

Attending Veterinarian (AV) to submit a letter to each granting agency indicating that the rabbits in question would be held in the laboratory animal facility under the supervision of Animal Resources and the Veterinary Department. The cost of the animals and per diems could be split by each PI. The letter could state the reason for this unique situation is to reduce animal numbers and save money, as clearly stated by Bergman. This would show each granting agency that IACUC approval

would proceed only if the funding agency agreed to allow this animal usage. I think everything must be reported to the funding agency and be 'out in the open' to avoid any misunderstandings in case the situation is ever brought into question.

Alternatively, Bergman could wait until Wycroft's study is completed and have the rabbits transferred to her protocol. This would indicate that the responsibility for these rabbits had been transferred entirely to Bergman. However, this defeats

Bergman's purpose as indicated early in the case report since she wanted to perform her experiments concurrently.

1. Gracely, E.J. in *The IACUC Handbook* (eds. Silverman, J., Suckow, M.A. & Murthy, S.) 13:12 (CRC Press, Boca Raton, FL, 2000).
2. ARENA/OLAW. *Institutional Animal Care and Use Committee Guidebook* 2nd edn. (National Institutes of Health, Bethesda, MD, 2002).

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### A word from OLAW

*In response to the issues raised in this scenario, the Office of Laboratory Animal Welfare (OLAW) offers the following clarification and guidance:*

This complex scenario raises multiple questions. To sort out the tangle, the IACUC is faced with establishing priority among overlapping directives. Is it more important to reduce the number of animals used or limit the number of procedures performed on individual animals? These issues must be reconciled with the IACUC's practical need to monitor the activities of individual investigators and specific animals. In a further complication, all of these issues must be handled in accordance with the terms and conditions of the funding.

The PHS *Policy* does not specifically address the use of animals in an approved study being reconsidered for additional use in unrelated research when the simultaneous use involves noninvasive procedures. Dual use of animals may be an appropriate way to reduce the number of animals used if it can be accomplished without a negative affect on the animals or the scientific integrity of either project. However, in the scenario described here, the proposed blood collections involve changes in the nature, frequency, and number of procedures to be performed and could result in greater discomfort to the rabbits than the previously approved behavioral protocol<sup>1,2</sup>.

Since both PIs support the dual use, the IACUC should review the proposal, as it would any proposal, according to section IV.C.1.a–g of the PHS *Policy*<sup>3</sup>. If the IACUC approves the proposed changes, they may then decide whether to require that (1) the previously approved protocol be amended to include the approved changes, or (2) a separate protocol be developed to cover the use of the animals as blood donors. In either case the potential impact of the dual use on each research project must be described.

From a grants management perspective, the responsibilities to NIH funding components will vary depending upon the timing of grant approval and IACUC consideration:

- **If dual use of animals is planned before applying for the grant.** The description of animal use in a competing grant application should mention proposed simultaneous noninvasive dual use and describe any anticipated affect on the science.

- **If the decision in favor of dual use of the animals occurs after grant submission, but before grant award.** If simultaneous dual use is not described in the grant application and the IACUC approval is obtained after the application is submitted to NIH, then the IACUC approval date will be submitted to NIH after approval. This submission should include a description of the dual use.

- **If the decision in favor of dual use of the animals occurs after grant award.** After a grant award is made, the PI is responsible for the scientific or technical aspects of the grant, and would not need prior approval from the NIH Grants Management Official to implement dual use unless it constitutes a change in scope from the approved award. Change in scope is defined as a "change in the direction, type of research, or other areas that constitute a significant change from the aims, objectives or purposes of the approved project<sup>4</sup>." In this case, the addition of blood collection to the behavioral protocol does constitute a change in scope and would require prior approval. However, if a dual use is approved by an IACUC and implemented post-award, the dual use of the animals must be described in any subsequent progress reports to NIH.

There may be a simple solution for this particular scenario: because rabbit blood is readily available from commercial supply houses, perhaps the best solution would be for the investigator to purchase the needed reagent.

1. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986; reprinted 2002).
2. NIH Grants Policy Statement, Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General—Part 5 of 7, Administrative Requirements, Changes in Project and Budget. [http://grants2.nih.gov/grants/policy/nihgps\\_2001/part\\_ii\\_a\\_5.htm](http://grants2.nih.gov/grants/policy/nihgps_2001/part_ii_a_5.htm).
3. OLAW website. Frequently Asked Questions, Protocol Review, Question 6. [http://grants.nih.gov/grants/olaw/faqs.htm#proto\\_6](http://grants.nih.gov/grants/olaw/faqs.htm#proto_6).
4. US Government Principle IV. <http://grants.nih.gov/grants/olaw/references/phspol.htm#USGovPrinciples>.

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