

Is reproducibility an IACUC's concern?

Dr. Charlotta Jones studied the activation of rabbit spinal neurons by magnetic fields. Jones' latest IACUC protocol went through an uneventful pre-review by a laboratory animal veterinarian and now was undergoing designated member review by two scientists on the committee. One of the two had general familiarity with the technique used by Jones and knew that there were publications which questioned the reproducibility of that technique. As part of his written review he asked that Jones comment on the published critiques to assure the committee that animals were not being "inappropriately used." Jones took that request as an affront to her ability as a scientist and refused to comment on the critiques.

To avoid a personal argument with Jones, the reviewer called for full committee review and the IACUC invited Jones to the meeting. After the reviewer provided the background for his concerns and responded to a few questions, Jones entered the room, was introduced to the committee, and briefly described her

research goals and methods. When the chairman asked about the publications critiquing the reproducibility of her work, Jones replied that her previous publications had undergone peer review from respected journals, and that she was the recipient of peer reviewed federal funding for her research. She added that everybody in the room knew that in the past few years there have been many articles citing difficulties in reproducing the published findings of scientists in many fields of research and she did not see her studies as being immune from that problem. In her own case, she said, part of the problem may arise from some journals limiting the amount of technical details allowed in the Materials and Methods section of her publications, but the techniques she used were the same ones used by other researchers in her field. When a committee member suggested that Jones perform some pilot studies to help validate the reproducibility of her methods, Jones reminded the committee that three years earlier it had previously asked for, received, reviewed, and approved the findings from

her pilot studies and to repeat them again would be a waste of time and animals. The chairman thanked Jones for her participation and told her that she would be informed of the IACUC's decision.

During the subsequent discussion of the protocol, it became obvious that the scientists on the IACUC, who composed the majority of the committee's voting members, were in favor of approving Jones' protocol as submitted, largely because they felt that her federal funding provided strong evidence for the quality and importance of her research. The other members of the committee seemed likely to follow the lead of the scientists. Would you also follow the scientists? If not, what would be your concerns? □

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On the reproducibility of methods or findings

The vertebrate animal section of a grant proposal from federal agencies such as the NIH requires the PI to address four criteria: description of procedures; justifications; minimization of pain and distress; and method of euthanasia. In particular, a concise description of the proposed procedures to be used for live animals must be provided with enough details for evaluation by study section or review panel. Therefore, the funded research grant to Jones must have had enough details of the animal experiments to have been reviewed and approved by its funding agency.

Jones' findings using her technology have been published in respected journals, suggesting her methods have been peer-reviewed by referees with appropriate expertise in the field and accepted by the journals as well. Most journals require authors to include a statement in their manuscript that live vertebrate animal experiments have been reviewed and approved by the IACUC.

As all federal funded grants also require congruency with the IACUC, the studies proposed by Jones must have been approved

by the IACUC before the grant was officially funded. We suspect that the IACUC protocol application may be a *de novo* renewal of Jones' previously approved protocol. Therefore, Jones' technology was previously reviewed and approved by the IACUC. Furthermore, Jones' pilot studies had previously been asked for, reviewed, and approved three years ago, indicating that Jones and her team have appropriate expertise to conduct studies on the activation of rabbit spinal neurons by magnetic fields. We agree that another pilot experiment is not necessary.

While it is important to note that as new information becomes available, investigators may need to make changes to previously approved animal protocols, it is not very clear how the publications questioned the reproducibility of the technology used by Jones. If this is just a general discussion of her technology, it is generally not a concern from the IACUC's perspective. The IACUC may raise concern if these publications provide details of apparent flaws and experimental evidence in Jones' technology. It is understandable that a technology

may not be fully reproduced by another laboratory without appropriate training and detailed technical support, especially for vertebrate animal-related methods. The lack of detailed descriptions of the technology is often due to limited space for the Materials and Methods section in most journals. Certainly it would be of concern if no other labs could reproduce the technology and had detailed protocols from Jones. However, it seems that her technology is similarly done in other labs.

Taken together, we are more likely to approve this protocol considering that Jones has a reviewed and funded federal grant, prior peer-reviewed publications, and a previously approved IACUC protocol using this technology. □

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