



This document is scheduled to be published in the Federal Register on 10/30/2015 and available online at <http://federalregister.gov/a/2015-27717>, and on FDsys.gov

[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-day Comment Request; A Generic Clearance for the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Data and Specimen Hub (DASH)

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 NICHD, 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 proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and for Further Information: To obtain a copy of the data collection plans and forms, submit comments in writing, 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 forms must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

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 are 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

Type of Form	Number of Respondents	Frequency of Response	Average Time Per Response (in Hours)	Total Annual Burden Hour
Request for Account	120	1	5/60	10
Submit De-identified Data	36	1	2	72
Request De-identified Data	60	1	1	60

Dated: October 23, 2015.

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[FR Doc. 2015-27717 Filed: 10/29/2015 8:45 am; Publication Date: 10/30/2015]