



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 proposed 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: Rebecca F. Rosen, Ph.D., Director of the Office of Data Science and Sharing, Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Institutes of Health, 6710B Rockledge Drive, Bethesda, MD 20817, or call non-toll-free number 301-827-4602, or email your request, including your address to: 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 06/30/2024, 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 wish to extend their data access beyond the standard three-year period, remove a Biospecimen Annual Report form that is no longer in use, extend the information collection in Institutional Certifications to cover both data and biospecimen submissions, and implement minor revisions on previously approved forms, including additional field options and language revisions that do not impact the nature of information being collected or its associated burden.

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 select 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 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 enables Users to catalog studies and data collections stored in other external archives to facilitate their discovery through DASH. Users submitting studies or external resources 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 lead research and training to understand human development, improve reproductive health, enhance the lives of children and adolescents, and optimize abilities for all. 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 biospecimens (stored in NICHD contracted Biorepository) must register for an account. Users who wish to submit a study catalog and/or external resource 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. For data and/or biospecimen requests, information is collected both for initial data and/or biospecimen access and then throughout the request duration to maintain access. This includes research objectives and analysis plans, research teams, and institution information, as well as significant findings details for annual progress reports or extension justification for data request renewals.

The information collected throughout these processes 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 and aligns with DASH data sharing policies. The primary uses of the information collected from Users by NICHD will be to:

- Communicate with the Users regarding data submission, study catalog submission, external resource catalog submission, data requests, and biospecimen requests;
- Monitor data submissions, study catalog submission, external resource catalog submission, data requests, and biospecimen requests;
- Notify interested Users of updates to data and biospecimens available through

NICHD DASH; and

- Help NICHD understand the use of NICHD DASH study data and biospecimens by the research community.

All the data collected from use of NICHD DASH are for the purposes of internal administrative management of NICHD DASH, with the exception of the Recipient's approved use of DASH data and/or biospecimens, Recipient name and institution, and significant findings reporting in the Data Request Annual Use Report, which may be shared on the DASH website or in publications describing the performance and value of the DASH system for the broader scientific community.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 433.

Estimated Annualized Burden Hours

Annual Burden Hours Estimate				
Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hour
User Registration	900	1	5/60	75
Data and Biospecimen Catalog Submission	36	1	2	72
Institutional Certification Template	36	1	5/60	3
Data Request	150	1	1	150
Biospecimen Request	4	1	1	4
Data Request Annual Progress Report	240	1	30/60	120
Study Catalog Submission	2	1	30/60	1
External Resource Catalog Submission	4	1	15/60	1
Data Request Renewal	42	1	10/60	7
Total	1414	1414		433

Dated: March 6, 2024.

Jennifer M. Guimond,

Project Clearance Liaison,

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

National Institutes of Health.

[FR Doc. 2024-05404 Filed: 3/13/2024 8:45 am; Publication Date: 3/14/2024]