Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Nancy Lewis Ernst, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–451–7383, *nancy.ernst@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: May 7, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–11210 Filed 5–10–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 on Aging Initial Review Group; Behavior and Social Science of Aging Review Committee NIA–S.

Date: June 12–13, 2013.

Time: 4:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard Long Beach Downtown, 500 East First Street, Long Beach, CA 90802.

Contact Person: Rebecca Jo Ferrell, Ph.D., Scientific Review Branch, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7703, *rebecca.ferrell@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: May 6, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–11209 Filed 5–10–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Biotechnology Activities; Recombinant DNA Research: Proposed Actions Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)

SUMMARY: The NIH Office of Biotechnology Activities (NIH OBA) proposes to revise the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* to streamline review of certain human gene transfer trials that present a low biosafety risk. Specifically, the NIH OBA proposes to remove the requirement that institutional biosafety committees (IBCs) review and approve certain human gene transfer clinical trials that use plasmids and certain attenuated, non-integrating viral vectors, provided the clinical trial follows an initial study in humans that was previously approved by an IBC registered with the OBA. This initial trial will have established the safety of the proposed dose of the gene transfer product (vector and transgene) in a comparable population (adults or children). The initial study should have been conducted in the same country as the proposed study to control for potential variability in infectious disease backgrounds of the participants.

An initial IBC review is important to evaluate the safety of the product and to set standards for administration; however, for well-characterized vectors, in the absence of any unexpected toxicities in the initial study, subsequent biosafety assessments may not provide any additional information. While a single IBC review does not pose an undue burden, as the gene transfer field advances and more Phase II and Phase III multisite trials are developed, the time, effort and expense associated with multiple IBC reviews can be significant without adding commensurate value in the form of additional recommendations to protect the health and safety of the subject, health care worker, and community.

IBCs play a critical role in the evaluation of new products and their review can inform other oversight bodies, such as Institutional Review Boards. However, given the competing demands on IBCs, this change will provide IBCs with the option of focusing their efforts on those clinical trials where review will be most productive. While IBCs will no longer be *required* to review all clinical trials using the same product, each institution can implement its own policies regarding the need to review such trials and the information that a principal investigator (PI) should submit regarding the safety of the previous trial. For example, an institution may designate the Biological Safety Officer and the IBC Chair to review data from the initial trial and determine whether a subsequent trial using the same agent meets the exemption criteria outlined herein. The institution may also set its own policies regarding the need for the PI to inform the IBC about enrollment, any relevant new biosafety findings, and completion of the trial.

This policy will only exempt human gene transfer clinical trials from IBC review under Section III–C–1. It does not apply to basic, nonclinical research. In addition, it does not create an exemption from registration of the trial with the NIH OBA or the Recombinant DNA Advisory Committee (RAC) review and reporting requirements. By continuing to require registration and reporting on these trials, the NIH OBA will be able to continue to monitor adverse events or incident reports of accidental exposures by health care workers delivering these agents and, if necessary, provide information regarding these events to investigators, IBCs, and the public. The NIH OBA will also be able to assess whether this change in policy has any adverse impact on the biosafety of gene transfer trials.

DATES: All comments should be submitted by June 12, 2013.

ADDRESSES: Comments may be submitted to the NIH OBA by email at *oba@od.nih.gov*; by fax to 301–496–9839; or by mail to the NIH Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892–7985. All written comments received in response to this notice will be available for public inspection in the NIH Office of Biotechnology Activities, 6705 Rockledge Drive, Suite 750, Bethesda, Maryland, weekdays between the hours of 8:30 a.m. and 5:00 p.m.

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