

NICEATM and ICCVAM members before the meeting. Written public statements received after the deadline may be reviewed by NICEATM and ICCVAM at a future date.

Materials submitted to accompany oral public statements or standalone written statements should include the submitters name, affiliation (if any), mailing address, telephone, email, and sponsoring organization (if any) with the document. National Toxicology Program guidelines for public statements are at http://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf.

Responses to this notice are voluntary. No proprietary, classified, confidential, or sensitive information should be included in statements submitted in response to this notice or presented during the meeting. This request for input is for planning purposes only and is not a solicitation for applications or an obligation on the part of the U.S. Government to provide support for any ideas identified in response to the request. Please note that the U.S. Government will not pay for the preparation of any information submitted or for its use of that information.

Background Information on ICCVAM and NICEATM: ICCVAM is an interagency committee composed of representatives from 17 federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods and integrated testing strategies with regulatory applicability and promotes the scientific validation and regulatory acceptance of testing methods that more accurately assess the safety and hazards of chemicals and products and replace, reduce, or refine (enhance animal well-being and lessen or avoid pain and distress) animal use.

The ICCVAM Authorization Act of 2000 (42 U.S.C. 285l-3) establishes ICCVAM as a permanent interagency committee of NIEHS and provides the authority for ICCVAM involvement in activities relevant to the development of alternative test methods. Additional information about ICCVAM can be found at <https://ntp.niehs.nih.gov/go/iccvam>.

NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts and publishes analyses and evaluations of data from new, revised, and alternative testing approaches. NICEATM and ICCVAM work collaboratively to evaluate new

and improved testing approaches applicable to the needs of U.S. federal agencies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods and strategies for validation studies and technical evaluations. Additional information about NICEATM can be found at <https://ntp.niehs.nih.gov/go/niceatm>.

Dated: March 26, 2021.

Brian R. Berridge,

Associate Director, National Toxicology Program.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-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 Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

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

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, 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 Email your request, including

your address to: NICHD.DASH@mail.nih.gov.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on January 14, 2021, page 3160–3162 (86 FR 3160–3162) 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.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: 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 Uses 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

Form name	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
Total	200	200	211

Dated: April 1, 2021.

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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