Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Jose H Guerrier, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301–435–1137, *guerriej@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: HIV/AIDS Innovative Research Applications.

Date: July 24, 2013.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Mark P Rubert, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301–435–1775, *rubertm@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 26, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–15768 Filed 7–1–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; SCORE Grant Applications.

Date: July 23, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Washington DC/Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Saraswathy Seetharam, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.12C, Bethesda, MD 20892–4874, 301–594–2763, *seetharams@nigms.nih.gov.*

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel Complex Phenotypes.

Date: July 24–25, 2013.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Room 3An.12, Bethesda, MD 20892–4874, (Virtual Meeting).

Contact Person: Lisa A. Dunbar, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.12, Bethesda, MD 20892–4874, 301–594–2849, *dunbarl@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: June 26, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–15771 Filed 7–1–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Announcement of Agency Decision: Recommendations on the Use of Chimpanzees in NIH-Supported Research

SUMMARY: This notice announces the responses to public comments and decisions of the National Institutes of Health (NIH) regarding the use of chimpanzees in research. In February 2012, the NIH charged a working group of the Council of Councils, a federal advisory committee, to provide advice on implementing recommendations made by the Institute of Medicine (IOM) Committee on the Use of Chimpanzees in Biomedical and Behavioral Research in its 2011 report, *Chimpanzees in Biomedical and Behavioral Research: Assessing the Necessity.* On January 22, 2013, the NIH Council of Councils (Council) accepted recommendations presented by the Working Group on the Use of Chimpanzees in NIH-Supported Research and provided these recommendations to the NIH. The NIH subsequently issued a request for comments to obtain broad public input on the 28 Council recommendations that the NIH is considering as it determines how to implement the IOM Committee's recommendations. This notice summarizes the comments received in response to the request for comments and announces the agency's decisions with respect to the Council recommendations. The NIH plans to prepare subsequent procedural guidance and technical assistance, as appropriate, to implement some of these decisions. Investigators should continue to follow existing guidance (see NOT–OD–12–025 at *http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-025.html*) regarding the submission of applications, proposals, or protocols for research involving chimpanzees until the NIH announces the procedural guidance.

FOR FURTHER INFORMATION CONTACT: The Division of Program Coordination, Planning, and Strategic Initiatives, Office of the Director, National Institutes of Health at *dpcpsi@od.nih.gov.*

SUPPLEMENTARY INFORMATION:

Background

The use of animals in biomedical and behavioral research has enabled scientists to identify new ways to treat illness, extend life, and improve health and well-being. Chimpanzees are our closest relatives in the animal kingdom, providing exceptional insights into human biology and requiring special consideration and respect. Although used very selectively and in limited numbers for biomedical research, chimpanzees have served an important role in advancing human health. However, new methods and technologies developed by the biomedical research community have provided alternatives to the use of chimpanzees in several areas of research.

In December 2010, the National Institutes of Health (NIH) commissioned a study by the Institute of Medicine (IOM) to assess whether chimpanzees are or will be necessary for NIH-funded biomedical and behavioral research. On December 15, 2011, the IOM Committee on the Use of Chimpanzees in Biomedical and Behavioral Research (IOM Committee) issued its findings along with a primary recommendation that a set of principles and criteria guide

the use of chimpanzees in biomedical and behavioral research in its report, *Chimpanzees in Biomedical and Behavioral Research: Assessing the Necessity* (*http://iom.edu/Reports/2011/Chimpanzees-in-Biomedical-and-Behavioral-Research-Assessing-the-Necessity.aspx*). The three principles that the IOM Committee proposed to assess the use of chimpanzees in current and potential future biomedical and behavioral research supported by the NIH were:

1. The knowledge gained must be necessary to advance the public's health;

2. There must be no other research model by which the knowledge could be obtained, and the research cannot be ethically performed on human subjects; and

3. The animals used in the proposed research must be maintained either in ethologically appropriate physical and social environments or in natural habitats.

The IOM Committee also developed two separate sets of criteria for assessing the necessity of using chimpanzees for biomedical research and for comparative genomics and behavioral research. Based on its deliberations, the IOM Committee concluded that, ''While the chimpanzee has been a valuable animal model in past research, most current use of chimpanzees for biomedical research is unnecessary . . .''

The IOM Committee considered case studies of current chimpanzee use in research to provide examples of its vision for applying its criteria. Based on these case studies, the IOM Committee concluded that the use of chimpanzees might continue to be required for some ongoing research on monoclonal antibody therapies; comparative genomics; and social and behavioral factors that affect the development, prevention, or treatment of disease. The IOM Committee was unable to reach consensus on the necessity of using chimpanzees to develop a prophylactic hepatitis C virus vaccine. It also acknowledged that new, emerging, or reemerging diseases could present challenges that might require the use of chimpanzees.

In December 2011, the NIH accepted the recommendations in the IOM Committee's report (*http://www.nih.gov/news/health/dec2011/od-15.htm*) and issued an interim agency policy in notice NOT–OD–12–025 (*http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-025.html*). This notice indicated that the NIH would not fund any new or other competing projects (renewal and revisions) for research involving chimpanzees and would not allow any new projects to go forward with NIH-owned (i.e., chimpanzees directly owned by the agency) or -supported research chimpanzees (i.e., chimpanzees not owned by the NIH but supported through NIH awards, such as grants and contracts). However, the NIH permitted currently funded research involving chimpanzees to continue. The policy remains in effect until the NIH issues a future notice in the NIH Guide for Grants and Contracts regarding research applications, proposals, and protocols requesting to use chimpanzees in accordance with the IOM Committee's recommendations.

The NIH established the Working Group on the Use of Chimpanzees in NIH-Supported Research (Council Working Group) within the Council of Councils, a federal advisory committee, on February 1, 2012, to provide advice on implementing the IOM Committee's recommendations and to consider the size and placement of the active and inactive populations of NIH-owned or -supported research chimpanzees. Research-active chimpanzees are currently used for research, whereas research-inactive chimpanzees are not currently used in research protocols but might be used for new projects that meet the IOM principles and criteria. The NIH charged the Council Working Group with: (1) Developing a plan for implementation of the IOM's guiding principles and criteria, (2) analyzing currently active NIH-supported research using chimpanzees to advise on which studies currently meet the principles and criteria defined by the IOM report and advising on the process for closing studies if any do not comply with the IOM recommendations, (3) advising on the size and placement of active and inactive populations of NIH-owned or -supported chimpanzees that may need to be considered as a result of implementing the IOM recommendations, and (4) developing a review process for considering whether potential future use of the chimpanzee in NIH-supported research is scientifically necessary and consistent with the IOM principles.

In developing its recommendations, the Council Working Group considered the scientific use of chimpanzees in research currently supported by the NIH and public comments received in response to a previous request for information (*see summary at http://dpcpsi.nih.gov/council/working_group.aspx#Summary*) in *NOT–OD–12–052* (*http://grants.nih.gov/grants/guide/notice-files/not-od-12-052.html*) *dated February 10, 2012, and a* ***Federal Register*** *notice dated February 23, 2012 (http://www.gpo.gov/fdsys/pkg/FR-2012-02-23/pdf/2012-4269.pdf);* obtained advice from external experts; and visited several facilities that house and care for chimpanzees. The Council Working Group's efforts culminated in a report containing 28 recommendations, available at *http://dpcpsi.nih.gov/council/pdf/FNL_Report_WG_Chimpanzees.pdf,* which the group submitted to the NIH Council of Councils on January 22, 2013. The NIH Council of Councils accepted these recommendations and provided them as advice to the NIH on January 22, 2013. The NIH subsequently issued a request for comments in the **Federal Register**, available at *http://www.gpo.gov/fdsys/pkg/FR-2013-02-05/html/2013-02507.html,* and the NIH Guide for Grants and Contracts, available at *http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-026.html,* to obtain broad public input on the 28 Council recommendations.

Public Comments, NIH Responses to These Comments, and NIH Decisions Regarding the Council Recommendations

This section lists the recommendations made by the Council of Councils, summarizes the public comments that the NIH received, and provides the agency's responses and decisions with respect to the recommendations. More than 12,500 individuals submitted comments in response to the request for comments issued in the NIH Guide for Grants and Contracts and the **Federal Register**. The discussion of comments below provides an overview of responses received during the public comment period and is not intended to capture the details of every comment. Responses received during the public comment period are available for public inspection at the NIH On-site FOIA Library, Building 31, Room 5B35, 9000 Rockville Pike, Bethesda, MD 20892, which is open 10:00 a.m. to 4:00 p.m. Monday through Friday and is closed on federal holidays. Those who plan to view the records must contact the NIH Freedom of Information Office at *nihfoia@mail.nih.gov* in advance.

A. Ethologically Appropriate Physical and Social Environments

Throughout its report, the IOM Committee used the term ''ethologically appropriate physical and social environments'' as a central principle for housing research-active and research-inactive chimpanzees. Because the IOM did not define this term, the Council defined ''ethologically appropriate physical and social environments'' as

''captive environments that do not simply allow but also, importantly, promote a full range of behaviors that are natural for chimpanzees.'' The Council offered 10 recommendations on ethologically appropriate physical and social environments. This section provides these 10 recommendations, a summary of public comments on these recommendations, and the NIH responses to the comments and decisions regarding the Council recommendations.

The NIH believes that it is important to describe the guidance currently used for the housing and care of NIH-owned or -supported research chimpanzees. Facilities housing chimpanzees owned by the NIH or used in NIH-supported research must comply with the recommendations in the *Guide for the Care and Use of Laboratory Animals, Eighth Edition* (*http://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf*), an internationally accepted primary reference on animal care and use whose contents form the foundation for the development of comprehensive animal care and use programs. The *Guide* provides: (1) A framework for institutional policies, management, and oversight of institutional animal care and use programs; (2) recommendations for housing, environmental enrichment, and animal well-being; (3) recommendations on space and social housing for nonhuman primates and the physical characteristics of animal facilities, including special facilities for behavioral studies and imaging; and (4) guidance on veterinary care and maintaining the health and well-being of laboratory animals. The *Guide* also addresses the regulatory requirements that govern animal research activities in the United States, including the federal Animal Welfare Act and regulations and the Public Health Service Policy on Humane Care and Use of Laboratory Animals.

Any Council recommendations accepted by the NIH will not replace the body of laws, regulations, and policies that already govern the care and housing of the NIH research chimpanzees but, instead, will supplement existing policies.

1. Size of Social Groupings (Recommendation EA1)

Recommendation EA1 states: ''Chimpanzees must have the opportunity to live in sufficiently large, complex, multi-male, multi-female social groupings, ideally consisting of at least 7 individuals. Unless dictated by clearly documented medical or social circumstances, no chimpanzee should be required to live alone for extended periods of time. Pairs, trios, and even small groups of 4 to 6 individuals do not provide the social complexity required to meet the social needs of this cognitively advanced species. When chimpanzees need to be housed in groupings that are smaller than ideal for longer than necessary, for example, during routine veterinary examinations or when they are introduced to a new social group, this need should be regularly reviewed and documented by a veterinarian* and a primate behaviorist.

''*In this context, the Working Group defines a ''veterinarian'' as a licensed, graduate veterinarian with demonstrated expertise in the clinical care and welfare of nonhuman primates (preferably chimpanzees) and who is directly responsible for the routine clinical care of the animal(s) in question.''

Comments: A large number of commenters supported Recommendation EA1. Many believed that implementing this recommendation would enable facilities to replicate the social environments of chimpanzees in the wild or in sanctuaries. Others noted that ethologically appropriate housing conditions could make chimpanzees a more valuable research model and enhance the validity of results derived from research using them by enabling chimpanzees to express more fully species-appropriate behaviors.

Other commenters expressed concern that the Council recommended arbitrary standards instead of recommending housing conditions that target such outcomes as chimpanzee physical and mental well-being. For example, a number of commenters noted that elderly or infirm chimpanzees might benefit from long-term housing in smaller groups to accommodate their individual medical or social needs.

A large number of commenters favored social groups of at least 7 chimpanzees, with rare exceptions for single or pair housing. Some stated that 7 chimpanzees might be too few for a social group and recommended that group sizes be similar to those in the wild, which, according to commenters, include more than 7 chimpanzees. Other commenters supported the recommendation to house chimpanzees in groups of at least 7 members in theory but indicated that captive chimpanzees might not have the complete set of social skills needed to function safely in larger groups.

A few commenters questioned the scientific basis for the recommended group size of at least 7 animals. Some stated that the average party size of wild chimpanzee groups is more than 7 members. Others pointed to studies that document group sizes as small as 3 or 4 members and recommended that the NIH determine group size based on individual chimpanzee behavioral characteristics, existing social group composition and compatibility, and the professional judgment of chimpanzee behaviorists or veterinarians familiar with the animals. These commenters agreed on the importance of achieving a balance between the needs of social groupings and individual chimpanzees. Some commenters did not support the recommendation to house chimpanzees in social groups that have fewer than 7 animals under certain circumstances, even with proper documentation of the need for such conditions by a veterinarian and primate behaviorist. These commenters wanted more details concerning the ''clearly documented medical or social circumstances'' and ''extended periods of time'' that would warrant smaller group sizes. Others stated that research chimpanzees should never be housed singly or in pairs or should never be housed in such conditions for more than a week. It was also suggested that veterinarians are not sufficiently sensitive to chimpanzees' psychological needs to assess their suitability for group versus individual housing. A few commenters recommended requiring consultation with a behavioral primatologist to determine whether a plan to house chimpanzees singly or in pairs is appropriate. Others wondered why the Council defined ''veterinarian'' but not ''primate behaviorist'' and suggested that the NIH define this term.

Response: The NIH accepts Recommendation EA1. We agree that chimpanzees should have the opportunity to live in sufficiently large and complex groups of 7 chimpanzees or more. Unless compelling factors prevent social housing, the chimpanzees owned or supported by the NIH already live in compatible social groups of varying sizes depending on the individual chimpanzee characteristics, the facility, and the nature of the research conducted, if any. We also believe that housing chimpanzees in larger groups has the potential to offer greater social complexity and more environmental stimuli than housing them in smaller groups. At the same time, the agency believes that chimpanzee facilities should evaluate individual chimpanzees to determine their suitability for successful integration into larger social groups. We agree with the Council recommendation that facility staff knowledgeable about

chimpanzee well-being (i.e., veterinarians and primate behaviorists) are well-positioned to determine a chimpanzee's suitability for group versus single housing based on that chimpanzee's best interests. The agency disagrees with the comment that veterinarians are not sufficiently sensitive to chimpanzees' psychological needs to make such determinations.

The NIH believes that the recommendation is sufficiently flexible and permits facilities to adjust the sizes of research chimpanzee social groups as necessary, as long as these facilities support any downward adjustments with proper documentation and regular reviews by a veterinarian and a primate behaviorist. Experts in chimpanzee well-being, such as primate behaviorists and veterinarians, currently use their professional judgment to balance the needs of individual chimpanzees with those of chimpanzee social groups. The agency expects that facilities will continue to do so.

In the context of this recommendation, the NIH defines a ''primate behaviorist'' to include a behavioral scientist knowledgeable in primate behavior and socialization requirements.

2. Primary Living Space and Climbing Height (Recommendations EA2 and EA4)

Recommendation EA2 states: ''The density of the primary living space of chimpanzees should be at least 1,000 ft^2 (93 m^2) per individual. Therefore, the minimum outdoor enclosure size for a group of 7 animals should be 7,000 ft^2 (651 m^2).''

Comments: A large number of commenters who discussed Recommendation EA2 supported this recommendation. Some commenters emphasized that the amount of space recommended is the minimum area needed, and larger enclosures that more closely replicate the amount of space available to chimpanzees in the wild (suggestions ranged from 2,000 ft^2 to several acres) are preferable. Other commenters encouraged the NIH to identify data in the scientific literature on the appropriate area for chimpanzee housing.

In contrast, several commenters argued that the recommended 1,000 ft^2 area is arbitrary and unnecessary, is not based on or is contrary to the published literature, and does not accurately reflect the opinions of some of the experts consulted by the Council Working Group. Several commenters pointed out that certain publications cited by the Council Working Group pertain to gorillas or to spaces smaller than 1,000 ft^2. In the absence of sufficient supporting scientific evidence, these commenters did not believe that larger housing environments would improve chimpanzee well-being. Others suggested that rather than establishing minimum space requirements, the NIH should consider the complexity and quality of the environment, including the opportunity for chimpanzees to take temporary refuge from other members of their group.

Commenters also expressed concerns about whether any facility could meet the proposed space recommendation; some asserted that the federal sanctuary system does not provide this amount of space to all of its chimpanzees. In general, these commenters were concerned that the recommendation would set a bar that is too high for research facilities to meet as a way to ban the use of chimpanzees in NIH-supported research. A suggestion was that research facilities might satisfy this recommendation by rotating chimpanzees between smaller and larger enclosures every few weeks.

Several commenters, including some who supported the recommendations on ethologically appropriate environments and some who did not, were concerned about the construction costs for facilities to comply with the recommendation and the recommendation's inflexible specifications. A few commenters suggested tactics to minimize the costs of upgrading primate research facilities, including adapting current facilities so that they could be used as sanctuaries at a later time. Others suggested expanding the existing federal sanctuary system, arranging with other existing sanctuaries to house NIH-owned chimpanzees, or moving all NIH-owned chimpanzees to privately owned locations rather than NIH-supported institutions.

Response: The NIH does not accept Recommendation EA2. Although the NIH agrees that sufficient square footage is needed for chimpanzees to travel, patrol, coexist in social groups of 7 or more members, and sometimes separate from others, the agency is concerned about the lack of scientific consensus on the recommended square footage and is especially concerned about whether the published literature supports 1,000 ft^2 per chimpanzee. We agree that the scientific literature on ethologically appropriate physical and social environments for captive chimpanzees appears to be scant. However, determining the appropriate housing space density is important because, according to this recommendation, the amount of space should increase linearly with the number of chimpanzees housed in the area (see Recommendation EA2) and because spaces of this size might be costly to construct. We also note that the Association of Zoos and Aquariums (AZA) and the Global Federation of Animal Sanctuaries recommend space densities that differ from each other and from the one in Recommendation EA2. In addition, the area recommended by these other groups does not scale linearly with the number of chimpanzees.

We agree with commenters that constructing spaces offering 1,000 ft^2 per chimpanzee might be difficult and costly and would likely require substantial government funding. We appreciate the examples given of alternative ways to provide the recommended square footage, such as rotating chimpanzees into larger enclosures on a regular basis, and other suggestions to conserve costs.

We recognize the diligence of the Council Working Group in defining and recommending parameters for the new concept of ''ethologically appropriate.'' However, because of concerns about the scientific basis for this recommendation and the expected costs of implementing it, the agency will review the space density requirements with respect to the promotion of species-appropriate behavior.

Recommendation EA4 states: ''Chimpanzees should have the opportunity to climb at least 20 ft. (6.1 m) vertically. Moreover, their environment must provide enough climbing opportunities and space to allow all members of larger groups to travel, feed, and rest in elevated spaces.''

Comments: A large number of commenters who responded to this topic agreed with Recommendation EA4. A few commenters indicated that the NIH should provide natural climbing structures (e.g., trees) that allow more than 1 chimpanzee to climb or descend at the same time and to rest on multiple tiers of the structures. Others suggested that the NIH specify the types of climbing structures that facilities must provide (e.g., trees, playground equipment, ropes, and vines) and require facilities to place climbing structures far enough from walls to prevent chimpanzees from jumping out of open-air housing areas.

Other commenters expressed concern that this recommendation was too specific, research supporting the 20 ft. climbing height is lacking, and the published literature cited by the Council Working Group supports structures that are closer to 10 ft. than 20 ft. high.

Others noted that the ideal climbing height should depend on the habitat, which varies among chimpanzees in the wild (i.e., forest-dwelling chimpanzees spend more time off the ground than those living in savanna or woodland environments). These commenters and others encouraged the NIH to require facilities to provide climbing opportunities that promote species-specific behavior and accommodate the needs of individual chimpanzees, including physically challenged chimpanzees that require lower structures, rather than attempting to replicate specific aspects of forested environments.

Response: The NIH accepts Recommendation EA4. The recommended structures offer environmental complexity and encourage species-appropriate behaviors, including foraging, nesting, ranging, interacting, exercising, and separating from social groups. The NIH disagrees with commenters' suggestion to reduce or remove the recommended climbing height or not to require facilities to provide climbing opportunities. Although some chimpanzees in savanna or woodland environments might not have access to natural structures that are 20 ft. high, implementing this recommendation will provide opportunities for species-appropriate behavior, environmental complexity, and interacting with or separating from group members. The agency notes that some facilities already offer apparatus that is at least 20 ft. high for certain populations of captive chimpanzees.

3. Environmental Complexity, Nutrition, and Enrichment (Recommendations EA3, EA5–7)

Recommendation EA3 states: ''Chimpanzees must be housed in environments that provide outdoor access year round. They should have access to natural substrates, such as grass, dirt, and mulch, to enhance environmental complexity.''

Comments: A large number of commenters on Recommendation EA3 agreed with it or stated that its provisions serve as minimum requirements. Many indicated that natural substrates mimic wild conditions. A suggestion was to conduct research on the optimal composition of the natural substrates. Others indicated that using more durable synthetic materials instead of natural substrates could enhance environmental complexity.

Some commenters believed that the recommendation does not adequately address key elements of chimpanzees' natural environment, including trees, rocks, fresh water, and structures for exercise. Others argued that the NIH should also require facilities to provide shelter from the outdoors, access to sleeping dens, and the freedom to move to and from an indoor enclosure. Some noted that chimpanzees accustomed to artificial substrates, such as concrete floors, might not be comfortable with natural substrates and might need an acclimation period to become accustomed to the new environment. A few commenters wondered why the Council Working Group did not recommend dome-type structures, noting that the IOM Committee had described these structures as ethologically appropriate. Others expressed concern that this recommendation prohibits the use of synthetic structures and material.

Response: The NIH accepts Recommendation EA3 and believes that research chimpanzees need year-round access to natural substrates and the outdoors to enhance their environmental complexity. We believe that the recommendation does not need to list all possible natural substrates because such a list could not be exhaustive and would be unnecessarily prescriptive. We do not interpret the recommendation as precluding the use of synthetic materials (e.g., non-natural flooring) and structures (e.g., geodesic domes) but, instead, as ensuring that chimpanzees have access to various natural substrates intended to enhance their environment. The agency believes that Recommendation EA3 does not prevent facilities from accommodating the needs of chimpanzees that are accustomed to concrete flooring and have had limited prior exposure to natural substrates.

The NIH interprets this recommendation as calling for outdoor access without excluding the provision of indoor space. The NIH already requires facilities housing NIH research chimpanzees to comply with the *Guide for the Care and Use of Laboratory Animals, Eighth Edition* (*http://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf*) and the federal Animal Welfare Act and regulations. These standards require that facilities provide appropriate sheltered housing facilities necessary to protect the animals from extreme weather and to provide for their health and well-being.

Recommendation EA5 states: ''Progressive and ethologically appropriate management of chimpanzees must include provision of foraging opportunities and of diets that are varied, nutritious, and challenging to obtain and process.''

Comments: Commenters generally supported Recommendation EA5. However, some commenters believed that the NIH should specify the frequency of feeding and types of food that facilities must provide, require facilities to feed chimpanzees a diet that is natural or tailored to their health needs, and make all necessary nutrients available. Others recommended specific strategies for ensuring that chimpanzees are challenged when they collect food.

Response: The NIH accepts Recommendation EA5 and disagrees with the requested changes to this recommendation. We believe that dictating types of food, nutrients, feeding modalities, and feeding frequency for research chimpanzees would be overly prescriptive. Facilities that house research chimpanzees are in the best position to understand the specific health and dietary needs and preferences of the chimpanzees they house.

Recommendation EA6 states: ''Chimpanzees must be provided with materials to construct new nests on a daily basis.''

Comments: A large number of commenters who responded to this topic agreed with this recommendation. Some believed that the NIH should specify the types of materials that facilities should make available and the need to refresh these materials daily. Some identified the types of nesting materials, both natural and synthetic (e.g., blankets, newspaper, and other nondurable, nontoxic substances), that facilities should provide. A suggestion was that the NIH implement this recommendation only for chimpanzees that live primarily indoors because providing new, daily nesting materials would be unnecessary for chimpanzees with unlimited outdoor access. Others were concerned that the costs of materials and staff time required to provide new nesting materials daily would be prohibitive for facilities. Some commenters argued that some of the references cited to support this recommendation focused on other nonhuman primates (not chimpanzees) or did not mention nesting and that one reference was to a study in which a facility provided nesting materials daily for only a few days and not on a long-term basis. Others recommended that the types of nesting materials that are appropriate for captive chimpanzees be determined by research.

Response: The NIH accepts Recommendation EA6. We disagree with commenters' suggestion to specify the types of materials that facilities must

provide for nest construction or to require the daily provision of fresh materials. Research chimpanzee facilities are in the best position to gauge the kinds of nesting materials preferred by their chimpanzees and when these materials need to be refreshed or supplemented. Facilities that offer unlimited access to an outdoor environment that makes nest-building materials (e.g., trees, foliage, and grasses) readily available might already satisfy this recommendation. The NIH does not believe that research to determine the appropriate types of nesting materials for captive chimpanzees needs to be conducted and published before the NIH accepts this recommendation; doing so would unnecessarily delay the recommendation's implementation.

Recommendation EA7 states: ''The environmental enrichment program developed for chimpanzees must provide relevant opportunities for choice and self-determination.''

Comments: A large number of commenters who responded to this topic strongly supported this recommendation as a way to ensure both the complexity of the captive environment and chimpanzees' ability to exercise volition with respect to activity, social groupings, and other opportunities. A suggestion was to revise the wording of Recommendation EA7 to remove ''self-determination'' and provide more specifics on the choices that chimpanzees should be able to exercise, such as to select their social groups. It was noted that chimpanzee experts could help refine this recommendation to include, for example, a list of possible enrichment activities, such as puzzles, games, devices for retrieving foods, and perhaps touch-screen technologies, which might also be useful for certain types of noninvasive behavioral research. Another suggestion was for the NIH to implement this recommendation to the fullest extent possible without compromising human safety.

Response: The NIH accepts Recommendation EA7. We do not believe that the recommendation requires additional specificity because this could have the unintended consequence of omitting important activities or opportunities that would otherwise satisfy this recommendation.

4. Management (Recommendations EA8–EA10)

Recommendation EA8 states: ''Chimpanzee management staff must include experienced and trained behaviorists, animal trainers, and enrichment specialists to foster positive human–animal relationships and provide cognitive stimulation. Given the importance of trainer/animal ratios in maintaining trained behaviors, a chimpanzee population of 50 should have at least 2 dedicated staff members with this type of expertise. Positive reinforcement training is the only acceptable method of modifying behaviors to facilitate animal care and fulfillment of management needs. Training plans should be developed for each animal, and progress toward achieving established benchmarks should be documented.''

Comments: A large number of commenters agreed with Recommendation EA8. Agreement was almost uniform concerning the use of positive reinforcement for the stated purposes. However, a few commenters disagreed that positive reinforcement training alone would be sufficient for the stated purposes and suggested permitting the use of operant conditioning training and the use of timeouts, for example, to help modify behaviors that cannot be modified through positive reinforcement.

Others raised several additional concerns. Some suggested that the NIH specify the qualifications of the behaviorists mentioned in the recommendation, including an advanced degree (e.g., a Ph.D.) with several years of experience and/or experience with chimpanzees in both the wild and captivity. Suggestions for staff recruitment and retention included creating a chimpanzee husbandry internship, developing retention incentives for trained staff to minimize turnover, and having senior staff members mentor new employees. Another recommendation was that facilities conduct background checks to ensure that applicants for jobs at chimpanzee facilities have not violated laws, such as the federal Animal Welfare Act and regulations or NIH policies. Other commenters believed that 2 staff members would not be sufficient to care for 50 research chimpanzees and that the ratio should be increased (e.g., to 4 or 5 trained staff members for 50 research chimpanzees) to prevent excessive staff workloads. Another suggestion, based on the commenters' experience or opinion that the published literature does not support a specific staff-to-chimpanzee ratio, was that the NIH determine its staffing requirements for research chimpanzee facilities based on a performance outcome. Others expressed concern about the availability of funding to implement this recommendation.

Response: The NIH accepts Recommendation EA8. We believe that personnel working with NIH-owned and -supported research chimpanzees must include experienced and trained behaviorists and enrichment specialists to foster positive human–animal relationships and provide cognitive stimulation. Facilities that house and care for NIH-owned and -supported chimpanzees currently offer a level of staffing and expertise that is similar to the recommended level. Likewise, research facilities commonly use positive reinforcement training to habituate chimpanzees to husbandry and experimental procedures. The *Guide for the Care and Use of Laboratory Animals, Eighth Edition* (*http://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf*) and the federal Animal Welfare Act and regulations allow facilities to set performance standards to address the psychological well-being of chimpanzees.

Recommendation EA9 states: ''All personnel working with chimpanzees must receive training in core institutional values promoting psychological and behavioral well-being of chimpanzees in their care. These institutional core values should be publicly accessible.''

Comments: A large number of commenters agreed that all personnel working with chimpanzees must be trained in values promoting chimpanzee well-being. Some suggested that individuals working with chimpanzees have both training and experience in working with chimpanzees. Others expressed the concern that the recommendation does not address the need to monitor compliance with these values, such as through the use of cameras and NIH audits. Some commenters suggested credentials that trainers should have and noted the importance of ensuring that all staff members have received all required human vaccinations.

Response: The NIH accepts Recommendation EA9. We believe that personnel working with NIH-owned and -supported research chimpanzees must receive training in institutional values that promote the psychological and behavioral well-being of chimpanzees. Facilities that house and care for NIH-owned and -supported research chimpanzees provide such training, and the agency expects this practice to continue. We disagree with those who suggested that the recommendation specify the credentials that trainers must have. Individual institutions are sufficiently knowledgeable about and capable of designing staff training

programs that promote their core values. The NIH also notes that the *Guide for the Care and Use of Laboratory Animals, Eighth Edition* has established training and vaccination requirements for personnel working with chimpanzees (*http://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf*). The agency believes that each facility should have the discretion to decide whether to use cameras or other compliance-monitoring methods. We discuss the NIH's role in enforcing the accepted recommendations in the ''Other Comments'' section at the end of this document.

Recommendation EA10 states: ''Chimpanzee records must document detailed individual animal social, physical, behavioral, and psychological requirements and these requirements should be used to design appropriate individualized chimpanzee management in the captive research environment.''

Comments: A large number of commenters strongly agreed with Recommendation EA10. Several gave examples of the types of information that facilities should collect or suggested expanding the recommendation to specify the frequency of documentation and record reviews, the types of observations to be recorded, and the qualifications of individuals who conduct these reviews. Public access to these records was also requested. In addition, a few argued that because humans cannot know the psychological requirements of individual chimpanzees, the recommendation should not mention these requirements.

Response: The NIH accepts Recommendation EA10. Facilities that house and care for NIH-owned or -supported research chimpanzees keep and use documentation on the chimpanzees' needs and welfare to satisfy accreditation and existing federal requirements. The NIH expects these facilities to continue this practice. We disagree with the suggestion to remove the mention of chimpanzees' psychological requirements from this recommendation. As discussed in the agency's response to Recommendation EA9, the training for personnel working with research chimpanzees should include an emphasis on chimpanzees' psychological well-being to prepare staff to keep proper records. Similarly, the agency disagrees with the suggestion to specify the types of documentation that facilities must retain, the information they must capture, and the qualifications of staff who review the records. Facilities that house and care for NIH-owned and -supported research chimpanzees are required to keep records on the chimpanzee colonies pursuant to existing laws, regulations, and policies. The *Guide for the Care and Use of Laboratory Animals, Eighth Edition* (*http://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf*) and the federal Animal Welfare Act and regulations require facilities to keep records on the behavioral management of their chimpanzees. Restating these existing requirements in this recommendation would be unnecessarily duplicative.

5. Other Issues Related to Ethologically Appropriate Physical and Social Environments

Comments: Several commenters expressed concern that the recommendations apply only to research-active and research-inactive chimpanzees and not to other categories of NIH-owned chimpanzees (e.g., retired chimpanzees). Several recommended that the NIH require facilities housing NIH-supported chimpanzees to comply with the housing condition, enrichment, and training practices described in the AZA *Chimpanzee Care Manual* (*http://www.aza.org/uploadedFiles/Animal_Care_and_Management/Husbandry,_Health,_and_Welfare/Husbandry_and_Animal_Care/ChimpanzeeCareManual2010.pdf*) or in scientific or other journals. Some commenters believed that the NIH should specify minimum veterinary care requirements to maximize chimpanzee welfare.

Response: The NIH clarifies that any implemented Council recommendations will apply to research-active and -inactive populations of chimpanzees owned or supported by the NIH and any research using them, irrespective of who funds it. The implemented recommendations will also apply to NIH-supported research using chimpanzees, regardless of whether the agency owns or supports these animals. The Council recommendations do not apply to chimpanzees that are retired or permanently ineligible for biomedical research.

The NIH appreciates the suggested references to aid in the care and behavioral management of NIH-owned or -supported chimpanzees. We believe that facilities that house research chimpanzees are sufficiently knowledgeable about the current literature, including the AZA *Chimpanzee Care Manual* used by zoos that house chimpanzees. The NIH also notes that the *Guide for the Care and Use of Laboratory Animals, Eighth Edition* (*http://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf*) and the federal Animal Welfare Act and regulations have requirements regarding veterinary care for nonhuman primates, including chimpanzees.

B. Size and Placement of Research-Active and Research-Inactive Populations of NIH-Owned and NIH-Supported Chimpanzees

The Council provided 9 recommendations on the size and placement of research-active and research-inactive populations of NIH-owned and -supported research chimpanzees in the context of the IOM Committee's recommendations. The Council based these recommendations, in part, on the number of chimpanzees used in NIH-supported projects. Below are the recommendations on this topic, a summary of public comments on these recommendations, and the agency's response to these comments and decisions regarding the Council recommendations.

1. Chimpanzee Retirement (Recommendation SP1)

Recommendation SP1 states: ''The majority of NIH-owned chimpanzees should be designated for retirement and transferred to the federal sanctuary system. Planning should start immediately to expand current facilities to accommodate these chimpanzees. The federal sanctuary system is the most species-appropriate environment currently available and thus is the preferred environment for long-term housing of chimpanzees no longer required for research.''

Comments: Many commenters agreed with this recommendation, although most endorsed the retirement of all chimpanzees and not just a majority. Furthermore, a large number of commenters agreed that the federal sanctuary system is the most species-appropriate environment and should be expanded to accommodate the chimpanzees currently used in research. Another suggestion was that the federal sanctuary be subject to regulations to ensure the well-being of the research chimpanzees.

Others questioned the quality of care provided by sanctuaries or found the recommendation vague. In addition, a concern was that sanctuaries do not provide an appropriate level of care for research chimpanzees that have health conditions. Other commenters suggested that the NIH consider moving chimpanzees to sanctuaries, including sanctuaries that are not part of the federal sanctuary system, as long as they satisfy applicable standard of care

requirements, such as those followed by members of the North American Primate Sanctuary Alliance or required for accreditation by the Global Federation of Animal Sanctuaries.

A few commenters did not agree with the recommendation, partly because the Council Working Group presented no evidence that the federal sanctuary system is the ''most species-appropriate environment'' for research chimpanzees.

The need to fund chimpanzee retirement was a common theme in many comments on Recommendation SP1. Several commenters suggested asking Congress and other entities to allocate the funds necessary to construct additional sanctuary space for research chimpanzees. Others stated that cost should not be a factor in deciding whether to retire additional chimpanzees. It was also noted that the funding limits of the Chimpanzee Health Improvement Maintenance and Protection (CHIMP) Act of 2000—the law that authorizes the NIH to establish and maintain a system of sanctuaries for the lifetime care of chimpanzees no longer needed for research—could affect the agency's decisions about retiring chimpanzees no longer needed for research.

Response: The NIH partially accepts SP1 and intends to implement the following: ''Subject to the availability of additional sanctuary space and the elimination of funding restrictions on the federal sanctuary system imposed by the CHIMP Act, the majority of NIH-owned chimpanzees will be designated for retirement and transferred to the federal sanctuary system. Planning to expand current facilities to accommodate the additional chimpanzees will continue once the funding restrictions have been eliminated.''

We agree that the majority of chimpanzees that the NIH owns could be eligible for retirement, but the federal sanctuary system needs additional capacity. Although the federal sanctuary system plans to use private funding to construct additional space to house chimpanzees from the New Iberia Research Center, these new areas will not be sufficient to accommodate the majority of NIH-owned chimpanzees that the Council recommended retiring. The NIH is currently unable to fund expansion of the sanctuary due to funding limitations in the CHIMP Act.

The NIH believes that adding standards to Recommendation SP1 or specifying the nature of the veterinary care that sanctuaries provide would be unnecessarily duplicative. The standards of care for chimpanzees held in the federally supported sanctuary system (42 CFR Part 9), which have been in effect since October 2008, govern the facilities that have contracts or subcontracts with the federal government to operate the federally supported chimpanzee sanctuary system. In addition, these regulations and the standards in the *Guide for the Care and Use of Laboratory Animals, Eighth Edition* (*http://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf*) govern the veterinary care of chimpanzees in the federal sanctuary system.

Because of funding limitations and the lack of available space in the federal sanctuary system to house additional chimpanzees, the NIH is not in a position to implement Recommendation SP1. Instead, the agency agrees with the recommendation subject to the availability of additional sanctuary space and the elimination of funding restrictions so that the agency can provide additional funding to the federal sanctuary system.

2. Maintaining 50 Chimpanzees for Research (Recommendations SP2 and SP3)

Recommendation SP2 states: ''A small population of chimpanzees should be maintained for future potential research that meets the IOM principles and criteria. Based on an assessment of current research protocols and interviews with content experts and current research facility administrators, this colony is estimated to require approximately 50 chimpanzees. The size and placement of this colony should be reassessed on a frequent basis (approximately every 5 years) to ensure that such a colony is still actually needed and that the animals are not overused.''

Comments: A large number of commenters strongly disagreed with Recommendation SP2, asserting that no chimpanzees should be retained for future research that meets the IOM principles and criteria and/or that chimpanzees might be needed for noninvasive research only. Among other things, they argued that the genetic and physiologic differences between humans and chimpanzees render the chimpanzee a poor scientific model for studying human diseases. Several commenters cited HIV studies that ultimately showed that the chimpanzee model had limited utility for studying this virus. Those who disagreed with this recommendation believed that no scientific basis or public health need exists for keeping a reserve population for research and/or that using chimpanzees in research is unethical. Some noted that discontinuing chimpanzee research would align U.S. policies with those of other nations that prohibit chimpanzee use in research. Others added that stopping chimpanzee use in research would conserve funds. In general, these and other commenters asserted that all research involving chimpanzees should end and that the NIH should not keep 50 chimpanzees for research.

In contrast, several commenters strongly supported keeping 50 chimpanzees available for research, although a suggestion was that 25 chimpanzees would suffice because 50 is too many. Those supporting Recommendation SP2 argued that due to the similarities between chimpanzees and humans, the chimpanzee model has been key to scientific advancements, including the development of interventions to treat or prevent certain diseases. These commenters noted that this model could continue to serve as a useful, and in some cases the only, animal model for studying certain human diseases, such as emerging diseases or other public health threats, the hepatitis C virus, and human behavior.

Some commenters were concerned about the potential loss of the chimpanzee model for studying hepatitis C. They indicated that neither cell culture systems nor other animal models can replace chimpanzees in studies of the hepatitis C virus. Commenters noted that although cell cultures are useful for studying the hepatitis C virus life cycle and evaluating therapeutic drug candidates, they cannot be used for vaccine development. Commenters also noted that two mouse models for hepatitis C virus infection are currently in use but have limitations. The commenters noted that vaccine safety and efficacy must be tested in models with a working immune system, but the existing mouse models lack an intact immune system or are immune deficient and, therefore, cannot be used to test hepatitis C virus vaccines. A few commenters recommended that the NIH establish a new committee to consider the need for chimpanzees in hepatitis C research.

Several commenters expressed concern that 50 chimpanzees would be insufficient to meet possible demands resulting from the need to address known and emerging biomedical and other public health threats. These commenters urged the NIH to reconsider the population size needed for future research on the hepatitis C virus and other conditions because chimpanzees used in research will age, will develop age-related illnesses, or could be exposed to viruses that would make

them unsuitable for biomedical research. It was, instead, recommended that the NIH maintain a population of 200 chimpanzees that are available for research, in part due to concerns that the NIH would be prohibited from replacing chimpanzees in the group of 50 reserved for research.

Several commenters believed that 5-year reassessments are too infrequent and, instead, recommended conducting assessments more frequently. In addition, several commenters wondered how the NIH would select the research animals, how many projects these animals would be involved in, and/or whether the healthiest chimpanzees would be prevented from retiring. Others expressed concern that the 50 chimpanzees selected would experience negative emotional and/or social effects if they were separated from their social groups.

Response: The NIH accepts Recommendation SP2. In accepting the IOM Committee's recommendations, the NIH agreed that although most current uses of chimpanzees for biomedical research are unnecessary, some ongoing research might be necessary but any such research must be consistent with the IOM principles and criteria. The NIH recognizes that one matter left unsettled by the IOM Committee was the use of chimpanzees to develop a prophylactic vaccine for the hepatitis C virus. The agency believes that the hepatitis C virus is an example of research that warrants the further use of chimpanzees as long as this research is consistent with the IOM Committee's principles and criteria.

The agency disagrees that the number of chimpanzees for future research needs to be reconsidered at this time. Those who suggested fewer chimpanzees (e.g., 25) did not provide a rationale for this number other than to say that 50 chimpanzees seemed to be too many. Although the NIH appreciates the argument to keep up to 200 chimpanzees available for research and understands the concern that the NIH might not be able to replenish the proposed population of approximately 50 chimpanzees, the NIH finds the Council Working Group's rationale for this recommendation to be compelling.

The NIH would like to clarify its strategy for selecting the approximately 50 chimpanzees to maintain for research. Our intent is to consult with scientists, veterinarians, and primate facility directors who oversee the research-active and -inactive chimpanzees owned or supported by the NIH. These individuals are familiar with these particular chimpanzees, their social groupings, their health status, and other characteristics that could determine their suitability for research. We understand and share concerns about separating chimpanzees from their social groups. Social groups will be among the many important factors that the NIH will consider to select NIH-owned or -supported chimpanzees that will be maintained for future research. The NIH intends to review its decision to retain approximately 50 chimpanzees for research at least every 5 years.

In addition, the Council advised continuing several comparative genomics or behavioral research projects involving 290 chimpanzees, many of which are not owned or supported by the NIH; meaning that a currently active project may continue until the end of the current project period but is not eligible for a no-cost extension or other means to extend the original project term (see Council Working Group report, at *http://dpcpsi.nih.gov/council/working_group_message.aspx*, for further clarification of this concept). However, the Council Working Group concluded that the NIH should not maintain a large reserve colony of chimpanzees for minimally invasive research because many of these research needs could be met in nontraditional research settings, such as accredited sanctuaries or zoos. The NIH would like to clarify that researchers may request NIH funding for minimally invasive research using chimpanzees that are not part of the research colony of approximately 50 NIH-owned or -supported chimpanzees, but the NIH will review these applications, proposals, and protocols for consistency with the IOM principles and criteria. See the discussion of the Council recommendations regarding this review process below under ''Review Process for Future Requests to Use Chimpanzees in NIH-Supported Research.'' In addition, the environments in which NIH-supported research involving chimpanzees is conducted must be consistent with the NIH accepted recommendations for ethologically appropriate environments.

Recommendation SP3 states: ''This small chimpanzee colony should be maintained at a facility that has the characteristics of ethologically appropriate physical and social environments described in this report. Thus, plans should be made now to ensure that ethologically appropriate physical and social housing conditions will be available within 3 to 5 years. Maintaining the chimpanzee colony at a single facility could be advantageous to minimize costs and maximize management flexibility.''

Comments: Although a few commenters believed that creating a separate colony of chimpanzees for research would be fiscally irresponsible, many commenters on Recommendation SP3 agreed with this recommendation. In addition, several suggested that the NIH require changes to chimpanzee housing conditions immediately and not within 3 to 5 years as recommended. In contrast, others stated that 3 to 5 years might not be enough time to construct or renovate chimpanzee facilities.

Several commenters voiced concern that housing all 50 chimpanzees in a single facility could put the animals at risk of contracting contagious diseases, such as tuberculosis. Others strongly opposed the use of any chimpanzees in research and suggested retiring all NIH-owned and -supported chimpanzees to a sanctuary. Another suggestion was to house any colony of chimpanzees retained for research in accredited sanctuaries or sanctuary-like settings in which only noninvasive or minimally invasive behavioral research is permitted.

Response: The NIH partially accepts Recommendation SP3, subject to further consideration of the data supporting the recommended space density (see previous discussion on Recommendation EA2). We believe that the 3-to-5-year timeframe recommended by the Council should be sufficient for planning, designing, obtaining permits for, and constructing facilities that are consistent with the recommendation.

In determining whether to keep the research chimpanzee colony in one facility or several facilities, the NIH will carefully consider such factors as the cost and management benefits of both options and safeguards to protect the chimpanzees from colony-wide infections. The agency acknowledges the suggestion that the NIH house the chimpanzees available for research in sanctuary settings that permit limited types of behavioral research. Although the agency agrees that observational research can occur in the federal sanctuary system, this type of research will not satisfy all of the needs noted in the reports of the IOM Committee or Council. Thus, we do not believe that the approximately 50 research chimpanzees could be housed in the federal sanctuary system.

3. Demographic Constitution of Colony and Breeding (Recommendations SP4 and SP7)

Recommendation SP4 states: ''The demographic constitution of this small chimpanzee colony is important to maximize its utility for research. Ideally, the colony should be age and sex

stratified, have an approximately 50:50 sex ratio, and be composed primarily of animals that are healthy and younger than 30 years. At least half of this population should be physiologically naïve to infection (e.g., hepatitis or HIV). When this colony is formed, best practices should be used for maintaining current social groupings, whenever possible, to minimize adverse stress.''

Comments: Many of the commenters who addressed this recommendation agreed with the proposed colony composition. Others supported the recommendation as long as the recommended demographic constitution is best for the animals and the colony or stated that the group cannot be age stratified if all of the animals are under age 30. In addition, some commenters were concerned that if some of the chimpanzees are naïve to infection and others become or are infected, the colony would be further subdivided and might therefore not comply with the other Council recommendations, including the recommendation pertaining to group size (see Recommendation EA1). Some expressed concern that housing equal numbers of animals of both sexes in groups could lead to injuries and deaths. It was also suggested that chimpanzees younger than 3 years or those with compromised health be retired and not be available for research. The remaining commenters generally disagreed with the recommendation, stating that no colony of chimpanzees should be kept for research.

Response: The NIH accepts Recommendation SP4. The NIH intends to use the Council recommendation and the best available data to guide its selection of the most appropriate animals to maintain for current and anticipated future research. Consideration of social group requirements, stratification concerns, and possible unintended consequences (e.g., aggression or compromised health of naïve chimpanzees) will be among the many important factors that the agency will use to select the chimpanzees to maintain for future research. The agency also intends to select only healthy chimpanzees for this colony, as the Council suggests. The NIH does not own or support any research-active or research-inactive chimpanzees younger than 3 years.

Recommendation SP7 states: ''The NIH should not, on its own, revitalize breeding strategies to derive a population of chimpanzees for any research, including for new, emerging, or reemerging disease research.''

Comments: Nearly all commenters on Recommendation SP7 agreed that the NIH should not revitalize breeding strategies. Several commenters suggested the use of contraception to prevent accidental breeding within the research chimpanzee colony, and others suggested that no new chimpanzees be added to the NIH-owned population and be used for research. A few added that revitalizing breeding would incur additional costs and exacerbate existing space concerns.

In contrast, a few commenters who supported the availability of chimpanzees for research believed that a limited breeding program should be reestablished to repopulate the colony after research chimpanzees currently owned or supported by the NIH age, expire, or become otherwise unsuitable for research.

Response: The NIH accepts Recommendation SP7. We do not agree with some commenters that a chimpanzee-breeding program needs to be reestablished at this time. The cost of caring for a chimpanzee over its lifetime can range from $300,000 to $500,000. This cost alone is a considerable deterrent to revitalizing the breeding of NIH-owned or -supported research chimpanzees. Furthermore, as the IOM Committee observed, alternatives to the use of chimpanzees in some areas of research are now available, and the NIH expects that additional alternative research models will continue to be developed.

4. Funding Priorities for Behavioral and Comparative Genomics Research (Recommendation SP5)

Recommendation SP5 states: ''The NIH should review its funding priorities for comparative behavioral, cognitive, and genomics studies using chimpanzees. The NIH should consider targeting funding for low-burden projects that can be conducted in nontraditional research settings that can maintain ethologically appropriate environments or projects that use materials collected during routine veterinary examinations.''

Comments: Many commenters stated that chimpanzees should not be used in any research (even noninvasive or minimally invasive research) and, as a result, disagreed with this recommendation. However, some of these commenters agreed that materials collected from chimpanzees during routine veterinary exams could be used for research. Others stated that the recommendation was unclear but disagreed with it in general because they believe that all chimpanzee and/or other animal research should stop. For the most part, however, commenters on this recommendation favored a review by the NIH of its funding priorities for comparative genomics and behavioral research using chimpanzees.

Several commenters wondered why this recommendation addresses behavioral research partly because the tasks associated with behavioral research can be enriching for captive chimpanzees. These commenters emphasized the scientific value of chimpanzees for behavioral and neuroscience research due to their cognitive skills, including basic language, self-recognition, and empathy, as well as similarities between chimpanzee and human brain structure and function.

Commenters familiar with behavioral research stated that nontraditional settings, such as sanctuaries, might allow only noninvasive behavioral research and would not be conducive to or would not allow some other types of cognitive and behavioral research. It was also suggested that sanctuaries would not make behavioral research a priority. Another suggestion was that if the NIH relocates most of its chimpanzees to a sanctuary where some behavioral research could occur, a research advocate should be appointed to the sanctuary's board of directors to promote the creative use of chimpanzees in ways that do not disturb the animals' retirement.

Response: The NIH accepts Recommendation SP5. We acknowledge that many commenters disagreed with this recommendation because of their belief that the use of chimpanzees in research is unnecessary. However, the agency does not share this view.

In response to questions about why the Council addressed behavioral research in its recommendations, the NIH has funded behavioral research using chimpanzees, so this type of research was within the group's purview. During its review, the Council Working Group found that most of the chimpanzees used in NIH-supported research are enrolled in behavioral research protocols. In its report, the Council Working Group concluded that the need for chimpanzees in behavioral research is not negligible but that the NIH should reexamine its programmatic priorities in this area. We appreciate the detailed information that some commenters supplied about behavioral, neuroscience, and related research for the agency's consideration.

The NIH agrees with those commenters who noted that the regulations governing the federal sanctuary system permit only noninvasive behavioral studies in these

facilities, so some invasive types of behavioral research would not be permitted in the federal sanctuary system. Non-observational, NIH-funded behavioral research might be permissible in other settings, such as zoos; however, the extent to which these entities could satisfy the ethologically appropriate conditions that the NIH plans to implement is unknown. As the agency considers its priorities in behavioral and comparative genomics research, it will take into account both the types of behavioral, neuroscience, and related research that might be conducted using chimpanzees and the relevant regulations that could limit this kind of research in nontraditional settings.

5. New, Emerging, and/or Reemerging Diseases and the Use of Alternative Animal Models (Recommendations SP6, SP8, and SP9)

Recommendation SP6 states: ''The NIH should not support any long-term maintenance of chimpanzees intended for research on new, emerging, or reemerging diseases in animal biosafety level 2 or greater biocontainment-level facilities.''

Comments: A large number of commenters agreed that the NIH should not support any long-term maintenance of chimpanzees intended for research on new, emerging, or reemerging diseases. Many did not support any research on chimpanzees. Others agreed that biomedical research using chimpanzees should stop but found the wording of this recommendation confusing, especially the reference to ''level 2 or greater biocontainment-level facilities.'' Some commenters believed that implementing Recommendation SP6 would threaten national security in the event of an outbreak, while others wondered what would constitute a ''national security risk.'' A few commenters stated that future research on the hepatitis C virus would necessitate biosafety level 2 (BSL–2) facilities and disagreed with Recommendation SP6 because it would prevent hepatitis C virus research. Another concern was that chimpanzees, which are typically held in BSL–2 facilities because they are very susceptible to human respiratory viruses and bacterial infections, could no longer be held at this biosafety level if the NIH accepted this recommendation.

Response: The NIH accepts Recommendation SP6 and will not support the long-term maintenance of chimpanzees for the stated research purposes. Information about biosafety and BSLs is available at *http://www.cdc.gov/training/QuickLearns/biosafety/*.

The NIH strongly disagrees with the view that this recommendation would prohibit facilities from continuing to practice BSL–2 precautions and possibly other safeguards that are already in place to protect the health of the chimpanzees and facility personnel. The agency reiterates that the Council recommendations do not alter existing safety regulations, requirements, and policies that dictate the precautions that must be taken for the safe handling of, care of, interaction with, and other exposures of NIH-owned and -supported research chimpanzees to protect the health and safety of both the chimpanzees and the individuals in charge of their care. The agency expects facilities housing NIH-owned and -supported research chimpanzees to continue taking the applicable safety and health precautions.

The NIH also does not interpret this recommendation as prohibiting research on the hepatitis C virus using chimpanzees, which is conducted in BSL–2 facilities due to the nature of the virus and because facilities use BSL–2 precautions as a best practice in chimpanzee colonies. Furthermore, the chimpanzee is a longstanding and informative model for this research. The agency interprets Recommendation SP6 as discouraging long-term plans to use chimpanzees for research in higher containment conditions on new, emerging, or reemerging diseases.

The NIH does not agree with commenters who stated that implementing this recommendation would threaten national security. Chimpanzees are not used for research conducted in high-biocontainment conditions (BSL–3 or BSL–4). Only other nonhuman primates, other animal models, or non-animal-based technologies have been used for research to address public health threats requiring high-biocontainment conditions.

Recommendation SP8 states: ''The NIH should collaborate with other federal agencies (i.e., Centers for Disease Control and Prevention and Food and Drug Administration) and departments (i.e., Department of Defense and Department of Homeland Security) when considering any future plan for placement, maintenance, and use of chimpanzees in research in response to a new, emerging, or reemerging disease that could represent a national security risk to the United States.''

Comments: Of the commenters who responded to Recommendation SP8, many disagreed with the recommendation, mainly due to the opinion that all chimpanzee and/or other animal research should end. However, other commenters agreed with Recommendation SP8. Some of these commenters desired more restrictions on such future use. Others desired fewer restrictions.

Response: The NIH accepts Recommendation SP8. We do not believe that adding restrictions on the use of chimpanzees for new, emerging, or reemerging diseases would be helpful in achieving our public health mission.

Recommendation SP9 states: ''In light of evidence suggesting that research involving chimpanzees has rarely accelerated new discoveries or the advancement of human health for infectious diseases, with a few notable exceptions such as the hepatitis viruses, the NIH should emphasize the development and refinement of other approaches, especially alternative animal models (e.g., genetically altered mice), for research on new, emerging, and reemerging diseases.''

Comments: Many commenters supported Recommendation SP9, agreeing that the development of alternative animal models is a step toward eliminating the use of chimpanzees in research. These commenters, however, emphasized that the NIH should only select an alternate animal model after considering whether the human health benefits of the research justify this model's use. In contrast, many commenters disagreed with Recommendation SP9 because they believed that no animals should be used in research. Others stated that the recommendation marginalizes the contributions of chimpanzees to scientific research.

Response: The NIH accepts Recommendation SP9 and plans to continue to support research to develop and validate non-animal-based models to help further reduce the use of other animal models in research. Research using chimpanzees has prevented hundreds of thousands of human deaths and illnesses due to hepatitis A and B and has resulted in advances in the development of the hepatitis C and polio vaccines and treatments for leukemia, other cancers, and other devastating diseases. Our position is that the chimpanzee has been a valuable research model for improving human health.

C. Review Process for Future Requests To Use Chimpanzees in NIH-Supported Research

The final element of the Council Working Group's charge was to develop a process for considering whether the potential future use of chimpanzees in

NIH-supported research is scientifically necessary and consistent with the IOM principles and criteria. The Council offered 9 recommendations in this area. Below are these recommendations, summaries of comments on these recommendations, the agency's response to these comments, and its decisions regarding this set of recommendations.

In some of these recommendations, the Council called for the NIH to create an ''independent Oversight Committee for Proposals Using Chimpanzees in NIH-supported Research (Oversight Committee)'' to advise the NIH on whether the proposed use of chimpanzees in research is consistent with the IOM principles and criteria. In its January 22, 2013, deliberations, the Council of Councils encouraged the agency to consider various options for placing the Panel's consideration of research involving chimpanzees. The NIH notes that the recommended Oversight Committee must abide by applicable federal laws, regulations, and policies and, thus, must play an advisory role only and cannot have decision-making authority. Decisions about funding for NIH-supported research are made solely by the NIH and not its advisory bodies. For these reasons, the NIH is not able to accept portions of some recommendations on the review process for future requests to use chimpanzees in NIH-supported research. Instead, the NIH partially accepts some of these recommendations and provides language for implementing the portions of the recommendations that satisfy applicable laws, regulations, and policies. For example, to be consistent with certain laws and regulations, the NIH refers to the ''Oversight Committee'' as the ''Chimpanzee Research Use Panel'' (the Panel). In addition, the NIH has decided to use a single process to assess the consistency with the IOM principles and criteria of grant applications, contract proposals, intramural research protocols, and third-party research requests involving chimpanzees.

The NIH proposes to establish the Panel as a working group of the Council of Councils, a federal advisory committee. The Panel will consider whether requests to the NIH to use chimpanzees in research are consistent with the IOM principles and criteria. Panel members will convene before the NIH makes funding decisions but after the NIH peer review or technical evaluation processes are completed for grant applications, contract proposals, and intramural research protocols. In accordance with laws governing the federal advisory committee process, the Panel will present its recommendations to the Council of Councils, which, in turn, will make recommendations to the appropriate NIH Institute or Center director(s).

1. Oversight Committee Composition (Recommendations RP1 and RP3)

Recommendation RP1 states: ''The NIH should replace the Interagency Animal Models Committee with an independent Oversight Committee for Proposals Using Chimpanzees in NIH-supported Research (Oversight Committee) to advise on the proposed use of chimpanzees in research. The current Interagency Animal Models Committee is not considered independent from other individuals and bodies that review and approve grant applications to the NIH, contains no members of the public, and thus does not fully meet the spirit of the IOM principles and criteria.''

Comments: Many of those who commented on this topic agreed with the recommendation. Among those who disagreed with this recommendation, some were concerned that the proposed Oversight Committee could stifle behavioral research. One suggestion was that the NIH not charge this new committee with reviewing behavioral research but, instead, consider the institutional animal care and use committee's approval to be sufficient. In addition, a few asked why research with chimpanzees would be subject to more scrutiny than research with other animals and noted that this type of oversight committee duplicates the activities of the existing NIH peer review system used to evaluate grant applications. Some commenters raised the concern that animal rights advocacy groups would seek a separate type of review for proposed research using other species if the NIH implements Recommendation RP1. Others stated that all chimpanzees used in research should be moved to the federal sanctuary system or were not sufficiently familiar with the Interagency Animal Models Committee to provide an opinion on this recommendation.

Response: The NIH partially accepts Recommendation RP1 and intends to implement the following: ''The NIH will replace the Interagency Animal Models Committee with the independent Chimpanzee Research Use Panel to advise on the proposed use of chimpanzees in research.''

The Interagency Animal Models Committee was a federal group chartered to oversee all federally supported biomedical research involving chimpanzees. The agency plans to replace this committee with the Panel, which will function independently of review processes currently used to assess grant applications, contract proposals, and intramural research protocols. The Panel will include members of the public and will consider whether requests to the NIH to use chimpanzees in research are consistent with the IOM principles and criteria.

The NIH disagrees with some commenters' suggestions to exclude behavioral research involving chimpanzees from the Panel's consideration of whether proposed research is consistent with the IOM Committee's principles and criteria. Verifying whether proposed research meets the IOM Committee's criteria for behavioral research will help the NIH determine whether that research is consistent with the IOM Committee's recommendations. The agency disagrees with commenters that using the Panel to consider whether proposed behavioral research meets the IOM principles and criteria will stifle research in this field.

Recommendation RP3 states: ''The Oversight Committee should be comprised of individuals with the specific scientific, biomedical, and behavioral expertise needed to properly evaluate whether a grant, intramural program, contract, or other award mechanism supporting research using chimpanzees complies with the IOM principles and criteria.''

Comments: Many commenters who responded to this recommendation strongly agreed with it. Among those who agreed, several suggested that the NIH not compensate Oversight Committee members for their reviews and that this committee include at least one animal welfare representative, members of animal protection groups (such as Jane Goodall), experts in chimpanzee conservation, and/or scientists with disease-specific expertise. Some also wanted the NIH to expand the number of public representatives on the committee. Several voiced concern that including only scientific members on the committee would not be in the best interests of the chimpanzees. For those who disagreed with the recommendation, the main concerns were the composition of this committee and the belief that all research chimpanzees should be retired.

Response: The NIH partially accepts Recommendation RP3 and intends to implement the following: ''The Chimpanzee Research Use Panel will be comprised of individuals with the specific scientific, biomedical, and behavioral expertise needed to properly

evaluate whether requests to use chimpanzees in research that is supported by a grant, intramural program, contract, or other award mechanism are consistent with the IOM principles and criteria.''

In addition, the NIH agrees with the Council recommendation regarding the Panel membership, namely, that it should consist of 1 or more scientists, veterinarians, primatologists, bioethicists, and statisticians; and 2 or more public representatives. NIH officials will advise on process issues and provide information but will not be members of the Panel.

2. Review Process (Recommendations RP4–RP6)

Recommendation RP4 states: ''Investigators seeking NIH funding to conduct research using chimpanzees must explain in their application how their proposed research complies with the IOM principles and criteria. This supplemental information must address all of the questions posed in the decision-making algorithm in this report and provide sufficient detail for consideration by the Oversight Committee. This information is in addition to the vertebrate animal section and/or applicable animal study protocol. The NIH might wish to develop a form or other suggested template for investigators to use for this purpose.''

Comments: Many commenters on this topic supported Recommendation RP4 and requested that the template have, and that researchers adhere to, strict guidelines. Commenters suggested that investigators be required to justify the need to use chimpanzees by explaining how the proposed research would contribute substantially to human health and by specifying which other animal models or alternatives have been tested or considered.

Several commenters stated that the proposed decision-making process is ambiguous and needs clear-cut criteria. Some of the wording in the Council Working Group's decision-making algorithm was also of concern because it could be interpreted to mean that research cannot be conducted in chimpanzees if it can be conducted in humans. More specifically, a concern was that research to compare the chimpanzee's genome to a human's genome would not be permitted.

In general, those who disagreed with Recommendation RP4 did so because they believed that all chimpanzees should be retired from research. Others argued that because of the IOM Committee's finding that using chimpanzees in research is largely unnecessary, the process described in Recommendation RP4 is not needed.

Response: The NIH partially accepts Recommendation RP4 and intends to implement the following: ''Investigators proposing to the NIH to conduct research using chimpanzees must demonstrate that their proposed research is consistent with the IOM principles and criteria. The supplemental information that these investigators provide must address all of the questions posed in the decision-making algorithm in the Council Working Group report and provide sufficient details for consideration by the Chimpanzee Research Use Panel. This information is in addition to the vertebrate animal section and/or applicable animal study protocol.''

The NIH plans to develop a form or other suggested template for investigators to use for this purpose. In addition, the agency will determine the timing and most appropriate format for collecting the supplemental information that investigators proposing to use chimpanzees in research will need to submit. The existing technical and/or peer review processes applicable to grant applications, contract proposals, or intramural research protocols will continue without modification. The Panel will function separately from these existing processes.

The NIH does not interpret the recommendations of the IOM Committee or the Council or the Council Working Group's decision-making algorithm as prohibiting comparative genomics research or other research that compares biology or behavior in humans and chimpanzees to answer a scientifically meritorious question. The IOM Committee provided explicit criteria to guide comparative genomics and behavioral research that proposes to use chimpanzees for those purposes.

Recommendation RP5 states: ''To ensure that the scientific use of chimpanzees is justified, the animal numbers and group sizes must be statistically justified before the NIH approves any proposed research project involving the use of chimpanzees.''

Comments: Many commenters on this topic agreed that researchers must statistically justify the requested sample size of chimpanzees for the proposed research. However, some commenters wondered what the term ''statistically justified'' means. Others were concerned about who would decide when the use of chimpanzees is or is not statistically justified.

Those who disagreed with Recommendation RP5 generally believed that the NIH should not fund any chimpanzee research and that the scientific use of chimpanzees is never justified. Others stated that not all experimental designs involving chimpanzees require statistical analyses of animal numbers and group sizes. A suggestion was that a chimpanzee might concurrently serve as its own control in, for example, studies to determine the dose of a drug that maximally binds to a target or the half-life of a test compound.

Response: The NIH partially accepts Recommendation RP5 and intends to implement the following: ''To ensure that the scientific use of chimpanzees is justified, the proposed animal numbers and group sizes must be statistically or scientifically justified before the NIH approves any proposed research project involving the use of chimpanzees.''

We believe that the intent of this recommendation is to ensure that the number of chimpanzees proposed for a study is sufficient to yield meaningful results. Mathematical calculations, often described as statistical power analyses, are commonly used to ensure that studies include enough test subjects to provide confidence that the observed results would not have occurred by chance.

The NIH appreciates the view that researchers must statistically justify the numbers of chimpanzees that they propose to study. At the same time, the NIH wishes to prevent the use of more chimpanzees than are needed for a study. The NIH is willing to consider applications, proposals, and protocols for research that request to use fewer chimpanzees than the statistically justified number if doing so can appropriately meet the scientific need.

Recommendation RP6 states: ''Investigators need not include supplemental information on chimpanzee use for proposals involving the following, and these proposals will be exempt from Oversight Committee review:

- The use of any biomaterials, including pathological specimens, collected and/or stored prior to submission of the research proposal, or as part of a research grant or contract that has undergone Oversight Committee review and approval, or as part of regular veterinary (health) examinations;
- Other observational or non-interventional studies, such as behavioral observations in the wild that do not result in contact or otherwise interfere with the chimpanzees being observed; or
- Noninvasive collection of samples from the wild in a manner that does not result in contact or otherwise interfere

with the chimpanzees during the collection.''

Comments: Many commenters agreed with Recommendation RP6. Several also supported the use of chimpanzee specimens collected and stored post mortem as well as development of a chimpanzee tissue-sharing network among researchers to facilitate comparative genomics and other research. A few commenters found the wording of this recommendation unclear. As with the other review process recommendations, those who disagreed generally did so because they did not believe that chimpanzees should be used in any research.

Response: The NIH partially accepts Recommendation RP6 but will use the Chimpanzee Research Use Panel described above instead of an Oversight Committee. In addition, NIH understands ''proposals'' to include research applications, proposals, or protocols. Thus, NIH intends to implement the following: ''Investigators need not include supplemental information on chimpanzee use for research applications, proposals, or protocols involving the following because they will be exempt from Chimpanzee Research Use Panel consideration:

- The use of any biomaterials, including pathological specimens, collected and/or stored prior to submission of the research application, proposal, or protocol, as part of a research project that has undergone Chimpanzee Research Use Panel consideration and subsequent NIH approval, or as part of regular veterinary (health) examinations;
- Other observational or non-interventional studies, such as behavioral observations in the wild that do not result in contact or otherwise interfere with the chimpanzees being observed; or
- Noninvasive collection of samples from the wild in a manner that does not result in contact or otherwise interfere with the chimpanzees during the collection.''

The agency plans to issue a future notice in the *NIH Guide for Grants and Contracts* with procedural guidance for implementing these decisions.

3. Placement of the ''Oversight Committee'' Review (Recommendations RP2 and RP7–RP9)

Recommendation RP2 states: ''The Oversight Committee should be separate from extramural initial review groups, intramural scientific program personnel, and Institute or Center directors. In addition, the Oversight Committee's reviews should take place after the standard reviews and approvals by these entities. The Oversight Committee's reviews will focus on whether the proposed research is consistent with the IOM principles and criteria for the use of chimpanzees in research.''

Comments: Many commenters on this topic agreed with Recommendation RP2. A prevailing sentiment was that the Oversight Committee members should have no vested interest in or potential financial gain from using chimpanzees for research. Several repeated that public members with no ties to research should be part of this committee. Others held the opinion that this separate committee would be better positioned than an existing NIH committee to give priority to the animals' well-being during these reviews.

Those who disagreed that the NIH should establish an additional committee for this purpose were concerned that members would oppose research for nonscientific reasons. These commenters raised concerns about the potential that the Oversight Committee would duplicate scientific reviews at the NIH and delay approvals of grants, contracts, and intramural projects. Several disagreed with the recommendation because they believed that chimpanzees should not be used in research and, therefore, that the NIH does not need a committee of this sort. Some commenters wondered how members of this committee would be selected.

Response: The NIH partially accepts Recommendation RP2 and intends to implement the following: ''The Chimpanzee Research Use Panel will be separate from extramural peer review groups, contract evaluation panels, and intramural scientific review procedures. In addition, the Chimpanzee Research Use Panel's considerations will take place after the standard reviews (e.g., after the reviews by peer review panels, technical evaluation panels, and NIH Institute and Center advisory councils) and will focus on whether the proposed research is consistent with the IOM principles and criteria for the use of chimpanzees in research.''

Recommendation RP7 states: ''The Oversight Committee review should take place after the Center or Institute director approves a proposal so that the key elements of the review are publicly accessible to the extent allowable by federal regulations. The Oversight Committee should review all requests for grants, contracts, intramural projects, and third-party projects rather than establishing a separate review process for each mechanism. Funding of an award for research involving the use of chimpanzees that has received an Institute or Center director's approval will be conditional and subject to the subsequent evaluation by the Oversight Committee.''

Comments: Many commenters agreed with Recommendation RP7 and emphasized the need for full disclosure and transparency of the Oversight Committee's activities. Some commenters suggested that the Oversight Committee proceedings be open to the public. Another suggestion was that the Oversight Committee's reviews occur before the NIH peer review or after the peer review but before the NIH approves the project for funding. Those who disagreed with Recommendation RP7 believed that all research chimpanzees should be sent to a sanctuary and that the NIH should not fund any chimpanzee and/or other animal research.

Response: The NIH partially accepts Recommendation RP7 and intends to implement the following: ''The NIH will convene the Chimpanzee Research Use Panel after completing the standard review processes for grant applications, contract proposals, and intramural research protocols. The NIH will charge the Chimpanzee Research Use Panel with considering grant applications, contract proposals, intramural research protocols, and third-party research requests rather than establishing a separate review process for each mechanism.''

The agency acknowledges commenters' requests that the Panel's activities be open to the public or otherwise transparent. However, to protect the confidentiality of research applications and proposals, proprietary interests, and researcher privacy, discussions and recommendations about specific applications or proposals are not available to the public. Standard information about funded research will continue to be available at *http://projectreporter.nih.gov/reporter.cfm.* The NIH intends to provide the public with details about general processes that the Panel will follow, the criteria for selecting its members, and the decision-making algorithm that the Panel will use in applying the IOM principles and criteria.

Recommendation RP8 states: ''The Oversight Committee will base its reviews on the supplemental information provided by investigators on how the proposed research complies with the IOM principles and criteria and all relevant documents (including animal study protocols and grant applications) required to make informed determinations for all funding requests (grants, contracts, and intramural

projects) and other requests to use chimpanzees (e.g., third-party projects).''

Comments: Many commenters strongly agreed with Recommendation RP8. A suggestion was to allow the Oversight Committee to hold onsite inspections although, ideally, the use of chimpanzees in research would be banned entirely. Those who disagreed with Recommendation RP8 disapproved of using chimpanzees for research and believed that the animals should be sent to a sanctuary.

Response: The NIH partially accepts Recommendation RP8 and intends to implement the following: ''The Chimpanzee Research Use Panel will base its assessments on the supplemental information provided by investigators that explains how the proposed research is consistent with the IOM principles and criteria and all relevant documents (including animal study protocols and grant applications) necessary to provide informed recommendations about requests to NIH to use chimpanzees in research (i.e., NIH-sponsored grants, contracts, intramural projects, and third-party projects).''

Recommendation RP9 states: ''The Oversight Committee will determine whether each application meets or does not meet the IOM principles and criteria based on the votes of a majority of all voting members. At its members' discretion, the Oversight Committee may vote on whether different components or parts of an application meet or do not meet the IOM principles and criteria.''

Comments: Many commenters who responded agreed with Recommendation RP9. One suggestion was to require a favorable three-fourths majority vote before the Oversight Committee determines that the research meets the IOM principles and criteria. Others disagreed with the recommendation because they believed that chimpanzees should not be used for research or because the composition of the Oversight Committee is unknown.

Response: The NIH partially accepts Recommendation RP9. The agency intends to implement the following: ''The Chimpanzee Research Use Panel will advise on whether each application, proposal, and protocol meets or does not meet the IOM principles and criteria based on the votes of a majority of all voting members. At its members' discretion, the Chimpanzee Research Use Panel may vote on whether different components or parts of an application, proposal, or protocol meet or do not meet the IOM principles and criteria.''

D. Review of NIH-Supported Research Projects Using Chimpanzees

The NIH requested public comments on a summary in the Council Working Group's report of the group's reviews of 30 research projects involving the use of NIH-owned or -supported chimpanzees. The Council recommended ending 6 of 9 biomedical research projects, 5 of 13 comparative genomic and behavioral research projects, 1 colony housing and care project, and the research components of 3 of the remaining 7 colony housing and care projects. The report did not identify the 30 projects. The NIH asked for input on the outcomes of the project reviews summarized in the report.

Comments: Of the commenters who addressed this topic, a small subset favored the Council recommendations regarding research projects using chimpanzees. Most commenters opposed the continuation of any research involving chimpanzees, stating that all experimentation on chimpanzees should end and all research chimpanzees should be relocated to a sanctuary. Others opposed only the recommendations to continue biomedical research and believed that the behavioral research studies should continue. Several commenters noted their difficulty providing input on the Council Working Group's reviews of research projects because the report did not include project details; these respondents requested that the NIH make the details on these projects public.

In an effort to preserve the scientific integrity of chimpanzee-based research projects that the Council's recommended ending, a suggestion was to encourage the researchers to use another research model to achieve the scientific objectives of their original projects. A concern was that it would be unfair to change the rules and interrupt current research; it was argued that ongoing projects should be allowed to continue and to maintain their original level of funding and timeframe. A few commenters questioned whether the Council Working Group had the requisite expertise to review some of the research.

Response: The NIH accepts the recommendations on the research projects reviewed by the Council Working Group. The NIH intends to phase out the projects that the Council recommended ending in such a way as to avoid causing unacceptable losses to research programs or an impact on the animals, as the IOM Committee suggested. The agency appreciates the comments received on the summary-level information provided and those suggesting that certain projects not end as a result of the Council recommendations. The NIH's acceptance of the IOM Committee's report and any Council recommendations reflects a shift in the agency's scientific priorities away from chimpanzee research that does not critically need this model. This announcement does not prohibit researchers affected by the Council recommendation from disclosing the details of their research.

The NIH does not agree with those who suggested that the Council Working Group lacked the expertise required to review research involving chimpanzees. The Council Working Group members and consultants included experts in behavioral sciences; infectious diseases, including hepatitis; use of alternative models; neuroscience and cognition; colony management; and veterinary medicine.

E. Other Comments

This section summarizes comments that were not directed at a specific Council recommendation or address topics not discussed previously. Commenters discussed ending animal-based research, the recommendations' applicability to other animal models, funding for alternatives to chimpanzees, funding for and enforcement of any implemented recommendations, and the composition of the Council Working Group. A number of commenters commended the NIH for accepting public input and convening the Council Working Group. Many applauded the Council recommendations and the group members for their work and careful consideration of the issues.

1. Ending All Animal-Based Research and Testing

Comments: Many commenters asked the NIH to end all chimpanzee and/or animal-based research and to use alternative approaches instead. Some commenters based this opinion on the perceived inefficiencies of animal-based research for solving human health problems, but, in most cases, these commenters argued that the use of animals in research is inhumane, unfair, and unethical. For example, some stated that the laboratory environment cannot meet the complex intellectual, social, psychological, and emotional needs of chimpanzees. Others believed that chimpanzees, because of their genetic similarity to humans, experience the world in a similar manner to humans and, therefore, should be treated more like humans (e.g., should provide consent before participating in research

and have the opportunity to pursue happiness). Many argued that currently available non-animal alternatives, such as computer simulations, should facilitate the phasing out of animal-based research. Other commenters suggested that rather than fund animal-based studies, the NIH should allocate more funds toward developing and expanding these non-animal alternatives, which, in their opinion, might be more cost effective than animal-based experiments. Many commenters did not want their tax dollars used for chimpanzee and/or other animal-based experiments.

Response: The NIH emphasizes that the use of animals in research continues to be central to understanding, treating, and preventing many diseases and conditions that cause human suffering and death. Although we believe that ceasing all animal research at this time would be imprudent, the NIH maintains high standards for the use of animals in research. In addition, the agency is a major proponent of the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (Principles), which provide an ethical framework for the use of live animals in research. Scientists must adhere to the Principles in their conduct of research, testing, and training that is funded by the NIH. The Principles require that procedures involving animals be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society. Researchers must select animal models for procedures that are of an appropriate species and quality and must use the minimum number of animals required to obtain valid results. Furthermore, researchers must consider the use of alternative methods to animal models, such as mathematical models, computer simulations, and in vitro biological systems.

The agency also funds efforts to develop alternative ways to conduct research without using animal models. These technologies include improved molecular analysis techniques to study various diseases and three-dimensional chips with living cells and tissues that might accurately model the structure and function of human organs.

2. Applying the Recommendations beyond the NIH and to Other Animal Models

Comments: Several commenters suggested that the recommendations apply beyond the NIH to other agencies of the federal government, private industry, and private laboratories. A concern was that the use of privately owned chimpanzees might increase if the NIH-owned chimpanzees were no longer available for research; expanding the reach of the recommendations would help mitigate some of these concerns. Others wished the NIH to apply the recommendations to other animal models.

Response: Any Council recommendations implemented by the NIH will apply to research-active and -inactive populations of chimpanzees owned or supported by the NIH and any research using them, irrespective of who funds it. The implemented recommendations will also apply to NIH-supported research using chimpanzees, regardless of whether the agency owns or supports these animals. However, the NIH lacks authority to apply the Council recommendations to other agencies of the federal government, private industry, or private laboratories.

3. Enforcing the Accepted Recommendations

Comments: One suggestion was for the NIH to create a new entity, separate from the Oversight Committee that the Council Working Group recommended, to enforce the other recommendations, especially those regarding ethologically appropriate housing, that the NIH accepts. Some believed that this entity should conduct frequent inspections (i.e., more than once yearly) of facilities that house research chimpanzees and have the legal authority to terminate unacceptable practices.

Response: The NIH believes that the Council recommendations provide the NIH with sufficient guidance without the need for additional external oversight. NIH-funded institutions must comply with the federal Animal Welfare Act and regulations, the Public Health Service Policy, and the *Guide for the Care and Use of Laboratory Animals, Eighth Edition* (*http://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf*). Any recommendations regarding the use of chimpanzees in research that the NIH implements will supplement these existing statutes and policies. The NIH Office of Laboratory Animal Welfare (OLAW) oversees all NIH-supported research activities that involve animals. OLAW monitors NIH-funded institutions to ensure their compliance with animal welfare laws and policies. OLAW also investigates allegations of animal welfare abuses and inappropriate animal care in NIH-funded studies.

4. Funding for Chimpanzee Retirement and Facility Construction

Comments: Several commenters expressed concern about funding to implement the Council recommendations. They stated that the current national fiscal climate will probably limit the amount of money made available to fund new construction or other facets of the Council recommendations.

Several commenters suggested ways that the NIH could financially support the implementation of the recommendations. One suggestion from numerous commenters was for the NIH to transfer the funds currently used to support chimpanzees in laboratories to sanctuaries. Others recommended fundraising to pay for construction and other costs. Some asserted that caring for chimpanzees in sanctuaries rather than research facilities might save money or suggested supporting chimpanzees through for-profit entities or by retiring the chimpanzees in place.

Another concern was that funding would be diverted from important research to pay for the recommendations' implementation and for additional chimpanzee housing when the size of the population is decreasing. Some stated that existing facilities offer high-quality conditions and care and have trained staff to provide enrichment and health care, and keeping chimpanzees in these facilities would save transportation costs.

Response: The agency understands commenters' concerns about the prospect of future expenditures to implement the Council recommendations. As the NIH gains a better understanding of the resources needed to implement the recommendations, it will explore options for funding their implementation.

5. Composition and Impartiality of the Council Working Group

Comments: Certain commenters expressed concern about the composition of the Council Working Group. A few stated that the Council Working Group seemed to be biased in favor of scientific research. However, many commenters on this topic stated that certain Council Working Group members were biased against research and the group lacked the necessary scientific diversity to reach the stated conclusions about behavioral and neuroscience research. Several commenters were also concerned that 1 or more Council Working Group members had conflicts of interest that

prevented them from being impartial and that these members might have swayed the group to recommend the retirement of most chimpanzees. Others who expressed knowledge of the Council Working Group's activities commented that the members failed to seek diverse input on a range of matters, including certain scientific issues and U.S. laboratory facilities. These commenters stated that the group should have included NIH-funded experts in chimpanzee behavior and chimpanzee research in general. Some commenters believed that the NIH should appoint a new committee to consider the use of chimpanzees in research.

Response: The agency believes that the composition of the Council Working Group and consultants was appropriately balanced to provide advice to the Council on NIH-supported research involving chimpanzees and implementing the IOM Committee's recommendations. Members and consultants included experts in behavioral sciences; infectious diseases, including hepatitis; use of alternative models; neuroscience; cognition; colony management; and veterinary medicine. The Council Working Group was charged with providing recommendations on how to implement the IOM Committee's recommendations. The NIH had already accepted the IOM recommendation that most current use of chimpanzees in research is unnecessary.

6. Additional Comments

Comments: A few commenters expressed confusion about the number of chimpanzees currently used in NIH-supported and other research. Some had difficulty aligning the number of chimpanzees in NIH-supported research with the census data on NIH-owned or -supported research chimpanzees. Others commented on captive chimpanzee conservation and captive chimpanzees' status as a threatened species. A number of commenters disliked the length of the request for comments form and would have preferred a different format, such as checkboxes to indicate agreement or disagreement with the Council recommendations.

Response: The census of chimpanzees on page 32 of the Council Working Group report includes only the chimpanzees that the NIH owns or supports. This table is not a census of all chimpanzees available for research in the United States. According to the IOM Committee's report (*http://iom.edu/Reports/2011/Chimpanzees-in-Biomedical-and-Behavioral-Research-Assessing-the-Necessity.aspx*), approximately 300 additional chimpanzees available for research are privately owned and housed in research facilities not supported by the NIH. The research projects that the Council Working Group reviewed involved chimpanzees owned or supported by the NIH and chimpanzees that are privately owned and not supported by the agency.

The NIH recognizes that on June 12, 2013 the U.S. Fish and Wildlife Service proposed a rule that would list captive chimpanzees as endangered rather than threatened (*http://www.fws.gov/policy/library/2013/2013-14007.pdf*). The NIH will prepare for a potential final rule that lists captive chimpanzees as endangered and intends to adapt its policies on research projects using chimpanzees to comply with the guidelines that the U.S. Fish & Wildlife Service will establish in its final rule. In addition, we acknowledge concerns about the length of the request for comments form and appreciate the suggestions for easing comment entry in the future.

Conclusion

The NIH expresses its appreciation for the comments it received on the Council recommendations on the use of chimpanzees in NIH-supported research. The agency used these comments to inform its decisions about these recommendations and explained its rationale in its responses to the comments in this notice. The NIH recognizes the Council Working Group for its diligence in responding to its charge to advise the NIH on implementing the IOM Committee's recommendations. The NIH intends to prepare procedural guidance and technical assistance for researchers, facility staff, and agency staff to ensure proper implementation of these decisions. Investigators should continue to follow existing guidance (see NOT–OD–12–025 at *http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-025.html*) regarding the submission of applications, proposals, or protocols for research involving chimpanzees until the NIH announces the procedural guidance.

Dated: June 26, 2013.

Francis S. Collins,

Director, National Institutes of Health.

[FR Doc. 2013–15791 Filed 7–1–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies Federal agencies of the Laboratories and Instrumented Initial Testing Facilities (IITF) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); and on April 30, 2010 (75 FR 22809).

A notice listing all currently certified Laboratories and Instrumented Initial Testing Facilities (IITF) is published in the **Federal Register** during the first week of each month. If any Laboratory/IITF's certification is suspended or revoked, the Laboratory/IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any Laboratory/IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at *http://www.workplace.samhsa.gov.*

FOR FURTHER INFORMATION CONTACT: Giselle Hersh, Division of Workplace Programs, SAMHSA/CSAP, Room 7–1051, One Choke Cherry Road, Rockville, Maryland 20857; 240–276–2600 (voice), 240–276–2610 (fax).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71. The ''Mandatory Guidelines for Federal Workplace Drug Testing Programs'', as amended in the revisions listed above, requires strict standards that Laboratories and Instrumented Initial Testing Facilities