DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; Member Conflict: AIDS and AIDS Related Research.

Date: August 9, 2016.

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

Agenda: To review and evaluate grant applications.

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

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*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Methods for HIV Prevention Packages.

Date: August 9, 2016.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Shalanda A. Bynum, Ph.D., MPH, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3206, Bethesda, MD 20892, 301–755–4355, *bynumsa@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: AIDS and Related Research Applications.

Date: August 9, 2016.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Robert Freund, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5216, MSC 7852, Bethesda, MD 20892, 301–435–1050, *freundr@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR14–066: SPF Macaque Colonies.

Date: August 12, 2016.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Shiv A. Prasad, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5220, MSC 7852, Bethesda, MD 20892, 301–443–5779, *prasads@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(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: August 1, 2016.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–18548 Filed 8–4–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 the following 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 Institute of Allergy and Infectious Diseases Special Emphasis Panel NIAID Clinical Trial Implementation Grant (R01).

Date: September 1, 2016

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health RM 5C100, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Lynn Rust, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G42A National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, (240) 669–5069, *lrust@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: August 1, 2016.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–18550 Filed 8–4–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Public Comment on the Proposed Changes to the NIH Guidelines for Human Stem Cell Research and the Proposed Scope of an NIH Steering Committee's Consideration of Certain Human-Animal Chimera Research

SUMMARY: The National Institutes of Health (NIH) is requesting public comment on a proposal to amend Section IV and Section V of the NIH Guidelines for Human Stem Cell Research and on the proposed scope of certain human-animal chimera research that will be considered internally by an NIH steering committee to provide programmatic input to the director of the relevant NIH Institute(s) or Center(s) or equivalent NIH officials responsible for funding decisions.

DATES: Written comments must be received by the NIH on or before September 6, 2016 in order to be considered.

ADDRESSES: Public comments may be entered at: *http://grants.nih.gov/grants/rfi/rfi.cfm?ID=57*. Comments may also be mailed to: Office of Science Policy, National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892, 301–496–9838. Comments will be made publicly available. Comments received, including any

personal information, will be posted without change to *http://grants.nih.gov/grants/rfi/responses_57.cfm*.

SUPPLEMENTARY INFORMATION: On July 7, 2009, the NIH issued the NIH Guidelines for Human Stem Cell Research (''Guidelines'') 74 FR 32170 (July 7, 2009) to implement Executive Order 13505 (March 9, 2009), as it pertains to NIH-funded stem cell research, to establish policy and procedures under which the NIH will fund such research, and help ensure that NIH-funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law.

Since the Guidelines were issued in 2009, growing knowledge and advancement of stem cell biology has created new research opportunities. Some scientists are exploring strategies for growing human tissue and organs in animals through the introduction of human pluripotent cells into early stage embryos of non-human vertebrate animals. These experimental designs raise questions regarding where the human cells might go in the developing animal and how they might function, such as whether the human cells might contribute to the central nervous system and affect the cognition of the animal.

While considering these issues, on September 23, 2015, the NIH issued a funding moratorium (*http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-158.html*) on ''NIH Research Involving Introduction of Human Pluripotent Cells into Non-Human Vertebrate Animal Pre-Gastrulation Embryos.'' The NIH subsequently held a workshop with experts on November 6, 2015, to review the state of the science and discuss animal welfare issues.

The workshop illustrated that while there are significant challenges to creating chimeric models, there is clear interest and potential in producing animal models with human tissues or organs for studying human development, disease pathology, and eventually organ transplantation. In the interest of moving the field forward while preserving the NIH's opportunity to provide continuing assessment and oversight of this emerging area of research, the NIH has decided to establish a steering committee to provide programmatic input to the director of the relevant NIH Institute(s) or Center(s) (or equivalent NIH official responsible for funding decisions) on certain human-animal chimera research proposals. The committee will be composed of federal employees. The committee is expected to consider and offer the director of the relevant NIH Institute(s) or Center(s) (or equivalent NIH official responsible for funding decisions) programmatic input on factors, such as, (1) the characteristics of the human cells to be introduced (including potency and any modifications of those cells); (2) characteristics of the recipient animal (*e.g.,* species, stage of development, and any modifications that affect location or function of human cells); (3) other data relevant to the likely effects on the animal (*e.g.,* changes in cognition, behavior, or physical appearance); (4) planned monitoring (including animal welfare assessments); and (5) any staging of proposed research (*e.g.,* assessing the outcome of a particular experiment before conducting a further experiment). This internal programmatic work will be conducted independent of, and in addition to, the usual peer review procedures for research at the NIH. The relevant IC director(s) will consider the input from the steering committee, in addition to other NIH programmatic input, as well as the funding recommendations and evaluations of the initial Scientific Review Group and the relevant Institute or Center's Advisory Council or Board. The committee will also monitor trends in this general field of research and the use of new technologies, and may provide such analysis and advice to the NIH leadership.

The NIH also proposes to revise the Guidelines to expand the existing prohibition on introducing human pluripotent stem cells into blastocyst stage nonhuman primate embryos to include pre-blastocyst stage nonhuman primate embryos; and to expand the prohibition on research involving the breeding of animals where the introduction of hESCs or human induced pluripotent stem cells may contribute to the germ line to include any human cells that may result in the formation of human gametes.

Therefore, NIH is requesting public comment on:

(1) The following proposed changes to the Guidelines.

Sections IV and V of the Guidelines currently state:

IV. Research Using hESCs and/or Human Induced Pluripotent Stem Cells That, Although the Cells May Come From Eligible Sources, Is Nevertheless Ineligible for NIH Funding

This section governs research using hESCs and human induced pluripotent stem cells, *i.e.,* human cells that are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers. Although the cells may come from eligible sources, the following uses of these cells are nevertheless ineligible for NIH funding, as follows:

A. Research in which hESCs (even if derived from embryos donated in accordance with these Guidelines) or human induced pluripotent stem cells are introduced into non-human primate blastocysts.

B. Research involving the breeding of animals where the introduction of hESCs (even if derived from embryos donated in accordance with these Guidelines) or human induced pluripotent stem cells may contribute to the germ line.

V. Other Research Not Eligible for NIH Funding

A. NIH funding of the derivation of stem cells from human embryos is prohibited by the annual appropriations ban on funding of human embryo research (Section 509, Omnibus Appropriations Act, 2009, Pub. L. 111–8, 3/11/09), otherwise known as the Dickey Amendment.

B. Research using hESCs derived from other sources, including somatic cell nuclear transfer, parthenogenesis, and/or IVF embryos created for research purposes, is not eligible for NIH funding.

The NIH is proposing to amend the Guidelines as follows:

IV. Research Not Eligible for NIH Funding:

A. Research in which human pluripotent stem cells are introduced into non-human primate embryos up through the end of the blastocyst stage, is not eligible for funding.

B. Research involving the breeding of animals where the introduction of human cells may contribute to the germ line, is not eligible for funding.

C. NIH funding of the derivation of stem cells from human embryos is prohibited by the annual appropriations limitations on the funding of human embryo research (see *e.g.* Section 508, Omnibus Appropriations Act, 2016, Pub. L.114–113, 12/18/15), otherwise known as the Dickey Amendment.

D. Research using hESCs derived from other sources, including somatic cell nuclear transfer, parthenogenesis, and/or IVF embryos created for research purposes, is not eligible for NIH funding.

(2) The NIH is also requesting public comment on the proposed scope of research (*e.g.,* grant applications, contract proposals, intramural research protocols, etc.) to be considered by an NIH steering committee to provide programmatic input to the director of the relevant Institute or Center (or equivalent NIH official responsible for funding decisions). The NIH proposes the scope of research include research in which:

a. Human pluripotent cells are introduced into non-human vertebrate embryos, up through the end of the gastrulation stage, or

b. human cells are introduced into post-gastrulation non-human mammals (excluding rodents), such that there could be either a substantial contribution or a substantial functional

modification to the animal brain by the human cells.

While the NIH seeks public comment on the proposed changes to the Guidelines, and on the proposed scope for an NIH steering committee's consideration of certain research, NOT–OD–15–158 will remain in effect.

Dated: July 28, 2016.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2016–18601 Filed 8–4–16; 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 the following 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 Heart, Lung, and Blood Institute, Special Emphasis Panel, Pediatric Heart Network Data Coordinating Centers (U24).

Date: August 30, 2016.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7182, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Susan Wohler Sunnarborg, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA National, Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7182, Bethesda, MD 20892 *sunnarborgsw@nhlbi.nih.gov.*

(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: July 29, 2016.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–18549 Filed 8–4–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2016–0640]

Eighth Coast Guard District; Interim Outer Continental Shelf Risk-Based Resource Allocation Methodology

AGENCY: Coast Guard, DHS.

ACTION: Notice of availability and request for comments.

SUMMARY: The Coast Guard announces the availability of an interim risk based resource allocation methodology for inspections of certain Outer Continental Shelf (OCS) units in the Eighth Coast Guard District (D8) area of responsibility (AOR). This interim methodology will be implemented for a five-month trial period beginning August 1, 2016. After the trial period, the methodology will be finalized within D8 and submitted to Coast Guard Headquarters (CG–CVC) for consideration at the national level.

DATES: Comments and related material must be received by the Coast Guard on or before September 6, 2016.

ADDRESSES: You may submit comments identified by docket number USCG–2016–0640 or view documents mentioned in this notice as being available in the docket using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: For information about this document call or email Steve Sutton, Coast Guard; telephone 202-671–2151, email *steve.sutton@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Discussion

This interim risk based resource allocation methodology is intended to improve implementation of the requirements contained in 33 CFR 140.101(c), 143.120(c), and 143.210(a) by employing interagency consultation and by establishing increased focus on the industrial mission and regulatory compliance and casualty data. It builds upon the risk based matrix created for foreign Mobile Offshore Drilling Units (MODU), which was published in the **Federal Register** (76 FR 39885) by the Coast Guard in 2011 by applying similar principles to other OCS units and adding consultation with the Bureau of Safety and Environmental Enforcement (BSEE). This methodology will reallocate Coast Guard inspection resources from lower risk, fixed interval activities to higher risk activities prior to commencing an industrial mission. The Coast Guard will periodically evaluate MODUs and OCS facilities that either perform drilling or well-workover or are due for a Coast Guard regulatory inspection to assign an inspection priority and scope using risk matrices. For example, under this methodology Coast Guard inspection resources previously used to conduct an annual Certificate of Compliance inspection of a lower risk stacked MODU may be reallocated to conduct a higher risk inspection of any MODU or OCS facility with a drilling rig prior to commencement of drilling.

Outreach to the Offshore Operator's Committee

On June 8, 2016, the Coast Guard conducted outreach to the offshore Operators' Committee at its annual general meeting in Houston, TX. The presentation, presentation script, and transcript of questions and answers from this outreach are available on the docket where indicated under **ADDRESSES**.

Public Participation and Request for Comments

We encourage you to submit comments (or related material) on the interim risk based resource allocation methodology for inspection of OCS units in the D8 AOR. We will consider all submissions and may adjust our action based on your comments, although we do not anticipate a written response to comments. If you submit a comment, please include the docket number for this notice, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice of availability, and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted to the docket.

We accept anonymous comments. All comments received will be posted