Supporting Statement A for Clearance for

**Data and Specimen Hub (DASH) (NICHD)**

**OMB Number: 0925-0744, Expiration Date: 6/30/19**

Date: November 1, 2018

Check off which applies:

* New

X

* Revision
* Reinstatement with Change
* Reinstatement without Change
* Extension
* Emergency
* Existing

**Note: This is a revision to a previously approved information collection.**

**Text highlighted in Yellow has been added or amended.**

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**Attachments**

Attachment A2.1: NICHD DASH – User Registration (Approved OMB Number: 0925-0744)

Attachment A2.2: NICHD DASH – Data Submission (Approved OMB Number: 0925-0744

Attachment A2.3: NICHD DASH – Institutional Certification Template

Attachment A2.4: NICHD DASH – Data Request (Approved OMB Number: 0925-0744)

Attachment A2.5: NICHD DASH – Biospecimen Request Form

Attachment A2.6: NICHD DASH – Data Use Annual Progress Report

Attachment A2.7: NICHD DASH – Biospecimen Use Annual Progress Report

Attachment A3.1: DASH Privacy Impact Assessment.

## A. Justification

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 request biospecimens from the pre-existing NICHD repository, submit the Institutional Certification for data/biospecimen inventory, and submit DASH data/biospecimen Annual Progress Report for the NICHD Data and Specimen Hub (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 store and access de-identified study data from studies funded by NICHD. NICHD is adding an inventory of biospecimens that are available at the NICHD Biorepository, and will create a committee to review biospecimen requests from investigators Approved requests will be forwarded to the NICHD biospecimen repository for processing.

Anyone can access NICHD DASH to browse and view descriptive information about the studies and study data archived in NICHD DASH without creating an account. Users who wish to submit or request study data and/or biospecimen inventories 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 biospecimen inventories will be required to provide additional supporting information to ensure proper use and security of NICHD DASH study data and biospecimen inventories. Additionally, Users will be required to submit an annual progress report to provide data and/or biospecimen usage information. The information collected from Users who register in NICHD DASH and submit or request data and/or biospecimen inventories will be used to monitor submissions and requests, Users’ experience with DASH, as well as to notify interested recipients of updates to study data or biospecimen inventories available through NICHD DASH.

The potential for public benefit to be achieved through sharing study data and/or biospecimen inventories 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; 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.

## A.1 Circumstances Making the Collection of Information Necessary

This document contains information supporting a request for the OMB to approve a clearance for the collection of information during user registration, data submission, Institutional Certification submission, data request, biospecimen request, and annual progress report request associated with NICHD DASH. [Public Law 87-838](https://history.nih.gov/research/downloads/PL87-838.pdf) (enacted October 17, 1962) authorized the establishment of Institute of Child Health and Human Development for the conduct and support of research and training relating to maternal health, child health and human development, including research and training in the special health problems and requirements of mothers and children and in the basic sciences relating to the processes of human growth and development, including prenatal development. The information to be collected will be used for identifying Users and ensuring proper use and security of NICHD DASH study data and/or biospecimen inventories.

NICHD conducts and funds over 2000 clinical research studies annually. Most of these studies are conducted at various academic and research institutions across the U.S. as well as other countries. The data and biospecimens generated from these studies are under the purview of the study investigators and are not easily accessible due to challenges with storage locations, formats and structure. To address these challenges and enable broader data and biospecimen sharing, NICHD established DASH (<https://dash.nichd.nih.gov/>)- a centralized resource for researchers to store and access de-identified study data and biospecimen inventories- a list of biospecimens available at the NICHD Biorepository- from studies funded by NICHD. DASH will allow NICHD funded extramural and intramural investigators to comply with NIH data sharing policies. It will enable investigators to organize, store, mine, and access study data in addition to biospecimens, available from the NICHD Biorepository, for purposes of secondary research.

Establishing a central data and biospecimen inventory sharing resource such as NICHD DASH also meets the objectives of various NIH and federal data sharing initiatives, including:

* *NIH Big Data to Knowledge (BD2K) Program (2012)* – Includes the Data and Informatics Initiative aimed at facilitating the use of and maximizing the value of biomedical data by improving data sharing policies, cataloging research data
* *Federal Policy on Public Access (Feb 2013)*– The White House Office of Science Technology and Policy Memo on increasing access to the results of federally funded scientific research includes an objective to store digitally formatted scientific data enabling search, retrieve, and analyze capabilities
* *The White House Open Data Policy (May 2013)* – Mandates that ‘data are released to the public in ways that make the data easy to find, accessible, and usable’

By facilitating study data and biospecimen inventory sharing, NICHD will promote the secondary use of study data and biospecimens already collected; reinforce open scientific inquiry; bring together investigators from multiple disciplines; and ultimately, advance the scientific mission of NICHD.

To enable data sharing through DASH, information on Users, research studies and associated biospecimen will be collected from the Users of the system. User information stored in NICHD DASH is protected under the Privacy Act of 1974 ([Pub.L. 93–579](http://legislink.org/us/pl-93-579), 88 Stat. [1896](http://legislink.org/us/stat-88-1896), enacted December 31, 1974, 5 U.S.C. [§ 552a](http://www.law.cornell.edu/uscode/5/552a.html)), which establishes a Code of Fair Information Practice that governs the collection, maintenance, use, and dissemination of personally identifiable information about individuals maintained in systems of records by federal agencies. Though the study data and biospecimen inventories stored in NICHD DASH will be de-identified, risks to individuals, groups, or communities will be balanced carefully with potential benefits of the knowledge to be gained through NICHD DASH. To protect the privacy of research participants and the confidentiality of their data and/or biospecimens, the NICHD DASH Data Access Committee (DAC) and the NICHD DASH Biospecimen Access Committee (BAC) will review the request for the proposed study data and biospecimen, as well as monitor the use of NICHD DASH data and NICHD Biorepository biospecimens, respectively.

## A.2 Purpose and Use of the Information Collection

The initial information collection package that was approved by OMB included forms for user registration, data submission and data request forms for NICHD DASH. To date, DASH has a total of 557 registered users, 63 study data submissions, and 72 approved data requests. This revised information collection package is being submitted to OMB to obtain clearance for the collection of information during Institutional Certification submission, biospecimen submission and request, and annual progress report submission to NICHD DASH.

**Users creating an account** to register will electronically submit essential information necessary to uniquely identify them in NICHD DASH (*Attachment A.2-1 User Registration).*

**Users submitting study data and biospecimens** to NICHD DASH will be required to provide information about the study investigator and descriptive information about the study. They will also be required to upload study documentation and data (*Attachment A.2-2 Data Submission, one new question added to previously approved information collection form; p. 4: “Do you have any biospecimen available for sharing from this study?).* NICHD DASH is adding a new form for Institutional Certificationfrom the submitting institution stating that the data, biospecimens, and the biospecimen inventory have been de-identified to the standards set forth in the HHS Regulations for the Protection of Human Subjects and that an Institutional Review Board or Privacy Committee has assessed the proposed data and/or biospecimen sharing for risks, privacy considerations, and alignment with informed consent (*New information collection form; Attachment A.2-3 Institutional Certification Template).*

**Users requesting de-identified study data** will be required to provide information about the study investigator and a brief description of the proposed research use of the study data requested from NICHD DASH. The investigator and the authorized institutional official will be required to sign a NICHD DASH Data Use Agreement stating that the recipient will use the study data only for the approved research; will not share study data with individuals’ other than the approved affiliates; will protect study data confidentiality, will not attempt to identify individual participants from whom study data were obtained; and will follow appropriate study data security protections (*Attachment A.2-4 Data Request)*. The NICHD DASH DAC will review the study data requests to determine whether the proposed research use is scientifically and ethically appropriate and does not conflict with constraints or study data use limitations identified by the institutions that submitted the study data to NICHD DASH.

**Users requesting biospecimens** through NICHD DASH from the NICHD Biorepository will be required to upload the Biospecimen Request Form and submit a Material Transfer Agreement. The Biospecimen Request Form must include a brief description of the proposed research use of the biospecimens, the funding source, and the optimal and minimal amount required for the biospecimen (*New information collection form; Attachment A.2-5 Biospecimen Request Form).* The investigator and designated institutional official will be required to sign a NICHD DASH Material Transfer Agreement stating that the recipient will abide by appropriate laws, rules, and regulations associated with human subjects research and private information; will not share biospecimens with individuals other than the approved affiliates; will protect biospecimen confidentiality; will not attempt to identify participants from the biospecimens; will follow appropriate biospecimen security protections; and will limit the use of biospecimens for the approved research plan only.

The DASH BAC will evaluate the scientific and ethical appropriateness of the request as well as ensure that the research plan does not conflict with the biospecimen use limitations provided by the submitter of the biospecimens. The DASH BAC will also ensure that the Users requesting biospecimen(s) through NICHD DASH from the NICHD Biorepository meet the appropriate security measures (e.g., physical security, information technology security, user training).

**Users of study data and/or biospecimens** will be asked to submit an Annual Progress Report summarizing research accomplishments, patent applications (or approvals), and any updates to the list of affiliates (*New information collection forms; Attachment A.2-6 Data Use Annual Progress Report; Attachment A.2-7 Biospecimen Use Annual Progress Report)*. Annual reports are a standard reporting tool used by NIH with grants and contracts, and for use of NIH resources such as data and biospecimens. This requirement will be specified in the material transfer agreement. Many of the fields in the Annual Progress Report will be auto-populated by the system.

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, data requests and biospecimen requests
* Monitor data submissions, data requests and biospecimen requests
* Notify interested Users of updates to data and biospecimen inventories stored in NICHD DASH
* 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 certain information provided in the Annual Progress Reports such as aggregate number of publications or any significant findings from data and biospecimen use, are for the purposes of internal administrative management of NICHD DASH. The aggregate number of publications or significant findings from DASH data or biospecimen reuse may be used in publications describing value of the DASH system for the broader scientific community.

## A.3 Use of Information Technology and Burden Reduction

User information collected in NICHD DASH will be through the web-based portal that enables Users to electronically register for an account, request data access, request biospecimens, submit data, and submit biospecimen inventories. User accounts will be automatically generated. If the User who registers in the system is the same as the Submitter or Requestor, the system will auto-populate the User information fields from the registration page minimizing the burden on the User. Similarly, any study information field that recurs in the system will be auto-populated from prior entry. For the annual progress reports, the system will auto-populate the research plan, affiliates, collaborators and associates fields from the data or specimen request to minimize the burden on the User. NICHD DASH is designed such that Users will not be asked to enter information more than once in the system.

A Privacy Impact Assessment (PIA) has been completed for NICHD DASH by the NICHD Privacy Office. NICHD DASH will operate in accordance with existing NIH policies and the Federal Privacy Act to ensure that no sensitive or personally identifiable information, located in federal systems of records is being shared in violation of these policies.

## A.4 Efforts to Identify Duplication and Use of Similar Information

NICHD DASH is primarily a resource for the biomedical research community that includes both NICHD funded and non-funded investigators. Information collected from these Users is not available in any other systems or federal records; hence this data collection is unique.

## A.5 Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study.

## A.6 Consequences of Collecting the Information Less Frequently

Information will be collected only once from each User for each study data and biospecimen inventory submission, and study data or biospecimen request. Once entered into NICHD DASH, the system will store the data and auto-populate when the User performs other functions related to the specific study.

The information requested in NICHD DASH electronic forms does not ask Users to generate any new information other than what they already have available and is fundamental to conducting any research study. The information is gathered following a User initiated-request and is collected on a needed basis. An Annual Progress Report is necessary to keep track of progress of study data and biospecimen use from NICHD DASH to ensure that research conducted with DASH data and NICHD biospecimens conforms to the Data Use Agreement and the Material Transfer Agreement, respectively.

## A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

Not Applicable.

## A.8.1 Comments in Response to the Federal Register Notice

The 60-Day Federal Register notice was published on April 27, 2018, Vol. 83, pg. 18575. No public comments were received.

## A.8.2 Efforts to Consult Outside Agency

During the planning phase of establishing a data archive, the NICHD DASH Committee conducted an extensive feasibility analysis of over 18 NIH and external data archives to determine if any of the existing archives would be adequate to meet NICHD’s data sharing goals. The NICHD DASH Committee consulted experts and viewed demonstrations from many of the archives, including the National Heart Lung and Blood Institute (NHLBI) Biologic Specimen and Data Repository Information Coordinating Center (BioLINCC), the National Children’s Study (NCS), NICHD’s Biospecimen Repository Access and Data Sharing program (BRADS) and CDC’s National Health and Nutrition Examination Survey (NHANES). The feasibility analysis included evaluations of the breadth of research data topics and types, ease of data submission and discovery, policies and governance, system scalability and flexibility, and advanced functionality such as data analytics and linkage to biospecimens.

## A.9 Explanation of Any Payment of Gift to Respondents

No incentives will be provided to respondents.

## A.10 Assurance of Confidentiality Provided to Respondents

Data collected in NICHD DASH will be stored and used according to the Federal Privacy Act of 1974. The Federal Privacy Act ensures that no sensitive or personally identifiable information, located in federal systems of records (e.g., Recipient NIH records), is being shared. A system of records is any group of records under the control of a federal agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual.

The information requested from the User seeking to submit study data and/or biospecimen inventories, request study data in NICHD DASH, and request biospecimens through NICHD DASH available from the NICHD Biorepository may be made public in part or in whole for tracking and reporting purposes. A Privacy Impact Assessment (PIA) has been completed for NICHD DASH by the NICHD Privacy Office. NICHD DASH will operate in accordance with existing NIH policies and the Federal Privacy Act to ensure that no sensitive or personally identifiable information, located in federal systems of records is being shared in violation of these policies.

**Study data and/or biospecimen inventory submitters** through an Institutional Certification are required to provide assurance that the study data, biospecimen inventory, and biospecimen(s) have been de-identified to the standards set forth in the HHS Regulations for the Protection of Human Subjects and that an Institutional Review Board or Privacy Committee has assessed the proposed study data, biospecimen inventory, and biospecimen(s) sharing for risks, privacy considerations, and alignment with the informed consent. Study data and/or biospecimen inventories submitted to NICHD DASH will be stored initially in a staging area until the de-identification status is verified by the archive staff and approved by the respective NICHD Division/Branch/Center Chief of the study. Only study data and/or biospecimen inventories that have been approved will be shared with the research community.

**Study data and/or biospecimen requestors** through the NICHD DASH Data Use Agreement orthrough the NICHD DASH Material Transfer Agreement are provided a Privacy Act Notification pursuant to Public Law 93-579, Privacy Act of 1974, 5 U.S.C. Section 552a. Authority for the collection of the information requested from Users comes from the authorities regarding the establishment of the National Institutes of Health, its general authority to conduct and fund research and to provide training assistance, and its general authority to maintain records in connection with these and its other functions (42 U.S.C. 203, 241, 289l-1 and 44 U.S.C. 3101), and Section 301 and 493 of the Public Health Service Act. These records will be maintained in accordance with the Privacy Act System of Record Notice 09-25-0200 (<http://oma.od.nih.gov/public/ms/privacy/pafiles/0200.htm>) covering “Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD”.

## A.11 Justification for Sensitive Questions

The ‘multi-race’ category question in the Data Submission Form is of sensitive nature but it is included because DASH is an archive for storing study data and biospecimen inventories from NICHD funded studies that have been completed, including those conducted prior to 1977, when OMB defined new race standards and eliminated the ‘multi-race’ category. NICHD DASH preserves the originally collected study data and/or biospecimen ‘as is’ and does not manipulate any of the fields. Therefore, NICHD DASH system will need to reflect race categories that these older studies used.

None of the other information collected during study data and/or biospecimen inventory submission, data request in NICHD DASH, or biospecimen request through DASH for biospecimens available in the NICHD Biorepository include questions of a sensitive nature, such as salary, Social Security number, use of alcohol or drugs, sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

A.12.1 Estimates of Hour Burden Including Annualized Hourly Costs

|  |
| --- |
| **Annual Burden Hours Estimate** |
| **Form** | **Number of Respondents** | **Number of Responses per Respondent**  | **Average Time Per Response (in Hours)** | **Total Annual Burden Hour** |
| User Registration | 200 | 1 | 5/60 | 17 |
| Data and Biospecimen Inventory Submission | 36 | 1 | 2 | 72 |
| 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** | **464** |  | **204** |

\*The total number of respondents of 200 include all respondents who are required to complete registration (200) and a subset of those registered respondents who perform data and biospecimen inventory submission (36), data request (60), and biospecimen request (60) process. The total frequency of response includes the frequency for registration (200\*1), data and biospecimen inventory submissions (36\*1), data requests (60\*1), biospecimen requests (36\*1), data use annual reports (60\*1), biospecimen use annual report (36\*1) and Institutional Certification, data and biospecimen inventory, if applicable (36\*1).

## A.12.2 Annualized Cost to Respondents

|  |
| --- |
| **Total Annual Cost Burden Estimate** |
| **Form** | **Total Annual Burden Hours** | **Wage rate** | **Total Costs** |
| User Registration | 17 | $45.68 | $776.56 |
| Data and Biospecimen Inventory Submission | 72 | $45.68 | $3,288.96 |
| Data Request  | 60 | $45.68 | $2,740.80 |
| Biospecimen Request | 36 | $45.68 | $1,644.48 |
| Data Use Annual Progress Report | 10 | $45.68 | $456.80 |
| Biospecimen Use Annual Progress Report | 6 | $45.68 | $274.08 |
| Institutional Certification for Study Data and Biospecimen Inventory, if applicable | 3 | $45.68 | $137.04 |
| **Total Cost** | **$9,318.72**  |

Salary/Wage Source: Bureau of Labor Statistics/Occupational Employment and Wages, May 2016: Occupational Code 19-1042, Medical Scientists, national estimates: <http://www.bls.gov/oes/current/oes191042.htm>

## A.13 Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no additional costs other than the respondents’ burden given in A12.

## A.14 Annualized Cost to the Federal Government

The annualized cost to the federal government is $ 14,781

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Staff** | **Grade/Step** | **Salary** | **% of Effort** | **Fringe (if applicable)** | **Total Cost to Gov’t** |
| **Federal Oversight -**  Application Lead/ Program Officer | GS-15/ Step 4 | $ 144,945 | 2.0 |  | $ 2,898.90 |
| **Contractor Cost** – Archive Administrator/ Content Analyst |  | $ 118,830 | 10.0 | N/A | $ 11,883.00 |
| **Total Cost** | **$ 14,781.90**  |

Salary/Wage Source: Office of Personnel Management 2017 General Schedule Locality Salary Table for various GS-levels; contractor rates based on GSA IT schedules.

## A.15 Explanation for Program Changes or Adjustments

NICHD DASH is expanding its functionality to facilitate biospecimen sharing. The new functionality will enable investigators to access biospecimens, available from the NICHD Biorepository, for purposes of secondary research. Establishing a central biospecimen inventory sharing resource through NICHD DASH also helps address the objectives of various NIH and federal data sharing initiatives. Enabling these new functionalities, however, will necessitate additional information gathering, as described in section A.2, Purpose and Use of the Information Collection.

An Annual Progress Report is necessary to keep track of progress of study data and biospecimen use from NICHD DASH to ensure that research conducted with DASH data and NICHD biospecimens conforms to the Data Use Agreement and the Material Transfer Agreement, respectively.

## A.16 Plans for Tabulation and Publication and Project Time Schedule

All the data collected from use of NICHD DASH except for information provided in the Annual Progress Report are for the purposes of internal administrative management of NICHD DASH. Information gathered through the Annual Progress Report may be used in publications describing performance of the DASH system.

## A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

Not applicable.

## A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

The data in NICHD DASH are collected in a manner consistent with the certification statement. No exceptions are requested.