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(2) If the suspension and proposed revocation of OTP certification are denied, the revocation will not take effect and the suspension will be lifted immediately. Public notice will be given by publication in the FEDERAL REGISTER. The Secretary will notify DEA within 5 days that the OTP's registration should be restored, if applicable.

§ 8.34 Court review of final administrative action; exhaustion of administrative remedies.

Before any legal action is filed in court challenging the suspension, proposed revocation, or adverse action, respondent shall exhaust administrative remedies provided under this subpart, unless otherwise provided by Federal law. The reviewing official's decision, under §8.28(e) or §8.33(a), constitutes final agency action as of the date of the decision.

Subpart E [Reserved]

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

Sec.

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AUTHORITY: 42 U.S.C. 216, 287a–3a.

SOURCE: 73 FR 60423, Oct. 10, 2008, unless otherwise noted.

§ 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 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).

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.

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 Office of Research Infrastructure Programs (ORIP) within the Division of Program Coordination, Planning and Strategic Initiatives (DPCPSI), 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 2015, there were seven 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.

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.

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.

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 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 ORIP/DPCPSI/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.

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 ORIP/DPCPSI/NIH/HHS with some matching funds from the nonprofit contractor.

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/carrier 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.

[73 FR 60423, Oct. 10, 2008, as amended at 85 FR 54273, Sept. 1, 2020]

§ 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