**“Ethics, Scientific Merit Review, and Harm-Benefit Analysis in Animal Research”**

Webinar Summary: PRIM&R January 30, 2013

Presenters: Jerry Collins and Ernie Prentice

On January 30, 2013, PRIM&R held a webinar titled *Ethics, Scientific Merit Review, and Harm-Benefit Analysis in Animal Research*. This 90-minute session was presented by Jerry Collins, PhD, professor of anesthesiology at the Yale School of Medicine and former chair of the Yale institutional animal care and use committee (IACUC), and Ernest D. Prentice, PhD, the associate vice chancellor for academic affairs and the institutional official for the animal care and use program at the University of Nebraska Medical Center.

Dr. Prentice began his presentation by positing that IACUCs play the role of a gatekeeper charged with ensuring that the use of animals in research is both ethically and scientifically justified. He defines “ethics” as the branch of philosophy dealing with values of right and wrong as they relate to human conduct and with good and bad as they relate to motive. It is important to recognize that each of us has “personal ethics,” which are shaped by a variety of internal and external factors. People often disagree on what is ethical, with one relevant example being the contradicting ethical arguments made by animal rights activists and researchers regarding the use of animals in scientific research. Each of these groups acts in accordance with its own set of personal ethics, though they do not arrive at the same conclusion. Dr. Prentice disclosed that he supports the use of animals in research, so long as they are treated humanely, and the research has scientific merit to help the public at large.

Dr. Collins introduced the topic of scientific merit, and whether it ought to be considered by IACUCs when reviewing a research protocol. Some members of the research community believe that IACUC review of research should be limited to the health and wellbeing of animal subjects, and should not include discussion of scientific merit. This opinion is usually supported by the argument that because a large portion of funding requests undergo peer review by experts who make decisions about the scientific merit of proposed research, it is unnecessary for an IACUC with less specific expertise to duplicate these efforts. Dr. Collins proposed that this argument relies on a flawed underlying assumption, namely that the type of review performed by a peer review group is similar to that done by an IACUC. Dr. Collins believes that these processes are distinct: study groups are tasked with selecting the best protocol from a group, whereas IACUCs are responsible for evaluating the ethical and scientific validity of a study. Dr. Collins cited excerpts from the Public Health Service (PHS) Policy on Scientific Merit, the Guide for the Care and Use of Laboratory Animals, and federal regulations to support his argument that evaluating scientific merit falls within the jurisdiction of an IACUC.

If the IACUC has the authority to consider scientific validity when reviewing a research protocol, as Dr. Collins suggests, it must also assess the potential harms and benefits of the study to determine whether the potential value of the research to society justifies the use of animals.

Dr. Prentice expanded upon this reasoning by arguing that ethical research requires ethical costs to be at least balanced, and preferably outweighed, by the potential benefits. The ethical costs may include pain, discomfort, distress, morbidity, and mortality suffered by the animal subject that may vary both by procedure and by species.

Unfortunately, there is no algorithm or formula to quantitatively measure and compare potential costs and benefits of research. Rather, the IACUC members must form a judgment based on the application of the three Rs, sound reasoning, and the exchange of ideas. This deliberation should incorporate nuanced discussion of the relative magnitude of both costs and benefits, even in situations where there exists the potential for high societal value. Dr. Prentice provided ten cardinal ethical principles to be considered in harm-benefit analysis:

1. Because human beings occupy a higher moral status than other members of the animal kingdom, ethics demands that animals be used humanely in research prior to the involvement of humans and ultimately for the benefit of humankind.
2. Whenever scientifically feasible and reasonably available, a no-animal model should be used instead of a live animal model.
3. Reduction of animal subjects should not be used as a rationale for reusing an animal in multiple trials, especially if the wellbeing of the animal will be compromised.
4. Pain must be minimized to the greatest extent possible within justifiable scientific constraints and without regard to the degree of an animal’s sentience.
5. Using an intervention which causes the least possible pain, discomfort, distress, morbidity, and mortality reduces the ethical costs of the research.
6. An intervention which causes pain carries a higher ethical cost when performed on a more sentient animal subject.
7. The greater the potential scientific value of the research, the more acceptable a higher ethical cost becomes, within ethically based limits.
8. The higher the ethical costs, the greater the imperative to review the research at a full committee meeting of the IACUC.
9. The physical and social wellbeing of the animals and the psychological wellbeing of the humans who use the animals ought also to be taken into consideration.
10. Investigators and the IACUC should partner to achieve the most favorable ethical cost-benefit relationship possible.

Drs. Prentice and Collins concluded the webinar with a robust question and answer session. In addition to clarifying some points made in the webinar, the presenters also introduced and elaborated on some new ideas. In this segment, the presenters affirmed that an IACUC should be duly constituted with representatives from a broad spectrum of the research community so that the group may possess adequate expertise in order to judge the scientific validity of a protocol. The presenters also emphasized the importance of working with principal investigators to resolve conflicts or concerns, and stressed that these issues are often subtle and require thorough investigation and discussion.

Thank you to the PRIM&R Knowledge Center