finalized, will represent the current thinking of FDA on the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: April 7, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–08682 Filed 4–14–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Solicitation of Nominations for Membership To Serve on the Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Request for nominations.

SUMMARY: The Health Resources and Services Administration (HRSA) is seeking nominations of qualified candidates to be considered for appointment as members of the Advisory Committee on Heritable Disorders in Newborns and Children (Committee). The Committee provides advice, recommendations, and technical information about aspects of heritable disorders and newborn and childhood screening to the Secretary of Health and Human Services. HRSA is seeking nominations of qualified candidates to fill three positions on the Committee.

Authority: Section 1111 of the Public Health Service (PHS) Act, Title XI, § 1111(g)(1) (42 U.S.C. 300b–10(g)(1)), as amended by the Newborn Screening Saves Lives Reauthorization Act of 2014. The Committee is governed by the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. App.), and 41 CFR part 102–3 and 41 CFR part 102–3, which set forth standards for the formation and use of advisory committees.

DATES: Written nominations for membership on the Committee must be received on or before May 16, 2016.

ADDRESSES: Nomination packages must be submitted electronically as email attachments to Alaina Harris, Genetic Services Branch, Maternal and Child Health Bureau, Health Resources and Services Administration, *aharris@hrsa.gov.*

FOR FURTHER INFORMATION CONTACT: Alaina Harris, Genetic Services Branch, Maternal and Child Health Bureau, HRSA, at *aharris@hrsa.gov* or (301) 443–0721. A copy of the Committee Charter and list of the current membership can be obtained by accessing the Advisory Committee Web site at *http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders.*

SUPPLEMENTARY INFORMATION: The Committee is chartered under section 1111 of the Public Health Service (PHS) Act, 42 U.S.C. 300b–10, as amended by the Newborn Screening Saves Lives Reauthorization Act of 2015 (Act). The Committee was established in 2003 to advise the Secretary of the U.S. Department of Health and Human Services regarding newborn screening tests, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having or at risk for heritable disorders. In addition, the Committee provides advice and recommendations to the Secretary concerning the grants and projects authorized under section 1109 of the PHS Act and technical information to develop policies and priorities for grants, including those that will enhance the ability of the state and local health agencies to provide for newborn and child screening, counseling and health care services for newborns, and children having or at risk for heritable disorders.

The Committee is governed by the provisions of Public Law 92–463, as amended (5 U.S.C. App. 2), and 41 CFR part 102–3, which set forth standards for the formation and use of advisory committees. The Committee reviews and reports regularly on newborn and childhood screening practices for heritable disorders, recommends improvements in the national newborn and childhood heritable screening programs, and recommends conditions for inclusion in the Recommended Uniform Screening Panel (RUSP). The Committee's recommendations regarding additional conditions/inherited disorders for screening that have been adopted by the Secretary are included in the RUSP and constitute part of the comprehensive guidelines supported by the Health Resources and Services Administration. Pursuant to section 2713 of the Public Health Service Act, codified at 42 U.S.C. 300gg–13, non-grandfathered health plans and group and individual health insurance issuers are required to cover screenings included in the HRSA-supported comprehensive guidelines without charging a co-payment, co-insurance, or deductible for plan years (*i.e.,* in the individual market, policy years) beginning on or after the date that is 1 year from the Secretary's adoption of the condition for screening.

Nominations: HRSA is requesting nominations to fill three (3) positions for voting members to serve on the Committee. Nominations of potential candidates for consideration are being sought for individuals who are medical, technical, or scientific professionals with special expertise in the field of heritable disorders or in providing screening, counseling, testing, or specialty services for newborns and children at risk for heritable disorders; who have expertise in ethics (*i.e.,* bioethics) and infectious diseases and who have worked and published material in the area of newborn screening; members of the public having special expertise about or concern with heritable disorders; or representatives from such federal agencies, public health constituencies, and medical professional societies as determined to be necessary by the Secretary to fulfill the duties of the Advisory Committee established under subsection (b) of section 1111 of the Public Health Service (PHS) Act, 42 U.S.C. 300b–10, as amended by the Newborn Screening Saves Lives Reauthorization Act of 2015 (Act). Interested applicants may self-nominate or be nominated by another individual and/or organization.

Individuals selected for appointment to the Committee will be invited to serve for up to 4 years. Members who are not federal officers or permanent federal employees are appointed as special government employees and receive a stipend and reimbursement for per diem and any travel expenses incurred for attending Committee meetings and/or conducting other business on behalf of the Committee, as authorized by section 5 U.S.C. 5703 for persons employed intermittently in government service. Members who are officers or employees of the United States Government shall not receive additional compensation for service on the Committee, but receive per diem and travel expenses incurred for attending Committee meetings and/or conducting other business on behalf of the Committee. Nominees will be invited to serve during calendar year 2017.

The following information must be included in the package of materials

submitted for each individual being nominated for consideration: (1) A statement that clearly states the name and affiliation of the nominee, the basis for the nomination (*i.e.,* specific attributes such as expertise in bioethics, evidence review, public health, laboratory, maternal and child health, or clinical expertise in heritable disorders, which qualify the nominee for service in this capacity), and that the nominee is willing to serve as a member of the Committee; (2) the nominee's name, address, and daytime telephone number and the home/or work address, telephone number, and email address; and (3) a current copy of the nominee's curriculum vitae. Nomination packages may be summited directly by the individual being nominated or by the person/organization recommending the candidate.

The Department of Health and Human Services will make every effort to ensure that the membership of the Committee is fairly balanced in terms of points of view represented. Every effort is made to ensure that individuals from a broad representation of geographic areas, gender, ethnic and minority groups, as well as individuals with disabilities are given consideration for membership. Appointments shall be made without discrimination on the basis of age, ethnicity, gender, sexual orientation, and cultural, religious, or socioeconomic status.

Individuals who are selected to be considered for appointment will be required to provide detailed information regarding their financial holdings, consultancies, and research grants or contracts. Disclosure of this information is necessary in order to determine if the selected candidate is involved in any activity that may pose a potential conflict with the official duties to be performed as a member of the Committee.

Jackie Painter,

Director, Division of the Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes of Health (NIH) Office of Science Policy (OSP) Recombinant or Synthetic Nucleic Acid Research: Action Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)

SUMMARY: The NIH OSP is amending portions of the *NIH Guidelines* in order to provide investigators with biosafety guidance regarding the standards for containment of non-human primates (NHPs) in biosafety level (BL) 4 laboratories and to make such guidance consistent with the expectations articulated in the Centers for Disease Control and Prevention (CDC)/NIH Biosafety in Microbiological and Biomedical Laboratories 5th edition (BMBL). Specifically, the *NIH Guidelines* will allow for housing of NHPs in open caging in a dedicated animal holding room provided there are two physical barriers between that animal holding room and non-containment space within the laboratory, the animal holding room has negative air pressure with respect to any adjacent non-containment corridors, and there are specific decontamination protocols in place before the door to the animal holding room is opened to allow for the periodic transfer of new animals into the room. These amendments do not change the current containment requirements in the *NIH Guidelines* but rather offer an alternative for achieving primary containment without compromising safety.

In addition, the recertification requirement for biosafety cabinets in BL4 laboratories is updated in recognition of the technological standards for modern biosafety cabinets. The NIH OSP also is updating the validation requirements for equipment responsible for centralized heat decontamination of liquid effluents in laboratories working with large animals.

These amendments to the *NIH Guidelines* will be implemented immediately upon publication in the **Federal Register**. These changes were developed after extensive consultation with biosafety experts, directors of and principal investigators in BL4 facilities working with NHPs, and CDC's Division of Select Agent and Toxins (DSAT) leadership at a public workshop and discussion at a public Recombinant DNA Advisory Committee (RAC) meeting. Publication in the **Federal Register** will inform the scientific and biosafety communities.

FOR FURTHER INFORMATION CONTACT: If you have questions, or require additional information about these changes, please contact the NIH OSP by email at *SciencePolicy@od.nih.gov*, or telephone at 301–496–9838.

SUPPLEMENTARY INFORMATION: The first three editions of the BMBL and the *NIH Guidelines* were consistent in their approach to requiring primary containment for animal work in BL4 containment laboratories. However, in the early 1990s, the BMBL was amended and the fourth edition stated that animals housed in BL4 suit laboratories (*i.e.,* laboratories in which Class III cabinets are not used but instead personnel wear positive pressure protective suits) *should* be housed in a primary containment system (such as open cages covered with filtered bonnets and opened in laminar flow hoods or other equivalent containment systems). This language remains in the current BMBL (5th edition). With the change in the BMBL, primary containment caging was arguably preferred but no longer required under BL4 containment. In contrast, the *NIH Guidelines* have always required primary containment caging for all animals in BL4 laboratories.

Non-human primates are social animals and require environmental enrichment. Researchers in several U.S. BL4 laboratories engaged in NHP research approached the NIH OSP with concerns that primary containment caging in BL4 laboratories hindered the creation of an environment that allowed animals to benefit from adequate social interaction. Also based on risk assessments and experiences comparing several primary containment caging systems, the researchers concluded that primary containment caging may actually create new hazards for laboratory workers. These findings included interference with observation of the animals from outside the room leading to more frequent entries into the BL4 animal room to monitor the animals, and exacerbation of cramped working conditions created by the additional barriers required by some containment systems, which increases the difficulty of working in inflated pressure suits as well as the potential for damage to the pressure suit. In addition, investigators stated that current BL4 laboratory designs incorporate sophisticated engineering systems, which provide biosafety protection in a dedicated animal room equivalent to the primary containment caging required under the *NIH*