protocol registration process. Final IBC approval may then be granted.

RAC meetings will be open to the public except where trade secrets or confidential commercial information are reviewed. To enable all aspects of the protocol review process to be open to the public, information provided in response to Appendix M–I–A should not contain trade secrets or confidential commercial or financial information. Documentation submitted to the NIH OSP shall not be designated as 'confidential' in its entirety. In the event that a determination has been made that a specific portion of a document submitted should be considered as proprietary or trade secret, each specific portion should be clearly identified as such. The cover letter (attached to the submitted material) shall: (1) Clearly indicate what select portions contain information considered as proprietary or a trade secret; and (2) provide justification as to why this information is considered to be proprietary or trade secret. This justification must be able to demonstrate *with specificity* how release of that information will reveal a trade secret or will result in substantial competitive harm.

Appendix M–I–C–2 currently states:

Appendix M–I–C–2. Additional Clinical Trial Sites

No research participant shall be enrolled (see definition of enrollment in Section I–E–7) at a clinical trial site until the following documentation has been submitted to NIH OBA: (1) Institutional Biosafety Committee approval (from the clinical trial site); (2) Institutional Review Board approval; (3) Institutional Review Board-approved informed consent document; (4) curriculum vitae of the Principal Investigator(s) (no more than two pages in biographical sketch format); and (5) NIH grant number(s) if applicable.

Appendix M–1–C–2 will be amended as follows:

Appendix M–I–C–2. Additional Clinical Trial Sites

Within 30 days of enrollment (see definition of enrollment in Section I–E–7) at a clinical trial site, the following documentation shall be submitted to NIH OSP: (1) Institutional Biosafety Committee approval (from the clinical trial site); (2) Institutional Review Board approval; (3) Institutional Review Board-approved informed consent document; and (4) NIH grant number(s) if applicable.

There are no amendments to Appendix M–I–D, Safety Assessments in Human Gene Transfer Research.

The current appendices Appendix M–II, Description of the Proposal; Appendix M–III, Informed Consent; Appendix M–IV, Privacy; and Appendix M–V, Special Issues will be deleted in their entirety, except for Appendix M–III–B–2–b, Long Term Follow-Up which will be updated to include a reference to FDA's current guidance on this issue and will become Appendix M–II.

Appendix M–II will be amended as follows:

Appendix M–II. Long Term Follow-Up

To permit evaluation of long-term safety and efficacy of gene transfer, prospective subjects should be informed that they are expected to cooperate in long-term follow-up that extends beyond the active phase of the study. A list of persons who can be contacted in the event that questions arise during the follow-up period should be provided to the investigator. In addition, the investigator should request that subjects continue to provide a current address and telephone number.

The subjects should be informed of any significant findings resulting from the study will be made known in a timely manner to them and/or their parent or guardian including new information about the experimental procedure, the harms and benefits experienced by other individuals involved in the study, and any long-term effects that have been observed.

Additional guidance is available in the FDA Guidance for Industry: Gene Therapy Clinical Trials—Observing Subjects for Delayed Adverse Events (available at the following URL: *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/default.htm).*

Appendix M–VI Footnotes of Appendix M will be renumbered to Appendix M–III. Footnotes of Appendix M. There will be no amendment to the language.

Dated: March 15, 2016.

Francis S. Collins,

Director, National Institutes of Health.

[FR Doc. 2016–06448 Filed 3–21–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Advisory Committee to the Director, National Institutes of Health.

This meeting is open to the public but is being held by teleconference only. No physical meeting location is provided for any interested individuals to listen to and/or participate in the meeting. Any individual interested in listening to the meeting discussions must call 800–779–9040 and use Participant Passcode 5055308 for access to the meeting. Individuals needing special assistance should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Advisory Committee to the Director, National Institutes of Health.

Date: April 21, 2016.

Time: 4:00 p.m. to 6:00 p.m. EDT.

Agenda: The HeLa Genome Data Access working group will report on the evaluation of requests to access HeLa cell genome sequence data. The Clinical Center working group will present their final report to the Advisory Committee to the Director, NIH.

Place: National Institutes of Health, (Telephone Conference Call), Dial In Number 800–779–9040, Participant Passcode: 5055308.

Contact Person: Gretchen Wood, Staff Assistant, National Institutes of Health, Office of the Director, One Center Drive, Building 1, Room 126, Bethesda, MD 20892, Telephone: 301–496–4272, Email: *woodgs@od.nih.gov.*

Any interested person may file written comments with the committee by forwarding their statement electronically to the Contact Person at *woodgs@od.nih.gov.* The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested of the interested person.

Additional information for this meeting including both working group reports will be posted, when available, on the Advisory Committee to the Director, NIH, Web site (*http://acd.od.nih.gov*). Additional information about the HeLA Genome Data Access working group is available at *http://acd.od.nih.gov/hlgda.htm* and additional information about the Clinical Center working group is available at *http://acd.od.nih.gov/redteam.htm.*

Dated: March 15, 2016.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–06333 Filed 3–21–16; 8:45 am]

BILLING CODE 4140–01–P

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: Addictions, Depression, Bipolar Disorder, Schizophrenia.

Date: April 1, 2016.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Samuel C Edwards, Ph.D., IRG CHIEF, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435–1246, *edwardss@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: Developmental Brain Disorders, Chronic and Clinical Neurodegeneration.

Date: April 7, 2016.

Time: 2:00 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: Seetha Bhagavan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846. Bethesda, MD 20892, (301) 237–9838, *bhagavas@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: March 16, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–06334 Filed 3–21–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2016–0106]

Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0104

AGENCY: Coast Guard, DHS.

ACTION: Sixty-Day Notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval of revisions to the following collection of information: 1625–0104, Barges Carrying Bulk Hazardous Materials. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before May 23, 2016.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2016–0106] to the Coast Guard 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.

A copy of the ICR is available through the docket on the Internet at *http://www.regulations.gov.* Additionally, copies are available from: COMMANDANT (CG–612), ATTN: PAPERWORK REDUCTION ACT MANAGER, U.S. COAST GUARD, 2703 MARTIN LUTHER KING JR. AVE. SE., STOP 7710, WASHINGTON, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: Contact Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. In response to your comments, we may revise this ICR or decide not to seek approval of revisions of the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2016–0106], and must be received by May 23, 2016.

Submitting Comments

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, 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.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Information Collection Request

Title: Barges Carrying Bulk Hazardous Materials.

OMB Control Number: 1625–0104.

SUMMARY: This information is needed to ensure the safe shipment of bulk hazardous liquids in barges. The requirements are necessary to ensure that barges meet safety standards and to ensure that barge's crewmembers have the information necessary to operate barges safely.

Need: Title 46 U.S.C. 3703 authorizes the Coast Guard to prescribe rules