



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Proposed collection; 60-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 requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), the National Institutes of Health will publish periodic summaries of propose projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

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

**FOR FURTHER INFORMATION CONTACT:** To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Regina Bures, Ph.D., Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Institutes of Health, 6710B Rockledge Drive, Room 2160, Bethesda, MD 20817, or call non-toll-free number (301)- 496-9485 or E-mail your request, including your address to: [NICHD.DASH@mail.nih.gov](mailto:NICHD.DASH@mail.nih.gov). Formal requests for additional plans and instruments must be requested in writing.

**SUPPLEMENTARY INFORMATION:** Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: 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) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to 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.

Proposed Collection Title: Data and Specimen Hub (DASH)-0925-0744 expiration date 01/31/2022, 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 (OMB number: 0925-0744) to add the collection of additional information from Users who will submit information to NICHD Data and Specimen Hub (DASH) about studies, and data collections stored in publicly accessible external archives – a process hereinafter referred to as ‘cataloging’ in 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 share and access de-identified study data from studies funded by NICHD. DASH also serves as a portal for requesting biospecimens from selected DASH studies.

NICHD also supports other public archives, data collections, and resources, such as Data Sharing for Demographic Research (DSDR), NICHD/DIPHR Biospecimen Repository Access and Data Sharing (BRADS), the Down Syndrome Registry (DS-Connect), Zebrafish Information Network (ZFIN), etc. In addition to these NICHD-funded public archives, many collaborative studies funded through NICHD are dispersed across other

National Institutes of Health (NIH) designated archives, including the National Heart, Lung, and Blood Institute (NHLBI) Biologic Specimen and Data Repository Information Coordinating Center (BioLINCC), and other NIH-wide repositories, such as the Database of Genotypes and Phenotypes (dbGaP).

In an effort to link these data resources and increase the visibility of NICHD-funded studies and data collections, DASH will enable Users to catalog studies and data collections stored in other external archives to facilitate their discovery through DASH. Users submitting studies or data collections for cataloging in DASH will provide descriptive information about the study required to populate the Study Overview Page in DASH. This cataloging process closely mirrors the existing study data submission process in DASH; however, no study documentation or data will be uploaded to DASH. Requesters will be directed to the external archive via a URL link to obtain access to the data stored in the external archives and resources.

The potential for public benefit to be achieved through sharing study data and/or biospecimen inventories through DASH for secondary analysis is significant.

Additionally, the ability to centralize information regarding where to find, and how to access, studies, and data collections funded by NICHD stored across various public archives (i.e., cataloged studies and data collections) further helps to promote information discovery and reuse of data. 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; 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 and biospecimens 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 collections without creating an account. Users who wish to submit studies or request data stored in DASH, and/or request biospecimens (stored in NICHD contracted Biorepository) must register for an account; Users who wish to submit a study catalog and/or data collection catalog must also 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 biospecimens will be required to provide additional supporting information to ensure proper use and security of NICHD DASH study data and biospecimens. 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 regarding data submission, study catalog submission, data collection catalog submission, data requests and biospecimen requests;
- Monitor data submissions, study catalog submission, data collection catalog submission, data requests and biospecimen requests;
- Notify interested Users of updates to data and biospecimen inventories stored in NICHD DASH; and
- 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 211.

Estimated Annualized Burden Hours

Type of Form	Number of Respondents	Frequency of Response per Respondent	Average Time Per Response (in hours)	Total Annual Burden Hour
User Registration	200	1	5/60	17
Data and Biospecimen Inventory Submissions	36	1	2	72
Study Catalog Submission	10	1	30/60	5
Data Collection Catalog Submission	6	1	15/60	2
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
<b>TOTAL</b>	<b>200</b>	<b>200</b>		<b>211</b>

Dated: January 5, 2021.

**Jennifer M. Guimond,**

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*Eunice Kennedy Shriver National Institute of Child Health and Human Development,*

*National Institutes of Health.*