

# Compliant Cooperation for your Collaboration

At a crossroad in her research, Great Eastern University (GEU) faculty member, Dr. Altra Ipotesi, decided to take a new direction to help achieve her long-term research goals; specifically, to determine whether the novel compounds developed by Ipotesi would result in immunosuppression in a mouse model involving heart valve transplant. While the research portfolio at GEU is quite impressive, there were no faculty members with this expertise. Consequently, Ipotesi contacted colleagues at other institutions for help.

As it turned out, Dr. Jerry Silverman, from Great Western University (GWU), one of the leading experts in animal models involving heart valve transplant, agreed to send two of his senior lab members to teach Ipotesi and her lab technicians the surgery and techniques relevant to her research.

Wishing to ensure the involvement of the visiting scientists were consistent with GEU expectations, Ipotesi contacted GEU's IACUC Administrator, Gwen Skladnost, for advice. Skladnost informed Ipotesi that GEU didn't have any specific policies or procedures regarding visiting scientists. Consequently, Skladnost simply asked for a list of the visiting scientists and assurance that they would not enter the vivarium.

On the first day of training in Ipotesi's lab, Jerry's post-doc, Dr. Abigail, developed a severe allergic reaction and was rushed to GEU's hospital. Unexpectedly, Abigail, whom had no medically related concerns when working with mice, was extremely allergic to cats. They soon learned that Ipotesi shared a lab with two other GEU animal researchers, one of whom uses cats.

The day that Abigail was training members of the Ipotesi's lab on how to perform heart valve transplant surgery, a neighboring lab technician brought a cat carcass into the lab for dissection. The airborne allergens were significant enough for Abigail to develop an allergic response, which required medical intervention.

After filing an incident report, GEU's human resources and legal counsel was informed. GEU's legal team inquired about the processes the IACUC used for vetting visiting scientists. Skladnost informed them that the IACUC did not have a formal process to qualify them to work with GEU animals, but only required a list of the visitors' names and assurance that they wouldn't enter the vivarium.

What are your thoughts?

- What process should GEU have in place and who should oversee it (the IACUC? Occupational Health Services?)
- Should there be institutional-level policies and/or approvals for visiting scientists who are exposed to or work with animals?
- Should GEU have policies or practices in place to ensure technicians working in open labs are acquainted with all the potential hazards and risks?

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Published online: 2 February 2023  
<https://doi.org/10.1038/s41684-022-01107-8>

## A WORD FROM OLAW

In this scenario, the responsibility for overseeing the health and safety of visiting scientists is questioned. As described by other responders, the *Guide* is clear that the institution is responsible for what happens to animals in investigators' laboratories and that health and safety applies to all persons at risk<sup>1</sup>. Not only is the individual's risk to be determined, but the potential exposures due to laboratory design and ventilation must be evaluated and addressed<sup>1</sup>. Proper labeling of potential risks, including allergen exposure, at lab entryways and in

the areas within the lab should be evaluated and considered<sup>1</sup>. □

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Published online: 2 February 2023  
<https://doi.org/10.1038/s41684-022-01110-z>

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1. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. (National Academies Press, Washington DC, 2011) p 16, 20, 22±23.

# An Affidavit for Allergies

In this scenario, an unexpected exposure to animal allergens in an open lab occurred for a visiting scientist who was unaware of the potential for exposure. This could have been prevented by appropriate signage and risk management by the Occupational Health Service Program (OHSP) and by visitor screening by the IACUC, using a required form, or "affidavit" that visitors have to complete prior to visiting any areas where live or dead animals may be present on campus. The questionnaire should gather information on potential allergies or other health concerns that may preclude visitation of certain areas. Any answers of concern could result in follow-up with the occupational health specialists at the institution prior to clearance for visiting.

First and foremost, the GEU OHSP should be performing risk assessments in the laboratory areas and identifying where risks such as allergens are present. According to Chapter 2 of the *Guide*<sup>1</sup>, potential hazards such as animal allergens should be identified, and ongoing risk assessment should be done by the OHSP. Appropriate signage and training should be provided to all lab users in that space for potential allergen exposure as well as other hazards. This is especially important as the IACUC typically only identifies and inspects labs that have live animals brought in, versus other labs which could have carcasses or animal parts present.

The IACUC must then monitor the labs in which live animals are brought and all animal procedure areas. These areas should be subject to oversight including the tracking of visitors. Ideally, a visitation affidavit should be completed prior to accompanied entry into the lab or animal procedure areas. This form should collect data such as the reason for visiting, the species and procedures to be observed, and basic health information of the visitor, including potential allergies and to which species. Approval by the IACUC should be required prior to the visitor arriving at the institution. This would fit with the *Guide's* recommendations of evaluating an individual's medical history for pre-existing allergies. Based on the answers to the visitation form, the OHSP can then recommend proper preventative controls for the individual. Excellent communication between the IACUC and OHSP should be in place to identify risks for the visitor in areas where live or dead animals could be present.

The Protocol Review coordinators offer the following compliance considerations:

## 1. What process should GEU have in place and who should oversee it (the IACUC? Occupational Health Services?)

In regards to visiting scientists who handle animals and/or observe animal activities, the institution should ensure qualifications (experience and training) related to the specific procedures being performed, awareness of any related institutionally specific processes (e.g., donning and doffing of personal protective equipment (PPE)), and any work-related hazards. Specifically, according to the *Guide*:

- The institutional responsibility for education and training includes visiting scientists, i.e., "to ensure that they have the necessary knowledge and expertise for the specific animal procedures proposed and the species used"<sup>1</sup>.
- As part of the occupational health and safety program, institutional responsibilities for training personnel includes understanding the hazards associated with the animal activities, zoonosis, physical hazards (e.g., allergies), the use of proper PPE, and risks imposed by their workspace<sup>2</sup>.

While not regulation, the *Occupational Health and Safety in the Care and Use of Research Animals* states that: "Many institutions limit participation in their occupational health and safety programs to full-time employees who are involved in the care and use of animals. That approach fails to acknowledge that employment status is not a relevant criterion in exposure. Students, visiting scientists, volunteers, and other nonemployees can be subjected to substantial risks associated with exposure even during brief or sporadic involvement in animal care and use"<sup>3</sup>.

Further, many state and federal safety and labor regulations and/or laws could apply (such as U.S. Department of Labor (DOL) and Occupational Safety & Health Administration (OSHA)).

## 2. Should there be institutional-level policies and/or approvals for visiting scientists who are exposed to or work with animals?

The need to adhere to regulations and laws does not require institutional

(or other)-level policies, *per se*. Education, training, and processes to implement the regulation/law could suffice. However, many institutions (and IACUCs) find that policies are an effective communication tool and method for establishing programmatic expectations. That being said, IACUCs should work with other institutional units (e.g., legal) to ensure the processes/policies address institutional risk and liability.

## 3. Should GEU have policies or practices in place to ensure technicians working in open labs are acquainted with all the potential hazards and risks?

Animal Care and Use Programs have always faced difficulty in ensuring that non-animal users are adequately informed of any risk associated with being "near" animal activities. For example, despite covering cages and using freight elevators, non-animal users could still be exposed to allergens. The rising preference for building large, open labs that house multiple Principal Investigators (PIs) and a variety of types of research activities create opportunities for non-animal users to be exposed to allergens and other zoonoses.

Ensuring that visiting scientists are aware of the risk of working in open lab is no different than ensuring employees and students are aware of the same risks. Consequently, if institutions have adequate procedures (with or without policies) to educate, protect, and safeguard all members of the institution's community, then visiting scientists should be similarly protected. □

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Published online: 2 February 2023  
<https://doi.org/10.1038/s41684-022-01108-7>

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2. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. (National Academies Press, Washington DC, 2011) p 20.
3. National Research Council 1997. *Occupational Health and Safety in the Care and Use of Research Animals*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/4988>

Of course, this process is easier said than done, with the uncanny ability of investigators to simply forget important policies and required procedures, such as notifying the IACUC that a visitor is arriving. Maintaining strong communication and relationships with investigators, occupational

health specialists, and the IACUC is key to preventing unintentional exposures to hazards in laboratories working with animals. □

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Published online: 2 February 2023  
<https://doi.org/10.1038/s41684-022-01109-6>

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## Multiple Departments Working Together

Welcoming visitors to any facility requires multiple departments to work together. The *Guide* states: “The Institution should provide appropriate education and training to members of research teams including principal investigators, study directors, research technicians, postdoctoral fellows, students, and visiting scientists to ensure that they have the necessary knowledge and expertise for the specific animal procedures proposed and the species used”. The Great Eastern University (GEU)’s Occupational Health and Research Safety departments should be responsible for ensuring safe laboratory visitation. These two groups might need to involve other departments to gather the necessary information to provide a safe visit.

GEU should create an institutional-level visitor policy and a system for managing visitors within the Research Institute with a formal approval process. This new policy should include a form that needs to be filled out to capture data about the visiting scientists; for example, where the visitor will be in the Research Institute, if they will be working with any animals, and if they

have any known allergies. For efficiency, this form should also be laden with proper visiting procedures and details about the occupational health and safety risks of entering a lab space in which an animal could be present. Capturing and sharing this basic information back to the Occupational Health and Research Safety departments would allow them to determine what further information the visitor may need before their arrival or if it would be too hazardous for them to enter. GEU’s Legal department also might want to be involved in creating the institutional-level visitor policy, management system, and possible waivers.

Additionally, the GEU’s IACUC Office should have a policy that aligns with the institutional-level policy, which covers visitors working with live animals. The IACUC Office can then ensure that anyone working with live animals will receive all appropriate training and occupational health clearance before work begins. Occupational Health and Research Safety departments may be involved.

GEU’s Occupational Health and Safety departments should also have a

system in place to track and monitor potential hazards in every lab area. This includes knowing which areas animal tissue collections are performed. In addition, the IACUC should already be aware of any labs that take animals out of the vivarium and into lab space. In conjunction with all of these departments, visitors should be well informed about the potential hazards of the lab space. □

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Published online: 2 February 2023  
<https://doi.org/10.1038/s41684-022-01111-y>

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