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What are the limits of confidentiality for IACUC members?

Like many principal investigators, Dr. Loren Seligman often accepted invitations to present his work to colleagues at other institutions. During a talk at Underling College, Seligman described a new technique he developed that induces neuroglial cells to integrate genetic information contained in a viral vector. His long-range goal was to incorporate genetic information into the treatment of glioblastoma, a brain cell neoplasm.

Seligman had performed his preliminary work in tissue culture, and upon his return to Great Eastern University, he submitted an IACUC protocol application in which he proposed to test his viral vector treatment using an immunocompromised mouse model which had received a glioblastoma xenograft (a tissue transplanted from one

species into another). The protocol review was unremarkable until Seligman received an email from a neurologist at a nearby university who had heard about Seligman's work and was interested in a collaborative study. Seligman asked how the potential collaborator heard about his work and was told that an IACUC member had mentioned it to him. Seligman was furious. He considered his work to be confidential and could not believe that an IACUC member had broken confidentiality and discussed the study with a faculty member of another school. When the IACUC chairwoman intervened and questioned the committee member about the apparent breach of confidentiality, the member replied that Seligman himself had told him he was going to talk about his research

at Underling College. Why is it a big deal, he asked, if Seligman had already openly discussed his planned study at Underling? He added that he never would have mentioned it to anybody if he had thought that the study was confidential, but in his mind it was now public information. Seligman understood the confusion and calmed down, but he was adamant that a scientific presentation at a college was far different than a presentation at an advertised regional or national meeting. In his mind, there was still a breach of confidentiality.

What do you think? Was confidentiality violated? Is there any reason why an IACUC member should not discuss important research with a colleague outside of the IACUC?

RESPONSE

Leave the research presentations to the principal investigators

Gregory A. Hanley, DVM, PhD, DACLAM & Jennie Hoard, BS, rLATG

IACUCs and their members must be diligent not to release any confidential information. If Great Eastern University is registered with the USDA they are then required to comply with the Animal Welfare Act (AWA)¹, which specifically prohibits the release of confidential information by IACUC members (§2157; ref. 1).

In addition AWA regulations, the IACUC member's actions might also violate regulations on confidentiality to protect proprietary information. It must be decided if the animal model developed by Seligman is considered proprietary information that

requires such confidentiality. One type of proprietary information is trade secrets, which include scientific and technical methods or techniques². So, the argument could be made that the techniques developed by Seligman to induce neuroglial cells to integrate genetic information contained in a viral vector do fall under the definition of a trade secret. There is, however, a caveat to a technique being designated as a trade secret: the 'inventor' must have made reasonable efforts to keep the information confidential². In this case, since Seligman presented his technique during a talk at Underling College, he may have difficulty making the argument that the technique deserves confidential information status.

By disclosing information learned during an IACUC meeting, the IACUC member has opened himself up to possible repercussions. Under AWA (§2157; ref. 1), the disclosure can result in removal from the IACUC, payment of a fine, imprisonment and/or civil lawsuits. Additionally, actions

can be taken against the IACUC itself, as well as Great Eastern University.

How could this scenario have been prevented? Each IACUC member could have signed confidentiality or nondisclosure agreements. The offending IACUC member may not have understood his obligations. Frequently, the training of IACUC members does not address issues of confidentiality and proprietary information. Because the study was previously presented by Seligman, the IACUC member argued that it no longer qualified as confidential. Adequate training on confidentiality would have taught the member that such a decision is made by the University's legal counsel, not the IACUC.

What if, in subsequent IACUC submissions, Seligman argued against including details on methods he considered to be trade secrets? The idea of protecting proprietary information, while still providing sufficiently detailed information in a protocol to enable the IACUC to adequately

review the proposed activity, is addressed in the AWA (§2143,a,6,B; ref. 1). No part of the AWA may be “construed to require a research facility to disclose publicly or to the Institutional Animal Committee during its inspection, trade secrets or commercial or financial information which is privileged or confidential”¹. Frequently, the release of proprietary information to the IACUC is required to enable the committee to adequately perform its function. Having signed confidentiality agreements should prevent this quandary.

The relationship between confidential information and the IACUC review is complex. It might not be possible for the IACUC to assess the pain and/or distress of research animals without being provided information that is considered confidential. In such scenarios, providing IACUC members with training on the subject, as well as having them sign confidentiality agreements, is warranted. Lastly given the complex network of laws and regulations dealing with proprietary information, each institution should be strongly encouraged to use their institutional legal counsel.

1. Animal Welfare Act regulations. 9 CFR. Chapter I, Subchapter A, Part 2, Subpart C.
2. Chimes, M.J. & Sankar, P. In *The IACUC Handbook* 3rd ed. (eds. Silverman, J. Suckow, M. & Murthy, S.) 503-534 (Taylor and Francis, Boca Rotan, 2014).

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RESPONSE

Loose lips can sink ships—and potentially careers and institutions

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First and foremost, the IACUC Chair should recognize the delicacy of this situation and be prepared to take any warranted actions. The available information in this case is limited—exactly what the IACUC member revealed to his colleague is unknown. The IACUC member may

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:

The scenario raises concerns about whether a member of an Institutional Animal Care and Use Committee (IACUC) impermissibly shared information involving a research protocol.

For covered species, the Animal Welfare Act (AWA) makes it unlawful for any IACUC member to release, or reveal to another person, any confidential information of the research facility including any information that concerns or relates to: trade secrets, processes, operations, style of work, confidential statistical data, and income (§ 2157 (a–b); ref. 1).

The AWA’s provision on protecting confidential information is broad and applies to IACUC members regardless of whether a principal investigator elects to share information about his/her research. IACUC members must maintain confidentiality and not disclose trade secrets or proprietary information about activities and species regulated under AWA, or they risk exposure to penalties and damages for disclosing any such information. Penalties include removal from such Committee, and a fine of not more than \$1,000 and imprisonment of not more than one year, or if such violation is willful, a fine of not more than \$10,000 and imprisonment of not more than three years (§ 2157 (c); ref. 1). The principal investigator and/or research facility may also pursue action to recover damages incurred as a result of the violation (§ 2157 (d); ref. 1).

An institution is required to ensure all persons involved in animal care and treatment are qualified and provide training where necessary (§ 2.32; ref. 2). In light of this, IACUC member training must ensure the attendees understand their responsibilities under the AWA, including the requirement to maintain confidentiality.

Public Law 99-158, “Animals in Research”, requires that research institutions not disclose publicly trade secrets or commercial or financial information which is privileged or confidential (Sec. 495 (e); ref. 3). Therefore, the Public Health Service (PHS) requires that all material reviewed by IACUCs should be treated as confidential⁴. The institution should ensure that new IACUC members understand and meet their responsibility to maintain confidentiality.

1. Animal Welfare Act as Amended. 7 USC. Chapter 54.
2. Animal Welfare Act regulations. 9 CFR. Chapter I, Subchapter A.
3. Office of Laboratory Animal Welfare. Health Research Extension Act of 1985. *National Institutes of Health Office of Extramural Research*. <http://grants.nih.gov/grants/olaw/references/phspol.htm#HealthResearchExtensionActof1985> (1985).
4. Garnett, N. & Potkay, S. Use of Electronic Communication for IACUC Functions. *ILAR J.* **37**, 190–192 (1995).

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have simply mentioned Seligman’s broad research interests, or pointed his colleague to Seligman’s NIH grant abstract, for example, which is easily accessible to the public. If this were the case, it would not represent a violation of confidentiality and Seligman’s initial response would have been an over-reaction.

Based upon a review of the IACUC member’s actions and details of the disclosures, if a clear breach of peer-review confidentiality has occurred, the institution should take this situation very seriously. Such a

violation of federal regulations may cause the institution to be vulnerable to potential legal action.

The IACUC member was presumably not in attendance at the Underling College talk and would not have known precisely what substantive information Seligman discussed with his audience there. However, he did have access to the entire experimental plan (through Seligman’s IACUC protocol), which Seligman certainly would not have communicated to his listeners. Seligman was in control of the information revealed

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to the public during his talk—he could choose what to gloss over or leave out completely to protect his research. When the IACUC member revealed information about Seligman’s research, he appropriated Seligman’s control over information that was understood to be confidential. This is a clear ethical breach. It is unclear how much information the IACUC member revealed to his colleague. It was unlawful for the IACUC member to take it upon himself to reveal any confidential information regarding Seligman’s research. The Animal Welfare Act (AWA)¹ very clearly states that it is unlawful for an IACUC member to release confidential information learned through committee activities pertaining to his role as a member, and that doing so may incur severe penalties (§2157; ref. 1).

Moreover, the IACUC member’s contention that the revealed information is public, on the grounds that it was discussed in a public forum, is immaterial, as the AWA does not state the terms under which confidential information might then be considered public. It is certainly not the role of an IACUC member to make that determination. As such, Seligman is correct that a breach of confidentiality occurred. The IACUC chair should be familiar enough with the regulations to recognize the violation and inform the institutional official, and possibly the institution’s research integrity office and general counsel for further investigation.

The IACUC member should be well-versed regarding issues concerning confidentiality. Likewise, if he is an NIH peer reviewer or journal reviewer he should have such an understanding. At our institution, members undergo training and sign non-disclosure agreements as part of their IACUC member orientation.

Due to the IACUC member’s disclosure, Seligman and members of his lab may suffer damage to their careers, loss of intellectual property, publication loss, and delays in research progress. They might also have an added risk of being targeted by animal rights organizations. These are potential grounds for further civil legal actions against the IACUC member and the institution.

When inappropriate disclosures occur, as presented in this scenario, the IACUC Chair must reinforce the importance of confidentiality at the next convened meeting. The Great Eastern University should review current policy and training for all review committees on confidentiality, in order to reduce future occurrences and clarify institutional response.

1. Animal Welfare Act regulations. 9 CFR. Chapter I, Subchapter A, Part 2, Subpart C.

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RESPONSE

A matter of interpretation

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The information given about the case makes it difficult to determine whether or not confidentiality was broken between the IACUC member and Seligman. According to the Animal Welfare Act (AWA)¹, it is unlawful for IACUC members to release

information related to “trade secrets, processes, operations, style of work, or apparatus; or the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures, of the research facility” (§2157; ref. 1), as such information is considered to be confidential. Since the IACUC member released the identity of the researcher, as well as a description of the research itself, confidentiality seems to have been broken.

However, the case is clouded by the fact that Seligman presented his work at Underling University, which the IACUC member took to mean that Seligman’s identity and research was public knowledge, and therefore not confidential information. Therefore, it could be reasonably interpreted that confidentiality was not broken.

It is important to remember that breach of confidentiality is not dependent on intent. Even if the IACUC member does not intend to violate confidentiality, their actions could still do so. Certainly there are reasons not to reveal such information, such as the competitive nature of colleges and corporations, and the safety and security of those involved in sensitive animal-based research. There are also reasons for encouraging cooperation and communication between researchers and research institutions, within the limitations of confidentiality.

Minimally, Great Eastern University should develop a policy and institutional training around confidentiality for the IACUC members. With this approach, confidentiality could be better defined and maintained in the future.

1. Animal Welfare Act regulations. 9 CFR. Chapter I, Subchapter A, Part 2, Subpart C.