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:

This scenario deals with two important issues: designation of animal study areas and satellite facilities and IACUC inspections. An area that houses animals for greater than 12 hours is considered a study area under the Animal Welfare Act and Regulations (AWARs)¹, and one that houses animals for greater than 24 hours is considered a satellite facility under the Public Health Service *Policy on Humane Care and Use of Laboratory Animals* (PHS Policy)². As a result, this lab is subject to inspection by the IACUC at least once every six months or as often as it deems necessary to monitor animal well-being^{1,2}. The AWARs (9 CFR 2.31(c)(3)) allow the IACUC to use subcommittees comprising at least two IACUC members to conduct inspections. The PHS Policy² requires that IACUC inspections use the *Guide for the Care and Use of Laboratory Animals* (the *Guide*)³ as a basis for evaluation. The inspection in this scenario should review whether the requirements for hamsters under Part 3 Subpart B of the AWARs are met and whether the standards in the *Guide* for environment, housing and veterinary care are appropriately addressed^{1,3}. The OLAW Semiannual Facility Inspection Checklist may prove a valuable resource in determining the adequacy of the lab location and operating procedures⁴. The *Guide* allows for laboratory housing if the purpose meets scientific aims. If the designated member is unsatisfied with the investigator's rationale for the satellite facility, then the amendment must be modified to the reviewer's satisfaction or returned for full committee review. Specialized equipment is often a deciding factor in justifying laboratory housing. The housing should be limited to the period during which it is required, and occupational hazards and transportation issues should be addressed prior to final approval of the new location³.

1. Animal Welfare Act and Regulations. Code of Federal Regulations. Title 9. Sections 1.1, 2.31.c 2, 3.
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).
3. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. (National Academies Press, Washington, DC, 2011).
4. Public Health Service. *Semiannual Program Review and Facility Inspection Checklist* (US Department of Health and Human Services, Washington, DC, 2012).

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ranges for hamsters listed in the *Guide* (68–79 °F)¹? Finally, what is done with the animals after the four days of fluid collections? The proposed amendment should address these questions; if it does not, the IACUC should ask for clarifications during its review of the amendment.

In conclusion and on the basis of the information provided in this scenario, the Great Eastern University IACUC should not approve this amendment as the standards of animal care recommended by the *Guide* have not been met. The IACUC member who had questions about the rationale for the amendment submission always has the option of requesting full committee review.

1. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. (National Academies Press, Washington, DC, 2011).
2. Animal Welfare Act and Regulations. Code of Federal Regulations. Title 9. Section 2.31.c 2, 3.

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RESPONSE

Need scientific justification

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The Great Eastern IACUC must request Jeanie Cooley to provide scientific justification in her amendment submission in order for the IACUC to completely review and approve the amendment. The IACUC must meet with the IACUC member and animal facility supervisor that observed Cooley's lab to explain the finding of no potential regulatory problems; with the designated reviewer to address his or her concern; and with the IACUC office staff to discuss the possible deviations from the recommendations of the *Guide for the Care and Use of Laboratory Animals* (the *Guide*)¹.

The *Guide*¹ recommends that hamsters be housed in appropriate cages, maintained in a controlled environment, with an air flow rate of at least of 10–15 changes per

hour. Hamsters are nocturnal; if housed in the lab, they would be shielded from light but noise and possibly instrument vibration may be disruptive to their sleep–wake cycle. The lab must be secure to prevent other staff members from entering the animal location. Standard operating procedures should describe the husbandry procedures outside the main facility and indicate who will perform the procedures.

The Animal Welfare Act (AWA)² states that innovative primary enclosures that do not precisely meet the space requirements but that do provide hamsters with a sufficient volume of space and the opportunity to express species-typical behavior may be used at research facilities when approved by the IACUC.

The IACUC must discuss the scientific justification that explains the need to house the hamsters in Cooley's lab. The IACUC must review the justification and approve the departures from the recommendations of the *Guide*. IACUC approval of departures from these recommendations must be based on scientific, veterinary medical or animal welfare issues.