

NATIONAL INSTITUTES OF HEALTH

Report of the Chimpanzee Management Plan Working Group March 9, 2007

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The National Center for Research Resources (NCRR), one of the 27 Institutes/Centers of the National Institutes of Health (NIH), supports research to create and develop critical resources, models, and technologies. Within NCRR, the Division of Comparative Medicine (DCM) helps to meet the needs of biomedical researchers for high-quality, disease-free animals and specialized animal research facilities. Through grants, cooperative agreements, and contracts, the DCM supports national primate research centers and their field stations, resource-related projects, development of mammalian and nonmammalian animal model resources, postdoctoral training, and a variety of research projects. Within DCM, the Chimpanzee Management Program (ChiMP) supports long-term, cost-effective care and housing for chimpanzees.

Since 1995, a moratorium on the breeding of chimpanzees owned or supported by NCRR has been in place. In 1997, the National Academy of Sciences published a report "Chimpanzees in Research," which examined the issue. One of the report's recommendations was that a working group of experts from the research community be established to advise NIH on matters related to the moratorium. In response, the Chimpanzee Management Plan Working Group was established to serve as a fact-finding body that gathers information, analyzes relevant issues and facts, and provides interpretations to NCRR's advisory body, the National Advisory Research Resources Council (NARRC). The Working Group is comprised of non-government members with a wide range of scientific and non-scientific expertise. Three of its members also serve on the NARRC.

Since it was established, the Working Group has met periodically to review issues related to the moratorium. It last provided information to the NARRC in May 2005, at which time NCRR extended the moratorium through December 2007. The most recent working group session was held on March 9, 2007 to reassess the moratorium in the context of NCRR's current programmatic goals.

A summary of that session is below and will be presented to the NARRC at its meeting on May 22, 2007.

NCRR Introduction:

NCRR Acting Director Barbara Alving, M.D., reviewed for the group NCRR's financial responsibilities, programmatic goals and future funding situation, which is expected to be static or slightly decreased for the next few years (n.b., Dr. Alving has since been named Director of NCRR). Therefore, the benefits of chimpanzee resources need to be weighed against other

competing research resources in comparative medicine. With lifetime care of the average chimpanzee estimated at about \$500,000, breeding is a costly proposition. Therefore, ownership of new animals is a major issue.

Furthermore, Dr. Alving reminded the group of NCRR's commitment to fulfill its obligation to fund the federal chimpanzee sanctuary, as indicated in the CHIMP Act. Funded by an NCRR contract and construction grants, Chimp Haven opened in Oct. 2005 as the first federally funded sanctuary for chimpanzees no longer needed in biomedical research. An accounting has been made of such animals, and it has been determined that once the designated animals have been moved to Chimp Haven over the next year, the sanctuary will be at full capacity.

Therefore, any recommendation that calls for the expansion of chimpanzee resources must include financial support from sources outside of NCRR to fund such activities, according to Dr. Alving.

Presentations

Chimpanzees in Hepatitis Research: Dr. T. Jake Liang, Chief, Liver Diseases Branch, National Institute of Diabetes & Digestive & Kidney Diseases, NIH

Dr. Liang described how viral hepatitis has a world-wide impact. It is the leading cause of liver transplantation and there is no vaccine to prevent infection. The estimated health care costs are \$2-3 billion. More research is needed and the value of the chimpanzee model for Hepatitis C research is unquestioned, according to Dr. Liang.

The follow-up discussion by the group focused on how accurately the viral hepatitis pathogenesis model reflects the disease in humans and on the use of the current chimpanzee population for this research.

Summary of the October 2006 meeting "Chimpanzees in Research" held at the Yerkes National Primate Research Center: Dr. Stuart Zola, Director, Yerkes National Primate Research Center

Dr. Zola started from the premise that the importance of chimpanzees in research is not under debate, and then offered four points: 1. Comparative genomics will be possible for many disease entities, which could benefit infectious disease research and neuroscience investigations, among others; 2. In development of interventions, chimpanzees play a critical role (e.g. pharmacokinetics/pharmacodynamics); 3. The future need of the chimpanzee model is unknown (e.g., infectious diseases, monoclonal antibodies evaluation); and 4. There is a long "ramp-up" time to get the necessary chimpanzees for research. This preparation time is measured in years and decades.

Demographics of Research Chimpanzees: Dr. John VandeBerg, Director, Southwest National Primate Research Center and Southwest Foundation for Biomedical Research.

Dr. VandeBerg provided an assessment of the research chimpanzee population: The current U.S. population of research chimpanzees is about 1,000 of which approximately 50 percent are NCRR-owned. The current mean age of this population is 21 years. If there were no new births,

in 30 years this research population would largely cease to exist. Young adult research chimpanzees are usually the animal of choice for research. The number of suitable animals is impossible to assess; animals are used for different applications, some are used for multiple applications. Moreover, the Federal policy to maintain chimpanzees throughout their life spans has significant impact on the overall expense of this resource. Dr. VandeBerg estimates it would require 59 births per year to maintain the current population, using about 295 female breeders (284 are available today). Costs to sustain them would be \$9.5 million per year. During the discussion, it was recognized that some NCRR owned and supported chimpanzees currently available for research are not being used because they do not meet the desired criteria in terms of age and/or infectious status.

The Chimpanzee Facility Directors joined the working group discussion via teleconference.

They discussed various approaches for supporting researchers who need chimpanzee models, including partnerships with pharmaceutical companies. One suggestion was to consider a consortium approach with sharing of costs by other agencies, i.e., the National Science Foundation, Department of Defense, Department of Homeland Security, private foundations, and others. While some facility directors reported receiving 100 percent of their support for chimpanzee resources from NCRR, one director reported that only a small portion of his center's funding for chimpanzees comes from the NIH, down from 50 percent 10 years ago.

Another suggestion was to encourage the Facility Directors to come together and develop strategies for market evaluation and to determine how many centers are needed. The working group also discussed how a reduction in population would save costs to NCRR, and a participant suggested a plan to use those potential savings as an endowment to produce new animals. An alternative scenario suggested by a member would be to breed NCRR animals but have the offspring be owned by the facilities.

Recommendations by the Working Group Members

- 1. Working Group members did not make a definitive recommendation as to whether the chimpanzee breeding moratorium should be continued.
- 2. The existing chimpanzee facilities should develop a comprehensive business plan to support the chimpanzee resource into the future. Non-NCRR income at research facilities derives from the following: 1) research grants from other NIH Institutes and Centers, and 2) a charge to private users of fees and endowments associated with acute and chronic studies and studies of drug safety and efficacy. These charges should be standardized among the facilities.
- 3. Models for support of chimpanzees should be developed and should address legal issues of ownership. The current facilities needed for breeding should be defined. A model for the use of NCRR animals should be developed, e.g., assumption of ownership by the facility prior to breeding. It should be determined if NIH can provide endowments to

facilities if they assume ownership of NCRR owned breeders and progeny, [NIH Office of General Counsel will advise.]

4. Plans for retirement of animals at their current facilities should be considered as part of a business model. The facility directors should assess this possibility in the context of their current accommodations and compare predicted costs to the costs at the current federal and non-federal sanctuaries.

NCRR is reviewing these points and will present conclusions to the May 2007 Council.

Attendees

Working Group Members: Elizabeth Ford, D.V.M., M.P.V.M., (The Scripps Research Institute); Barbara Knowles, Ph.D., (The Jackson Laboratory); Thomas J. Kuehl, Ph.D., (Scott and White Memorial Hospital); Melinda Novak, Ph.D., (University of Massachusetts, Amherst and New England National Primate Research Center); Sarah Williams-Blangero, Ph.D., (Southwest National Primate Research Center); Sheila C. Zimmet, R.N, J.D., (Weill Medical College of Cornell University); Stuart Zola, Ph.D., Yerkes National Primate Research Center).

<u>Presenters</u>: Dr. Jake Liang (NIH/NIDDK); Dr. John Vandeberg (Southwest Foundation for Biomedical Research).

<u>Facility Directors</u>: (by telephone): Dr. Chris Abee, (MD Anderson); Dr. Bill Cummins, (Southwest Foundation); Dr. Jim Else (Yerkes); Dr. Rick Lee, (Alamogordo); Dr. Jeff Rowell, (New Iberia).

<u>NIH Staff</u>: Dr. Barbara Alving, Dr. Pat Brown, Dr. Franziska Grieder, Dr. John Harding, Dr. Robert Purcell, Ms. Ann Puderbaugh, Dr. Louise Ramm, Dr. James Taylor, Dr. Margaret Snyder, Dr. Harold Watson, Dr. William Watson.