

Division of Program Coordination, Planning, and Strategic Initiatives
Office of the Director, National Institutes of Health
Draft Meeting Minutes Council of Councils Working Group Teleconference
12:00–2:10 p.m., Thursday, September 20, 2012

Working Group Participants: Alan Barrett, Daniel Geschwind, Beatrice Hahn, K.C. Kent Lloyd, Daniel J. Povinelli, Stephen Ross, and Patricia Turner

Individual Consultants: Bruce Altevogt, Jeffrey Kahn, and Robert Sapolsky

NIH Staff: James M. Anderson, Lora Kutkat, and Betina Orezzaoli

Welcome and Roll Call

Dr. Anderson welcomed working group members to this conference call.

Confidentiality and Non-Disclosure

Ms. Kutkat reminded participants of the rules governing confidentiality and non-disclosure that were in effect for all participants on the call, including the consultants.

Update on September 5, 2012, Council of Councils (CoC) Meeting

Drs. Lloyd and Geschwind gave an update on the working group's activities at the September 5, 2012, CoC meeting. The working group will present its final recommendations to the CoC in late October 2012 for all projects currently funded by NIH that use chimpanzees. To prepare for this presentation, the working group needs to finalize its recommendations on the remaining NIH-funded projects (those with a previously deferred recommendation) during its October 18, 2012, teleconference.

Institute of Medicine (IOM) Report Clarifications

Speaking as individuals and not on behalf of the IOM committee, Drs. Altevogt, Kahn and Sapolsky presented to the working group some information and clarifications. They went on to provide their own post-hoc input on how terms like acquiescence and ethologically appropriate environments might be defined in the spirit of the IOM report. These definitions were provided independent from any of the deliberations conducted by the working group on these terms.

Acquiescence

According to the IOM committee representatives, a chimpanzee is "acquiescent" when the animal has been trained to present itself for testing, such as willingly putting its arm out for blood draws, and the animal may voluntarily end a testing session. This training must involve positive reinforcement only. The IOM's acquiescence criterion applies to both biomedical research and behavioral and comparative genomics research. A study in which a chimpanzee entered a room separated by a closed door from the animal's social group would be permissible if the testing session ended when the animal wanted to return to its social group. Researchers may conduct invasive procedures on an anesthetized chimpanzee if that animal was properly trained to acquiesce to anesthetization.

The IOM committee did not determine:

- Whether to postpone testing on chimpanzees until the animals are thoroughly trained.
- Whether chimpanzees must be alert during transportation to be considered acquiescent.
- How to determine that an animal is overly stressed or wants to end the testing session.
- How often a chimpanzee may undergo research procedures during a given time period.

The working group suggested replacing “acquiescent” with another term, such as “trained to voluntarily present,” to avoid implying that chimpanzees that are trained to present themselves for testing agree to undergo more extensive procedures. The presenters also clarified that “acquiescence” was intended to apply to both biomedical and behavioral research.

Ethologically Appropriate

In an ethologically appropriate social environment, the chimpanzee group is similar to groups in the wild, such as having members of both sexes and including 5–20 animals. An ethologically appropriate physical environment provides access to outdoor facilities, climbing structures, building materials to make nests, challenging foraging opportunities, and areas where low-ranking animals can hide from dominant animals or subgroups.

The IOM’s ethologically appropriate principle applies to how chimpanzees are housed for both biomedical research and comparative genomic and behavioral research and does not preclude the establishment of more stringent environmental standards. The IOM committee considered the animal care and housing issues to be separate from the ethics of using chimpanzees in research and the corresponding research testing environment. The ethologically appropriate principle was based on the welfare of chimpanzees and the benefit to research of using animals that behave as naturally as possible.

Working group members offered the following comments:

- The IOM’s minimum criteria go well beyond the criteria that the Association for Assessment and Accreditation of Laboratory Animal (AAALAC) uses. AAALAC accreditation is a necessary but not sufficient condition for ethologically appropriate environments.
- Using unstressed animals in research is important because the effects of captivity on physiology and the developmental potential of animals are not known.
- A potential result of the IOM’s principles could be that no facility can maintain chimpanzees for invasive research in a facility that is truly ethologically appropriate, but the IOM report (p. 28) helps to address this scenario.

Separation of Biomedical and Behavioral Research

The IOM committee representatives asserted that they developed separate criteria for biomedical research and comparative genomic and behavioral research because it was charged to do so. The committee tried to develop a single set of criteria for both categories of research but was unable to do so. The committee did not base this distinction on the fact that biomedical research might be more invasive than comparative genomic and behavioral research.

The IOM committee did not discuss how long animals may be removed from an ethologically appropriate environment for testing or consider chimpanzee conservation because it was not charged to do so. During a working group discussion of chimpanzee conservation, Dr. Anderson

explained that the working group should not address conservation because NIH is permitted to fund research but not conservation.

Public Health Necessity

The committee did not quantify the proximity that research involving chimpanzees must have to applications in humans.

Respiratory Syncytial Virus (RSV) Studies

The committee believed that, based on the current state of research on RSV and available animal models, the use of chimpanzees for RSV research is not currently justified. However, the committee's recommendations do not preclude the future use of chimpanzees for RSV studies if other animal models are not developed or additional vaccine candidates are needed.

Independent Oversight Committee

The working group plans to recommend the formation of an oversight committee that would review all proposals involving the use of NIH-supported chimpanzees in research to determine whether these proposals meet IOM principles and criteria. This plan was discussed at the September 5 Council of Councils meeting. Dr. Altevogt confirmed that this recommendation complies with the IOM's proposal.

Working Group Subgroup Updates

Review Process

Dr. Geschwind discussed a draft document that describes a proposed NIH oversight committee for research involving NIH-supported chimpanzees. The document describes the committee's purpose, composition, and review process.

Planning and Scheduling

The working group plans to conduct expert interviews.

Action Items

- Dr. Geschwind will circulate the draft document on the review process to the working group for feedback.
- The working group will send Ms. Kutkat the names of additional people to interview.
- Ms. Kutkat will schedule field trips for working group members to the Alamogordo, New Mexico, Primate Facility; Keeling Center for Comparative Medicine and Research near Bastrop, Texas; and Save the Chimps Sanctuary in Fort Pierce, Florida.
- NIH will post the draft summary of the group's August 1 meeting on the SharePoint site.
- The working group will schedule a call in late September or early October for updates on the Ethologically Appropriate, Size and Placement, and Emerging Diseases subgroups.
- The working group will meet with Dr. Francis Collins, Director of NIH, by teleconference on September 21, 2012.
- The working group will alert the IOM committee when its report is ready to be issued.