guidance is to assist sponsors in the clinical development of fixed combination drug products for the treatment of hypertension. The guidance focuses on development of two-drug combinations of previously approved drug products. This guidance incorporates the comments received for and finalizes the draft guidance for industry entitled ''Hypertension: Developing Fixed-Dose Combination Drugs for Treatment'' issued on January 26, 2018 (83 FR 3735). All the public comments received on the draft guidance have been considered, and the guidance was revised as appropriate primarily for editorial changes.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Hypertension: Developing Fixed-Combination Drug Products for Treatment.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that 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 in 21 CFR part 312 has been approved under OMB control number 0910–0014. The collection of information in the guidance for industry entitled ''Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims'' (available at *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm075072.pdf*) has been approved under OMB control number 0910–0670.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: November 1, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–24315 Filed 11–6–18; 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 19, 2018, 8:30 a.m. to November 19, 2018, 4:00 p.m., National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2W200, Bethesda, MD 20892 which was published in the **Federal Register** on October 30, 2018, 83 FR 54605.

The meeting notice is amended to change the meeting location from the National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2W200, Bethesda, MD 20892 to Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814. The meeting is closed to the public.

Dated: November 1, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–24293 Filed 11–6–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-day Comment Request: Data and Specimen Hub (DASH) (Eunice Kennedy Shriver National Institute of Child Health and Human Development)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Rohan Hazra, M.D., Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Institutes of Health, 6710B Rockledge Drive, Room 2113, Bethesda, MD 20817, or call non-toll-free number (301)–435–6868 or Email your request, including your address to: *rohan.hazra@nih.gov.*

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on April 27, 2018, page 18576 (Vol 83) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: Data and Specimen Hub (DASH) 0925–0774 exp. date 6/30/19—REVISION; *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH).

Need and Use of Information Collection:

This is a request to revise the previously approved submission to add the collection of additional information from Users who will request biospecimens, submit the Institutional Certification for data/biospecimen inventory, and submit DASH data/biospecimen Annual Progress Report for the NICHD Data and Specimen Hub (DASH). DASH has been established by NICHD as a data sharing mechanism for biomedical research investigators. It serves as a centralized resource for investigators to store and access deidentified study data and biospecimen inventories—a list of biospecimens available at the NICHD

Biorepository—from studies funded by NICHD. The potential for public benefit to be achieved through sharing study data and/or biospecimen inventories for secondary analysis is significant. NICHD DASH supports NICHD's mission to ensure that every person is born healthy and wanted, that women suffer no harmful effects from reproductive processes, and that all children have the chance to achieve their full potential for healthy and productive lives, free from disease or disability, and to ensure the health, productivity, independence, and well-being of all people through optimal rehabilitation. Study data and biospecimen sharing and reuse will promote testing of new hypotheses from data already collected, facilitate transdisciplinary collaboration, accelerate scientific findings and enable NICHD to maximize the return on its investments in research.

Anyone can access NICHD DASH to browse and view descriptive information about the studies and study data archived in NICHD DASH without creating an account. Users who wish to submit or request research data and/or biospecimen inventories must register for an account.

Information will be collected from those wishing to create an account, sufficient to identify them as unique Users. Those submitting or requesting data and/or biospecimen inventories will be required to provide additional supporting information to ensure proper use and security of NICHD DASH study data and biospecimen inventories. The information collected is limited to the essential data required to ensure the management of Users in NICHD DASH is efficient and the sharing of data and biospecimens among investigators is effective. The primary uses of the information collected from Users by NICHD will be to:

- Communicate with the Users with regards to their data submission, data requests and biospecimen requests
- Monitor data submissions, data requests and biospecimen requests
- Notify interested recipients of updates to data and biospecimen inventories stored in NICHD DASH
- Help NICHD understand the use of NICHD DASH study data and biospecimen inventories by the research community

All the data collected from use of NICHD DASH except for information provided in the annual progress reports are for the purposes of internal administrative management of NICHD DASH. Information gathered through the annual progress reports may be used in publications describing performance of the DASH system.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 204.

ESTIMATED ANNUALIZED BURDEN HOURS

Form	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hour
User Registration	200	1	5/60	17
Data Submission and Biospecimen Inventory Submissions	36	1	2	72
Data Request	60	1	1	60
Biospecimen Request	36	1	1	36
Data Use Annual Progress Report	60	1	10/60	10
Biospecimen Use Annual Progress Report	36	1	10/60	6
Institutional Certification Template	36	1	5/60	3
Total	200	200		204

Dated: November 1, 2018.

Jennifer M. Guimond,

Project Clearance Liaison, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health.

[FR Doc. 2018–24313 Filed 11–6–18; 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, 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 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 contract proposals, 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; Primate Center for Gene Therapy.

Date: November 30, 2018.

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

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7180, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Tony L Creazzo, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7180, Bethesda, MD 20892–7924, 301–827–7913.

(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: November 1, 2018.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–24294 Filed 11–6–18; 8:45 am]

BILLING CODE 4140–01–P