Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2015–28153 Filed 11–4–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–0990–New–30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for a new collection. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before December 7, 2015.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the Information Collection Request Title and document identifier HHS–OS–0990–New–30D for reference.

Information Collection Request Title: Information Collection Request Title: Evaluation of the Office on Women's Health Coalition for a Healthier Community Initiative.

Abstract: This collection is to provide data for the national evaluation of the U.S. Department of Health and Human Services (HHS), Office on Women's Health (OWH) Coalition for a Healthier Community (CHC) Initiative. The initiative supports 10 communities with grants to support coalitions in implementing gender-based public health systems approaches, evidence-based health interventions, and outreach and education activities to reduce barriers to and enhance facilitators of improvements in women and girls' health. Each of the grantees has implemented an IRB-approved local evaluation; however, OWH is seeking to collect core data across grantees to examine the extent to which the Government's investment has resulted in achieving OWH-related *Healthy People 2020* priorities and yields lessons learned upon which to plan future initiatives related to its mission.

Likely Respondents: The proposed collection includes plans for interviews with key staff (project directors, project coordinators, local evaluators), coalition members (including chairs and co-chairs), and community leaders connected to the coalitions. These respondents will also complete online surveys about their perceptions of the changes in their community as a result of coalition activities. Program participants and other community members exposed to the coalitions' activities through social media will also complete online surveys. Project directors and local evaluators also annually provide information to OWH on their coalition's functioning, the status of the cost-effectiveness analysis for their coalition's interventions, and the coalition's plans for sustainability. The following table summarizes the ''Total Estimated Annualized Burden—Hours'' by form and type of respondent.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs)	Total burden hours
1—Key Persons Discussion Guide for Telephone Interviews	90	2	1	180
2—Key Persons, Coalition Members, and Community Leaders Online Survey	200	1	20/60	67
3—Coalition Participants and Other Community Members Online Survey	510	1	20/60	170
4—Grantee Annual Report on Coalition Functioning, Cost-Effectiveness, and Sustainability Planning	10	2	2	40
Total				457

Terry Clark,

Asst Information Collection Clearance Officer.

[FR Doc. 2015–28156 Filed 11–4–15; 8:45 am]

BILLING CODE 4150–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. FDA–2015–D–3638]

Minutes of Institutional Review Board Meetings: Guidance for Institutions and Institutional Review Boards; Draft Guidance; Availability

AGENCY: The Office for Human Research Protections, Office of the Assistant Secretary for Health, Office of the Secretary, and the Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health, and the Food and Drug Administration (FDA) are announcing the availability of a draft guidance entitled ''Minutes of Institutional Review Board (IRB) Meetings: Guidance for Institutions and IRBs.'' The draft guidance is intended for institutions and IRBs that are responsible for the review and oversight of human subject research conducted or supported by the U.S. Department of Health and Human Services (HHS) or regulated by FDA. The purpose of the

draft guidance is to assist institutions and IRBs in preparing and maintaining minutes of IRB meetings (also referred to in the guidance as minutes) that meet the regulatory requirements for minutes set forth in FDA and HHS regulations. The draft guidance also provides general recommendations on the type and amount of information to be included in the minutes.

DATES: You can comment on any guidance at any time (21 CFR 10.115(g)(5)). To ensure that we consider your comment on this draft guidance before we begin work on the final version of the guidance, submit either written or electronic comments by January 4, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal*: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier* (*for written/paper submissions*): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–D–3638 for ''Minutes of Institutional Review Board Meetings: Guidance for Institutions and Institutional Review Boards; Draft Guidance; Availability'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- 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.

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 ''Minutes of Institutional Review Board Meetings: Guidance for Institutions and Institutional Review Boards; Draft Guidance; Availability.'' Because IRBs have been cited in OHRP determination letters and FDA warning letters as having inadequate minutes, OHRP and FDA are providing recommendations on the type and amount of information to include in minutes in order to help IRBs meet the regulatory requirements for minutes.

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 draft 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 draft guidance document which will clearly demonstrate the Agencies' harmonious approach to the topic of preparing and maintaining minutes of IRB meetings.

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 the current thinking of OHRP and FDA on minutes of IRB meetings. 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 have been approved under OMB control numbers 0910–0755 and 0910–0130. The collections of information referenced in this guidance that are related to IRB recordkeeping requirements under 45 CFR 46.115 have been approved under OMB control number 0990–0260.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ProposedRegulationsandDraftGuidances/default.htm,* or *http://www.hhs.gov/ohrp/newsroom/index.html,* or *http://www.regulations.gov.*

Dated: October 23, 2015.

Karen B. DeSalvo,

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

Dated: October 27, 2015.

Leslie Kux,

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

[FR Doc. 2015–27986 Filed 11–4–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute on Aging Special Emphasis Panel, November 12, 2015, 10:00 a.m. to November 12, 2015, 02:00 p.m., National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD, 20892 which was published in the **Federal Register** on October 19, 2015, 80 FR 63236.

The meeting notice is amended to change the date of the meeting from November 12, 2015 to November 24, 2015. The meeting is closed to the public.

Dated: October 30, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–28230 Filed 11–4–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of Therapeutics To Treat Brain Injury and Neurodegenerative Disease

AGENCY: National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR part 404.7, that the National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to Astrocyte Pharmaceuticals, Inc., (''Astrocyte''), a company incorporated under the laws of Delaware and having an office in Cambridge, Massachusetts, to practice the following inventions embodied in the following patent applications: US Provisional Patent Appl. No. 60/176,373 entitled, ''Methanocarba cycloalkyl nucleoside analogues,'' filed 14 Jan 2000 [HHS reference E–176–1999/0–US–01]; Intl. Appl. No. PCT/US01/00981, entitled, ''Methanocarba cycloalkyl nucleoside analogues,'' filed 12 Jan 2001 [HHS reference E–176–1999/0–PCT–02]; Australia Patent No. 2001230913, issued 13 Oct 2005 [HHS reference E–176–1999/0–AU–03]; Canada Patent No. 2.397,366, issued 15 Mar 2011 [HHS reference E–176–1999/0–CA–04]; European Patent Appl. No. 01903043.6 entitled, filed 12 Jan 2001 [HHS Ref No E–176–1999/0–EP–05]; US Patent No. 7,087,589, issued 8 Aug 2006 [HHS reference E–176–1999/0–US–06]; US patent No. 7,790,735, issued 8 Aug 2006 [HHS reference E–176–1999/0–US–07]; and Great Britain patent No. 1252160, issued 16 Aug 2006 [HHS reference E–176–1999/0–US–08]. The patent rights in these inventions have been assigned to the United States of America. The territories included in this license may be worldwide. The field of use may be related to ''Use of the patent rights in the development and sale of therapeutics for cerebral trauma, stroke, and neurodegenerative disorders.''

DATES: Only written comments or applications for a license (or both) which are received by the Technology Advancement Office of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) on or before November 20, 2015 will be considered.

ADDRESSES: Requests for copies of the patent application, patents, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Patrick McCue, Ph.D., Senior Licensing and Patenting Manager, Technology Advancement Office, The National Institute of Diabetes and Digestive and Kidney Diseases, 12A South Drive, Bethesda, MD 20892, Telephone: (301) 435–5560; Email: *patrick.mccue@nih.gov.* A signed confidentiality non-disclosure agreement will be required to receive copies of any patent applications that have not been published by the United States Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION:

The technology provides novel nucleoside and nucleotide derivatives that are agonist or antagonists of P1 and P2 receptors and may be useful in the treatment or prevention of various diseases including airway diseases, cancer, cardiac arrhythmias, cardiac ischemia, epilepsy, and Huntington's Disease.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the NIDDK receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Properly filed competing applications for a license received by the NIDDK in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: October 30, 2015.

Anna Z. Amar,

Acting Deputy Director, Technology Advancement Office, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health.

[FR Doc. 2015–28245 Filed 11–4–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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