

information are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The

collections of information in § 50.25 have been approved under 0910–0130.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity/21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
Written certification (sent to FDA)—50.23(e)(3).	150	3	450	0.25 (15 minutes)	113	\$100

¹ There are no capital costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity/21 CFR Section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours	Total operating and maintenance costs
Written certification (sent to IRB)—50.23(e)(1) and (e)(2)	150	3	450	2	900	\$0
Informed consent information—50.23(e)(4)	150	3	450	1	450	100
Total					1,350	100

¹ There are no capital costs associated with this collection of information.

Dated: April 4, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–08006 Filed 4–9–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Announcement of Agency Decision: Density of the Primary Living Space of Captive Chimpanzees Owned or Supported by the National Institutes of Health (NIH) or Used in NIH-Supported Research

SUMMARY: This notice summarizes the agency’s actions to obtain additional scientific input and announces the agency’s decision with respect to the space density of the primary living space of captive research chimpanzees owned or supported by the National Institutes of Health (NIH) or used in NIH-supported research. The NIH has prepared procedural guidance and technical assistance for researchers, facility staff, and agency staff to ensure proper implementation of the agency’s decisions. Investigators should follow guidance (see NOT–OD–14–024 at <http://www.grants.nih.gov/grants/guide/notice-files/NOT-OD-14-024.html>) regarding the submission of applications, proposals, or protocols for research involving chimpanzees.

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

SUPPLEMENTARY INFORMATION:

Background

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 in its report (see http://dpcpsi.nih.gov/sites/default/files/FNL_Report_WG_Chimpanzees_0.pdf) and provided these recommendations to the NIH. The NIH subsequently issued a request for information, <http://www.gpo.gov/fdsys/pkg/FR-2013-02-05/html/2013-02507.htm>, to obtain broad public input on the 28 Council recommendations the NIH considered as it determined how to implement the IOM Committee’s recommendations.

In June 2013, the NIH announced its decisions with respect to the Council of Councils’ recommendations; see http://dpcpsi.nih.gov/sites/default/files/NIH_

[response_to_Council_of_Councils_recommendations_62513.pdf](#). The agency accepted 27 of the 28 Council recommendations. Included in these were 10 recommendations describing the characteristics of a captive environment that allow for and promote a full range of behaviors that are natural for chimpanzees—or ethologically appropriate environments (EAE). The NIH accepted 9 of the 10 Council’s recommendations on EAE, including recommendations on enclosure height, foraging and diet, nesting materials, enrichment, a staff to chimpanzee ratio, staff training, and recordkeeping. The NIH did not accept Recommendation EA2—“The density of the primary living space of chimpanzees should be at least 1,000 ft² (93 m²) per individual. Therefore, the minimum outdoor enclosure size for a group of 7 animals should be 7,000 ft² (651 m²).”—based on comments received from the public. Because of concerns about the scientific basis for this recommendation and the expected costs of implementing it, the agency further reviewed the space density requirements with respect to the promotion of species-appropriate behavior.

While a large number of commenters who addressed Recommendation EA2 supported the recommendation, some commenters emphasized the amount of space recommended is the minimum needed and larger enclosures that more closely replicate the amount of space available to chimpanzees in the wild are

preferable. Other commenters encouraged the NIH to identify data in the scientific literature on the appropriate area for chimpanzee housing, while others argued that the recommended 1,000 ft² 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 noted that certain publications cited by the Council Working Group pertain to gorillas or to spaces smaller than 1,000 ft². 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.

The agency was concerned about the lack of scientific consensus and especially whether the published literature supports the Council's recommendation of providing 1,000 ft² of living space per chimpanzee. Given that concern, the NIH sought additional input on an individual basis on the space density needs of captive research chimpanzees from experts with extensive experience in veterinary medicine, behavioral management of primates, renovation of chimpanzee housing and research facilities, primate facility management, and behavioral primatology (<https://dpcpsi.nih.gov/sites/default/files/Space-Density-EAE-List-of-Experts.pdf>).

Independent of seeking expert input, the NIH commissioned a literature review, <https://dpcpsi.nih.gov/sites/default/files/ElseLitReviewFinal-110713.pdf>, focused on the space density needed to support an ethologically appropriate physical and social environment for captive chimpanzees in a research environment. The literature review was prepared by a pre-eminent veterinary primatologist. That individual was also asked to identify, review, and summarize relevant parts of U.S. regulations and other requirements.

The relevant animal welfare/regulatory requirements and guidance pertaining to the space density needs of captive research chimpanzees are summarized in the literature review (pages 2–4). The Animal Welfare Act Regulations, <http://www.gpo.gov/fdsys/pkg/CFR-2013-title9-vol1/xml/CFR-2013-title9-vol1-chap1-subchapA.xml>,

list the minimum space requirements for the nonhuman primate (NHP) weight category that includes chimpanzees as 25 ft² for floor area per animal, and 84 inches for enclosure height. 9 CFR part 3.80. The regulations note that many of the NHP requirements are generic and the conditions appropriate for one species do not necessarily apply to another. Per the regulations, the “minimum specifications must be applied in accordance with the customary and generally accepted professional and husbandry practices considered appropriate for each species, and necessary to promote their psychological well-being.” 9 CFR part 3, n. 2. The Chimpanzee Health Improvement, Maintenance, and Protection (CHIMP) Act (Pub. L. 106–551; <http://www.gpo.gov/fdsys/pkg/PLAW-106publ551/pdf/PLAW-106publ551.pdf>) directs the Secretary of Health and Human Services to develop by regulation standards for operating the federally supported sanctuary system to provide for the permanent retirement of chimpanzees that are no longer required for research. The regulations (42 CFR part 9) that implement the CHIMP Act do not specify enclosure size but stipulate that the size of the sanctuary facilities must be in accordance with the recommendations of *The Guide for the Care and Use of Laboratory Animals*, which align with the minimum space requirements of the *Animal Welfare Act Regulations*. The Association of Zoos and Aquariums and the Global Federation of Animal Sanctuaries recommend space densities that differ from each other and from the one in Recommendation EA2.

The remainder of this document summarizes the literature review and expert input.

Literature Review—Summary

The literature review revealed very limited empirical data is available on which to base a determination of the minimum space density necessary to provide an EAE for captive chimpanzees, and no quantitative data was found to support the figure of 1,000 ft²/individual chimpanzee. Relatively few investigators have reported data that measure chimpanzee well-being using space density as a variable, with Ross and his colleagues, who have been studying enclosure design in zoos for more than 10 years, being one of the notable exceptions. Ross *et al.* (2011a) postulated that once the “minimal size threshold is crossed” (as they speculated could possibly be the case with their Great Ape House facility—space density 12.2 m²/individual) they “would then expect diminishing

behavioral and welfare benefits with further increases.” Wilson (1982) made a similar observation, noting that increasing space beyond that required may have little effect on activity.

The literature review noted there was general consensus among essentially all investigators as to the importance of vertical space, climbable space, three-dimensional space, gross usable space, and other similar enclosure parameters, and the necessity for significant environmental complexity within the enclosure. The general impression gained from the literature review is that these parameters share equal importance with space density when captive chimpanzee well-being is considered. The difficulty is the lack of a simple, replicable way to measure them.

There was also general consensus that chimpanzees neither like nor use open spaces and in most situations they use only a small proportion of their enclosure space. This is consistent with conclusions of many investigators that the overall quantity of cage space alone has limited value when designing an enclosure to maximize the well-being of primates because the usefulness of space depends upon its quality rather than quantity (Reinhardt *et al.*, 1996; Wilson, 1982; Stoinski *et al.*, 2001; Ross *et al.*, 2011a) and, having no stimulatory value, space alone does not enhance an animal's environment (Reinhardt *et al.*, 1996).

The literature review also questioned whether the full range of wild chimpanzee behavior, particularly some aspects of fission-fusion, are applicable to captive situations, and whether some behaviors, such as traveling long distances in search for food or patrolling the borders of their territories, may in fact not be necessary for captive group well-being, nor desirable for group stability.

Expert Views—Summary

Independent of the literature review, the NIH sought input from individuals with extensive expertise in veterinary medicine; behavioral management of primates; renovation of chimpanzee housing and research facilities; primate and chimpanzee facility management; and behavioral primatology. The NIH contacted each expert individually and sought input on the question of space density needs of captive research chimpanzees. The calls with the individual experts preceded the preparation of the literature review to ensure that one process did not influence the other.

The views of the experts were very similar to the literature review. Each of

the experts emphasized the critical importance of environmental complexity rather than focusing only on the square footage of living space per chimpanzee as a means of ensuring species-typical behavior. The experts also noted that different animals/groups within a colony would require different stimuli to exhibit species-typical behavior. The experts reiterated the difficulty in identifying square footage requirements, including lack of published literature in this area. Based on their experience in behavioral management of chimpanzees, as veterinarians and by directing and operating facilities for captive research chimpanzees, several of the experts recommended minimum space needed to promote species-typical behavior. The recommendations ranged from 150–500 ft² of living space per animal.

Conclusion

The literature review demonstrated there is little published literature containing quantitative scientific data that can be used to support a determination of the minimum space density (horizontal surface area per animal) needed to support an EAE for captive chimpanzees. Furthermore, other aspects of enclosure design, such as complexity and vertical height, are considered by many experts to be more important than space density with respect to chimpanzee well-being and the promotion of species-specific behavior.

Based on both the literature review and recommendations from individual experts, it is clear that published guidelines for minimum living space area for captive research chimpanzees are variable. Encouraging species-typical behavior among chimpanzees does not simply result from providing a minimum square footage of living space per animal. Rather, the characteristics (complexity) of the space as well as enrichment opportunities have a significant effect on promoting species-typical behavior. The environment should take into account the individual chimpanzees' and colony characteristics, including social, health, age, and biological factors.

Based on the recommendation from the Council of Councils, the information contained in the literature review, and additional input from scientific, veterinary, and facility experts, the NIH has decided that the density of the primary living space of chimpanzees should be at least 250 ft² per chimpanzee. This decision supplements the agency decisions on the nine EAE recommendations made by the Council of Councils (see EA1, EA3–10 at

http://dpcpsi.nih.gov/sites/default/files/NIH_response_to_Council_of_Councils_recommendations_62513.pdf). The NIH expects the facilities it supports to monitor the chimpanzees for species-typical behavior.

The NIH has prepared procedural guidance and technical assistance for researchers, facility staff, and agency staff to ensure proper implementation of the agency's decisions. Investigators should follow guidance (see NOT–OD–14–024 at <http://www.grants.nih.gov/grants/guide/notice-files/NOT-OD-14-024.html>) regarding the submission of applications, proposals, or protocols for research involving chimpanzees.

Dated: February 25, 2014.

Francis S. Collins,

Director, National Institutes of Health.

[FR Doc. 2014–08062 Filed 4–9–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors, NHLBI.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Heart, Lung, and Blood Institute, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NHLBI.

Date: May 5–7, 2014.

Time: 6:00 p.m. to 5:30 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Robert S Balaban, Ph.D., Scientific Director, Division of Intramural Research, NHLBI, National Institutes of Health, Building 10, CRC, 4th Fl., Room 4–1581, 10 Center Drive, Bethesda, MD 20892, 301–496–2116.

Any interested person may file written comments with the committee by forwarding

the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: www.nhlbi.nih.gov/meetings/index.htm, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS).

Dated: April 4, 2014.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–07971 Filed 4–9–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Alternative Medicine; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council for Complementary and Alternative Medicine.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting 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 Advisory Council for Complementary and Alternative Medicine NCCAM Advisory Council Board.

Date: June 6, 2014.

Closed: 8:30 a.m. to 10:00 a.m.

Agenda: To review and evaluate grant applications.