• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Janet Donnelly, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5167, Silver Spring, MD 20993–0002, 301–796–4187; or Irene Stith-Coleman, Office for Human Research Protections, 1101 Wootton Pkwy., Suite 200, Rockville, MD 20852, 240–453–6900.

SUPPLEMENTARY INFORMATION:

I. Background

OHRP and FDA are announcing the availability of a draft guidance document entitled ''Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs.'' This guidance is intended to assist IRB administrators, IRB chairpersons, and other institutional officials responsible for preparing and maintaining written procedures for IRBs.

OHRP and FDA frequently receive requests for clarification regarding the scope and content of IRB written procedures. We recognize that procedures may vary among institutions and IRBs due to differences in the type of research studies reviewed by the IRB, institutional policy or administrative practices, number of IRBs at the institution, affiliation with an institution, and local and State laws and regulations. In order to provide guidance on the appropriate content of written procedures, while taking into account these variations, we created an IRB Written Procedures Checklist to assist IRBs in preparing and maintaining detailed written procedures suitable for their institutions. The IRB Written Procedures Checklist incorporates the HHS and FDA regulatory requirements for IRB written procedures and additional topics that we recommend including in written procedures. The draft guidance, when finalized, will supersede OHRP's July 1, 2011, ''Guidance on Written IRB Procedures'' and FDA's 1998 ''Appendix H: A Self-Evaluation Checklist for IRBs,'' (formerly part of FDA's Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors).

To enhance human subject protection and reduce regulatory burden, OHRP and FDA have been actively working to harmonize the Agencies' regulatory requirements and guidance for human subject research. This guidance document was developed as a part of these efforts. OHRP and FDA believe that it will be most helpful to the regulated community to issue a joint guidance document that will clearly demonstrate the Agencies' harmonized approach to the topic of preparing and maintaining IRB written procedures.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent OHRP's and FDA's current thinking on IRB written procedures. It does not establish any rights for any person and is not binding on OHRP, FDA, or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information referenced in this guidance that are related to IRB recordkeeping requirements under 21 CFR 56.115, including the information collection activities in the provisions in 21 CFR 56.108(a)(1) and (b), have been approved under OMB control number 0910–0130. The collections of information referenced in this guidance that are related to IRB recordkeeping requirements under 45 CFR 46.115, including the information collection activities in the provisions in 45 CFR 46.103(b)(4) and (5) have been approved under OMB control number 0990–0260.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ProposedRegulationsandDraftGuidances/default.htm, http://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/index.html*, or *http://www.regulations.gov.*

Dated: July 27, 2016.

Leslie Kux,

Associate Commissioner for Policy, U.S. Food and Drug Administration.

Dated: July 15, 2016.

Karen B. DeSalvo,

Acting Assistant Secretary for Health, U.S. Department of Health and Human Services.

[FR Doc. 2016–18191 Filed 8–1–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Advisory Council on Alzheimer's Research, Care, and Services; Meeting

AGENCY: Assistant Secretary for Planning and Evaluation, HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces the public meeting of the Advisory Council on Alzheimer's Research, Care, and Services (Advisory Council). The Advisory Council on Alzheimer's Research, Care, and Services provides advice on how to prevent or reduce the

burden of Alzheimer's disease and related dementias on people with the disease and their caregivers. The Advisory Council will hear from a number of CMS's HCIA awardees about their projects and their results. Additional presentations in the afternoon will include an overview of the 2016 Update to the National Plan, updates on progress towards a Care and Services Summit, and Federal workgroup updates.

DATES: The meeting will be held on August 1, 2016 from 9 a.m. to 5 p.m. EDT.

ADDRESSES: The meeting will be held in Room 620/630, Building 35A (Porter Building) of the National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892.

Comments: Time is allocated in the afternoon on the agenda to hear public comments. The time for oral comments will be limited to two (2) minutes per individual. In lieu of oral comments, formal written comments may be submitted for the record to Rohini Khillan, ASPE, 200 Independence Avenue SW., Room 424E, Washington, DC 20201. All comments should be submitted to *napa@hhs.gov* for the record and to share with the Advisory Council by April 20, 2016. Those submitting comments should identify themselves and any relevant organizational affiliations.

FOR FURTHER INFORMATION CONTACT: Rohini Khillan (202) 690–5932, *rohini.khillan@hhs.gov.* Note: Seating may be limited. Those wishing to attend the meeting must send an email to *napa@hhs.gov* and put ''August 1 Meeting Attendance'' in the Subject line by Friday, July 22, 2016 so that their names may be put on a list of expected attendees and forwarded to the security officers the Humphrey Building. Any interested member of the public who is a non-U.S. citizen should include this information at the time of registration to ensure that the appropriate security procedure to gain entry to the building is carried out. Although the meeting is open to the public, procedures governing security and the entrance to federal buildings may change without notice. If you wish to make a public comment, you must note that within your email.

SUPPLEMENTARY INFORMATION: Notice of these meetings is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)). Topics of the Meeting: The Advisory Council will hear from a number of CMS's HCIA awardees about their projects and their results. Additional presentations in the afternoon will include an overview of the 2016 Update to the National Plan, updates on progress towards a Care and Services Summit, and federal workgroup updates.

Procedure and Agenda: This meeting is open to the public. Please allow 45 minutes to go through security and walk to the meeting room. The meeting will also be webcast at *www.hhs.gov/live*.

Authority: 42 U.S.C. 11225; Section 2(e)(3) of the National Alzheimer's Project Act. The panel is governed by provisions of Public Law 92–463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: July 8, 2016.

Kathryn E. Martin,

Acting Assistant Secretary for Planning and Evaluation.

[FR Doc. 2016–18273 Filed 8–1–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of meetings of the National Center for Advancing Translational Sciences.

The meetings 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 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/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Cures Acceleration Network Review Board.

Date: September 15, 2016.

Time: 8:30 a.m. to 2:30 p.m.

Agenda: Report from the Institute Director.

Place: National Institutes of Health, Building 31, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Anna L. Ramsey-Ewing, Ph.D., Executive Secretary, National Center for Advancing Translational Sciences, 1 Democracy Plaza, Room 1072, Bethesda, MD 20892, 301–435–0809, *anna.ramseyewing@nih.gov*.

Name of Committee: National Center for Advancing Translational Sciences Advisory Council.

Date: September 15, 2016.

Open: 8:30 a.m. to 2:30 p.m.

Agenda: Report from the Institute Director and other staff.

Place: National Institutes of Health, Building 31, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Closed: 3:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Anna L. Ramsey-Ewing, Ph.D., Executive Secretary, National Center for Advancing Translational Sciences, 1 Democracy Plaza, Room 1072, Bethesda, MD 20892, 301–435–0809, *anna.ramseyewing@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: July 27, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–18291 Filed 8–1–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-day Comment Request; NCI's Center for Cancer Training Application Form for Graduate Student Recruitment Program (NCI)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the