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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-day comment request: A Clearance for the Eunice Kennedy Shriver National Institute of Child Health and Human Development Data and Specimen Hub (DASH)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), the National Institutes of Health, has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on October 30, 2015 on pages 66913-4 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.

DIRECT COMMENTS TO OMB: 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: NIH Desk Officer.

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

FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments, or

request more information on the proposed project, contact: Rohan Hazra, M.D., Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Institutes of Health, 6100 Executive Blvd., Room 4B11, Bethesda, MD 20892-7510, or call non-toll-free number (301)-435-6868 or E-mail your request, including your address to: hazrar@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

PROPOSED COLLECTION: Data and Specimen Hub (DASH), 0925-NEW, Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH).

Need and Use of Information Collection: The NICHD Data and Specimen Hub (DASH) is being established by NICHD as a data sharing mechanism for biomedical research investigators. It will serve as a centralized resource for investigators to store and access de-identified data from studies funded by NICHD. The potential for public benefit to be achieved through sharing research study data 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. Data sharing and reuse will promote testing of new hypotheses from data already collected, facilitate trans-disciplinary 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 data archived in NICHD DASH without creating an account. Users who wish to submit or request research study data 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 will be required to provide additional supporting information to ensure proper use and security of NICHD DASH data. The information collected is limited to the essential data required to ensure that the management of Users in NICHD DASH is efficient and the

sharing of data 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 or requests
- Monitor data submissions and data requests
- Notify interested recipients of updates to data stored in NICHD DASH
- Help NICHD understand the use of NICHD DASH data by the research community

There is no plan to publish the data collected under this request.

OMB approval is requested for 3 years. There are no costs to respondents other than their time.

The total estimated annualized burden hours are 142.

Estimated Annualized Burden Hours

Form	Number of Respondents	Frequency of Response	Average Time Per Response (in Hours)	Total Annual Burden Hour
User Registration	120	1	5/60	10
Data Submission	36	1	2	72
Data Request	60	1	1	60
Total	120	216		142

Dated: February 17, 2016.

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NICHD, NIH.

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