

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 9

[Docket No. NIH-2007-0927]

RIN 0925-AA31

Standards of Care for Chimpanzees Held in the Federally Supported Chimpanzee Sanctuary System

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: The National Institutes of Health (NIH) is issuing standards to implement provisions of the Chimpanzee Health Improvement, Maintenance, and Protection Act (CHIMP Act) authorizing the Secretary of the Department of Health and Human Services (HHS) to develop and publish standards of care for chimpanzees held in the sanctuary system supported by federal funds authorized under the CHIMP Act. This regulation applies to only those facilities receiving federal funds as a part of the federally funded chimpanzee sanctuary system.

DATES: This final rule is effective on November 10, 2008. The incorporation by reference listed in the rule is approved by the Director of the Federal Register as of November 10, 2008.

FOR FURTHER INFORMATION CONTACT: Jerry Moore, NIH Regulations Officer, Office of Management Assessment, National Institutes of Health, 6011 Executive Boulevard, Suite 601, MSC 7669, Rockville, Maryland 20892, or telephone 301-496-4607 (not a toll-free number).

SUPPLEMENTARY INFORMATION: On December 20, 2000, the United States Congress enacted the Chimpanzee Health Improvement, Maintenance, and Protection Act of 2000 (Pub. L. 106-551, "CHIMP Act"). Section 1 of this law amended the Public Health Service (PHS) Act by adding section 481C (42 U.S.C. 287a-3a). Section 481C authorizes the Secretary to provide for the establishment and operation of a sanctuary system to provide for the lifetime care of chimpanzees that have been used, or were bred or purchased for use, in research conducted or supported by the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), or other agencies of the Federal Government, and with respect to which it has been determined by the Secretary that the chimpanzees are not needed for

such research (i.e., surplus chimpanzees).

Section 481C(d) directs the Secretary to establish, by regulation, standards of care for operating the sanctuary system to provide for the permanent retirement of surplus chimpanzees. These standards of care for chimpanzees must ensure the well-being of the animals and the health and safety of the animals and the people caring for them. On April 5, 2001, the Secretary delegated to the Director, NIH, authorities to establish and operate the sanctuary system. Subsequently, the Director, NIH, delegated the authorities to the National Center for Research Resources (NCRR). Consequently, NCRR has the lead responsibility for coordinating all efforts on behalf of the Department of Health and Human Services (HHS) concerning the sanctuary system for surplus chimpanzees from both Federal and non-Federal sources. Section 481C(e) authorizes the Secretary to make an award of a contract to a private nonprofit entity (i.e., Sanctuary Contractor) under which the entity has the responsibility of operating (and establishing, as applicable) the sanctuary system and awarding subcontracts to individual sanctuary facilities that meet established standards. The NCRR/NIH must approve both contractor and subcontractor awards and NCRR/NIH will verify contractor and subcontractor (if applicable) qualifications through facility site visits, review of written documentation submitted to the contractor, and evaluation of available and current resources.

The NCRR/NIH will ensure compliance with the standards of care regulation through site visits (at least annually or more often if necessary), review of quarterly and annual reports, and any other measures deemed appropriate by the NCRR/NIH Project or Contracts Officer. Noncompliance with these standards or any other federal or state regulations may result in the NCRR/NIH invoking the provisions of the contract that allows the Government to terminate the contract and/or provide a management team to bring the sanctuary back into compliance. The sanctuary is covered by the Animal Welfare Regulations only if covered activities are performed. The CHIMP Act requires compliance with the Animal Welfare Act and the Federal contract and this regulation requires the Sanctuary Contractor to register with the United States Department of Agriculture (USDA) and agree to compliance inspections. Therefore, the USDA Inspectors responsible for enforcing the Animal Welfare Regulations will

perform inspections for compliance with the Animal Welfare Regulations at a frequency and time determined by the USDA staff. Once the contractor becomes a Registered or licensed Facility, the USDA will report noncompliance to NCRR/NIH as appropriate. The NCRR/NIH representative will review USDA inspection reports during on-site visits in order to monitor compliance with these final standards of care regulation. The sanctuary must also adhere to U.S. Public Health Service Policy on the Humane Care and Use of Laboratory Animals. If and when any noninvasive studies allowed under the CHIMP Act and this regulation are proposed for chimpanzees in the sanctuary, the Sanctuary Contractor must obtain an Animal Welfare Assurance from the NIH Office of Laboratory Animal Welfare (OLAW) and comply with the provisions of the policy. Finally, the sanctuary must obtain accreditation or certification by a nationally or internationally recognized body that performs such services. The sanctuary must achieve accreditation or certification within a reasonable period of time as determined by NCRR/NIH. In preparing these final standards of care, we considered the recommendations of the Board of Directors of the Sanctuary Contractor and the NCRR Chimpanzee Sanctuary Working Group and the applicable recommendations of the National Research Council made in its 1997 report entitled, "Chimpanzees in Research—Strategies for Their Ethical Care, Management, and Use." Individuals involved in developing recommendations from these groups represented a variety of professional areas including, veterinary medicine, chimpanzee behavior, animal protection, facility management, and nonhuman primate research and care. We also consulted other publications, including: *The Guide for the Care and Use of Laboratory Animals*, published by the National Research Council (NRC), *The Psychological Well-Being of Nonhuman Primates*, also an NRC publication; the *Public Health Service Policy on Humane Care and Use of Laboratory Animals*; the accreditation guidelines used by the Association for the Assessment and Accreditation of Laboratory Animal Care, International, and the American Zoological and Aquarium Association; and the USDA Animal Welfare Regulations codified in various parts of title 9, chapter 1, Subchapter A of the Code of Federal Regulations (CFR).

We are amending title 42 of the CFR by adding a new part 9 to establish

standards for operating the sanctuary system to provide for the permanent retirement of surplus chimpanzees. These standards of care apply to only the sanctuaries that are a part of the federally funded chimpanzee Sanctuary system. This final rule specifies the scope and specific standards that must be met by all contractors (primary or subcontractors) operating under the federally supported chimpanzee sanctuary system.

We announced our intention to issue the standards of care in the notice of proposed rulemaking (NPRM), "Standards of Care for Chimpanzees Held in the Federally Supported Chimpanzee Sanctuary System," that we published in the **Federal Register** of January 11, 2005 (70 FR1843-1858). The NPRM provided for a 60-day public comment period. In December 2007, the CHIMP Act was amended by the "Chimp Haven is Home Act" (Pub. L. 110-170), which terminated the authority for the removal of chimpanzees from the sanctuary system for research purposes, although noninvasive behavioral studies ["noninvasive research"] as defined herein is still permitted on site. Conforming amendments have been made to the final regulation.

I. Public Comments—General

We received 21 responses with 13 additional signatories (concurrences). The commenters generally expressed support for the regulation while taking the opportunity to comment on specific sections and paragraphs. One commenter stated the regulation was unnecessary because there are adequate regulations and policies already available to cover the care of chimpanzees in the sanctuary. However, the commenter expressed support given the fact that the regulation is in response to the CHIMP Act. Our consideration of and responses to the comments are discussed as follows.

Section 9.2 Definitions

Animal Care and Use Committee

(Comments) Several commenters objected to having a member of an animal protection organization (defined later in this section) on the committee, as set forth in the definition. They stated the individual(s) would hamper consensus and increase litigation. Another commenter noted the definition should clearly state that the requirement to have a member of an animal protection organization on the Animal Care and Use Committee (ACUC) is unique to this regulation and is not required by either the Animal Welfare

Regulations or the Public Health Service Policy on the Humane Care and Use of Laboratory Animals. The commenter also noted the ACUC must also meet the requirements of the PHS Policy if non-invasive research is performed at the sanctuary.

(Response) We have revised the definition to indicate that the requirement for an animal protection organization member on the ACUC is unique to this regulation and is not required by the Animal Welfare Regulations or the Public Health Service Policy.

Animal Protection Organization

(Comments) Several commenters stated the definition allowed animal protection organizations to define themselves without any requirements for training, experience, or proven performance. The commenters expressed concern that these individuals could be appointed to the ACUC and the Sanctuary Chimpanzee Care Committee (SCCC) despite a lack of nonhuman primate/chimpanzee experience.

(Response) The intent of the requirement to have a member of an animal protection organization is to ensure that an animal advocate is on the SCCC. The definition in the proposed regulation accomplishes that purpose and is not changed. A representative of such an organization is still required to be a member of the ACUC and the SCCC.

Exhibition

(Comments) Three commenters wrote that this definition needed further clarification to address visits by large groups that could be disruptive to the chimpanzees. Also, the commenters stated that the definition, as written, excludes limited viewing for educational purposes. They recommended the definition be modified to state that exhibition "does not include limited viewing for educational purposes."

(Response) We have modified the definition to state that the term exhibition "does not include limited viewing for educational purposes that is not disruptive to the chimpanzees."

Federally Owned Chimpanzees

(Comment) One commenter believed the definition should be broadened to include chimpanzees leased, loaned, or transferred to other biomedical/behavioral research facilities throughout the country.

(Response) We do not agree with the commenter on this issue. If we were to expand the definition to the extent

requested, the system would be overwhelmed and could not support the federally owned chimpanzees as currently defined.

Invasive Research

(Comment) One commenter noted that example 3 seemed to be a routine veterinary medical procedure and therefore should not be included in the definition of invasive research.

(Response) This example was not worded properly in the proposed rule. We have changed the example as follows: "(3) Surgery or implantation of devices that are not a part of a veterinary medical treatment or colony management practice."

(Comment) Another commenter noted that darting (example 8) is dangerous for chimpanzees and should only be used as a last resort for medical or other emergencies. The commenter also noted that personnel familiar to the chimpanzee in question should always be present if darting is necessary.

(Response) We believe the wording in this section appropriately addresses these issues and that rewording is unnecessary. Additionally, we might consider in the future incorporating into standard operating procedures a requirement that a person familiar with the chimpanzee be present at the time of darting, but not make it a regulatory requirement.

Section 9.3 Sanctuary Policies and Responsibilities

9.3(a)(4): (Comment) One commenter suggested this paragraph should read "Prohibit any invasive research except as outlined in the CHIMP Act, but permit noninvasive studies."

(Response) We have modified the wording to incorporate the above comment and to reflect the amendment of the CHIMP Act in December 2007 by the "Chimp Haven is Home Act," which terminated the authority for the removal of chimpanzees from the sanctuary system for research purposes.

9.3(a)(5): (Comments) Three commenters felt only educational viewing through camcorders or nonintrusive electronic means should be allowed. Additionally, they stated the visitor centers should be located away from the chimpanzees so they would not disrupt the chimpanzees' daily lives. Another individual stated that limited viewing should be defined. Another commenter stated facility design must include cameras to minimize the impact of visitors.

(Response) We do not agree the regulation should require facilities to install cameras. We believe the sanctuary staff should have the

flexibility to choose the technology needed to eliminate or reduce the impact of visitors on the chimpanzees. We agree that any visitor center associated with the sanctuary should be located in a manner that does not disrupt the chimpanzees' routine activities. Therefore, we have revised this paragraph to end with the phrase, "that does not adversely affect the chimpanzees' routine."

9.3(a)(7)(v): (Comments) Two commenters noted there are many Animal Protection Organizations (APOs) that focus on animal welfare, farm animals, endangered species, etc., and recommended that the individual represent an animal advocacy group with specific experience and expertise for advocacy for chimpanzees. One Commenter proposed the APO position be a rotating one (every three years) from a reputable sanctuary with experience in the care of chimpanzees formerly used in research. Two commenters stated there was no good reason to provide for an ill-defined APO member on the SCCC.

(Response) We disagree that the restrictions noted by the five commenters should be included in this regulation. They are too restrictive and would likely limit the ability of the Sanctuary to attract a representative that satisfies the needs of their program.

9.3(a)(vi)(B): (Comments) Two commenters wrote that no program should be approved that interferes with the chimpanzees' well-being.

(Response) We agree. We have revised the sentence to remove that statement.

9.3(7)(vi)(E): (Comments) One commenter stated there is a need to clarify the conditions under which the SCCC might function as an Animal Care and Use Committee. This commenter also questioned who appoints the members and evaluates the SCCC reports. One commenter noted if the ACUC reviews noninvasive study proposals, it must be constituted in accordance with the provisions of the PHS policy and the Animal Welfare Regulations (AWR). The same commenter suggested that anesthesia, euthanasia, and review of study proposals be addressed in separate paragraphs since study proposals must be reviewed by a PHS/AWR-sanctioned ACUC.

(Response) We agree with the commenters that further clarification is needed to address the comments raised. We have revised 9.3(a)(vi)(E) to effect the desired clarifications, and we have added a new paragraph 9.3(a)(vi)(F) to address anesthesia and euthanasia.

9.3(a)(8): (Comments) Two Commenters strongly supported the rule

requiring the prevention of reproduction in the sanctuary. They noted that offspring born in the sanctuary should remain with the mother until they are at least 4 years old; and offspring born in the sanctuary should belong to the sanctuary, not the Federal Government.

(Response) The length of time that offspring stay with the mother should be addressed in sanctuary operating policy based upon best available information rather than in the regulation. We agree that the sanctuary should retain ownership of offspring born there. Therefore, we have amended 9.5(a) (Chimpanzee ownership, fees, and studies) to add a statement to that effect.

9.3(a)(9): (Comment) One commenter stated chimpanzees should not be discharged from the Sanctuary for any reason.

(Response) In December 2007, the Chimp Act was amended by the "CHIMP Haven is Home Act," which terminated the authority for the removal of chimpanzees from the sanctuary system for research purposes.

9.3(a)(10): (Comments) Two commenters felt chimpanzees that are seropositive for, harbor, or have been exposed to infectious diseases should be socially housed with other chimpanzees that have a similar profile. One commenter indicated that the behaviorist should have experience working with chimpanzees with such exposures as well as disabled and old chimpanzees.

(Response) We appreciate the comments. However, we believe the issues raised are adequately covered under this section and, as written, the section allows the sanctuary to develop innovative ways to address these issues.

9.3(a)(11): (Comments) One commenter proposed the guidelines developed for accepting chimpanzees not owned by the Federal Government should be published for public comment.

(Response) We disagree. The CHIMP Act left this process to the Sanctuary Board of Directors with oversight from the Secretary, HHS. There was no requirement that guidelines for acceptance of non-government-owned chimpanzees be published for public comment.

9.3(a)(12) and (13): (Comments) Two commenters stated the location and numbering of this section implies that the Board of Directors (BOD) is subservient to the SCCC. They also suggested that we show the lines of authority from the BOD and the SCCC.

(Response) We agree the numbering and wording implies the Sanctuary BOD reports to the Sanctuary SCCC. This is

not the case. We have corrected this error in the final regulation.

9.3(a)(13)(ii): (Comment) One commenter indicated that we should consider seeking input from persons who are experts on chimpanzees in the wild not just behavioral experts for captive chimpanzees. This description of behaviorist was paraphrased from the CHIMP Act and, as written, does not exclude a person with experience in the behavior of chimpanzees in the wild. We have decided not to change this paragraph.

9.3(a)(13)(iii): (Comments) One commenter expressed strong support for including a member of an animal protection organization (APO) on the SCCC and indicated that the organization represented should have demonstrated advocacy for chimpanzees. Two commenters believed the inclusion of representation from an APO would be counterproductive and should not be mandatory.

(Response) We consider the representation of an APO on the SCCC appropriate. The Sanctuary Director, with the approval of the Board of Directors, will select the APO representative with the mission of the sanctuary in mind.

9.3(a)(13)(iv): (Comment) One commenter suggested that a sentence be added indicating that any chimpanzee removed from the Sanctuary for invasive research in accordance with the CHIMP Act must be placed in a PHS-assured facility.

(Response) In December 2007, the CHIMP Act was amended by the "Chimp Haven is Home Act," which terminated the authority for the removal of chimpanzees from the sanctuary system for research purposes. Therefore, this paragraph was deleted in the final rule.

9.3(a)(14): (Comments) Two commenters stated that chimpanzees should not be removed from the sanctuary for any reason. One commenter further expressed support for the public comment period and stated that it should be extended from 60 to 90 days.

(Response) In December 2007, the CHIMP Act was amended by the "Chimp Haven is Home Act," which terminated the authority for the removal of chimpanzees from the sanctuary system for research purposes. Therefore this paragraph was deleted in the final rule.

Section 9.4 Physical Facility Policy and Design

(Comments) One commenter stated strong support for the language present in the regulation that considers the

psychological and behavioral well-being and the social needs of all chimpanzees transferred from the laboratories. The commenter also indicated the regulation should require that chimpanzees formerly living in groups should not be sent to the Sanctuary without members of that group. Also, volunteer staff should not be allowed contact with any chimpanzees until after a six-month training period in order to maintain stable human interaction.

(Response) We agree that the psychological well-being and social needs of the chimpanzees are important considerations and have retained language in the regulation that considers the psychological well-being and social needs of all chimpanzees transferred from the laboratories. However, to include provisions in the regulation that would require that all chimpanzees residing in a group be sent to the Sanctuary together would be overly restrictive to the operations of the Sanctuary. Mandating a six-month training period for volunteers also restricts the administrative discretion of the staff to determine when a volunteer is properly trained and when access to the chimpanzees is appropriate.

(Comment) One commenter strongly supported the need to provide a facility with sufficient space for chimpanzees to engage in a full range of species-specific activities.

(Response) We agree. The regulation as written requires such space.

(Comments) Three commenters noted that the passage "the safe and sanitary equipment for both the chimpanzees and their human counterparts" was duplicative.

(Response) We agree and have removed the redundant sentence.

(Comment) One commenter objected to simply stating "the floor must not be slippery" because some areas may be inherently slippery. The commenter suggested that we change the wording to state "the floor must not be dangerously slippery."

(Response) We believe that 9.4(a)(ii) necessitates that the enclosure "prevent escape and injury to the chimpanzees". Therefore, phrasing regarding the slipperiness of the floor is redundant and has been removed.

(Comment) One commenter indicated it was unnecessary to limit the sanctuary system to a particular climate because there are successful chimpanzee sanctuaries in varying climates.

(Response) We believe that 9.4 necessitates indoor and outdoor enclosures that permit natural activities of chimpanzees. Climate is therefore

incorporated into the expectation of natural activities.

(Comments) Three commenters indicated that the use of strong chain link fencing with curved barbed wire is not a barrier to chimpanzees and it should be deleted as an example.

(Response) We agree. We have removed this example from the final regulation.

(Comments) Two commenters stated that space heaters should not be used for closed, indoor quarters because they can lead to fires or other health hazards. One commenter stated that support for this regulation depends upon the indoor and outdoor housing areas providing temperatures that are comfortable for chimpanzees; outdoor areas providing shelter to escape extreme temperatures, if necessary; and the sanctuary providing mechanical systems to achieve these goals.

(Response) We believe the regulation as written sufficiently addresses the concerns expressed by the commenter. We have revised the text to eliminate the reference to space heaters. Methods of providing for the comfort of the chimpanzees will likely vary depending upon the location of the facility.

Section 9.5 Chimpanzee Ownership, Fees, and Studies

9.5(a): (Comment) One commenter stated that the ownership of all chimpanzees in the federally supported sanctuary should belong to the sanctuary, not just the non-Government-owned ones.

(Response) The CHIMP Act specifically sets forth the requirement to transfer the title for non-Government-owned chimpanzees to the sanctuary. The Secretary uses the discretionary authority granted by the Act to retain Government ownership of federally owned chimpanzees. Therefore, we have made no changes in response to the comment.

9.5(b): (Comment) One commenter wrote that any chimpanzee from the four or five current biomedical research facilities currently housing chimpanzees for research should be exempt from entry fees.

(Response) The exemptions noted in this section are stated or implied in the CHIMP Act. The only biomedical research centers specifically exempted are the National Primate Research Centers.

9.5(b)(2): (Comments) One commenter suggested this paragraph should be amended to state that fees for non-Government-owned chimpanzees shall (rather than may) be levied in order to assure that adequate financial support is available. The commenter also

suggested the paragraph should emphasize that the sanctuary is primarily for chimpanzees that are no longer needed for federally supported research.

(Response) We note the concern of this commenter that the taxpayers are not committed to supporting chimpanzees from private entities. We have revised this paragraph to emphasize that while chimpanzees not owned or supported by the Federal Government may be accepted into the sanctuary, federal funds may not be used for their support, unless authorized by the Secretary or an authorized designee. We do not believe it is necessary to modify the current language to reiterate that the sanctuary is established primarily for chimpanzees that are no longer needed in federally funded biomedical research.

9.5(c)(3): (Comment) One commenter suggested adding a statement to this condition indicating that any chimpanzee owned by the Federal Government or a National Primate Research Center (NPRC), and available for transport, shall not be excluded from transport to the sanctuary because a lack of space exists.

(Response) It is unclear whether the commenter was implying that federally and/or NPRC-owned chimpanzees shall have first priority for space in the sanctuary, or whether space must always be available to accept chimpanzees from these sources whenever they are made available. If it is the former, then the fact that first priority is given to federally owned (or supported) and NPRC-owned chimpanzees is stated and/or implied elsewhere in this regulation and will be reemphasized here. If the reference is to the latter scenario, then the sanctuary will not be required to hold space for indefinite periods to accommodate unplanned transfer from these sources.

9.5(e): (Comment) One commenter wrote that the fees for accepting chimpanzees not owned by the Federal Government should be clearly defined in this regulation.

(Response) We disagree because any future changes in the fee structure would require revision of the regulation. Therefore, we have decided not to make any changes in response to the comment.

9.5(f): (Comments) Three commenters opposed the return to research of any chimpanzee in the sanctuary.

(Response) No invasive research will be allowed on chimpanzees in the sanctuary. However, the CHIMP Act does allow for noninvasive studies to be conducted in the sanctuary, provided the study does not affect the health,

well-being, and social status of the chimpanzees. In December 2007, the CHIMP Act was amended by the "Chimp Haven is Home Act," which terminated the authority for the removal of chimpanzees from the sanctuary system for research purposes. Therefore, all references to the procedures for returning chimpanzees to research were deleted from the final rule.

Section 9.6 Animal Care, Well-Being, Husbandry, Veterinary Care, and Euthanasia

9.6(a): (Comment) One commenter indicated support for language that considers the psychological and behavioral well-being and the social needs of the chimpanzees transferred from research laboratories. The commenter also noted the regulation should require that chimpanzees that formerly lived in a group should not be sent to the sanctuary without all members of that group, and that volunteer staff should be trained for at least 6 months before having direct contact with the chimpanzees. Actions expressed in the latter statement are deemed necessary to maintain stable human-chimpanzee interaction.

(Response) We do not agree that all chimpanzees belonging to a group prior to assignment to the sanctuary must be transported together as a group. Mandating the entities involved to follow such strict requirements is not practical. Nor do we agree that the regulation should set rigid standards mandating 6 month training regarding volunteers or other employees. These activities are best handled through policies developed by the sanctuary and monitored by the appropriate oversight agencies.

(Comments) Three commenters suggested (1) the reference to a cleaning schedule for indoor enclosures be changed to read "Indoor primary enclosures must be cleaned as often as required to maintain a clean and healthy environment, with a minimum of once daily"; (2) the outdoor enclosure must be monitored and cleaned on a routine basis, with routine defined as requiring daily monitoring and cleaning at least 3 times weekly; and (3) the phrase "if appropriate" should be removed as chimpanzees need food, water, and bedding at all times.

(Response) We believe 9.6(b) as revised addresses these concerns. The sanctuary system will gain experience with proper husbandry and dietary care, and this regulation provides sufficient flexibility for achieving the primary goal of promoting the chimpanzees' well-being. Specifically, the revised regulation states that chimpanzees

"must have access to food, water, and bedding at all times, unless medical or behavioral conditions dictate otherwise."

(Comment) One commenter suggested the reference for cleaning, feeding, and watering implements should be changed from the "Guide" to the Animal Welfare Regulations, paragraph 384.

(Response) The Guide is used as a reference for compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals and thus is appropriate for this regulation. Compliance with the Animal Welfare regulations is also mandatory.

(Comments) Three commenters supported keeping chimpanzees in pairs or larger groups and indicated the allowance for solitary needs further definition, i.e., specific medical and behavioral conditions that require solitary housing should be enumerated. The psychological deterrent must be considered before allowing solitary housing.

(Response) We agree that chimpanzees should be housed in groups of 2 or more and that the psychological ramifications of solitary housing be considered before it is done. We disagree with the suggestion to more specifically define the medical and behavioral conditions that require solitary housing. This determination should be made by the veterinarian and behaviorist.

(Comments) Several commenters also suggested that we should include running as a species-specific behavior.

(Response) We agree, and we have added running as a species-specific behavior.

(Comments) Three commenters indicated the requirement to have outdoor housing that must include elements of natural habitats such as trees, shrubs, grasses, potable water for drinking, and natural and artificial shelter would not be practical. They suggested this standard be applied only to facilities that have outside ranging areas.

(Response) Section 9.4 addresses the comment that outdoor areas provide sufficient space, habitat, and structures.

(Comments) Three commenters wrote this section did not sufficiently address enrichment and stated that more specific details were needed such as a list of items to be available, a list of prohibited items, and a list of social activities between chimpanzees and caregivers.

(Response) We do not agree that very specific details are needed in the regulation. To do so would be too prescriptive and would discourage innovation and variety. We have added

a sentence to indicate that enrichment techniques used should be those currently accepted practices.

(Comments) Two commenters expressed strong support for the requirement that chimpanzees be able to retreat when threatened.

(Comment) One commenter indicated that the site should have enough structures/areas to provide refuge and shade for all group members.

(Response) We agree. These concerns have been addressed in other sections of the regulation.

(Comments) One commenter supported the requirement to provide challenging feeding techniques. Three commenters addressed specific areas within this section. These areas were (1) the statement that commercial diet should be supplemented by natural foods should be revised to read that natural diet should be supplemented by commercial diet; (2) the statement that enrichment food must be provided a minimum of twice daily to engage chimpanzee interest; and (3) the need to include appropriate rodent and pest control measures, especially in a semi-tropical and tropical environment.

(Response) We believe the regulation provides sanctuary staff the flexibility to develop and implement innovative enrichment feeding schedules that might include an effective once-a-day feeding plan. The Facility Director and other staff are expected to provide appropriate care for chimpanzees, which would include appropriate rodent and pest control. As the regulation requires the sanctuary to be accredited by an outside organization, we expect that rodent and pest control will be addressed to achieve full accreditation.

(Comments) Four commenters stated this section should specifically outline or define the methods to be used to train chimpanzees to present arms for collection of blood collection or maintain previously learned related behaviors (more specifics needed on training and oversight). Also, commenters indicated that using punishment and negative stimuli should not be allowed.

(Response) We disagree that the regulation should outline specific methods that are allowed or not allowed for training chimpanzees to participate in certain clinical procedures. The law requires the sanctuary to use acceptable methods that represent current practices. We agree that physical punishment should be used only in life-threatening situations and should not be used routinely. We have revised the section to include the requirement to use current acceptable practices that do

not include physical punishment except in life-threatening conditions involving other chimpanzees or humans.

(Comments) We received several comments that paragraph 9.6(b)(3) in the notice of proposed rulemaking includes one comment indicating that information in that paragraph was redundant with information presented in section 9.7.

(Response) We agree the information here is redundant with the information presented in section 9.7. Therefore, we have deleted this paragraph and have addressed comments on this topic in section 9.7.

(Comments) Two commenters noted the regulation does not specifically address housing individuals with infectious diseases with healthy animals. They noted healthy chimpanzees should not be exposed or placed at risk by infected animals.

(Response) We agree. The regulation, as revised, expects the facility to be appropriately designed to reduce exposure. Additionally, the Facility Veterinarian is expected to have appropriate expertise to address infectious diseases.

(Comments) Five commenters expressed concern that anesthesia, if used to perform annual physicals, may place chimpanzees at risk and should not be used routinely. Visual observation and medical history should be sufficient in most cases. One commenter suggested that if anesthesia was necessary, the physical should be done when a chimpanzee is anesthetized for other reasons.

(Response) We agree that there can be risks associated with general anesthesia. However, the veterinarian is medically trained to assess and accommodate for the risk factors involved. The regulation as written does not specify that the physical must be done under general anesthesia. However, for safety reasons for both the chimpanzee and the individual performing the physical, it may be the logical thing to do. The Facility Veterinarian must use sound professional judgment in deciding when and if general anesthesia is needed or whether visual and historical information is sufficient. A statement to this effect has been added to this paragraph.

(Comment) One commenter stated that complete veterinary records and a comprehensive health history must accompany every chimpanzee sent to the sanctuary. The commenter noted that records of this sort were not required under Section 9.6, Animal care, Well-being, Veterinary care, and Euthanasia. We presume the comment is noted in regards to using the medical

history to determine the frequency and extent of the annual physical examination.

(Response) We disagree. We believe the medical records noted are required by this regulation. The requirement to submit complete records with chimpanzees accepted into the sanctuary can be found in one or more of the following sections: 9.5(d), 9.6, and 9.8(a)(3). We have added wording to section 9.6 to further emphasize the need for a complete medical history. The CHIMP Act states that the Secretary may deny a chimpanzee entry into the sanctuary if the complete medical and research history is not available.

(Comment) One commenter noted euthanasia for a chimpanzee with tuberculosis should be done only as a last resort.

(Response) We agree and believe the current wording encompasses the commenter's concern.

(Comment) One commenter stated that collection and banking of serum should only occur if it has a direct effect on the chimpanzees' health and not for research.

(Response) We agree and have added the appropriate wording to this paragraph.

(Comments) One commenter noted that additional tests should only be conducted if necessary for the health and safety of the chimpanzees. The commenter also suggested the Facility Veterinarian should consult with the veterinarian from the donating institution to gain additional information in order to eliminate the possible need for anesthesia.

(Response) We agree that additional tests should only be done for the health of the chimpanzee. We have revised this paragraph to clarify that point. We believe that requiring the Facility Veterinarian to consult with another veterinarian in the case would be inappropriate. However, nothing in the regulation precludes the facility veterinarian from holding such consultation.

(Comments) Two commenters stated that abnormal behavior and efforts to manage it should be clearly defined. Also, they noted the minimal provisions set forth in this paragraph were insufficient.

(Response) We disagree. The behaviorist and other professionals at the Sanctuary must be properly trained and capable of defining and implementing the specific plan for each chimpanzee without the constraints of specifics in the regulation. The plan and intervention will be reviewed by the appropriate federal officials when conducting inspections.

(Comments) One commenter indicated support for the language that emphasizes minimizing the use of physical and chemical restraints. Two commenters noted we need to explicitly define procedures for training chimpanzees to participate in certain activities in order to avoid the use of physical constraint. Further, the commenters stated that methods must not include any negative stimuli or punishment. Finally, they noted physical restraint should be prohibited unless methods are approved by the Board of Directors (no approval for research purposes).

(Response) We do not agree that the regulation must provide explicit detailed procedures for training chimpanzees to participate in certain activities in order to avoid the use of physical restraint. The specific methods are more appropriately left to the Sanctuary professional staff with oversight by the Board of Directors and appropriate Federal officials. The prior approval of training and restraint methods by the Sanctuary Board of Directors is expected to be handled by institutional policies and procedures if deemed appropriate by the sanctuary administration.

(Comments) Six commenters raised questions about what constituted adequate staff and staffing ratios for emergency, weekend, and holiday coverage. Two of these commenters also stated that Sanctuary staff and caregivers should be given radios for emergency communication.

(Response) The issue of appropriate staffing is addressed under sections 9.6 and 9.9. Experience will dictate the number and ratio of staff needed to provide adequate care for chimpanzees in the sanctuary environment. Insurance of communication devices is appropriately handled by institutional policies and procedures as opposed to specification in this regulation.

(Comments) Six commenters suggested changes to the paragraph regarding euthanasia. Several indicated that the sanctuary should have a policy on euthanasia from either the SCCC or the Board of Directors. Some stated that with pre-existing endpoints, the veterinarian would have some guidance in exercising professional judgment for performing euthanasia to relieve pain and/or suffering in a timely manner with SCCC review after euthanasia. Three of the commenters believed the decision to euthanize a chimpanzee should not be left to an individual veterinarian but the regulation should require consensus of at least two veterinarians.

(Response) We agree that the sanctuary must have a policy on euthanasia that, at a minimum, outlines when, why, how, and by whom euthanasia will be performed. The requirement to have a policy on euthanasia is stated elsewhere in the regulation, but we have added a sentence to that effect in this paragraph. However, the decision to euthanize a chimpanzee for medical reasons to relieve pain and/or suffering for humane reasons remains with the Facility Veterinarian.

Section 9.7 Reproduction

(Comments) Three commenters stated that offspring accidentally born in the sanctuary should be allowed to remain with the mother for a period of at least four years (or in one commenter's opinion, for life). If this is not possible, then the offspring should be placed with a surrogate mother.

(Response) There was disagreement among the experts who we consulted concerning the specific length of time offspring should remain with the mother. Therefore, we have added a sentence in this paragraph that states, in essence, that the sanctuary must have a contingency for handling births in the colony including the length of time the offspring should remain with the mother.

Section 9.8 Animal Records

(Comments) Five commenters raised questions about the method(s) of identification of chimpanzees and the need to define which agency will track chimpanzees for life and the methods used for identification. They noted that identification methods should be noninvasive and exclude tattoos unless the chimpanzee is already tattooed.

(Response) The vast majority of chimpanzees entering the sanctuary will already be identified. It is possible that chimpanzees entering from a private entity may not be permanently identified. The sanctuary must then determine the appropriate method of identification. We have decided to retain the wording used in the proposed regulation.

(Comments) Two commenters questioned whether the records or reports will be available to the public. One commenter suggested that reports should be published in the **Federal Register**.

(Response) There is no requirement in the CHIMP Act to publish reports pertaining to the Sanctuary in the **Federal Register**, and we have no plan to do so. The Agency's Sanctuary-related records will only be available

using existing federal laws for obtaining information from federal agencies.

(Comments) Two commenters stated that all necropsy records should be publicly available and published in the **Federal Register**. One commenter noted that the necropsy records should be reasonably available to any veterinarian caring for chimpanzees formerly used in research. To do otherwise is perceived to not recognize the importance of such information for the care and well-being of formerly used or supported chimpanzees.

(Response) The CHIMP Act specifies the distribution of necropsy records. We believe the current wording captures the essence of congressional intent. Therefore, we have decided not to change the wording in this section.

Section 9.9 Facility Staffing

(Comment) One commenter provided general comments stating that reasons for dismissal of staff should be recorded (ethics, attitude, misconduct, etc.). Also, rules should prohibit individuals with communicable disease from direct contact with chimpanzees.

(Response) We do not agree that the above items should be a part of the regulation. Documentation of actions taken against staff is governed by human resources policies that are not appropriate for inclusion in the regulation. Identification of communicable diseases that could affect chimpanzees and the restriction of staff direct contact with chimpanzees are issues best dealt with via the veterinary care and occupational health policies and procedures of the sanctuary.

(Comments) Two commenters indicated that the staffing ratio should be sufficient to maintain an effective program of behavioral enrichment.

(Response) We agree and have added a phrase indicating that sufficiently trained staff for behavioral enrichment must be available.

(Comments) Three commenters stated the section on signs of well-being should be revised to read that staff is trained to recognize all forms of distress, not just illness, and that signs of physical and psychological well-being are monitored.

(Response) We do not agree that the sentence in question needs to be revised. We believe it encompasses all issues of well-being as written.

(Comments) Two commenters indicated this paragraph should be more specific about the number or ratio of veterinarians needed for the sanctuary. One of the commenters suggested an explicit ratio should be recommended by the Board of Directors.

(Response) We disagree with the need to provide more specific numbers and ratios of veterinarians needed. We believe conditions may vary and capturing every possible variation in the regulation is not practical. The number needed is best deferred to the sanctuary administration that may or may not include recommendations from the Board of Directors, and will be assessed by the NIH staff. The adequacy of the veterinary care program will be monitored by federal agencies and, upon accreditation, the accrediting agency.

(Comment) One commenter stated the behaviorist's experience must also include working specifically with nonhuman primates during the introduction and formation of social groups. If they are unsuccessful in group formation, then they should consult with chimpanzee experts outside of the facility. The behaviorist should have access to the donating institution in order to observe behavior of incoming chimpanzees and discuss plans with individuals on site.

(Response) We believe the description of the behaviorist's qualifications as described in the existing paragraph is adequate. The comments provided are relevant but detailed description of the qualifications should be left to Sanctuary administration and staff.

Section 9.13 Other Federal Laws, Regulations, and Policies That Apply to This Part

(Comments) Three commenters noted that a segment of the Animal Welfare Regulations applicable to the chimpanzees in the sanctuary was omitted from section 9.13. The segment to which the commenters referred is AWR Part 3, Subpart D, "specifications for the humane handling, care, treatment, and transport of nonhuman primates."

(Response) We agree that a segment of the AWR was inadvertently omitted. We have included it in the final regulation.

(Comment) One commenter strongly suggested we should add State and Federal laws relating to human health and safety and environmental issues.

(Response) Any reference to state laws would have to be general since the states that may house sanctuary facilities are unknown at this time. In regards to federal laws mentioned, several of the laws the commenter had in mind are already applicable by virtue of the nature of the business of the entity, i.e., OSHA, EPA, etc. Other Federal laws or regulations that are applicable to the general nonhuman primate community are not applicable to the federally supported chimpanzee

sanctuary system because there will be no importation, invasive research, or air transportation of chimpanzees.

II. Changes Made in Response to Comments

We have made the following changes to the regulation in response to the comments that we received following publication of the notice of proposed rulemaking.

Section 9.2 Definitions

Animal Care and Use Committee

We have revised the definition of the term Animal Care and Use Committee (ACUC) to indicate that the requirement for a member of an animal protection organization member on the Committee is unique to this regulation and is not required by the Animal Welfare Regulations or the Public Health Service Policy.

Exhibition

We have revised the definition of Exhibition to state that it does not exclude limited viewing for educational purposes that is not disruptive to the chimpanzees.

Invasive Research

The example was not worded correctly in the proposed rule. We have modified the example to read as follows: “(3) Surgery or implantation of devices that are not a part of a veterinary medical treatment or colony management practice.”

Additionally, we have deleted our previous reference to the term “ISIS”, the acronym for the International Species Information System, because the agency no longer tracks chimpanzees in the Sanctuary.

Section 9.3 Sanctuary Policies and Responsibilities

We have revised paragraph 9.3(a) to read as follows:

(a) What are the policies and responsibilities governing the Sanctuary system? The policies and responsibilities of the Sanctuary system are to—

(1) Appoint a Board of Directors (BOD) responsible for the overall governance and direction of the Sanctuary. The BOD shall designate the Chief Executive Officer (CEO), who is responsible for the management and oversight of the daily operations of the Sanctuary and the performance of other delegated tasks. Subcontractors, if applicable, shall be governed by the policies that are developed by the Board of Directors of the primary contractor. In addition, the BOD shall:

(i) Ensure that chimpanzees accepted into the Sanctuary are not discharged;

(ii) Develop guidelines for accepting chimpanzees not owned by the Federal Government into the sanctuary if the conditions are met as outlined in 42 U.S.C. 287;

(iii) Ensure that the Board of Directors of the primary contractor consists of no more than thirteen (13) individuals, and that the conditions governing the terms of the Board members are in compliance with the CHIMP Act;

(iv) Include individuals with the following expertise and experience as set forth in the CHIMP Act;

(A) At least one veterinarian who is qualified in veterinary care of nonhuman primates. These qualifications may be met through postdoctoral training, experience, or both;

(B) Individual(s) with expertise and experience in zoological science and with knowledge in behavioral primatology;

(C) Individual(s) with experience in the animal protection field;

(D) Individual(s) with experience and expertise in the field of business and management of nonprofit organizations;

(E) Individual(s) knowledgeable and experienced in accrediting programs of animal care;

(F) Individual(s) with experience and expertise in containing biohazards;

(v) Ensure that a member of the Board of Directors serves as the Chair of the Board of Directors, who may be elected or appointed by the Board from among the individuals identified in paragraphs (a)(1)(iv)(A) through (F) of this section;

(vi) Ensure that no member of the board shall have been fined for, or signed a consent decree for, any violation of the Animal Welfare Act;

(vii) Ensure that a chimpanzee may not be removed from the sanctuary for research purposes;

(viii) Create a safe and species-appropriate physical and social environment for the lifetime care of chimpanzees;

(ix) Comply with all applicable provisions of the animal welfare regulations and other federal, state, and local laws, regulations, and policies;

(x) Achieve accreditations from appropriate accrediting bodies within a reasonable timeframe mutually agreed upon by the contractor and NCRR;

(xi) Prohibit any invasive research on the resident chimpanzees, but permit noninvasive and behavioral studies. Definitions for the terms *invasive* and *noninvasive* are set forth in § 9.2 of this part;

(xii) Prohibit exhibition of chimpanzees in the sanctuary [This

policy does not prohibit educational activities that may involve limited viewing of chimpanzees in their environment and that are designed to promote an understanding of chimpanzee behavior, well-being, or importance to the ecological system that does not adversely affect the chimpanzees' routine.];

(xiii) Staff the organization with people with appropriate experience; and

(xiv) Authorize the establishment of a Sanctuary Chimpanzee Care Committee (SCCC) that is appointed by and reports to the CEO or President of the company or corporation. The SCCC is responsible for overseeing the chimpanzee care program and operations to ensure that the health and well-being of the chimpanzees and the occupational safety of the staff are being addressed. The Committee must consist of no fewer than five people who must include:

(A) A chairperson knowledgeable of the needs of chimpanzees;

(B) A veterinarian with chimpanzee care experience;

(C) A behaviorist with experience in chimpanzee behavior;

(D) A member of the chimpanzee care staff; and

(E) Member or members from the community, including at least one with affiliation or employment with an animal protection organization as defined in § 9.2 of this part. (Note, this provision is unique to these standards of care and is not required by the Animal Welfare Regulations or the PHS Policy.)

(F) The SCCC will:

(1) Oversee and evaluate the chimpanzee care and socialization program;

(2) Review and approve proposed education programs. No program should be approved that might interfere with the chimpanzees' well-being or routine activities;

(3) Conduct a formal review of the program on a semiannual basis and submit reports to the Sanctuary director. The reports must be available for review by the USDA and NIH representatives during site visits;

(4) Establish a mechanism for receipt and review of concerns involving the care of chimpanzees and resolving such concerns;

(5) Review all such study proposals. The SCCC membership may require additional qualified individuals to perform the functions of an Animal Care and Use Committee (ACUC) if and when the need arises. The Contractor may establish a separate ACUC. The ACUC must be established in accordance with the applicable provisions of the Animal Welfare Regulations and the *Public*

Health Service Policy on Humane Care and Use of Laboratory Animals;

(6) Review all euthanasia events. Euthanasia events performed for medical or humane reasons must be based upon sound professional veterinary judgment that conforms to current veterinary medical practices and must be in the best interest of the chimpanzee. Euthanasia performed for emergency reasons without advance review by the SCCC shall be reviewed by the SCCC as soon as possible after the event to ensure compliance with established policy;

(7) Establish procedures to prevent any reproduction in the colony through appropriate permanent birth control, preferably by vasectomy of all sexually mature male chimpanzees in the sanctuary; and

(8) Develop procedures for maintaining chimpanzees that are seropositive for or harboring infectious agents or previously have been exposed to infectious agents (whether experimentally induced or naturally occurring), that will allow them to be accepted by the sanctuary and properly housed. The procedures must be submitted to the NCCR for approval.

Section 9.4 Physical Facility Policies and Design

We have revised the regulation in response to the comments that we received following publication of the notice of proposed rulemaking. Specifically, to improve the clarity of the regulation, we have made several revisions to the proposed 9.4 and renumbered the section accordingly. Statements in the proposed section that were determined to be redundant or superfluous relative to other sections in the regulation have been deleted.

The revised section reads as follows.

(a) *What standards apply to the facility design and physical plant?* The chimpanzee Sanctuary facility must be designed to provide sufficient space and variety of natural or artificial objects to accommodate natural activities of chimpanzees while restricting their movement and range to the defined area. Daily observation of chimpanzees within the enclosures is required and shall be accomplished with minimal disturbance to the chimpanzees. The facility design and physical plant should be in accordance with the recommendation of *The Guide for the Care and Use of Laboratory Animals (Guide)*, where applicable. The *Guide* is published by the National Research Council, 1996, International Standard Book Number 0-309-05377-3. The *Guide* is incorporated by reference in this section. The Director of the Federal

Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of the publication from the National Academy Press, 2101 Constitution Avenue, NW., Lockbox 285, Washington, DC 20055; or you may order it electronically via the Internet at <http://www.nap.edu>; or view it online at <http://oacu.od.nih.gov/regs/guide/guidex.htm>. You may inspect a copy at NIH, NCCR, 1 Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20817-4874, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(i) The facility design and physical plant consist of the following components: Indoor design features; outdoor design features; construction and construction materials; physical barriers; shelter; service support space, including storage areas for food, supplies, and equipment; personnel and administrative support space; quarantine and isolation facilities; treatment area; heating, ventilation, and air conditioning (HVAC); food preparation area; and animal waste treatment.

(ii) A housing system shall include indoor and outdoor enclosures that must be kept in good repair to prevent escape and injury to the chimpanzees, promote physical comfort, facilitate sanitation and servicing, and address the psychological well-being and social needs of the chimpanzees. Chimpanzees must be able to retreat from areas where they feel threatened or agitated by close human encounters or encounters with other chimpanzees.

(iii) Indoor areas shall have special areas for social introductions and medical treatment. Quarantine and isolation facilities are required for the Sanctuary. These facilities must be designed to prevent the spread of undesirable agents from quarantine and isolation rooms to other parts of the facility.

(iv) Outdoor areas must provide sufficient ranging space and either natural or artificial structures that chimpanzees can use for shelter or nesting areas to sleep, rest, or seek refuge from rain, direct sun, wind, and extreme temperatures.

(v) Animal waste from the sanctuary must be properly treated to remove known hazardous agents before discharging it into the environment in accordance with currently acceptable and effective waste treatment

procedures, including current industry standards and federal laws, regulations or guidelines, as applicable.

(vi) An area for treatment of and performing veterinary clinical procedures on chimpanzees must be provided at each sanctuary site. This area must be constructed and provisioned to perform emergency procedures, including minor surgery and emergency surgical procedures, complete physical examinations, and facilities for extended care of medical conditions as needed.

(b) *What security measures are required for the sanctuary?* The sanctuary must provide adequate security against unauthorized entry, sabotage, malicious damage, and theft of chimpanzees and property and must minimize any chance of escape by a chimpanzee.

The security staff must have training and/or experience in methods and equipment designed to detect possible security breaches and the ability to respond to security events in a timely and effective manner. Perimeter containment shall be used to protect the compound housing the chimpanzees consistent with the recommendations of the *Guide* (incorporated by reference, see paragraph (a) of section 9.4).

(c) *Is the sanctuary required to develop disaster and escaped animal contingency plans?* The sanctuary facility must prepare disaster and escaped animal contingency plans outlining simple and easy to follow plans for dealing with natural and man-made disasters and steps to be taken in case a chimpanzee escapes from the compound. The sanctuary also must provide adequate security against unauthorized entry, sabotage, malicious damage, and theft of chimpanzees and property and must minimize any chance of escape by a chimpanzee. Primary barriers must be constructed to prevent escape of chimpanzees and secondary or perimeter barriers must prevent entry of unauthorized persons into the facility, consistent with the recommendations of the *Guide* (incorporated by reference, see paragraph (a) of section 9.4).

Section 9.5 Chimpanzee Ownership, Fees, and Studies

We have revised paragraph 9.5(b)(2) to emphasize that although chimpanzees not owned or supported by the Federal Government may be accepted into the sanctuary, federal funds may not be used for their support, unless authorized by the Secretary or an authorized designee.

Section 9.6 Animal Care, Well-Being, Husbandry, Veterinary Care, and Euthanasia

We have revised the regulation in response to the comments that we received following publication of the notice of proposed rulemaking. Specifically, to improve the clarity of the regulation, we have made several revisions to the proposed 9.6 and renumbered the section accordingly. Statements in the proposed section that were determined to be redundant or superfluous relative to other sections in the regulation have been deleted.

The revised section reads as follows.

(a) *What are the requirements for promoting the well-being of sanctuary chimpanzees?* The goal of chimpanzee housing and management in the Sanctuary is to promote the chimpanzees' well-being.

(b) *What are the provisions for daily chimpanzee husbandry and care?*

Adequate and proper care for chimpanzees in the sanctuary must be provided with respect to physical environment, housing and husbandry, behavioral management, and population management and control. Specific requirements include the following:

(i) Chimpanzees must have access to food, water, and bedding at all times, unless medical or behavioral conditions dictate otherwise. Husbandry procedures shall represent current policies and practices and conform to standards set by a nationally recognized accrediting association in accordance with the *Guide* (incorporated by reference, see paragraph (a) of section 9.4).

(ii) Indoor primary enclosures must be cleaned as often as required to maintain a clean and healthy environment, with a minimum of once daily. Outdoor enclosures must be monitored daily and cleaned on a routine basis. Outdoor ranging areas will not require a routine cleaning schedule but must be monitored for excessive accumulation of waste or other unhealthy conditions. Housing areas shall provide sufficient space for chimpanzees to perform species-typical behavior and expression. Examples of such activities include but are not limited to natural movements, climbing, swinging, resting, running, group interactions, sleeping, etc. Feeding and watering implements must be sanitized at intervals required to maintain them in a sanitary condition, in accordance with the *Guide* (incorporated by reference, see paragraph (a) of section 9.4).

(iii) The federally supported chimpanzee sanctuary must employ a behavioral scientist knowledgeable in

primate behavior and socialization requirements. This individual shall provide primary leadership in developing, implementing, and monitoring the chimpanzee behavioral guidelines for the sanctuary. Enrichment techniques used shall be currently accepted practices. The sanctuary must provide for the expertise to plan, administer, and evaluate the effectiveness of the well-being program.

(iv) Many chimpanzees can be trained through positive reinforcement to cooperate with a variety of veterinary and chimpanzee care procedures. Efforts must be made to develop or maintain this capability for chimpanzees housed in the sanctuary to the extent possible. Trainers must use currently acceptable practices that do not include physical punishment.

(c) *What are the requirements for an adequate veterinary care and animal health program?*

The Sanctuary staff must provide sufficient resources of personnel, equipment, supplies, and facilities to enable the provision of adequate veterinary care as set forth in the *Guide* (incorporated by reference, see paragraph (b) of section 9.4) and in the American College of Laboratory Animal Medicine document, "The Provision of Adequate Veterinary Care," available on the Internet at <http://www.aclam.com>.

(i) If the sanctuary houses chimpanzees with infectious diseases, it must have a veterinarian knowledgeable in the infectious diseases and care of chimpanzees. The Facility Veterinarian is responsible for establishing and implementing a health monitoring system specifically designed to meet the health requirements of chimpanzees in the sanctuary. Routine observation and the prevention of disease, metabolic conditions, abnormal behavior and injury must be a priority focus of the Facility Veterinarian and staff.

(ii) Newly received chimpanzees must be quarantined for a period for physiological, psychological, and nutritional stabilization before their introduction to the rest of the group. The stabilization period must be lengthened appropriately if the chimpanzee has a significant medical problem or if abnormal medical findings are detected during the quarantine period. If the chimpanzee has not been given a complete physical examination within six months, an examination must be conducted during the stabilization period.

(iii) The sanctuary must implement appropriate methods for disease surveillance and diagnosis of diseases, which may include the following:

(iv) Tuberculin (TB) tests must be negative for two (2) consecutive tests before the chimpanzee is released from quarantine. Any chimpanzee that is suspected of harboring the TB organism, or that is diagnosed with TB will be isolated and treated until determined by the Facility Veterinarian to be of no health risk to other chimpanzees or humans. The Facility Veterinarian may recommend euthanasia in those cases that do not respond to therapy and in which the chimpanzee consequently experiences undue pain and suffering that cannot be alleviated. The procedures noted under § 9.6(d) must be observed if euthanasia is necessary.

(v) Fecal samples must be checked for parasites and parasitic ova.

(vi) A complete blood count and serum chemical panel must be obtained.

(vii) Additional serum for banking and/or testing shall be obtained as appropriate by the Facility Veterinarian and is considered beneficial for chimpanzee health.

(viii) If the donating facility did not test for the appropriate viruses, the sanctuary must perform a viral panel and serology for the various chronic hepatitis viruses and HIV.

(ix) Additional tests or procedures that are deemed beneficial to the chimpanzees' health may be required by the Facility Veterinarian.

(x) Chimpanzees are susceptible to many of the vaccine preventable diseases of human childhood. Appropriate vaccines must be considered and administered if deemed necessary, at the discretion of the Facility Veterinarian, to protect the chimpanzees in the sanctuary. Methods of disease prevention, diagnosis, and therapy must comply with those currently accepted in veterinary medical practice. Arrangements with diagnostic laboratories must be established before chimpanzees arrive at the sanctuary.

(xi) The sanctuary must minimize the use of physical and chemical restraint. Chimpanzees in the Sanctuary shall be trained to permit certain procedures with minimal or no restraint. Such procedures may include injections, dosing or other treatments, and cage-side health observations. However, chemical sedation sometimes may be appropriate for certain necessary medical interventions or for the safety of the chimpanzee and caregivers. If physical restraint measures are necessary, due consideration must be given to the temporary or permanent effects upon the chimpanzee and human and animal safety concerns.

(xii) Methods used to relieve pain must be documented in the chimpanzee medical or surgical records. These

records will be available for review by USDA and NIH representatives. The Facility Veterinarian must ensure that pain management is current and in accordance with acceptable veterinary medical practices.

(xiii) Chimpanzees must be cared for by qualified personnel on a daily basis, including weekends and holidays, to safeguard their well-being. Emergency veterinary care must also be available during these times. Notification procedures must be documented in the form of operating procedures.

(d) *Under what circumstances is euthanasia permitted?* As stated in section 481C(d)(2)(I) of the Public Health Service Act, as added by section 2 of the CHIMP Act, none of the chimpanzees may be subjected to euthanasia except when it is in the best interest of the chimpanzee involved as determined by the SCCC and the Facility Veterinarian. Therefore, euthanasia for medical or humane reasons is permitted. Euthanasia may be permitted for reasons of health or quality of life of the individual chimpanzee, including for disease, in connection with trauma, complications of aging, or for other humane reasons. The sanctuary must establish a policy on euthanasia that will provide conditions that must be met before euthanasia is permitted and guidance for performing euthanasia.

(i) Methods of euthanasia will be consistent with the most recent report of the American Veterinary Medical Association Panel on Euthanasia (2002), unless more reliable data becomes available. When euthanasia is performed, the veterinarian will determine the appropriate agent, and it will be administered only by properly trained personnel under the direction of the Facility Veterinarian. The decision to perform euthanasia will be made by the veterinarian in consultation with the Facility Director or Deputy Director.

(ii) The SCCC will participate in the decision in nonmedical emergencies. All euthanasia decisions must be reviewed by the SCCC, preferably prior to euthanasia. In emergencies, where euthanasia has to be performed immediately by the Facility Veterinarian, the circumstances and the decision by the Facility Veterinarian will be presented at the next scheduled or special meeting of the SCCC. The NCRR Project Officer must be notified of the euthanasia event within 72 hours by electronic or telephonic means. Euthanasia of individual chimpanzees may negatively affect the care staff and appropriate counseling and psychological support shall be considered.

Section 9.7 Reproduction

We have added sentences in this section indicating that the sanctuary must have a contingency plan for handling births in the colony that includes the length of time the offspring should remain with the mother. The sentences also indicate that documentation must be provided verifying that a vasectomy was performed and confirmed by removing and examining a segment of the Vas Deferens, or using another reliable test method to confirm the male is negative for sperm.

Section 9.8 Animal Records

We have deleted the requirement that all chimpanzees must be tracked for life by a single agency. We did this because NIH no longer funds this activity and the agency is not obligated to continue the tracking activity.

Section 9.9 Facility Staffing

We have made several revisions to the proposed 9.9 in order to improve the clarity of the regulation. Statements that were determined to be redundant or superfluous relative to other sections in the regulation were removed or modified.

The revised section reads as follows.

How many personnel are required to staff the chimpanzee sanctuary and what qualifications and training must the staff possess? (a) The professional, managerial, and support staff must be sufficient to support the scope and diversity of the activities and chimpanzee population of the sanctuary. The level of staffing shall be adequate to ensure that the chimpanzees receive appropriate health care, are well cared for, and the administrative and fiscal operations are sound and in keeping with current practices required by NCRR, NIH;

(b) There must be a sufficient number of appropriately trained animal care and technical personnel to provide appropriate care to the chimpanzees at all times, including evenings, weekends, and holidays. The number of animal care staff to chimpanzee ratio shall be adjusted as experience is gained during the operation of the sanctuary. Sufficiently trained staff also must be available to maintain adequate behavioral enrichment;

(c) The Facility Director must be a person with experience in chimpanzee care and socialization techniques. In addition, the Director must have management and administrative experience;

(d) The Biosafety Officer must have experience in developing and

monitoring biohazards and dealing with biosafety issues related to captive nonhuman primates. Experience in these areas dealing specifically with chimpanzees is desirable;

(e) The remaining staff, which may include part-time, full-time, or contractor Facility Veterinarian(s) and Behaviorist(s), must possess the skills, knowledge, and/or experience required to perform their duties, as elaborated within the regulation.

Section 9.10 Occupational Health and Safety Program (OHSP) and Biosafety Requirements

We have modified this section to improve the clarity of the regulation.

The revised section reads as follows.

(a) *How are employee Occupational Health and Safety Program risks and concerns addressed?* The sanctuary shall assure that an Occupational Health and Safety Program (OHSP) is developed and implemented in accordance with current veterinary medical practices and the guidelines and standards found in the *Guide* (incorporated by reference, see paragraph (a) of section 9.4);

(b) *How are biosafety concerns addressed?* The sanctuary shall institute and administer an effective biosafety program that addresses the biosafety hazards at that particular site. The program shall include identifying biohazards, outlining practices and procedures to be followed, providing personal safety equipment or protective clothing and equipment, and establishing a description of the facility requirements for working with hazardous agents or materials. Policies and procedures must be implemented to avoid exposure to environmental and animal hazards. Biosafety must be included in the training program for all sanctuary employees. In establishing a program, the sanctuary must use current accepted practices and publications prepared by the CDC, NIH, and professional societies specializing in biosafety. The input and guidance of personnel trained or experienced in biosafety are essential.

Complete records of both clinical and experimental agent exposure must accompany each chimpanzee sent to the sanctuary. The donating facility must also provide recent testing (for example, serology, virus culture, histology) so that the sanctuary staff is fully aware of the health condition of the arriving chimpanzee. The records may be created and retained in electronic form.

Section 9.11 Animal Transport

We have modified section 9.11 to clarify its objective to require

consistency with existing laws and regulations.

The revised section reads as follows.

The transportation of chimpanzees by surface or air must be in accordance with the requirements set forth in the Animal Welfare Act and Regulations and the International Air Transport Association (IATA) Live Animal Regulations and guidelines, as applicable.

Section 9.12 Compliance With the Standards of Care, and USDA and PHS Policies and Regulations

We changed the frequency of site visits from quarterly to annually.

Section 9.13 Other Federal Laws, Regulations, Policies, and Statutes That Apply to the Sanctuary

In section 9.13, we have added “part 3, subpart D—Specifications for the Humane Handling, Care, Treatment, and Transport of Nonhuman Primates” to the Animal Welfare Regulations reference.

We provide the following as public information.

Executive Order 12866

NIH has examined the impacts of this final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action under the Executive order.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. chapter 6) requires that we analyze regulatory proposals to determine whether they create a significant impact on a substantial number of small entities. Based on the analysis that follows, the Secretary certifies that this final rule will not have such impact.

1. Number and Type of Small Entities Affected

There are several small entities that privately fund nonhuman primate sanctuaries. However, the federally supported, contractor-operated chimpanzee sanctuary system, established by the CHIMP Act and covered under the standards of care, is

the only one of its kind in existence. Congress established the Sanctuary to provide lifetime care for chimpanzees that are no longer needed in federally supported research. The final rule applies only to a contractor or any subcontractor operating under a contract funded by NIH/NCRR for the sanctuary. Only one contractor is identified in the proposed rule as the prime contractor for the sanctuary system. The NCRR awarded this contract in September 2002. Additionally, a few subcontractors might be added in future years if the need arises. The subcontractors would be selected by the prime contractor (contingent upon NIH/NCRR approval) and report to the prime contractor. Approximately four or five biomedical research centers with chimpanzees will be responsible for the transport of animals to the sanctuary. The entities shipping chimpanzees to the sanctuary are required to comply with existing Animal Welfare Regulations administered by the USDA.

2. Net Cost of Compliance With the Proposed Rule

At the time NIH/NCRR awarded the contract in 2002, the contractor was aware of its role in establishing and complying with the proposed standards of care pursuant to the CHIMP Act. The costs necessary to comply with the standards of care were anticipated by the CHIMP Act and subsequent contract negotiations. The Request for Proposals and Statement of Work noted that standards of care would be developed in consultation with the selected contractor and that the contractor must comply with these standards. The contractor selected had several members of its Board of Directors familiar with chimpanzee care standards and had served as consultants to some of the agencies publishing such standards. Therefore, the contractor included resources needed to potentially comply with anticipated standards in its contract and construction grant proposals. There could be some additional unanticipated costs, but they are not obvious at this time. Under the terms of the contract, the Federal Government assumes responsibility for seventy-five percent of the operational cost that includes compliance with the proposed standards of care. The net costs to the contractor are twenty-five percent of the total costs of care and maintenance of the chimpanzees, including compliance with the proposed standards of care. We estimate that this will amount to \$875,000 to \$1 million per year for the contractor. We anticipate no net increase in the costs as a result of compliance with the

standards of care. We estimate that five or six research facilities might incur expenses in transporting animals to the Sanctuary, and thus will incur minor shipping costs (approximately \$10,000 to \$20,000 for one shipment for a total of six shipments/year). Subcontractors will likely have existing facilities and staff, though some might need to be upgraded. They would be eligible to compete for NIH Construction Grants the same as the prime contractor and thus match 10 percent of the construction cost. We do not anticipate the use of subcontractors in the foreseeable future because of the considerable amount of unused space available at the primary contractor. When the need arises for subcontractors in the operation of the Sanctuary, they will be selected by and report to the prime contractor, with verification of qualifications by NCRR/NIH.

3. The Percentage Cost of Compliance With the Proposed Rule

We estimate that the percentage cost for complying with the final rule is less than three percent of the total operational cost of the sanctuary. We anticipate that no additional staff is needed to comply with the final standards of care. The staffing under the terms of the contract is based upon the requirement to provide quality care and maintenance for the chimpanzees as required by the CHIMP Act and the contract.

Executive Order 13132

Executive Order 13132, “Federalism,” requires that federal agencies consult with state and local government officials in the development of regulatory policies with federalism implications. The Secretary reviewed this final rule as required under the Order and determined that it will not have federalism implications. The Secretary certifies that the final rule will not have an effect on the States or on the distribution of power and responsibilities among various levels of government.

Paperwork Reduction Act

Sections 9.3(a)(2)(xiv)(F)(3), 9.6(d)(ii), 9.8(a)(4), and 9.12(b) of this final rule contain reporting information collection requirements that are subject to OMB approval under the Paperwork Reduction Act of 1995, as amended (44 U.S.C. chapter 35). Sections 9.3(a)(2)(xiv)(F)(3), 9.5(c)(4), 9.5(e), 9.6(c)(xii), 9.6c(xiii), 9.6d(ii), 9.7, 9.8(a)(1–4), 9.8(b), 9.10(a), 9.10(b), and 9.12(b) contain recordkeeping requirements that also are subject to OMB approval under the Paperwork

Reduction Act. In addition, elements of disclosure are found in sections 9.3(a)(2)(vii)(F)(8), 9.4(c), 9.5(c), 9.5(e), 9.5(f)(2), 9.6(c)(xii), 9.6(c)(xiii), 9.6(d)(ii), 9.7, 9.10(a), and 9.10(b).

The title, description, and respondent description of the information collection and recordkeeping requirements contained in the proposed rule have been submitted to OMB for review. Other organizations and individuals desiring to submit comments on the information collection and recordkeeping requirements should send their comments to:

(1) Marilyn Tuttleman, Project Clearance Branch, National Institutes of

Health, Rockledge Centre 1, 6705 Rockledge Drive, Room 3509 Bethesda, Maryland 20817, telephone 301-435-0978 (not a toll-free number); and

(2) The Office of Information and Regulatory Affairs, OMB, New Executive Office Building, Room 10235, 725 17th Street, NW., Washington, DC 20503. Attention: Desk Officer for the National Institutes of Health, Department of Health and Human Services.

After we obtain OMB approval, we will publish the OMB control number in the **Federal Register**.

Title: Standards of Care for Chimpanzees Held in the federally

supported Chimpanzee Sanctuary System.

Description: The information collections and recordkeeping will be used by NIH and the Sanctuary Contractor and subcontractors to document proper and adequate care, identification, accountability, billing, regulatory compliance, and adherence to contract specifications and terms.

Respondent Description: Private nonprofit entities or institutions.

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

	Annual number of respondents *	Annual frequency	Average burden (hours)	Annual burden hours per response
Reporting:				
§ 9.3(a)(2)(xiv)(F)(3)	1-3	2	6	12
§ 9.6(d)(ii)	1-3	2	0.5	1
§ 9.8(a)(4)	1-3	4	5	20
§ 9.12(b)	1-3	1	6	6
Subtotal		9	17.5	39
Recordkeeping:				
§ 9.3(a)(2)(xiv)(F)(3)	1-3	2	2	4
§ 9.5(c)(4)	1-3	1	2	2
§ 9.5 (e)	1-3	1	4	4
§ 9.6(c)(xii)	1-3	4	0.1	0.4
§ 9.6(c)(xii)	1-3	1	2	2
§ 9.6(d)(ii)	1-3	4	1	4
§ 9.7	1-3	5	2	10
§ 9.8(a)(1-4)	1-3	1	0.5	5
§ 9.8(b)	1-3	5	2	10
§ 9.10(a)	1-3	12	0.2	2.4
§ 9.10(b)	1-3	3	1.5	4.5
§ 9.12(b)	** 1-3	1	3	3
Subtotal		40	20.3	51.3
Disclosure:				
§ 9.3(a)(2)(vii) (F)(8)	1-3	6	0.5	3
§ 9.4(c)	1-3	1	1	1
§ 9.5 (c)	1-3	1	0.1	0.1
§ 9.5(e)	1-3	1	8	8
§ 9.5(f)(2)	1-3	*** 1	2	2
§ 9.6(c)(xii)	1-3	0.2	8	1.6
§ 9.6(c)(xiii)	1-3	2	2	1
§ 9.6(d)(ii)	1-3	1	1	1
§ 9.7	1-3	5	2	10
§ 9.10(a)	1-3	10	0.2	2
§ 9.10(b)	1-3	10	0.2	2
Subtotal		38.2	25	31.7
Total	1-3	87.2	62.8	122

* Presently, there is only one (1) respondent, the Contractor for the federally supported chimpanzee sanctuary system. The estimates are based upon a maximum of three (3) respondents in the future.

** The reporting requirements for these sections vary because it is estimated that chimpanzees will be shipped six (6) times per year. This requires 6 notifications of shipment notices to the Project Officer. While not anticipated, it is possible that approximately one (1) of these shipments might require reporting because of undesirable conditions, a death, failure to provide adequate food or water, or other conditions affecting animal welfare. Such incidents must be reported immediately to the NCRR Project Officer, who will in turn work with the USDA representatives in investigating the matter.

*** 1-time event.

List of Subjects in 42 CFR Part 9

Animal welfare, humane care and treatment of chimpanzees, Incorporation by reference.

Dated: August 12, 2008.

Elias A. Zerhouni,

Director, National Institutes of Health.

Approved: September 30, 2008.

Michael O. Leavitt,

Secretary.

■ Accordingly, NIH amends title 42 of the Code of Federal Regulations by adding part 9 to read as follows:

PART 9—STANDARDS OF CARE FOR CHIMPANZEES HELD IN THE FEDERALLY SUPPORTED SANCTUARY SYSTEM

Sec.

- 9.1 Applicability and purpose.
- 9.2 Definitions.
- 9.3 Sanctuary policies and responsibilities.
- 9.4 Physical facility policies and design.
- 9.5 Chimpanzee ownership, fees, and studies.
- 9.6 Animal care, well-being, husbandry, veterinary care, and euthanasia.
- 9.7 Reproduction.
- 9.8 Animal records.
- 9.9 Facility staffing.
- 9.10 Occupational Health and Safety Program (OHSP) and biosafety requirements.
- 9.11 Animal transport.
- 9.12 Compliance with the Standards of Care, USDA and PHS policies and regulations.
- 9.13 Other federal laws, regulations, and policies that apply to this part.

Authority: 42 U.S.C. 216, 287a–3a.

§ 9.1 Applicability and purpose.

(a) *General.* The standards of care set forth in this part apply to the chimpanzee sanctuaries that are contracted (or subcontracted) to the Federal Government to operate the federally supported chimpanzee sanctuary system authorized by section 481C of the Public Health Service (PHS) Act, as amended (42 U.S.C. 287a–3a).

(b) *What is the purpose of the federally supported chimpanzee sanctuary system and the authority for establishing these standards of care regulation?* The Chimpanzee Health Improvement, Maintenance, and Protection Act (Pub. L. 106–551, referred to as the “CHIMP Act” or “Chimpanzee Retirement Act”) was enacted by Congress to provide for the establishment and operation of a sanctuary system to provide lifetime care for chimpanzees that have been used, or were bred or purchased for use, in research conducted or supported by the agencies of the Federal Government, and that are determined to be no longer needed for such research. The CHIMP

Act also mandates that standards of care for chimpanzees in the sanctuary shall be developed to ensure the well-being of chimpanzees and the health and safety of the chimpanzees.

(c) *To what chimpanzee sanctuaries do the standards of care in this part apply?* The standards of care set forth in this part apply to only those sanctuaries that are contracted or subcontracted to the Federal Government to operate the federally supported chimpanzee sanctuary system.

§ 9.2 Definitions.

As used in this part:

Adequate veterinary care means a program directed by a veterinarian qualified through training and/or experience to provide professional medical care to the chimpanzees within the Sanctuary and with the appropriate authority to provide this care. The program also provides guidance to all caregivers on all matters relating to the health and well-being of the chimpanzees.

American Zoo and Aquarium Association (AZA) means the professional society composed of individuals with various backgrounds and interests that are devoted to advancing the knowledge and understanding of zoo animals and the management of zoos in the United States.

American Zoo and Aquarium Association (AZA) Accreditation Standards are those standards developed by the AZA that are used to review, evaluate, and accredit zoos or zoological gardens. These standards cover a variety of areas including facilities, policies and procedures, training, staff qualifications, medical and animal care, husbandry and well-being procedures, and conservation, along with other specific areas.

Animal Care and Use Committee means the Institutional Animal Care and Use Committee established under section 13(b) of the Animal Welfare Act of 1985 and the Health Research Extension Act of 1985. For the purpose of these Standards of Care, it shall consist of at least five (5) members including the Chairperson, a Doctor of Veterinary Medicine (D.V.M. or V.M.D.) knowledgeable in nonhuman primate care and diseases and with delegated program responsibility, a member not affiliated with the Sanctuary, a scientist, and a member of the animal protection community. The requirement that a member of the ACUC must be from an animal protection organization is unique to this part and is not required under the Animal Welfare Regulations or the Public Health Service Policy on

the Humane Care and Use of Laboratory Animals. This Committee must be established if research as defined by the Animal Welfare Act Regulations and the Public Health Service Policy (research, teaching, testing, exhibition) is to be conducted at the sanctuary.

Animal protection organization means a nonprofit organization whose primary mission is protection of animals through positive advocacy and action.

Animal Resource Manager (or Animal Resource Supervisor) means the individual employee responsible for managing the nonprofessional staff providing care for the chimpanzees at the sanctuary. This individual may perform other duties as assigned by the Sanctuary Contractor.

Animal Welfare Act/Regulations means the Act of August 24, 1966 (Pub. L. 89–544, commonly known as the Laboratory Animal Welfare Act), as amended by the Act of December 24, 1970 (Pub. L. 91–579, the Animal Welfare Act of 1970), the Act of April 22, 1976 (Pub. L. 94–279, the Animal Welfare Act of 1976), and the Act of December 23, 1985 (Pub. L. 99–198, the Food Security Act of 1985), and as may be subsequently amended, and the United States Department of Agriculture (USDA) regulations implementing the Animal Welfare Act in title 9, chapter 1, subchapter A of the CFR.

Animal Welfare Assurance means the documentation from an institution assuring compliance with the PHS Policy on Humane Care and Use of Laboratory Animals. This policy is administered by the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health.

Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC) means the nonprofit organization that is recognized in the United States and abroad as being the body responsible for the accreditation of laboratory animal programs.

Behaviorist means a person hired by the sanctuary to administer or oversee the enrichment and behavioral program for the chimpanzees at the sanctuary. This individual must be qualified through training or experience.

Biosafety Officer means the individual responsible for establishing and monitoring workplace safety procedures designed to minimize or prevent injury or loss due to biohazards in accordance with policies established by the sanctuary administration.

Board of Directors (BOD) means the individuals selected by the Contractor to govern the nonprofit institution responsible for operating the federally supported chimpanzee Sanctuary

system. The board members must meet the qualifications and criteria stated in the CHIMP Act.

Chair of the Board of Directors means the individual chosen by the BOD or other legally empowered entity to carry out such action, who is responsible for chairing meetings and acting on behalf of the board. This individual reports directly to the Board.

Chief Executive Officer (CEO) means the principal person responsible for overall accomplishment of the mission of the chimpanzee sanctuary.

CHIMP Act means the Chimpanzee Health Improvement, Maintenance, and Protection Act of December 20, 2000 (Pub. L. 106–551) commonly known as the “CHIMP Act” or “Chimpanzee Retirement Act,” and any future amendments.

Chimpanzee means a member of *Pan troglodytes*. It excludes the pygmy chimpanzee (*Pan paniscus* or bonobo).

Chimpanzee caregivers (caregivers) mean all sanctuary technical and husbandry staff providing long-term care and services for the chimpanzees.

Contractor/Primary Contractor/Sanctuary Contractor means the nonprofit entity awarded a contract by the Federal Government to establish and operate the chimpanzee sanctuary system.

Euthanasia means the humane death of a chimpanzee accomplished by a method that produces rapid unconsciousness and subsequent death without evidence of pain or distress. The method must be consistent with the recommendations of the American Veterinary Medical Association Panel on Euthanasia.

Exhibition means exhibiting chimpanzees to the public for compensation. This definition excludes limited viewing for educational purposes that are not disruptive to the chimpanzees.

Facility director means the individual responsible for directing the overall activities at the Sanctuary site.

Facility Veterinarian means a person who has graduated from a veterinary school accredited by the American Veterinary Medical Association (AVMA) Council on Education, or who has a certificate issued by the AVMA’s Education Commission for Foreign Veterinary Graduates; has training and/or experience in the care and management of nonhuman primates; and has direct or delegated authority for activities involving chimpanzees at the federally funded chimpanzee sanctuary.

Federal agency means an executive agency as such term is defined in section 105 of title 5, United States Code, and refers to the agency from

which the research facility receives a Federal award for projects involving animals.

Federal Acquisition Regulations (FAR) means the codified rules applicable to contracts, specifically those sections of the FAR (48 CFR chapter 1, part 52) that are applicable to contracts between the Federal Government and a contractor (in this case a private, nonprofit entity under contract to operate the chimpanzee sanctuary system).

Federally owned chimpanzees mean chimpanzees that have been purchased by, bred by, or donated to a federal agency for use in biomedical/behavioral research. Chimpanzees whose ownership was subsequently transferred from Federal ownership via written transfer agreements are no longer federally owned.

Guide means *The Guide for the Care and Use of Laboratory Animals*, published by the National Academy of Sciences, Institute for Laboratory Animal Research of the National Research Council, 1996, International Standard Book Number 0–309–05377–3.

Housing facility means any land, premises, shed, barn, building, trailer, or other structure or area housing intended to house chimpanzees.

Indoor housing facility refers to any structure or enclosure (for example, cages, pens, rooms) for maintaining animals in a controlled environment that provides for normal physiological and behavioral needs.

Interstate air transport live animals (IATA) regulations means those regulations and standards covering the air transportation of nonhuman primates developed and implemented by the International Air Transportation Association.

Invasive research (studies) utilizes those procedures that cause more than momentary pain, distress, fear, discomfort, injury, or other negative modalities to a chimpanzee. Any procedure that enters or exposes a body cavity is considered to be invasive. Sanctuary chimpanzees may not be used in invasive research. This definition excludes any invasive procedure that is a part of veterinary, medical, or surgical care that is performed by or under the direction of the Sanctuary Veterinarian using acceptable veterinary practices. Some examples of invasive studies are:

(1) Experimental exposure to a substance that may be detrimental to a chimpanzee’s health (e.g., infectious disease, radiation). This does not include accidental exposures to infectious diseases transmitted from cage mates or from radiation or other exposures at the time of regularly

scheduled or necessary veterinary examinations and treatments;

(2) Any invasion of a body cavity;

(3) Surgery and surgical implantation of devices that are not a part of a veterinary medical treatment or colony management purposes.

(4) Behavioral studies that cause distress or discomfort, such as induction of a fear response;

(5) Testing of any drug;

(6) Purposeful manipulation of social groups or the removal from their social group or addition of individuals in order to conduct behavioral research (for example, on aggression). Creation and refinement of social groups will be necessary when the animals arrive at the Sanctuary and this should take place only when necessary in regards to colony management and should not be driven by independently initiated research studies;

(7) Restraint unless it is in conjunction with the annual exam or clinical care; and

(8) Darting or anesthesia induction other than at annual exam or in the case of an emergency in which the chimpanzee’s well-being is at stake.

National Primate Research Center (NPRC) means those centers supported by the National Center for Research Resources, National Institutes of Health, Department of Health and Human Services, as national resources for providing high-quality nonhuman primate research resources and facilities. As of June 2007, there were eight such centers.

National Research Council means the component of the National Academy of Sciences that advises the Federal Government on matters related to science, research, and research resources.

Noninvasive research (studies) means the use of procedures that depend upon close observation of chimpanzee behavior or on medical information collected during the course of normal veterinary care. These procedures do not require removal of the chimpanzees from their social group or environment, or require a separate anesthetic or sedation event to collect data or record observations. Some examples of noninvasive studies are:

(1) Visual observation;

(2) Behavioral studies designed to improve the establishment and maintenance of social groups. These activities may cause stress as a result of novel interactions between chimpanzees and caregivers, but they are not considered invasive as long as they are intended to maximize the well-being of the chimpanzees;

(3) Medical examinations as deemed necessary to oversee the health of the chimpanzees, in the least invasive manner possible. Collection of samples routinely obtained during a physical examination for processing during this time is also considered noninvasive since a separate event is not required;

(4) Administration and evaluation of environmental enrichment used to promote the psychological well-being of the chimpanzees; and

(5) Actions taken to provide essential medical treatment to an individual chimpanzee exhibiting symptoms of illness. This applies only to serious illness that cannot be treated while the chimpanzee remains within the colony.

Nonfederally owned chimpanzees mean chimpanzees that have not been purchased by, bred by, or donated to the Federal Government for use in federally supported research projects. In accordance with the CHIMP Act, chimpanzees owned on the date of passage of the CHIMP Act by a National Primate Research Center may enter the sanctuary system without requiring the NPRC to pay a fee. Offspring born in the sanctuary is owned by the Sanctuary Contractor.

Outdoor housing facility (area) means corrals, Primadomes (a prefabricated outdoor housing unit), fenced open areas, or similar structures or areas for maintaining chimpanzees with access to adequate protection from the extremes of environmental elements and harsh weather conditions.

Outdoor ranging area means an area that allows chimpanzees greater ranging space than corrals or other outdoor housing area and includes a variety of vegetation, shrubbery, grasses and trees, thereby providing for a fairly unrestricted natural setting for the chimpanzees to engage in species-appropriate activities. The area is secured by an outer perimeter barrier.

Project Officer means the individual designated by the Federal Government to represent the contracting officer and interests of the federal agency, within defined areas, in monitoring and overseeing the chimpanzee sanctuary system contract.

Sanctuary or federally supported chimpanzee sanctuary system means the sanctuary or sanctuary system established by the Federal Government through contracting with a private, nonprofit entity, for the purpose of carrying out the provisions of the CHIMP Act of 2000. The system includes a primary Contractor and may include additional subcontractors as required. This sanctuary system is supported primarily from funds allocated by NCR/NIH/HHS with some

matching funds from the nonprofit contractor.

Sanctuary Chimpanzee Care Committee (SCCC) or similar designated committee means the group of individuals designated by the CEO of the sanctuary that reviews and monitors adherence to the policies, procedures, and regulations at the sanctuary.

Sanctuary Contractor means the nonprofit, private entities selected by NCR/NIH to develop and operate the chimpanzee sanctuary system. This contractor is also known as the "primary contractor" for the sanctuary system.

Sanctuary Director means the individual who provides day-to-day direction and oversight to the employees responsible for performing the daily tasks at the facility.

Secretary means the Secretary of Health and Human Services or his/her designee.

Subcontractor means a private, nonprofit entity selected by the primary contractor to provide additional sanctuary services.

Surplus chimpanzees means chimpanzees that are no longer needed in research and that were used, or were bred or purchased for use, in research conducted or supported by the Federal Government.

USDA licensed intermediate handler/carryer means any person, including a department, agency, or instrumentality of the United States or of any State or local government, who is engaged in any business in which it receives custody of animals in connection with their transportation in commerce and who is licensed by the USDA.

Zoonotic disease(s) means diseases that are transmissible from chimpanzees to humans.

§ 9.3 Sanctuary policies and responsibilities.

(a) *What are the policies and responsibilities governing the sanctuary system?* It will be the policies and responsibilities of the sanctuary system to: (1) Appoint a Board of Directors (BOD) responsible for the overall governance and direction of the Sanctuary. The BOD shall designate the Chief Executive Officer (CEO), who is responsible for the management and oversight of the daily operations of the sanctuary and the performance of other delegated tasks. Subcontractors, if applicable, shall be governed by the policies that are developed by the Board of Directors of the primary contractor.

(2) Direct the BOD to:

(i) Ensure that chimpanzees accepted into the sanctuary are not discharged;

(ii) Develop guidelines for accepting chimpanzees not owned by the Federal

Government into the sanctuary if the conditions are met as outlined in 42 U.S.C. 287;

(iii) Ensure that the Board of Directors of the primary contractor consists of no more than thirteen (13) individuals, and that the conditions governing the terms of the Board members are in compliance with the CHIMP Act;

(iv) Include individuals with the following expertise and experience as set forth in the CHIMP Act;

(A) At least one veterinarian who is qualified in veterinary care of nonhuman primates. These qualifications may be met through postdoctoral training, experience, or both;

(B) Individual(s) with expertise and experience in zoological science and with knowledge in behavioral primatology;

(C) Individual(s) with experience in the animal protection field;

(D) Individual(s) with experience and expertise in the field of business and management of nonprofit organizations;

(E) Individual(s) knowledgeable and experienced in accrediting programs of animal care;

(F) Individual(s) with experience and expertise in containing biohazards;

(v) Ensure that a member of the Board of Directors serves as the Chair of the Board of Directors, who may be elected or appointed by the Board from among the individuals identified in paragraphs (a) (1) (iv) (A) through (F) of this section;

(vi) Ensure that no member of the board shall have been fined for, or signed a consent decree for, any violation of the Animal Welfare Act;

(vii) Create a safe and species-appropriate physical and social environment for the lifetime care of chimpanzees;

(viii) Comply with all applicable provisions of the animal welfare regulations and other federal, state and local laws, regulations, and policies;

(ix) Achieve accreditations from appropriate accrediting bodies within a reasonable time frame mutually agreed upon by the Contractor and NCR/NIH;

(x) Prohibit any invasive research on the resident chimpanzees, but permit noninvasive studies (Definitions for the terms *invasive* and *non-invasive* are set forth in § 9.2 of this part.);

(xi) Prohibit exhibition of chimpanzees in the sanctuary (This policy does not prohibit educational activities that may involve limited viewing of chimpanzees in their environment and that are designed to promote an understanding of chimpanzee behavior, well-being, or importance to the ecological system that

does not adversely affect the chimpanzees' routine.);

(xii) Staff the organization with people with appropriate experience; and

(xiii) Authorize the establishment of a Sanctuary Chimpanzee Care Committee (SCCC) that is appointed by and reports to the CEO or President of the company or corporation.

The SCCC is responsible for overseeing the chimpanzee care program and operations to ensure the health and well-being of the chimpanzees and the occupational safety of the staff are being addressed. The Committee must consist of no fewer than five people who must include:

(A) A chair (person) knowledgeable of the needs of chimpanzees;

(B) A veterinarian with chimpanzee care experience;

(C) A behaviorist with experience in chimpanzee behavior;

(D) A member of the chimpanzee care staff; and

(E) Member or members from the community, including at least one with affiliation or employment with an animal protection organization as defined in § 9.2 of this part.

(F) The SCCC will:

(1) Oversee and evaluate the chimpanzee care and socialization program;

(2) Review and approve proposed education programs. No program should be approved that might interfere with the chimpanzees' well-being or routine activities;

(3) Conduct a formal review of the program on a semiannual basis and submit reports to the Sanctuary Director. The reports must be available for review by the USDA and NIH representatives during site visits;

(4) Establish a mechanism for receipt and review of concerns involving the care of chimpanzees and resolving such concerns;

(5) Review all noninvasive study proposals. The SCCC membership may require additional qualified individuals to perform the functions of an Animal Care and Use Committee (ACUC) if and when the need arises. The contractor may establish a separate ACUC. The ACUC must be established in accordance with the applicable provisions of the Animal Welfare Act regulations, the Public Health Service Policy on Humane Care and Use of Laboratory Animals, and these standards of care;

(6) Review all euthanasia events. Euthanasia events performed for medical or humane reasons must be based upon sound professional veterinary judgment that conforms to current veterinary medical practices and

must be in the best interest of the chimpanzee. Euthanasia performed for emergency reasons without advance review by the SCCC shall be reviewed by the SCCC as soon as possible after the event to ensure compliance with established policy;

(7) Establish procedures to prevent any reproduction in the colony through appropriate permanent birth control, preferably by vasectomy of all sexually mature male chimpanzees in the sanctuary; and

(8) Develop procedures for maintaining chimpanzees that are seropositive for or harboring infectious agents or previously have been exposed to infectious agents (whether experimentally induced or naturally occurring) that will allow them to be accepted by the sanctuary and properly housed. The procedures must be submitted to NCR/NIH for approval.

(b) *Who is responsible for developing or revising sanctuary policies?* (1) The Sanctuary Contractor is responsible for developing, revising, and implementing policies affecting the sanctuary.

(2) The federal agency (NCR/NIH) designated by the Secretary must concur with any changes that substantially change existing policies. The Secretary, or designee, will determine if a policy change will have a substantial impact upon current policy after consultation with the Sanctuary Contractor.

§ 9.4 Physical facility policies and design.

(a) *What standards apply to the facility design and physical plant?* The chimpanzee sanctuary facility must be designed to provide sufficient space and variety of natural or artificial objects to accommodate natural activities of chimpanzees while restricting their movement and range to the defined area. Daily observation of chimpanzees within the enclosures is required and shall be accomplished with minimal disturbance to the chimpanzees. The facility design and physical plant should be in accordance with the recommendation of *The Guide for the Care and Use of Laboratory Animals (Guide)*, where applicable. The *Guide* is published by the National Research Council, 1996, International Standard Book Number 0-309-05377-3. The *Guide* is incorporated by reference in this section. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of the publication from the National Academy Press, 2101 Constitution Avenue, NW., Lockbox 285, Washington, DC 20055; or you may order it electronically via the Internet at <http://www.nap.edu>; or view it online at

<http://oacu.od.nih.gov/regs/guide/guidex.htm>. You may inspect a copy at NIH, NCR, 1 Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20817-4874, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to <http://www.archives.gov/federal-register/code-of-federal-regulations/ibr-locations.html>.

(1) The facility design and physical plant consist of the following components: Indoor design features; outdoor design features; construction and construction materials; physical barriers; shelter; service support space, including storage areas for food, supplies, and equipment; personnel and administrative support space; quarantine and isolation facilities; treatment area; heating, ventilation, and air conditioning (HVAC); food preparation area; and animal waste treatment.

(2) A housing system shall include indoor and outdoor enclosures that must be kept in good repair to prevent escape and injury to the chimpanzees, promote physical comfort, facilitate sanitation and servicing, and address the psychological well-being and social needs of the chimpanzees. Chimpanzees must be able to retreat from areas where they feel threatened or agitated by close human encounters or encounters with other chimpanzees.

(3) Indoor areas shall have special areas for social introductions and medical treatment. Quarantine and isolation facilities are required for the sanctuary. These facilities must be designed to prevent the spread of undesirable agents from quarantine and isolation rooms to other parts of the facility.

(4) Outdoor areas must provide sufficient ranging space and either natural or artificial structures that chimpanzees can use for shelter or nesting areas to sleep, rest, or seek refuge from rain, direct sun, wind, and extreme temperatures.

(5) Animal waste from the Sanctuary must be properly treated to remove known hazardous agents before discharging it into the environment in accordance with currently acceptable and effective waste treatment procedures, including current industry standards and Federal laws, regulations or guidelines, as applicable.

(6) An area for treatment of and performing veterinary clinical procedures on chimpanzees must be provided at each Sanctuary site. This area must be constructed and provisioned to perform emergency

procedures, including minor surgery and emergency surgical procedures, complete physical examinations, and facilities for extended care of medical conditions as needed.

(b) *What security measures are required for the sanctuary?* The sanctuary must provide adequate security against unauthorized entry, sabotage, malicious damage, and theft of chimpanzees and property and must minimize any chance of escape by a chimpanzee. The security staff must have training and/or experience in methods and equipment designed to detect possible security breaches and the ability to respond to security events in a timely and effective manner. Perimeter containment shall be used to protect the compound housing the chimpanzees consistent with the recommendations of the *Guide* (incorporated by reference, see paragraph (a) of this section).

(c) *Is the sanctuary required to develop disaster and escaped animal contingency plans?* The sanctuary facility must prepare disaster and escaped animal contingency plans outlining simple and easy to follow plans for dealing with natural and man-made disasters and steps to be taken in case a chimpanzee escapes from the compound. The Sanctuary also must provide adequate security against unauthorized entry, sabotage, malicious damage, and theft of chimpanzees and property and must minimize any chance of escape by a chimpanzee. Primary barriers must be constructed to prevent escape of chimpanzees and secondary or perimeter barriers must prevent entry of unauthorized persons into the facility, consistent with the recommendations of the *Guide* (incorporated by reference, see paragraph (a) of this section).

§ 9.5 Chimpanzee ownership, fees, and studies.

(a) *Who owns the chimpanzees in the federally supported sanctuary?* The Federal Government retains ownership of chimpanzees owned by the Federal Government at the time they enter the sanctuary system. Non-federally owned or supported chimpanzees will be owned by the sanctuary. The chimpanzees shall continue to be maintained in the sanctuary throughout their lifetime and shall not be discharged from the sanctuary except as specifically indicated in the CHIMP Act.

(b) *Is there a charge for placing chimpanzees in the sanctuary?* No fees shall be charged by the Sanctuary Contractor for federally owned or supported chimpanzees entering the sanctuary. Chimpanzees that were owned by a NPRC when the CHIMP Act

became effective are also admitted without payment of fees. Fees for maintenance of the chimpanzees alluded to above are provided for in the contract between the Federal Government and the Sanctuary Contractor.

(c) *May the sanctuary agree to accept chimpanzees that are not owned by the Federal Government?* The sanctuary may accept chimpanzees that are not owned by the Federal Government subject to the following conditions:

(1) Ownership of the chimpanzee must be transferred to the sanctuary;

(2) Fees for these chimpanzees may be levied based on a range of considerations that include most importantly, the well-being of the chimpanzee and, secondarily, factors that include (but are not limited to) the resources available to support the chimpanzee; the health, age, and social history of the chimpanzee; and other relevant factors affecting the cost of caring for the chimpanzee. While chimpanzees not owned or supported by the Federal Government may be admitted to the sanctuary, federal funds may not be used for their support unless authorized by the Secretary or an authorized designee;

(3) Available space exists in the sanctuary; and

(4) An agreement exists between the sanctuary system and the NCR/NIH documenting that the chimpanzee may be brought into the sanctuary.

(d) *What additional conditions apply when nongovernmental owned chimpanzees transfer to the chimpanzee sanctuary?* The following additional conditions apply when nongovernmental owned chimpanzees transfer to the chimpanzee sanctuary:

(1) Chimpanzees transferred to the sanctuary sites must be permanently incapable of reproduction, for example, by vasectomy, tubal ligation, or another reliable procedure;

(2) Complete histories must accompany each chimpanzee. Any chimpanzee missing documentation for any period of research or other use may not be transferred to the Sanctuary without the concurrent authorization of the Sanctuary Contractor's Board of Directors and the NCR/NIH; the records may be created and retained in electronic form; and

(3) Appropriate screening of each chimpanzee must be performed to assess the likelihood of the chimpanzee being a health or safety threat to the care staff and/or other chimpanzees.

(e) *What are the criteria for acceptance and the fees for admission into the sanctuary for nongovernmental owned chimpanzees?* The chimpanzee

Sanctuary Contractor, in conjunction with NCR/NIH, must establish criteria and a fee system for acceptance of nongovernmental owned chimpanzees. Funds collected for this purpose must be accounted for and used to help defray the expenses incurred in operating the sanctuary.

(f) *Under what circumstances might a chimpanzee from the sanctuary be returned to research at a United States research facility?* In December 2007, the CHIMP Act was amended by the "Chimp Haven is Home Act," which terminated the authority for the removal of chimpanzees from the sanctuary system for research purposes.

§ 9.6 Animal care, well-being, husbandry, veterinary care, and euthanasia.

(a) *What are the requirements for promoting the well-being of sanctuary chimpanzees?* The goal of chimpanzee housing and management in the sanctuary is to promote the chimpanzees' well-being.

(b) *What are the provisions for daily chimpanzee husbandry and care?* Adequate and proper care for chimpanzees in the sanctuary must be provided with respect to physical environment, housing and husbandry, behavioral management, and population management and control. Specific requirements include the following:

(1) Chimpanzees must have access to food, water, and bedding at all times, unless medical or behavioral conditions dictate otherwise. Husbandry procedures shall represent current policies and practices and conform to standards set by a nationally recognized accrediting association in accordance with the *Guide* (incorporated by reference, see paragraph (a) of § 9.4).

(2) Indoor primary enclosures must be cleaned as often as required to maintain a clean and healthy environment, with a minimum of once daily. Outdoor enclosures must be monitored daily and cleaned on a routine basis. Outdoor ranging areas will not require a routine cleaning schedule but must be monitored for excessive accumulation of waste or other unhealthy conditions. Housing areas shall provide sufficient space for chimpanzees to perform species-typical behavior and expression. Examples of such activities include but are not limited to natural movements, climbing, swinging, resting, running, group interactions, sleeping, etc. Feeding and watering implements must be sanitized at intervals required to maintain them in a sanitary condition, in accordance with the *Guide* (incorporated by reference, see paragraph (a) of § 9.4).

(3) The federally supported chimpanzee sanctuary must employ a behavioral scientist knowledgeable in primate behavior and socialization requirements. This individual shall provide primary leadership in developing, implementing, and monitoring the chimpanzee behavioral guidelines for the sanctuary. Enrichment techniques used shall be currently accepted practices. The sanctuary must provide for the expertise to plan, administer, and evaluate the effectiveness of the well-being program.

(4) Many chimpanzees can be trained through positive reinforcement to cooperate with a variety of veterinary and chimpanzee care procedures. Efforts must be made to develop or maintain this capability for chimpanzees housed in the sanctuary to the extent possible. Trainers must use currently acceptable practices that do not include physical punishment.

(c) *What are the requirements for an adequate veterinary care and animal health program?* The sanctuary staff must provide sufficient resources of personnel, equipment, supplies, and facilities to enable the provision of adequate veterinary care as set forth in the *Guide* (incorporated by reference, see paragraph (b) of § 9.4). For additional guidance see the American College of Laboratory Animal Medicine document, "The Provision of Adequate Veterinary Care," available on the Internet at <http://www.aclam.org>.

(1) If the sanctuary houses chimpanzees with infectious diseases, it must have a veterinarian knowledgeable in the infectious diseases and care of chimpanzees. The Facility Veterinarian is responsible for establishing and implementing a health monitoring system specifically designed to meet the health requirements of chimpanzees in the sanctuary. Routine observation and the prevention of disease, metabolic conditions, abnormal behavior and injury must be a priority focus of the Facility Veterinarian and staff.

(2) Newly received chimpanzees must be quarantined for a period for physiological, psychological, and nutritional stabilization before their introduction to the rest of the group. The stabilization period must be lengthened appropriately if the chimpanzee has a significant medical problem or if abnormal medical findings are detected during the quarantine period. If the chimpanzee has not been given a complete physical examination within six months, an examination must be conducted during the stabilization period.

(3) The sanctuary must implement appropriate methods for disease

surveillance and diagnosis of diseases, which may include the following:

(4) Tuberculin (TB) tests must be negative for two (2) consecutive tests before the chimpanzee is released from quarantine. Any chimpanzee that is suspected of harboring the TB organism, or that is diagnosed with TB will be isolated and treated until determined by the Facility Veterinarian to be of no health risk to other chimpanzees or humans. The Facility Veterinarian may recommend euthanasia in those cases that do not respond to therapy and in which the chimpanzee consequently experiences undue pain and suffering that cannot be alleviated. The procedures noted under § 9.6 (d) must be observed if euthanasia is necessary.

(5) Fecal samples must be checked for parasites and parasitic ova.

(6) A complete blood count and serum chemical panel must be obtained.

(7) Additional serum for banking and/or testing shall be obtained as appropriate by the Facility Veterinarian and is considered beneficial for chimpanzee health.

(8) If the donating facility did not test for the appropriate viruses, the sanctuary must perform a viral panel and serology for the various chronic hepatitis viruses and HIV.

(9) Additional tests or procedures that are deemed beneficial to the chimpanzees' health may be required by the Facility Veterinarian.

(10) Chimpanzees are susceptible to many of the vaccine preventable diseases of human childhood. Appropriate vaccines must be considered and administered if deemed necessary, at the discretion of the Facility Veterinarian, to protect the chimpanzees in the sanctuary. Methods of disease prevention, diagnosis, and therapy must comply with those currently accepted in veterinary medical practice. Arrangements with diagnostic laboratories must be established before chimpanzees arrive at the sanctuary.

(11) The sanctuary must minimize the use of physical and chemical restraint. Chimpanzees in the sanctuary shall be trained to permit certain procedures with minimal or no restraint. Such procedures may include injections, dosing or other treatments, and cage-side health observations. However, chemical sedation sometimes may be appropriate for certain necessary medical interventions or for the safety of the chimpanzee and caregivers. If physical restraint measures are necessary, due consideration must be given to the temporary or permanent effects upon the chimpanzee and human and animal safety concerns.

(12) Methods used to relieve pain must be documented in the chimpanzee medical or surgical records. These records will be available for review by USDA and NIH representatives. The Facility Veterinarian must ensure that pain management is current and in accordance with acceptable veterinary medical practices.

(13) Chimpanzees must be cared for by qualified personnel on a daily basis, including weekends and holidays, to safeguard their well-being. Emergency veterinary care must also be available during these times. Notification procedures must be documented in the form of operating procedures.

(d) *Under what circumstances is euthanasia permitted?* As stated in section 481C(d)(2)(I) of the Public Health Service Act, as added by section 2 of the CHIMP Act, none of the chimpanzees may be subjected to euthanasia except when it is in the best interest of the chimpanzee involved as determined by the SCCC and the Facility Veterinarian. Therefore, euthanasia for medical or humane reasons is permitted. Euthanasia may be permitted for reasons of health or quality of life of the individual chimpanzee, including for disease, in connection with trauma, complications of aging, or for other humane reasons. The sanctuary must establish a policy on euthanasia that will provide conditions that must be met before euthanasia is permitted and guidance for performing euthanasia.

(1) Methods of euthanasia will be consistent with the most recent report of the American Veterinary Medical Association Panel on Euthanasia (2002), unless more reliable data becomes available. When euthanasia is performed, the veterinarian will determine the appropriate agent, and it will be administered only by properly trained personnel under the direction of the Facility Veterinarian. The decision to perform euthanasia will be made by the veterinarian in consultation with the Facility Director or Deputy Director.

(2) The SCCC will participate in the decision in nonmedical emergencies. All euthanasia decisions must be reviewed by the SCCC, preferably prior to euthanasia. In emergencies, where euthanasia has to be performed immediately by the Facility Veterinarian, the circumstances and the decision by the Facility Veterinarian will be presented at the next scheduled or special meeting of the SCCC. The NCRR Project Officer must be notified of the euthanasia event within 72 hours by electronic or telephonic means. Euthanasia of individual chimpanzees may negatively affect the care staff and

appropriate counseling and psychological support shall be considered.

§ 9.7 Reproduction.

Chimpanzee reproduction is prohibited in the sanctuary. Therefore, all males must be sterilized by vasectomy before acceptance into the system, or, as a temporary measure, housed apart from females until they are sterilized. Vasectomies are advisable because they are minimally invasive and because effectiveness of the vasectomy may be validated through laboratory testing for semen. Seminal collection techniques must be carefully evaluated to avoid painful stimuli. Other proven methods of birth control may be used under special conditions deemed appropriate by the Facility Veterinarian and SCCC. The Facility Veterinarian must determine the appropriate test(s) to use to validate sterility. A veterinarian experienced in performing vasectomies in chimpanzees should perform the operation. Documentation must accompany each male accepted to the sanctuary system attesting to the fact that the male has been vasectomized and laboratory tests confirm that a segment of the Vas Deferens has been removed, or that the test used is reliable and is negative for sperm. The sanctuary must have a contingency plan for handling accidental births that includes the length of time the offspring is expected to remain with the mother.

§ 9.8 Animal records.

(a) *What records must be maintained for chimpanzees in the sanctuary and how are they managed?* (1) Contractors and Subcontractors operating the federal chimpanzee sanctuary system must maintain appropriate records to allow for accountability and disposition of chimpanzees under their care as required by the USDA Animal Welfare Regulations (9 CFR 2.35). The records may be created and retained in electronic form.

(2) The animal records currently required by the USDA Animal Welfare Regulations are also required for these standards. Chimpanzees must be individually and permanently identifiable.

(3) Retrievable records must be maintained for a minimum of three years beyond the disposition or death of each chimpanzee in accordance with the Animal Welfare Regulations section 2.35(f) (9 CFR 2.35(f)). Original records or a copy must be transferred if the chimpanzee moves to a different facility. The records must include standard information, including

permanent individual identification, research use(s), reproductive status (past and present), a summary or copy of the medical and behavioral history, the sire's identification number (if available), the dam's identification number, birth date, sex, and date acquired by the sanctuary. The disposition date must also be noted, if applicable, including whether the chimpanzee died or was transferred to another site in the federal sanctuary system. The records may be created and retained in electronic form.

(4) The contractor and any subcontractor(s) operating the federally supported chimpanzee sanctuary must provide special, quarterly, and annual progress reports to the designated Federal officials as identified in the contract. The annual report must also contain a statement that certifies the sanctuary is in full compliance with these standards of care regulation.

(b) *What are the rules governing the disposition of necropsy records?* The CHIMP Act requires that necropsy records from chimpanzees previously used in federally funded research projects be made available on a reasonable basis to investigators engaged in biomedical or behavioral research. In order to comply with this provision, the contractor for the sanctuary system must devise a plan that will allow interested parties to contact the sanctuary and receive necropsy records when they become available. Records may be provided free of charge but requesters may be required to pay for packaging and shipping costs. The records may be created and retained in electronic form.

§ 9.9 Facility staffing.

How many personnel are required to staff the chimpanzee sanctuary and what qualifications and training must the staff possess? (a) The professional, managerial, and support staff must be sufficient to support the scope and diversity of the activities and chimpanzee population of the sanctuary. The level of staffing shall be adequate to ensure that the chimpanzees receive appropriate health care, are well cared for, and the administrative and fiscal operations are sound and in keeping with current practices required by NCRR/NIH;

(b) There must be a sufficient number of appropriately trained animal care and technical personnel to provide appropriate care to the chimpanzees at all times, including evenings, weekends, and holidays. The number of animal care staff to chimpanzee ratio shall be adjusted as experience is gained during the operation of the sanctuary.

Sufficiently trained staff also must be available to maintain adequate behavioral enrichment;

(c) The Facility Director must be a person with experience in chimpanzee care and socialization techniques. In addition, the Director must have management and administrative experience;

(d) The Biosafety Officer must have experience in developing and monitoring biohazards and dealing with biosafety issues related to captive nonhuman primates. Experience in these areas dealing specifically with chimpanzees is desirable;

(e) The remaining staff, which may include part-time, full-time, or contractor Facility Veterinarian(s) and Behaviorist(s), must possess the skills, knowledge, and/or experience required to perform their duties, as elaborated within the regulation.

§ 9.10 Occupational Health and Safety Program (OHSP) and biosafety requirements.

(a) *How are employee Occupational Health and Safety Program risks and concerns addressed?* The sanctuary shall assure that an Occupational Health and Safety Program (OHSP) is developed and implemented in accordance with current veterinary medical practices and the guidelines and standards found in the *Guide* (incorporated by reference, see paragraph (a) of section 9.4);

(b) *How are biosafety concerns addressed?* The sanctuary shall institute and administer an effective biosafety program that addresses the biosafety hazards at that particular site. The program shall include identifying biohazards, outlining practices and procedures to be followed, providing personal safety equipment or protective clothing and equipment, and establishing a description of the facility requirements for working with hazardous agents or materials. Policies and procedures must be implemented to avoid exposure to environmental and animal hazards. Biosafety must be included in the training program for all Sanctuary employees. In establishing a program, the Sanctuary must use current accepted practices and publications prepared by the CDC, NIH, and professional societies specializing in biosafety. The input and guidance of personnel trained or experienced in biosafety are essential. Complete records of both clinical and experimental agent exposure must accompany each chimpanzee sent to the sanctuary. The donating facility must also provide recent testing (for example, serology, virus culture, histology) so that the

sanctuary staff is fully aware of the health condition of the arriving chimpanzee. The records may be created and retained in electronic form.

§ 9.11 Animal transport.

The transportation of chimpanzees by surface or air must be in accordance with the requirements set forth in the Animal Welfare Act and Regulations and the International Air Transport Association (IATA) Live Animal Regulations and guidelines, as applicable.

§ 9.12 Compliance with the Standards of Care, and USDA and PHS policies and regulations.

(a) *How will compliance with the standards set forth in this part be monitored and what are the consequences of noncompliance with the standards?* The federally supported chimpanzee sanctuary must comply with the standards of care set forth in this part and include a statement in the Annual Progress Report certifying compliance with these standards of care in accordance with the terms of the current contract between NCRR and the Sanctuary Contractor. A designated representative of the Secretary will monitor compliance. The responsibility

to monitor compliance with the standards is delegated to NCRR/NIH/HHS. The NIH/NCRR Project Officer for this contract will conduct scheduled site visits at least one time annually (or more often if necessary) and review monthly and quarterly reports submitted to the Project and Contract Officer. Subcontractors are subjected to the same provisions. Failure to comply with the standards set forth in this part, or to correct deficiencies noted within the allowable time period, could result in termination of the contract by the Federal Government (HHS/NIH), or allow the Secretary to correct the deficiencies according to the terms and conditions outlined in the contract. The Secretary may impose additional sanctions on the contractor up to, and including, authorizing assumption or reassignment of the management of the sanctuary contract.

(b) *To what type of outside review or inspection will the federally supported sanctuary be subjected?* As noted in paragraph (a) of this section, the contractor for the sanctuary will be monitored on a regularly scheduled basis by representatives of NCRR/NIH/HHS. The NCRR representative will use facility site visits, reports, personal

contact, and any other means as appropriate to ensure compliance with these standards. The contractor and subcontractors are required to obtain and maintain an Animal Welfare Assurance from NIH's Office of Laboratory Animal Welfare (OLAW) when chimpanzees are used for noninvasive studies as authorized in the CHIMP Act. In addition, the sanctuary must achieve accreditation by a nationally recognized animal program accrediting body (such as the AAALAC, the AZA, or similar recognized body) within a time frame to be determined by NCRR/NIH. The federally supported sanctuary must comply with the requirements set forth in the Animal Welfare Regulations (9 CFR parts 1 through 3).

§ 9.13 Other federal laws, regulations and statutes that apply to the sanctuary.

(a) Animal Welfare Act (7 U.S.C. 2131–2159).

(b) Animal Welfare Regulations, 9 CFR, subchapter A, parts 1 and 2; part 3, subpart D—Specifications for the Humane Handling, Care, Treatment, and Transport of Nonhuman Primates.

[FR Doc. E8–23518 Filed 10–9–08; 8:45 am]

BILLING CODE 4140-01-P