



APR 20 2001

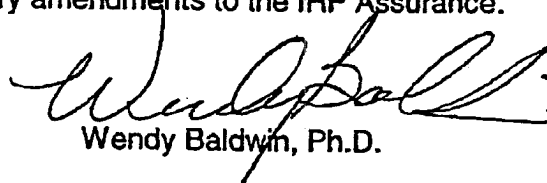
TO: Michael M. Gottesman, M.D.  
Deputy Director for Intramural Research, NIH

Judith L. Vaitukaitis, M.D.  
Director, National Center for Research Resources

FROM: Deputy Director for Extramural Research, NIH

SUBJECT: Memorandum of Understanding - Alamogordo Primate Facility

This correspondence conveys the Memorandum of Understanding referenced during the March 9 meeting with Dr. Kirschstein, where the decision was reached to include the animal activities of the Alamogordo Primate Facility under the Intramural Research Program (IRP) Animal Welfare Assurance. Following approval of this memorandum, the Office of Laboratory Animal Welfare will be asked to approve the necessary amendments to the IRP Assurance.



Wendy Baldwin, Ph.D.

Attachment

cc: Ruth Kirschstein, M.D.

This Memorandum of Understanding (MOU) establishes responsibility for a group of research chimpanzees acquired recently by the National Institutes of Health (NIH) from the Coulston Foundation, Alamogordo, New Mexico. The approximately 257 chimpanzees were all exposed to real or potential human pathogenic microorganisms in experiments funded by the Public Health Service (PHS) through the NIH. Under an agreement among the Coulston Foundation, the NIH, and the United States Department of Agriculture (USDA) Animal Plant Health Inspection Service (APHIS), the NIH assumed ownership of the animals and committed to care for the chimpanzees at a particular set of facilities on the Holloman Air Force Base (HAFB), New Mexico (under contract) to be known as the Alamogordo Primate Facility (APF). The APF and all animal activities conducted therein are covered by a Use Permit between the NIH and the United States Air Force (USAF). The APF will be operated as a Government Owned - Contractor Operated (GOCO) entity.

As the funding for the APF GOCO will come from the NIH, the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) requires that the animal activities, and associated support operations and facilities, be performed under an Animal Welfare Assurance (Assurance) approved by the NIH Office of Laboratory Animal Welfare (OLAW).

This MOU establishes the specific responsibilities related to the APF among the National Center for Research Resources (NCRR), the GOCO contractor, and the Deputy Director for Intramural Research (DDIR), in his role as Institutional Official for the Intramural Research Program (IRP) Assurance. The NIH has decided to place the APF and its associated animal activities under the existing IRP Assurance, which was first filed in 1986. The NCRR provides funding and oversight for PHS-funded investigators requiring the use of nonhuman primates to support their research, and more recently developed the centralized, national NIH Chimpanzee Management Program (ChiMP). To take advantage of NCRR's management history and to minimize any real or perceived duplication of management oversight, NCRR will be responsible for the day-to-day management of the APF, its associated animal activities, and the management of the GOCO contract.

NCRR will provide all resources (funding & FTE's) necessary to maintain and oversee the health and well-being of the animals, the operation and maintenance of the APF, including any costs associated with the Use Permit with the USAF, and any costs necessary to achieve Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) accreditation of the Animal Care and Use (ACU) program at the APF. For the purposes of this agreement, NCRR's responsibility for the animals at the APF shall be restricted to no more than the 257 NIH-owned chimpanzees in residence at the APF at the time this agreement is signed. It is understood that the routine veterinary care, animal husbandry, and facility operation and maintenance shall be provided by a commercial contractor (hereinafter referred to as the Contractor) responsible to the Director, NCRR or designee.

The NCRR will provide travel funds and any extraordinary expenses required by the DDIR, or designee, associated with the inclusion, oversight and assessment of compliance of the ACU program at the APF as a component of the IRP Assurance.

For the purposes of the amended Assurance encompassing the APF, the Director, NCRR shall report to the DDIR, in his role as Institutional Official for animal activities at the APF, equivalent to the same accountabilities of the IC Directors/Scientific Directors, as set forth in NIH Policy Manual 3040-2 "Animal Care and Use in the Intramural Program" (PM 3040-2). To enable the Director, Office of Animal Care and Use (OACU) to carry out the specific responsibilities outlined in PM 3040-2, the appropriate staff members of the NCRR (and/or ChiMP) will establish and maintain open and regular communications regarding ACU activities at the APF. This will include appointing an *ex officio* member of the OACU staff as a member of the ChiMP Working Group.

The DDIR hereby delegates authority to the Director, NCRR, who may re-delegate to the Director, Comparative Medicine Program, to appoint the members of the APF Animal Care and Use Committee (ACUC). The Director, NCRR, or designee, shall further appoint or identify a senior veterinarian at the APF to serve as the Animal Program Director (APD) for the APF. The ACUC Chair and APD shall be governed by the applicable provisions of PM 3040-2.

NCRR will require, through the GOCO contract, that all ACU activities at the APF be performed in compliance with NIH Policy Manual 3040-2 and the NIH IRP Assurance. As such, all practices and procedures must comply (or be equivalent) with applicable Policy Manuals, Guidelines, and support programs referenced in the Assurance, including provision of training and occupational safety and health services. This shall include submission of semiannual ACUC reports of facility inspections and program reviews, listings of active Animal Study Proposals, and preparation of the APF "Annual Report of Research Facility" for the United States Department of Agriculture. This shall also include an explicit requirement that the ACU program at the APF seek AAALAC accreditation. Preparations for seeking accreditation should be implemented as quickly as possible and a schedule of milestones prepared between the NCRR and the Contractor. In keeping with the provisions of PM 3040-2, the Director, NCRR, or designee and the Director, OACU shall assist the Contractor to prepare for and seek AAALAC accreditation of the ACU program at the APF. Due to the geographic and operational isolation of APF ACU activities relative to the other components identified in the Assurance, it is the intent that the APF be a separately accredited component, rather than being associated with one of the existing AAALAC files.

Both the APF ACUC and the IACUC of the institution sponsoring the research must approve any research involving the animals at the APF. The Director, NCRR, or designee, and the DDIR, or designee, shall jointly develop a definition of the categories of research that may be allowed using chimpanzees at the APF.

All routine animal and support activities performed at the APF shall be conducted in accordance with Standard Operating Procedures developed by the Contractor and subsequently approved by the Director, NCRR, or designee.

Any instances of animal death or injury must be reported to the OACU within 24 hours. Those incidents in turn, will be reported to the DDIR. Any such incidents deemed to be significant deficiencies according to PHS Policy will be verbally reported to the OLAW and followed-up in writing upon completion of appropriate ACUC investigations and implementation of corrective actions.

Requests for information or inquiries/allegations regarding activities at the APF shall be first directed to the Director, NCRR, or designee. The NCRR shall promptly notify the OACU (on behalf of the DDIR) of any inquiries that may lead to or that have public, media, or congressional interest.

Judith L. Vaitukaitis, M.D.  
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National Center for Research Resources

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