

A current perspective on the role and needs of IACUC unaffiliated members

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To be considered properly constituted, an IACUC must include at least one member who is unaffiliated with the research institution. The unaffiliated member, whose role on the Committee is to represent the general public, is often a non-scientist with little or no previous exposure to the concepts described in the animal-use protocols he or she is charged with reviewing. Needless to say, this knowledge gap can present problems. The author, himself an unaffiliated IACUC member, provides advice for those who may choose to serve in this capacity and suggestions for the institutions that rely on their services.

Under federal law, most institutions that conduct biomedical research involving animals must maintain an Institutional Animal Care and Use Committee (IACUC). These Committees are charged with critiquing and approving written research ‘protocols’ that describe proposed animal experimentation. They are also responsible for oversight, inspection, and enforcement of the institution’s ongoing animal housing and welfare programs and practices^{1–3}. The Committees are composed of people who are affiliated with the institution (researchers, scientists, and veterinarians, for example), as well as at least one person who is unaffiliated with the institution¹. The unaffiliated member (UM) is appointed to represent the interests of the general public at large in monitoring animal research¹. In addition, the Public Health Service *Policy on Humane Care and Use of Laboratory Animals* (PHS Policy), applicable to those institutions conducting research funded by the National Institutes of Health, mandates that the Committee include at least one non-scientist member, such as a member of the clergy, an ethicist, or a lawyer².

In 2005, I completed just under eight years of service as a UM on the University of Wisconsin College of Letters and Science Animal Care and Use Committee and a one-year appointment to the university’s All-Campus IACUC that helps set campus-wide animal care policy. My personal experience was both fulfilling and challenging. My cohorts on the Committees and in the support structure were—almost universally—highly competent and committed to their work and to animal welfare. I would certainly encourage others to serve as UMs. At the same time, I learned something about

how the system was designed to work, and something about how it works in practice. While I cannot suggest that my experience was exactly the same as that of every UM at every institution, I believe there are likely some commonalities.

Prior to joining the IACUC, I had experience with narrow areas of animal research relating to dairy cows as a result of my work as a lawyer, but no exposure to the matrix of regulations that govern institutional animal research. My general knowledge of animals and their behavior was mostly based on having pets, taking my kids fishing, and occasionally watching the Discovery Channel. I was previously unaware of the regulated nature of animal-based research. In this regard, I probably had the same knowledge base as many—if not most—of the people who agree to serve as UMs.

My training and orientation for this service was limited, and this seems to be typical⁴. In a short and informal orientation, I learned that I would participate on a committee with veterinarians and animal researchers to bring a layperson’s perspective to the review of proposals for research projects using animals. I was given the *Guide for the Care and Use of Laboratory Animals*³, a copy of the portions of the Code of Federal Regulations covering the Animal Welfare Act⁵, and a few other basic items before my tenure began. I do not remember even seeing a protocol until I was first presented with one for review. As is apparently common, my real education was mostly on-the-job training⁴. I eventually had the chance to go to a convention presented by Public Responsibility in Medicine and Research (PRIM&R) and over the years attended an occasional local training session, such as an

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IACUC 101 program. However, these presentations, as well as most of the vast amount of information on standards for animal research, care, and regulatory compliance, were not aimed at the non-scientist, non-laboratory-animal user, or non-researcher. The majority of resources presuppose a level of understanding of animal physiology, animal behavior, biochemistry, statistics, and research regulation that most lay people do not possess. Protocol review presents a fairly high initial barrier to non-expert review; complex, technical, and highly specialized scientific concepts are involved. Protocols often contain an alphabet soup of acronyms that are incomprehensible to the layperson without significant, time-consuming effort at decoding them. Aside from providing general review of technical subject matter, the UM serves a special role on the Committee as the voice of the ‘community’. I learned that in this respect, there was little readily available information to guide the UM in meeting this unique responsibility. As a result, I had questions. For instance:

- As a lay person, was I required to fully understand every nuance of the scientific explanations in a protocol?
- How much should I rely on the expertise of other members of the Committee?
- How much Committee meeting time was it reasonable to expect to be used for answering my ‘unscientific’ questions?
- How much was I on my own to find answers?

Some of this may fall into the ‘common sense’ category, but with no experience in a process, finding your footing can be a challenge, and little in my training or orientation provided me with direction. At the same time, having ‘no experience’ or stake in the system is probably what best qualifies a UM to be a public representative on a Committee.

UMs are supposed to be non-laboratory-animal users⁶ (and quite often are not scientists), but nonetheless are expected to understand that a ‘power analysis’ suggests the minimum number of animals required in a project to achieve a reliable scientific result. UMs are expected to be independent, unbiased, free of conflicts of interest, and uncompensated, but also able to read and understand complex scientific experiments^{6–10}. UMs are expected to bring the general interests of the community¹¹ to a research approval process that itself is a balance of scientific, legal, and ethical standards and interests. Some members of the public would allow no research involving animals. Others focus on the benefits they see such research brings to human medicine, agriculture, or the environment. Still others reject any connection between research on animals and advances in human affairs. Determining the sense of the community is not simple.

While lawyers, clergy members, and ethicists are encouraged to serve as UMs², there is little if anything

in the regulations or developed by the institutions that describes what UMs should take into account in determining the community sense^{4,9,12}, nor, in my experience, is there much easily located training or basic-background material targeted at the specific role of the UM. Others have also noted that UMs would appreciate and benefit from increased training focused on their specific Committee position, including the availability of online discussion forums^{4,13}. For a UM to fulfill the duty as an outsider who must speak truth to power, greater support and attention to his or her needs and training are required. All of the members of the IACUC except the UM and the non-scientist arrive with some knowledge of the protocol process, laboratory animal science, university research, and the like. The UM typically, and perhaps ideally, has little of that background. Thus, they require considerably more education and orientation than other IACUC members. It is likely they do not receive it unless they take the job on themselves, a task that itself can be difficult given their primary time commitments to other things, and the lack of targeted UM resources. The IACUC has now existed for over twenty years. Observations about the need to improve and enhance UM participation are not new^{13–16}. How much progress has been made in this area could be debated, but perhaps some practical suggestions would be more useful.

There has been no groundswell of demand for the kinds of steps or projects that follow. This may simply be the result of UMs having little time to organize themselves. They are volunteers and, in many instances, outside the research complex. But UMs play too important a role for their specific needs not to be systematically addressed by those who benefit from their service.

A REMINDER ON PLAIN LANGUAGE

There is an obvious tension between technical descriptions of complex scientific research and review of these proposals by non-scientists. However, it is hard to over-emphasize how important it is that, at a minimum, the scientific goal of the proposed research be stated in plain language. Protocol drafters must remain acutely aware that UMs, as protocol reviewers, are probably closest to the man or woman on the street than anyone else who will likely read their research proposal. Some investigators have seen non-scientific reviewers as just a ‘necessary evil’¹⁶ and review of research proposals by lay persons can be ‘troubling’ to investigators because these reviewers lack scientific knowledge and experience⁸. At the same time, some UMs have reported feeling intimidated by the review process⁴, and certainly the technical language in protocols can obscure scientific and ethical issues and impair proper review^{8,9}. The best response to such concerns is clearly drafted, plain-language statements of the research purpose, and UMs have long indicated that more help in understanding

technical language would be beneficial^{9,13}. If a modestly above-average high school student cannot easily grasp the scientific goal of the protocol, then the drafter has failed. (The writer is mindful that similar criticisms have been directed at times at his profession.) Given the level of public resources committed to animal research, large institutions should engage technical copywriters to assist investigators drafting protocols if those investigators do not personally possess the skills to write a protocol that meets this standard. This is not to say that protocols should be drafted entirely in lay terms, but meaningful review by non-scientists requires a balance in protocol drafting that investigators must keep in mind.

CREATE AN INTEGRATED UM HANDBOOK OR GUIDE

Given the legal obligation of the institution to support the IACUC^{17,18} and the unique responsibility placed on the UM, institutions—either individually or as part of a joint effort—need to take a more active part in UM-specific training and support. While there may be little UM-specific training and orientation information in circulation, a good starting point would be to organize and package what is already available. In 1997, it was reported that 46% of surveyed UMs wanted brochures or handbooks describing the role of the UM¹³, and a similar result is likely in a survey today. UMs are volunteers with primary obligations to family and work. They should not be left to rummage for the information they need to do their jobs. While there is a flood of general information available, a nationally sponsored project to prepare a downloadable handbook, paper, or guide targeted for the UM would be a step in the right direction. Useful information, in addition to the standard regulatory materials and guidelines, could perhaps include some of the articles cited in this paper's endnotes to give the UM a feel for the experiences of others. A new project to broadly survey and interview UMs with the goal of aggregating and including their experience over the last ten years in the handbook would be helpful. Every UM should not have to reinvent the wheel, and this type of project would provide valuable orientation to prospective UMs as to the kinds of issues they may encounter and how to approach them. If not created by an individual research institution, one of the national organizations should be encouraged to develop and periodically update a package of materials or guide directed at the specific function of the UM. Each institution should, at a minimum, include this material in its orientation.

ESTABLISH A UM ORGANIZATION AND ELECTRONIC COMMUNICATIONS NETWORK

Institutions that conduct animal research should be encouraged to support the formation of a modest organization for UMs to find each other, communicate, share concerns, questions, and ideas, and obtain training that focuses on their specific needs. An organization structure

for UMs that identifies and disseminates information specifically prepared for UMs could work as a subunit or affiliate of one of the existing organizations. Research institutions should be encouraged to pay the dues for membership or otherwise provide financial support. If nothing else, the sponsorship and technical support of a list serve, or other electronic method of communication targeted to UMs, would be a cost effective way to establish a network for UMs to learn from each other.

IMPROVE CONTINUING EDUCATION

In the ordinary course of their daily work, affiliated committee members and researchers learn much about important scientific and regulatory developments in the animal care and welfare arena that the UM has no practical way to learn, given that the UM is generally not part of the animal research establishment. However, this information can be critical to performing the work of the Committee. The UM may not hear about a regulatory change or, for that matter, a change in institutional policy. It should not be taken for granted that the UM will know what everyone else on the Committee may regard as baseline information, nor should it be considered less important that the UM have that knowledge. From the institutional training standpoint, systematic updates on relevant developments likely of particular interest or value to UMs should be provided.

If periodic email updates or news services covering issues important to animal welfare or protocol review are ordinarily used by investigators or administrators, the institution should make sure their UMs are aware of those services and make them available. Better still would be the creation, by a national organization, of a periodic email newsletter or digest containing relevant update information prepared specifically for UMs.

It is common for lawyers and other professionals to participate in 'lunch-hour' teleconferences or short webinars on topics of continuing educational interest that allow for real-time question and answer sessions. These are cost effective in that they do not involve travel or large commitments of time, but provide useful news and training on specific issues. While similar programs are apparently used in the animal care and research field, the development of periodic one-hour programs in this format that specifically target UMs would be useful. Quick updates on regulatory developments, compliance issues, or problems that have arisen at facilities around the country would be valuable. Once again, an organization is needed to take the lead to arrange UM-focused programs.

CREATE A SYSTEM FOR SHARING INSTITUTION-SPECIFIC INFORMATION

Apart from information of a general character that is relevant to the UM's Committee work, UMs often are outside the range of important institution-specific

information flow. This can be a significant problem. For example, during a period between semi-annual IACUC facility inspections or monthly protocol review meetings, it may become common knowledge around the institution that a particular animal housing facility is temporarily pressed to capacity or having problems hiring qualified support personnel. The UM generally has no way to learn these facts. Yet, without this information, the UM's ability to properly assess a new protocol that proposes increasing the animal housing load is impaired. Everyone on the Committee—except the UM—may be aware through formal or informal information channels of an incident or problem (animal illnesses or deaths, or occupational safety incidents, for instance) that might not rise to the level requiring formal IACUC review or action, but which would be relevant to overall assessment of institutional practices, regulatory compliance, or specific protocol review.

Institutions need to be attuned to the fact that while UMs are, for important reasons, outsiders by design, a negative consequence is that they are also effectively shielded from important, day-to-day, institution-specific animal-care information. UMs should not have to make decisions in a vacuum, and affirmative steps to systematically communicate significant occurrences are required. Research facilities need to develop a method for keeping UMs aware of events and problems that might not otherwise rise to the level of requiring formal reporting to the IACUC, but which nonetheless are essential to a proper understanding of what is going on in the animal care culture of an institution.

CONCLUSION

Service on an IACUC can be a wonderfully interesting and challenging experience. It requires a significant investment of time, but brings with it a chance to play a meaningful part in assuring that animals in research are treated as humanely as possible. It also provides the chance to learn and work with great people, new ideas, and exciting technologies. UMs play a special role, have special obligations, and have distinct needs in the regulation of animal research. In order to ensure the humane and legal use of animals and guarantee the UM's independence in the review process, UMs need specialized training and support. The institutions that use IACUCs have an obligation to be creative and take affirmative steps to do more to make certain that UMs are able to fulfill their obligations to the public trust

as reviewers of research practices and regulators of research facilities.

COMPETING INTERESTS STATEMENT

The author declares no competing financial interests.

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