Council of Councils Working Group on the Use of Chimpanzees in NIH-Supported Research National Institutes of Health Bethesda, Maryland Meeting Summary: February 2, 2012

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. Charles Rice, Ph.D.* Stephen Ross, Ph.D.* Patricia Turner, M.Sc., D.V.M.*

*via teleconference

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. Terri R. Clark, D.V.M Lora Kutkat Bettina Orezzoli Robert Purcell, M.D. Margaret Snyder, Ph.D. Kate R. Tapley, J.D. Harold Watson, Ph.D. Desiree von Kollmar

Guests

Bruce Altevogt, Ph.D., Study Director, IOM Jeffrey Kahn, Ph.D., M.P.H., IOM Committee Chair Diana Pankevich, Ph.D., Associate Program Officer, IOM

I. Welcome and Introductions: James M. Anderson, M.D., Ph.D.

Dr. James Anderson opened the meeting and thanked the working group members for their willingness to provide expert advice on implementing the recommendations presented by the Institute of Medicine (IOM) in its report, "Chimpanzees in Biomedical and Behavioral Research: Assessing the Necessity." This is an official working group of the NIH Council of Councils, a body that provides advice to the NIH Director and other appropriate delegated officials on matters related to the policies and activities of the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI).

Dr. Anderson provided some background information leading to the formation of the working group. While used very selectively and in limited numbers for medical research, chimpanzees have served an important role in advancing human health in the past. However, new methods and technologies developed by the biomedical research community have provided alternatives to their use in several areas of research. In December 2010, NIH commissioned an IOM study to assess whether chimpanzees are or will be necessary for biomedical and behavioral research. In December 2011, IOM issued its report with the primary recommendation that the use of chimpanzees in research be guided by a set of principles and criteria. NIH Director Dr. Francis Collins accepted the IOM recommendations and announced the formation of this working group to provide advice on the implementation of the recommendations, and to consider the size and placement of the active and inactive populations of NIH-owned or -supported

chimpanzees. NIH will not issue any new awards for research involving chimpanzees until processes for implementing recommendations are in place.

II. Overview of the IOM Report "Chimpanzees in Biomedical and Behavioral Research: Assessing the Necessity": Bruce M. Altevogt, Ph.D., Jeffrey Kahn, Ph.D., M.P.H.

Dr. Altevogt provided an overview of the NIH charge to the IOM: To review the current use of chimpanzees in NIH-funded biomedical and behavioral research that is needed for the advancement of the public's health. The committee explored contemporary and anticipated biomedical research questions to determine if chimpanzees are or will be necessary for research discoveries and to determine the safety and efficacy of new prevention or treatment strategies. If biomedical research questions are identified, the committee was asked to: describe the unique biological/immunological characteristics of the chimpanzee that made it the necessary animal model for use in the types of research; and provide recommendations for any new or revised scientific parameters to guide how and when to use these animals for research. The IOM committee was also asked to explore contemporary and anticipated behavioral research questions to determine if chimpanzees are necessary for progress in understanding social, neurological, and behavioral factors that influence the development, prevention, or treatment of disease.

Dr. Altevogt reviewed the project timeline and emphasized the numerous opportunities for receiving public input, including a public workshop held in August 2011. During its meetings the committee obtained background information on the current use of chimpanzees, explored potential alternative research models to chimpanzees, and sought public comment about the scientific necessity for chimpanzees. The IOM committee reviewed the inventory of chimpanzees available for research.

Dr. Kahn reiterated that the committee was charged with developing its criteria based on the premise of necessity. As such it developed three principles of necessary use on each broad category of biomedical or behavioral and social sciences research and then derived criteria for assessing the necessity of research in each area. Specific and full scientific justification for use of the chimpanzee must meet all three criteria. Assessment of whether proposed uses meet these criteria should be done prospectively on a study-by-study basis. It is important that justification be substantiated, including adequate supporting evidence. Dr. Kahn presented several case studies to illustrate how to apply the criteria in deciding what is considered sufficient benefit to meet the threshold of necessity.

Dr. Kahn also said the IOM committee reached several general conclusions in addition to developing the criteria for review. NIH should limit the use of chimpanzees in biomedical research and in comparative genomics and behavioral research unless the criteria are met for each area of research. Regarding the future use of chimpanzees the committee could not predict or forecast future need of this animal model and encourages use of the criteria established when assessing the potential necessity of chimpanzees for future research uses. In addition, a new emerging or re-emerging disease or disorder may present challenges to treatment, prevention, and/or control that defy chimpanzees. Furthermore, the criteria set forth in the report are intended to guide not only current research policy but also decisions regarding potential use of the chimpanzee in future research. The NIH process of review should be different from current practice and there should be transparency and public participation, which has not been the case in the past. Dr. Kahn discussed IOM's deliberations regarding the term "ethologically appropriate" as it pertains to the housing of chimpanzees.

III. Charge to the Working Group: James M. Anderson, M.D., Ph.D.

Dr. Anderson reviewed the role of the working group and its charge, which will be posted for public comment, along with the working group roster. A final publicly accessible report will be the product of the working group. Its task is to focus on implementation; therefore, it needs to develop a process not only for reviewing the current chimpanzee projects but also for reviewing future applications. The working group will also have to develop a framework and processes for review. Additional challenges focus on the housing and number issues, which the IOM committee did not address, but this working group will have to address and make recommendations.

IV. NIH-Supported Chimpanzees and Chimpanzee Research: Harold Watson, Ph.D.

There are six NIH-supported chimpanzee facilities. In some of these facilities all of the animals are owned by NIH or supported through NIH funds. In other facilities, the animals are owned by the facility but supported by NIH. The costs of NIH-supported chimpanzees vary across facilities, primarily because of cost sharing and economies of scale. Research and program income helps reduce costs, as does research sponsored by private industry. There are two types of costs associated with the long-term care of chimpanzees owned by NIH—facility construction costs and chimpanzee care and welfare. About10-30 percent of the animals are being used in research at any given time.

Dr. Watson described the facilities in detail. He also described a chimpanzee management plan that includes a reserve of approximately 170 animals; research facilities between which animals can be moved; research inactive animals that may become eligible for retirement; and retired animals at the sanctuary. Noninfected animals cannot be moved until there is space for them. All of the facilities have large outdoor activity areas, and walls, some with moats (chimpanzees cannot swim). There are long-term health implications for some of these animals; however, they receive excellent veterinary care. Dr. Watson said it would be important for the working group to define the terms "research active" and "research inactive" and to help NIH decide where these animals will be kept.

V. Next Steps

A preliminary plan was developed for going forward, recognizing that it might evolve as the Working Group becomes more familiar with the issues and the IOM report. As an initial step, reviewing active projects is a high priority. The projects will be divided up for review according to the agreed on subgroupings.