Council of Councils Working Group on the Use of Chimpanzees in NIH-Supported Research

Teleconference Summary February 24, 2012 Meeting

Working Group Members Present

Daniel Geschwind, M.D., Ph.D., (Co-Chair) K.C. Kent Lloyd, D.V.M., Ph.D., (Co-Chair) R. Alta Charo, J.D. Beatrice Hahn, M.D. Daniel J. Povinelli, Ph.D. Stephen Ross, Ph.D. Patricia Turner, M.Sc., D.V.M., D.V.Sc. Charles Rice, Ph.D.

Working Group Members Absent

Stanley Lemon, M.D.

NIH Staff Present

James M. Anderson, M.D., Ph.D. Patricia A. Brown, V.M.D., M.S. Lora Kutkat Margaret Snyder, Ph.D.

After introductory remarks by the Co-Chairs and the NIH, Drs. Ross and Povinelli opened the Working Group call by discussing a subgroup meeting that took place at the Lincoln Park Zoo in Chicago on February 16, 2012. The purpose of the meeting was to explore several broad and specific issues related to the IOM report and its implementation. Major considerations are summarized below.

First, is there an immediate need to offer interim advice on the size and placement of NIH-owned chimpanzees? There are several current or pending NIH decisions that will influence the transfer of chimpanzees between NIH-funded institutions, including the decision to transfer chimpanzees from Alamogordo Primate Research Center to Texas Biomedical Research Center, and the pending contract to fund the housing of the population of retired chimpanzees currently living at Chimp Haven. At the very least, something must be done about extending the contract at Chimp Haven. The Working Group discussed whether chimpanzees should be moved into maximally ethologically appropriate surroundings and more publicly acceptable habitats. It also was discussed whether the Working Group should advise NIH to delay decisions on the transfer of chimpanzees between institutions until further progress can be made by the Working Group on the definition of "ethologically appropriate."

The Working Group discussed whether it should consider cost in any of its recommendations and was told that economic factors can be provided in their final report if the WG considers them critical for planning the future "size and placement" issues. The Working Group also might recommend that NIH no longer maintain housing for these animals if that is their recommendation based on a thorough review.

A second consideration is whether the IOM criteria make it more difficult to do less invasive research because of the seemingly double standard regarding acquiescent animals and their use in biomedical versus behavioral research. As written, do the IOM criteria imply that it should be easier to conduct research that is more harmful to chimpanzees than to conduct research that is less harmful? Is this an intended or unintended consequence of the IOM report that needs immediate reconsideration and rectification?

The Working Group discussed the meaning of acquiescence and drew analogies with other areas of research, for example, the concept of assent and dissent in pediatric research. It was noted that the difference here is that there is no legal relationship with chimpanzees, that is, there is no legal guardian. The Working Group has to explore the meaning of acquiescence, voluntariness, and training to achieve acquiescence. Another ethical consideration is that the normal benefit/risk analysis used in assessing human research does not apply here, because chimpanzees are not aware that research benefits may accrue. Another issue to explore is why IOM made the assumption that biomedical research is inherently more invasive.

It was suggested that the Working Group might develop a scale on which to assess research with chimpanzees based on a continuum that involves assessing the effect of what is being done to the animal in terms of pain and distress, both acute and long-term.

Other factors to be considered, in addition to how the experiment will be performed, are whether the animals are truly acquiescent, and how they are being housed outside of the research context.

Thus, in addition to defining the conditions and procedures under which experimental protocols can be conducted it is essential that the Working Group address the IOM recommendation that chimpanzees "must be maintained either in ethologically appropriate physical and social environments or in natural habitats." There was discussion about whether the IOM report is factually flawed about what constitutes ethologically appropriate when it cites the AALAC standards. Current AALAC standards allow for housing conditions that, in the opinions of Drs. Ross and Povinelli, are not "ethologically appropriate."

The working group reviewed a preliminary set of overarching principles provided by Drs. Ross and Povinelli. It was agreed that the draft principles are a good place to start although concern was expressed that they don't necessarily consider the benefit of research with chimpanzees. It was suggested that the Working Group use the review of grants as a way to identify principles. Such principles will emerge on a case-by-case basis, and certain themes well surface, which the working group can discuss and revise on an ongoing basis.

The following preliminary plan was developed for going forward in the next few weeks, recognizing that it might evolve.

In the coming weeks Drs. Povinelli and Ross will contact Dr. Jeffrey Kahn, Chair of the IOM Committee to seek clarification on the following issues:

- 1. the IOM committee's conception of acquiescence, and why it is part of the criteria for behavioral and comparative genomics research but not biomedical research (an apparent double standard);
- 2. the intended meaning of "ethologically appropriate environment"; and
- 3. whether an effort was made to bridge the gap with the AALAC standards.

In addition to seeking clarification on these issues, the Working Group will check in with the IOM Chair and staff on a regular basis as it responds to its charge.

Subgroups were assigned:

- Colony Management: Ross, Hahn, Povinelli
- Implementation: Charo, Turner, Ross
- Process Review: Rice, Povinelli, Lemon

All members will review research grants, and the Co-Chairs will work with all of the subgroups. Grants will be discussed at in-person meetings.

The grants will be divided up across the entire Working Group. Members were asked to consider whether they would need additional expertise in reviewing grants or responding to their charge. A list of experts will be posted on SharePoint. Dr. Anderson will let the members know the NIH policy on their use of subject matter experts.

In the coming week, each grant will be assigned to two reviewers, who can work together on the review. Ms. Kutkat will screen for conflicts of interest and private information will be redacted. An administrative review will be conducted by the co-chairs to ensure that all grants actually involve chimpanzee research in which either the research or the animal is supported by NIH. All members will have access to all grants involving chimpanzees, unless a conflict exists. Reviewers with questions for the PI can submit them to Ms. Kutkat and she will request a response. The co-chairs urged the group to quickly assess whether they have questions for the PI as that will take some time to orchestrate. Each member will have a folder on SharePoint of their grants.

Reviews should: 1) determine whether the project meets the IOM criteria and be able to justify why or why not, 2) consider the adequacy of the IOM principles in review, 3)

develop a list of themes to be discussed with the entire group, and 4) nominate one grant for the entire group to discuss because it illustrates a particular issue or problem. In one month, the group will reconvene to discuss the reviews.

The co-chairs will look at all grants that focus on facilities and training.

There was discussion about convening a meeting at one of the chimpanzee facilities so Working Group members can observe and better understand the environment in which the animals are housed as well as what might constitute "acquiescent behavior."

Information is posted on SharePoint about three of the chimpanzee facilities.

The co-chairs stated that the review process will be responsive to task 2, analyze currently active research. This process will inform task 1, developing a plan for implementing the IOM principles and recommendations.

Staff will circulate dates for future meetings. The Working Group will meet in person in Los Angeles, CA May 14-15, 2012. The co-chairs will provide a status report to the Council of Councils at its June meeting.