the regulations to achieve optimal research findings. □

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- Code of Federal Regulations, Title 9, Chapter 1, Subchapter A — Animal Welfare: Part 2 Regulations. §2.31(c)(3)
- Code of Federal Regulations, Title 9, Chapter 1, Subchapter A — Animal Welfare: Part 2 Regulations. §2.31(c)(6-7)
- Code of Federal Regulations, Title 9, Chapter 1, Subchapter A — Animal Welfare: Part 2 Regulations. §2.31(a)
- Code of Federal Regulations, Title 9, Chapter 1, Subchapter A — Animal Welfare: Part 2 Regulations. §2.31(d)(1)
- Code of Federal Regulations, Title 9, Chapter 1, Subchapter A — Animal Welfare: Part 2 Regulations. §2.31(e)(1-4)
- Code of Federal Regulations, Title 9, Chapter 1, Subchapter A — Animal Welfare: Part 2 Regulations. §2.31(d)(8)