



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 by [INSERT DATE 60 DAYS AFTER THE DATE OF 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 E-mail your request, including your address to: SupportDASH@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 07/31/2027, REVISION, 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 in the process of moving its existing data repository to the Biomedical Research Informatics Computing System (BRICS) data repository platform operated by the NIH Center for Information Technology (CIT). This requires changes to the existing OMB approved DASH forms to meet the CIT BRICS platform structure and also to incorporate NIH Requirements for Controlled-Access Data Repositories (CADRs) from the Required Security and Operational Standards for NIH Controlled-Access Data Repositories (NOT-OD-25-159) Guidebook. Specifically, we will revise the Data and Biospecimen Catalog Submission form to add items required for study milestone tracking and remove outdated policy compliance items. In addition, we will add new data collection, submission, and sharing assurances to the Institutional Certification Template and reduce the number of items on the User Registration form. The Data Request, Biospecimen Request, and Data Request Annual Progress Report forms will have minor revisions to add field options and update language that does not impact the nature of information being collected or its associated burden. Finally, we are removing three forms that are no longer in use by DASH: the Data Request Renewal Form, External Resource Catalog Submission form, and Study Catalog Submission form.

DASH was established by NICHD as a data and biospecimen sharing mechanism for biomedical research investigators. It serves as a centralized resource for investigators to share and access de-identified clinical and population health data from studies funded by NICHD. DASH also serves as a portal for requesting biospecimens from select DASH studies. NICHD researchers may generate other types of scientific data that cannot be shared in DASH. Investigators submitting data to DASH can indicate in their submissions if related study data are shared in other NIH data repositories and where those data are shared, for investigators to find and request access as needed.

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 study data shared across other public archives 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.

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 and to comply with NIH Requirements for CADR's.

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 by NICHD will be to:

- Communicate with the Users regarding data and biospecimen catalog submission, data requests, and biospecimen requests;
- Monitor data and biospecimen catalog submissions, 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 Progress 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 is 1,010. The proposed difference is a

6-hour reduction in the annualized burden.

Estimated Annualized Burden Hours

	Form Name	# of Respondents	# Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden (in hours)
1	User Registration	1482	1	5/60	124
2	Institutional Certification Template	37	1	10/60	6
3	Data Request Annual Progress Report	313	1	30/60	157
4	Data Request	637	1	1	637
5	Data and Biospecimen Catalog Submission	37	1	2	74
6	Biospecimen Request	12	1	1	12
	Total	2,518	2,518		1,010

Dated: May 21, 2026

Jennifer M. Guimond,

Project Clearance Liaison,

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

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