Supporting Statement A for

Data and Specimen Hub (DASH) (NICHD)

OMB Number: 0925-0744, Expiration Date: 06/30/2024

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Check off which applies:

- New
- ✗ Revision
- Reinstatement with Change
- Reinstatement without Change
- Extension
- Emergency
- Existing

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Table of Contents

Attachments

Attachment A.2-1: NICHD DASH – User Registration

Attachment A.2-2: NICHD DASH – Data and Biospecimen Catalog Submission

Attachment A.2-3: NICHD DASH – Institutional Certification Template

Attachment A.2-4: NICHD DASH – Data Request

Attachment A.2-5: NICHD DASH – Biospecimen Request

Attachment A.2-6: NICHD DASH – Data Request Annual Progress Report

Attachment A.2-7: NICHD DASH – Study Catalog Submission

Attachment A.2-8: NICHD DASH – External Resource Catalog Submission

Attachment A.2-9: NICHD DASH – Data Request Renewal

Attachment A.3-1: DASH Privacy Impact Assessment

Attachment A.3-2: Privacy Act Memo

A. Abstract

This is a request to revise the previously approved submission for an additional three years. These revisions were to remove an inactive form no longer in use, add an additional form that is currently required to manage data requests, revise a previously approved form to add clarity and expand functionality, and increase burden estimates, along with minor form revisions (e.g. renaming "Data Collection Catalog" to "External Resource Catalog").

The NICHD Data and Specimen Hub (DASH) has been established by NICHD as a data sharing mechanism for clinical research studies. It serves as a centralized resource for investigators to share and access de-identified study data funded by NICHD. DASH also serves as a portal for requesting biospecimens from select DASH studies.

The public can access NICHD DASH to browse and view descriptive information about the studies and data collections without creating an account. A registered account is required for Users who wish to submit studies, request data (stored in DASH) and/or biospecimens (stored in NICHD contracted Biorepository), or external resource catalog. A 'catalog' in this context refers to the submission of information to NICHD DASH about studies and data collections stored in publicly available external archives.

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 and biospecimen catalog submission, study catalog submission, external resource catalog submission, Institutional Certification submission, data request, biospecimen request, annual progress report, and request renewal associated with NICHD DASH. Public Law 87-838 (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 catalogs.

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 sharing and biospecimen access, NICHD established DASH (https://dash.nichd.nih.gov/) – a centralized resource for researchers to store and access de-identified study data and biospecimen catalogs (a list of biospecimens available at the NICHD contracted biorepository). DASH allows NICHD funded investigators to comply with National Institutes of Health (NIH)

data sharing policies and enables access to study data and biospecimens for purposes of secondary research.

Establishing a central data and biospecimen catalog 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)* – Requires that 'data are released to the public in ways that make the data easy to find, accessible, and usable.'
- *NIH Data Management and Sharing Policy (January 2023)* – Requires all research funded by NIH that generates scientific data to submit a Data Management and Sharing Plan outlining how data will be managed and shared, accounting for potential restrictions or limitations, and then comply with the awardee's plan as approved by the NIH ICO.

By facilitating study data, biospecimen catalog, study catalog, and external resource catalog 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 biospecimens 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, 88 Stat. 1896, enacted December 31, 1974, 5 U.S.C. § 552a), which establishes a Code of Fair Information Practice that governs the collection, maintenance, use, and dissemination of personally identifiable information (PII) about individuals maintained in systems of records by federal agencies. Though the study data and biospecimen catalogs 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 biospecimens, as well as monitor the use of NICHD DASH data and NICHD biorepository biospecimens, respectively.

A.2 Purpose and Use of the Information Collection

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. Additionally, these 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 biospecimens, or submit study catalogs and/or external resource catalogs, will be used to monitor submissions and requests, oversee Users' experiences with DASH, and notify interested recipients of updates to study data or biospecimen catalogs available through NICHD DASH.

The potential for public benefit to be achieved through sharing study data and/or biospecimen catalogs 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 external resources) 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.

The initial information collection package that was approved by OMB included forms for user registration, data and biospecimen catalog submission, and data request forms for NICHD DASH. A revised information collection package previously submitted and approved by OMB included additional forms for Institutional Certification submission, biospecimen submission and request, annual progress report, study catalog and external resource catalog submission to NICHD DASH. To date, DASH has a total of 4893 registered users, 225 study data submissions, 616 approved data requests, and 16 biospecimen requests. This revised information collection package is being submitted to OMB to extend DASH clearance for the continued collection of information and obtain clearance for collection of information during data request renewals.

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 and Biospecimen Catalog Submission)* and a form for Institutional Certification from the submitting institution stating that the data and the biospecimen catalog have been de-identified to the standards set forth in the U.S. Department of Health and Human Services (HHS) Regulations for the Protection of Human Subjects and that an Institutional Review Board, Privacy Board, and/or equivalent body has assessed the proposed data and/or biospecimen catalog sharing for risks, privacy considerations, and alignment with informed consent (*Attachment A.2-3 Institutional Certification Template)*.

Users submitting a study catalog to NICHD DASH will be required to provide descriptive information about the study and where the study is stored. Data and documentation associated with studies cataloged in DASH will not be submitted or be available for request through DASH. Users must navigate to the external

archive to request and obtain these study related items, using the study URL provided by the submitter in DASH *(Attachment A.2-7 Study Catalog Submission)*.

Users submitting an external resource catalog to NICHD DASH will be required to provide descriptive information about the external resource and where it is stored. Data and documentation associated with external resources cataloged in DASH will not be submitted or available for request through DASH. Users must navigate to the external archive to request and obtain these external resource related items, using the external resource URL provided by the submitter in DASH *(Attachment A.2-8 External Resource Catalog Submission)*.

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 Organizational Representative/Signing Official (AOR) 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 sign 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 (*Attachment A.2-5 Biospecimen Request Form)*. The investigator and designated Authorized Organizational Representative/Signing Official (AOR) 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 (*Attachment A.2-6 Data Request Annual Progress Report)*. Annual progress reports are a standard reporting tool used by NIH with grants and contracts, and for use of NIH resources such as data and biospecimens.

Similarly, Users who wish to maintain access to data and/or biospecimens beyond the three-year period specified in the Data Use Agreement/Material Transfer Agreement will be required to submit a Renewal Request indicating the justification for the extension (*New information collection form; Attachment A2-10 NICHD DASH – Data Request Renewal*). These requirements will be specified in the Data Use Agreement/Material Transfer Agreement. Most of the fields in the Renewal Form and 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 and biospecimen catalog submission, study catalog submission, external resource catalog submission, data requests and biospecimen requests.
- Monitor data and biospecimen catalog submissions, study catalog submission, external resource catalog submission, data requests and biospecimen requests.
- Notify interested Users of updates to data and biospecimen catalogs stored in NICHD DASH
- Help NICHD and the public understand the use of NICHD DASH study data and biospecimen catalogs 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.

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, submit biospecimen catalogs, catalog information associated with studies stored in an external public data archive, and catalog information associated with data collections stored external to DASH. User accounts will be automatically generated. If the User who registers in the system is the same as the Submitter or Requester, 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 fields for their research plan, affiliates, collaborators, and associates from the data or biospecimen 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 (*Attachment A.3-1 DASH Privacy Impact Assessment*). 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 (Attachment A.3-1).

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-NICHD funded investigators. Information collected from these Users is not available in any other systems or federal records; hence this data collection is unique.

NICHD also supports other public archives, data collections, and resources that are hosted external to NIH, such as Data Sharing for Demographic Research (DSDR), 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 that support archiving of other data types, 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 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.

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, study catalog, external resource catalog, and biospecimen submission, and study data or biospecimen request. Once information is entered into NICHD DASH, the system will store it and use it to 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 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 Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

The 60-Day Federal Register notice was published on March 14, 2024, Federal Register Vol. 89, No. 51, pp. 18650-18652. No public comments were received.

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 catalogs, catalog studies or external resources, request study data and/or biospecimens through NICHD DASH 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 (Attachment A.3-1) and the Privacy Act Memo (Attachment A.3-2) from the NICHD ISSO is attached. 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 catalog submitters through an Institutional Certification are required to provide assurance that the study data and/or biospecimen catalog 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 catalog, and biospecimen(s) sharing for risks, privacy considerations, and alignment with the informed consent. Study data and/or biospecimen catalogs 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 catalogs that have been approved will be shared with the research community.

Study data and/or biospecimen requesters through the NICHD DASH Data Use Agreement or through 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 NIH, 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 https://oma.od.nih.gov/forms/Privacy%20Documents/PAfiles/0200.htm) covering "Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD", (Attachment A.3-2).

A.11 Justification for Sensitive Questions

Race and ethnicity of study participants are recorded in the Study Catalog Submission and Data and Biospecimen Catalog Submission forms (*Attachments A2-2 and A2.7*). The information is collected to provide potential data and biospecimen Users with a description of study participant characteristics so they can determine whether the data or biospecimens are relevant to their research question.

Because DASH is an archive, race and ethnicity reporting preserves the originally collected study data and/or biospecimen 'as is' and does not manipulate any of the fields. This principle has been approved in DASH's prior OMB approvals. The race and ethnicity reporting format follows the 1997 SPD 15 standards with the addition of a 'multi-race' category option to accommodate studies completed prior 1977, when OMB eliminated the 'multi-race' category.

We have reviewed the updated standards and respectfully request an exemption from using the new format for 3 reasons:

1. Submitters are reporting on information that has been collected under older formats. In order to provide accurate information to potential Users, DASH will need to reflect the categories that these older studies used.
2. NIH is not yet requiring investigators to use the new data format in applications or research performance progress reports, so most investigators submitting data to DASH will be unfamiliar with the new format. It is unclear when NIH investigators will be expected to convert to the new format.
3. If we adopted the new format, submitters would be forced to translate their data summaries into new categories and may need to email customer support for direction. We estimate that the translating the information into new categories and potentially seeking assistance could add an additional 25 minutes to the catalog submission form burden .

DASH will be updated to accommodate the new race and ethnicity standards for data and biospecimen catalogs in the future, when NIH has implemented the new format.

None of the other information collected during study data and/or biospecimen catalog submission, study catalog submission, external resource catalog submission, data request, or biospecimen request through DASH 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

Table 12-1 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 Hours**
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**

A.12.1 Annual Cost to Respondent

Table 12-2 Annualized Cost to Respondents

Total Annual Cost Burden Estimate			
Type of Respondent	**Total Annual Burden Hours**	**Hourly Respondent Wage Rate**	**Respondent Cost**
Medical Scientist	433	$54.03	$23,394.99

Salary/Wage Source: Bureau of Labor Statistics/Occupational Employment and Wages, May 2023: Occupational Code 19-1042, Medical Scientists, Except Epidemiologists, national estimate for mean hourly wage.

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 A.12.

A.14 Annualized Cost to the Federal Government

The annualized cost to the federal government is $**31,662.22**

Cost Description	Grade/Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight – Application Lead / Program Officer	GS-15/ Step 4	$180,359	2.0		$3,607.18
Contractor Cost – IT Project Support		$134.88/hr	208 annual hours (10% effort)	N/A	$ 28,055.04
Total Cost					**$31,662.22**

Salary/Wage Source: Office of Personnel Management 2024 General Schedule Locality Salary Table for various GS-levels; contractor rates based on IT contractor project support rates.

A.15 Explanation for Program Changes or Adjustments

NICHD DASH is maintaining its current functionality to facilitate the findability of NICHD-funded studies and data collections shared through other publicly accessible archives. The number of responses from the last submission increased by 934 (1414 – 480) and the burden hours increased by 222 hours (433-211). Website functionality and associated data collection will remain largely the same as previous OMB approvals. Most form changes involve only minor adjustments and updated language, which do not impact the associated burden. Examples of such minor changes include adding a checkbox to indicate if a data submission is related to an existing DASH study (*Attachment A.2-2: NICHD DASH – Data and Biospecimen Catalog Submission*) and updating terminology from "Data Collection Catalog Submission" to "External Resource Catalog Submission" (*Attachment A.2-8: NICHD DASH – External Resource Catalog Submission*).

Notable changes beyond minor form revisions include the following: one form addition (*Attachment A.2-9 Data Request Renewal*), one form removal (*Previous Attachment A.2-7 Biospecimen Use Annual Progress Report*), one form redesign (*Attachment A.2-3 Institution Certification Template*), and increased usage estimates.

The Data Request Renewal Form (*Attachment A.2-9 Data Request Renewal*) was added for this submission. This form operates in conjunction with the existing request processes and forms and is required to track and maintain approved data requests. One form from the previous OMB submission was removed (*Previous Attachment A.2-7 Biospecimen Use Annual Progress Report*) because it is not used in current DASH processes and is considered inactive. Note that the Data version of this form (*Attachment A.2-6 Data Request Annual Progress Report*) is still in use and has therefore been retained from the previous submission.

The Institutional Certification Template (*Attachment A.2-3 Institution Certification Template*) has undergone considerable revision. Whereas the previously approved version was designed solely for data submissions, an updated version has been created to satisfy Institutional Certification requirements for both data and biospecimen catalog submissions, plus several text changes for additional clarity. Neither of these changes imparts additional burden for either the User or DASH support.

The last notable change from the previous OMB submission is within usage estimates (*Section 1.12*), which have been increased significantly for several forms. Since the prior estimates from 2021, DASH has experienced consistent growth, resulting in higher usage, more active and new users, and increased activity with both study submissions and data and/or biospecimen requests. Increased requests also result in increased Data Request Annual Progress Reports and Data Request Renewals, as these forms are part of the request life cycle. Based on feedback, the burden for the Data Request Annual Progress Report has been increased from 10 minutes to 30 minutes. All other current estimates were derived from current usage and adjusted by approximately 10% to account for continued growth through the coming years.

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

All the data collected from use of NICHD DASH are for the purposes of internal administrative management of NICHD DASH, with the exception of certain information that may be shared publicly as stipulated in the terms of the Data Use Agreement (DUA). This shareable data includes information regarding the approved use of DASH data and/or biospecimens, Recipient name and institution, and findings reported in the Annual Progress Reports, such as publications and other significant findings. Information gathered through the Data Request 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.