

Suspended in Terminated Access

During morning rounds, Great Eastern University (GEU)'s husbandry staff found an issue in one of the rabbit rooms. There were two cages marked as a singly housed males, but one cage was

empty, and the second contained two rabbits. After a careful review of the records, it was determined that a lab member accidentally placed the two rabbits into the same cage when returning them to the vivarium. The

attending veterinarian (AV), Dr. Tracy Thompson, was called to assess the animals. Thompson, concerned about the welfare of the male rabbits, indicated they must be immediately separated because they could start fighting. The Principal Investigator (PI), Dr. T. Guaio, was not totally surprised when Thompson informed him of the situation, and he immediately followed up with his laboratory technician, Li Wang. Dr. Guaio discovered that Li Wang had made the same error not more than a week ago. At that time, Wang rectified the situation immediately. Now, even more concerned, Thompson called the IACUC Chair and IACUC Director to discuss the matter.

Dr. Thompson was adamant that this was an allegation of non-compliance and that action needed to be taken immediately. Unfortunately, due to absences, it was impossible to get a quorum of the IACUC voting members together (even for an emergency videoconference) for a few weeks. In the interim, the AV terminated Wang's access to the vivarium to mitigate the risk of ongoing animal welfare issues until the committee had the opportunity to consider the case. Since Wang was the only individual trained to perform the activity and Wang's access to the vivarium was removed, one of the PI's specialized procedures could not be conducted. During IACUC deliberation of the allegation of non-compliance, one member asked if the removal of Wang's access to the vivarium was equivalent to suspending an animal activity since, in their opinion, it was "institutional intervention that results in the temporary or permanent interruption of an activity"; and, if so, wasn't an IACUC vote required to implement the suspension of an activity?

What do you think: is the act of suspending Wang's access equivalent to a suspension (i.e., a temporarily interrupting an activity) and did it require an IACUC vote? □

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1. NIH/OLAW, *Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals*. <https://grants.nih.gov/grants/guide/notice-files/not-od-05-034.html>

A WORD FROM OLAW AND USDA

Response from OLAW

In this scenario, the attending veterinarian terminates a lab member's access to the vivarium. An IACUC member raises questions during committee discussion about 1) whether the veterinarian's action is equivalent to an IACUC suspension, and 2) if a vote by the IACUC is required to take such action. As discussed by other responders, the incident does not qualify as a "suspension" because Public Health Service Policy (IV.C.6) states that: "The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present"¹. The *Guide* describes the attending veterinarian's responsibilities to include "monitoring and promoting animal well-being at all times during animal use"². This would include the authority to halt animal activities that do not comply with institutional policies or negatively affect animal welfare until the IACUC can meet and consider the matter³. Because another individual could be enlisted to continue the activity following training by the principal investigator, the funded activity is not impacted.

Assuming that pairing rabbits is the default housing in the vivarium and that the IACUC approved single housing for the study, the research staff member's repeated mistakes deviate from the protocol and have put the animals at risk of injury. If this is the case, such an incident is reportable to OLAW with corrective and preventive measures addressed⁴. Institutions are reminded that "IACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with the Policy, Animal Welfare Act, the *Guide*, or the institution's Animal Welfare Assurance" is reportable to OLAW⁴. If in doubt about whether an incident is reportable, OLAW recommends a preliminary call from an authorized institutional representative

to the OLAW Division of Compliance Oversight^{4,5}.

Response from USDA

The central question raised in this scenario is whether or not the suspension of a lab member's access to the vivarium by the attending veterinarian constitutes suspension of an approved activity. The simple answer is, no, it does not, as all respondents have done a good job illustrating here. As was well noted, under the Animal Welfare Regulations, the IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present⁶. The activity could proceed if the principal investigator opted to replace the suspended employee with other appropriately trained personnel. □

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3. National Institutes of Health, Office of Laboratory Animal Welfare. *ARENA/OLAW Institutional Animal Care and Use Committee Guidebook*. 2nd Edition. p 161. 2002. <https://olaw.nih.gov/sites/default/files/GuideBook.pdf>
4. National Institutes of Health, Office of Extramural Research 2005. Notice NOT-OD-05-034, *Guidance on Prompt Reporting to OLAW under the PHS Policy on Human Care and Use of Laboratory Animals*. <http://grants.nih.gov/grants/guide/notice-files/not-od-05-034.html>
5. Office of Laboratory Animal Welfare, National Institutes of Health. *Reporting Noncompliance* webpage. <https://olaw.nih.gov/guidance/reporting-noncompliance.htm>
6. 9CFR, Chapter 1, Subchapter A, Subpart C, § 2.31 Institutional Animal Care and Use Committee.

Is a Suspension Without IACUC Vote a Suspension?

Given that the IACUC is empowered to suspend a project if it finds non-compliance with the PHS Policy, the Guide, Institutional Assurance,

or violations of the Animal Welfare Regulation, is this empowerment extended to the institutional-appointed Attending Veterinarian (AV)^{1,2}? The AV will need

to be empowered to have the appropriate authority to support a comprehensive animal care and use program that ensures the health and well-being of animals. If Great Eastern University (GEU) has a written policy that describes the AV's authority that includes suspending an animal-related activity prior to IACUC review, if warranted because of serious and urgent animal welfare and safety concerns, then Dr. Thompson followed the duties expected of someone with AV authority. Although an immediate convened IACUC meeting couldn't be secured, there was proper hierarchical notification to the IACUC Chair, IACUC Director, and the PI, Dr. Guaio, of Dr. Thompson's concerns which are critical in ensuring institutional accountability and communication for the welfare of the rabbits.

Dr. Thompson may have identified this event as serious non-compliance based on: (1) a failure to adhere to IACUC-approved protocol by not following the single-housing experimental design, (2) creating a condition that jeopardizes the health or well-being of the rabbit with the two rabbits potentially fighting, and (3) the continuing non-compliance as demonstrated by what Dr. Guaio shared with the repeat error by the laboratory technician. The AV terminating access to the vivarium is a form of temporary suspension, and the IACUC at a convened meeting with quorum can vote to approve the suspension of access, modify, or lift it. There is no complete suspension of any or all protocol activities; thus Dr. Guaio can still perform the animal activities as approved, amend the protocol to add qualified personnel, or make arrangements with the animal care staff so the animals are properly monitored and/or initiated experiments can be saved, if allowed, according to the protocol.

When the IACUC does convene and vote with a majority in favor of terminating access and animal activities cannot be conducted, then this will be an IACUC suspension. The IACUC can determine that the AV was acting under the institution's delegated authority to immediately terminate access, which is not equivalent to a suspension of a project/protocol. The Institutional Official will need to be consulted about the IACUC suspension and promptly report to the regulatory agencies, such as the USDA (since rabbits

COMPLIANCE CONSIDERATIONS

The Protocol Review coordinators offer the following compliance considerations:

1. What is a "suspension"?

One critical clarification about the use of the term "suspension" (or suspended) is that while it is often used interchangeably with a variety of invented IACUC actions, it is limited, by federal mandates, to an animal activity.

According to the Animal Welfare Act regulations¹:

- "The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the description of that activity provided by the principal investigator and approved by the Committee. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present".
- "If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to APHIS and any Federal agency funding that activity..."

Additional guidance provided on the APHIS website is that the only incidents of protocol noncompliance that are required to be reported to USDA, APHIS are protocol suspensions² (recall that protocols are not part of any federal mandate).

If animal activities are supported by PHS funds, then IACUCs must adhere to the PHS Policy³:

- "The IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
 - a. any serious or continuing noncompliance with this Policy;

- b. any serious deviation from the provisions of the *Guide*; or
- c. any suspension of an activity by the IACUC."

- According to the NIH, OLAW must be notified in case of "IACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with the Policy, Animal Welfare Act, the *Guide*, or the institution's Animal Welfare Assurance."⁴

2. Is the act of suspending Wang's access equivalent to temporarily interrupting an activity?

In this scenario, no suspension of an animal activity occurred. Even though Wang was the only person in Guaio's lab who could perform the animal activity, the activity itself could still be performed (e.g., Guaio could have hired a veterinary/vivarium staff to perform the animal activity or found a qualified collaborator or newly hired lab member to perform the activity). □

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3. Public Health Service. *PHS Policy on Humane Care and Use of Laboratory Animals*. (U.S. Department of Health and Human Services, National Institutes of Health, Bethesda, MD, 2015).
4. NIH/OLAW, *Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals*. <https://grants.nih.gov/grants/guide/notice-files/not-od-05-034.html>

are a USDA-covered species), the Office of Laboratory Animal Welfare (if GEU is a PHS-awardee institution), as well as to any relevant funding agencies with the details of the incident and appropriate corrective and preventative actions.

Dr. Guaio may attempt to appeal the IACUC decision, so IACUCs should consider incorporating an appeal process into their policies and guidelines before such events are

raised³. If the AV's authority is also unclear, this can result in a delay in action or can lead to an improper decision, which ultimately impacts the well-being of the animals.

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Do. Or Do Not. There is No Suspension

To address the elephant, or the rabbit, in the room, removing someone's access to a Great Eastern University (GEU) animal facility, even if that person is the only individual trained to perform animal-related duties, is not equivalent to a suspension. Even if Li Wang could not access their animals, there were other research-related activities that Li may participate in that would continue to benefit the grant, e.g., writing, maintaining animal use protocols, managing substances, managing project data, and coordinating research subjects¹. The lack of access to animals does not mean that Dr. Guaio's research enterprise stops or even be interrupted; thus, in and of itself, removing access is not equivalent to a suspension of their research activity.

Suspension of an activity is clearly defined in both the Animal Welfare Act and Regulations (AWAR)² and Public Health Service (PHS) Policy³. Only the IACUC, by a majority of a quorum at a convened meeting, has the authority to suspend an activity^{2,3}; the attending veterinarian (AV), IACUC chair, or IACUC office director do not. The decision to remove Li's access by one or even the group of program leaders was not a suspension, nor should it be considered as such.

Furthermore, conditions of the suspension should be associated with a non-compliance with applicable provisions of the AWAR, the *Guide*, the institution's

Assurance, or the PHS Policy³. Those provisions may include that the activity is not conducted in accordance with the activity, i.e., protocol, provided by the investigator and approved by the IACUC². Although possible, it is unlikely that the protocol included a justification that group housing rabbits would interfere with the research. With no protocol non-compliance, inadvertent pair housing shouldn't warrant an IACUC decision to suspend. Another provision that the IACUC could consider is that housing must be directed by a veterinarian or scientist that is trained and experienced in the proper care of the species being maintained and/or studied³. If group housing is counter to the rabbit housing strategy outlined by the AV, then by inadvertently pair housing these two rabbits, Li Wang may have committed an offense to be considered punishable by a suspension. That said, the same provision also states that living conditions of animals should contribute to their health and comfort. Although it has been debated whether male rabbits should be group housed, rabbits are indeed social species and exhibit affiliative behaviors and other positive outcomes when socially housed, even amongst other males^{4,5}. Based on the AV's fervent response, it seems as though GEU singly houses rabbits by default—a living condition that may not contribute to the rabbits' best health and comfort. Thus, the rabbit housing program

should include at least some form of social experience, and not doing so could also be considered non-compliance with the above referenced provisions.

Taking into consideration that Li's decision to group house the rabbits seems like an oversight, despite doing so twice, and even if GEU's rabbit housing policy is single-by-default, an IACUC decision to suspend the protocol or the rabbit housing program would seem heavy-handed, although the Committee would have the authority to do so.

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