Supporting Statement A for

Data and Specimen Hub (DASH) (NICHD)

OMB Number: 0925-0744, Expiration Date: 07/31/2027

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Check off which applies:

- ● New
- × Revision
- ● Reinstatement with Change
- ● Reinstatement without Change
- ● Extension
- ● Emergency
- ● Existing

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A. Abstract

This request is being submitted as a revision. The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) Data and Specimen Hub (DASH) was established by NICHD as a data sharing mechanism for clinical and population health 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 without creating an account. A registered account is required for Users who wish to submit studies, request access to NICHD DASH data, search for available biospecimens, and request biospecimens stored in the NICHD contracted Biorepository.

NICHD is in the process of migrating DASH data to a new instance of the Biomedical Research Informatics Computi (BRICS) platform operated by the NIH Center for Information Technology (CIT). This requires changes to the existing Office of Management and Budget (OMB)-approved DASH forms to align with the BRICS platform structure and to incorporate new NIH Requirements for Controlled-Access Data Repositories (CADRs) from the Required Security and Operational Standards for NIH Controlled-Access Data Repositories (NIH CADR Guidebook), hereinafter referred to as "NOT-OD-25-159" (https://www.grants.nih.gov/grants/guide/notice-files/NOT-OD-25-159.html).

Six (6) NICHD DASH information collection forms have been updated (*Attachments A.1 - A.6*) and three (3) forms have been removed. No (0) forms have been added. Revision details are provided in Section A.15.

A.1 Circumstances Making the Collection of Information Necessary

This document supports a request for the OMB to approve a clearance for the collection of information during user registration, data and biospecimen catalog submission, Institutional Certification for data and biospecimen catalog submission, data access request, biospecimen access request, and data and biospecimen access progress and closeout reports associated with NICHD DASH. Public Law 87-838 (enacted October 17, 1962) authorized the establishment of the NICHD 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 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 2,000 clinical research studies annually. These studies are conducted at various academic and research institutions across the U.S. as well as other countries. 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 location, format, 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 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 in a CIT-managed data repository platform also meets the objectives of various NIH and federal data sharing initiatives, including the *NIH Data Management and Sharing Policy (NIH DMS Policy)*, effective January 2023, which requires all research funded by NIH that generates scientific data to submit a Data Management and Sharing Plan (DMS 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 Institute, Center, or Office (ICO). It also supports the 2022 Office of Science and Technology Policy's *Desirable Characteristics of Data Repositories for Federally Funded Research*, which identifies necessary characteristics of online, public access data repositories to help ensure that research data is findable, accessible, interoperable, and reusable (FAIR) to the greatest extent possible, while integrating privacy, security, and other protections (https://bidenwhitehouse.archives.gov/wp-content/uploads/2022/05/05-2022-Desirable-Characteristics-of-Data-Repositories.pdf).

By facilitating study data and biospecimen catalog sharing, NICHD promotes the secondary use of study data and biospecimens already collected; reinforces open scientific inquiry; brings together investigators from multiple disciplines; and ultimately, advances the scientific mission of NICHD.

To enable data sharing through NICHD DASH, information has been collected on Users, research studies, and associated biospecimens. 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 have been de-identified, risks to individuals, groups, or communities have been 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 and monitor the use of NICHD DASH data and NICHD biorepository biospecimens, respectively.

A.2 Purpose and Use of the Information Collection

Information collected from Users wishing to create an account will be sufficient to identify them as unique Users in the NICHD DASH system and to comply with user access requirements in NOT-OD-25-159. Users submitting or requesting data and/or biospecimens will be required to provide information to ensure proper use and secure handling of NICHD DASH study data and biospecimens, in alignment with the

standard data submission and access processes and security standards and practices in NOT-OD-25-159. Users submitting data will be required to provide an institutional attestation that the data and biospecimen catalog being submitted are appropriate for sharing in NICHD DASH, following the standard language in NOT-OD-25-159. Users with approved data and biospecimen requests will be required to submit an annual progress or closeout report to provide data and/or biospecimen usage information and comply with data access process and security standards in NOT-OD-25-159 and biospecimen access terms. The information collected from Users who register in NICHD DASH and submit or request data and/or biospecimens will be used to monitor submissions and requests, oversee Users' experiences with DASH, notify interested recipients of updates to study data or biospecimen catalogs available through NICHD DASH, and maintain User and NICHD DASH compliance with NOT-OD-25-159.

The potential for public benefit to be achieved through sharing study data and/or biospecimens through DASH for secondary analysis is significant. 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 promotes 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.

To date, DASH has supported a total of 9,484 registered Users, 268 study data submissions (9 of which included biospecimen catalog submissions), 962 approved Data Access Requests and 16 approved Biospecimen Access Requests. This revised information collection package is being submitted to OMB to revise NICHD DASH clearance for use of the forms indicated below.

Users **creating an account** will electronically submit information necessary to uniquely identify them in the NICHD DASH repository and access the password-protected section of NICHD DASH. (*Attachment A.2-1)*.

Users **submitting study data and biospecimens** to NICHD DASH will be required to provide an Institutional Certification attesting 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, 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)*. In a separate form, Users will provide information about the study team and about the study data and/or biospecimens being submitted (*Attachment A.2-2*).

Users **requesting de-identified study data** will be required to provide information about the study team 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/SO) will be required to sign the NICHD DASH Data Access Request and appended Data Use Certification (DUC) attesting that the investigator and approved users will use the study data only for the approved research; will not share study data with individuals' other than the approved users; 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)*. The NICHD DASH Data Access Committee (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** from the NICHD contracted biorepository will be required to upload the Biospecimen Access Request and sign a Material Transfer Agreement. The request must include information about the study team, 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)*. The investigator and designated Authorized Organizational Representative/Signing Official (AOR/SO) will be required to sign a NICHD DASH Material Transfer Agreement and appended Biospecimen Access Request 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 NICHD DASH Biospecimen Access Committee (BAC) will evaluate the scientific and ethical appropriateness of the request and ensure that the research plan does not conflict with the biospecimen use limitations provided by the submitter of the biospecimens.

Users of study data and/or biospecimens will be asked to submit an Annual Progress Report or Closeout Report summarizing research accomplishments, publications, patent applications (or approvals), and any updates to the list of approved users (*Attachment A.2-6)*. Annual reports are a standard reporting tool used by NIH with grants and contracts for use of NIH resources such as data and biospecimens. These requirements have been specified in the Data Use Certification and Material Transfer Agreement and are mandated for data access in NOT-OD-25-159. For Users submitting Closeout Reports for data or biospecimen access, this form will capture the reason they no longer need access and provide assurance of data deletion, as required in NOT-OD-25-159. Previously submitted User and study information fields in the Annual Progress Report/Closeout Report auto-populate by the NICHD DASH system. The approved use of DASH data and/or biospecimens, the findings outlined in the Annual Progress Report/Closeout Report may be shared on the DASH website or in publications describing the performance and value of the DASH system for the broader scientific community.

Across these forms, the information collected is limited to essential data required to ensure the internal administrative management of Users in NICHD DASH is efficient and the sharing of data and biospecimens among investigators is effective and complies with all NIH policies and standards. The primary uses of information collected will be to:

- Communicate with Users regarding data and biospecimen catalog submission, data requests, and biospecimen requests.
- Monitor data and biospecimen catalog submissions, data requests, and biospecimen requests.

- Meet the standard data submission and access processes and security standards and practices in NOT-OD-25-159.
- Support NICHD staff tracking of NIH DMS Policy compliance via the Institutional Certification and the Data and Biospecimen Catalog Submission forms.
- Notify interested Users of updates to data and biospecimen catalogs stored in NICHD DASH.
- Help NICHD and the public understand the secondary use of NICHD DASH study data and NICHD biospecimens by the research community.

A.3 Use of Information Technology and Burden Reduction

User information in NICHD DASH will be collected through the web-based NICHD DASH portal that enables Users to electronically register for an account, request data access, request biospecimens, submit data, and submit biospecimen catalogs. NICHD DASH is designed such that Users will not be asked to repeatedly enter duplicative information. Instead, the system will auto-populate verified User information fields from the registration page, minimizing the User burden. Similarly, any study information fields that recur in the system will be auto populated from a prior entry. Users will be able to make changes as needed and allowable if study information changes.

CIT, in collaboration with NICHD and the NIH Privacy Office, is conducting an updated Privacy Impact Assessment (PIA) for NICHD DASH. 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 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-NICHD funded investigators. Information collected from these Users is not available in any other systems or federal records; this data collection is unique. In addition to the BRICS platform, users will be able to search for data available in NICHD DASH in a NIH-wide dataset search tool.

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 submission, biospecimen catalog submission, and study data or biospecimen request. Once information is entered into NICHD DASH, the system will store and auto-populate fields when the User performs other functions related to the specific study. Information is gathered only following a User-initiated request and collected only as needed for NICHD DASH to adhere to relevant data stewardship and IT security policies and requirements.

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 (FRN) was published on May 27, 2026, Federal Register Vol. 91, No. 101, pp. 31471-31473. One request for information was received for the data collection plan and tools to be provided. This was sent to the requester on June 29, 2026. There were no public comments.

NICHD DASH has been an operational repository since 2015. Ongoing system updates are informed by NIH and other federal policies and requirements and best practices from the research community.

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 is 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 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 or symbol.

The information requested from the User seeking to submit study data and/or biospecimen catalogs, or request study data and/or biospecimens through NICHD DASH may be made public in part or in whole for tracking and reporting purposes. An updated Privacy Impact Assessment (PIA) is in progress for NICHD DASH. 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 shared in violation of these policies.

Study data and/or biospecimen requesters through the NICHD DASH Data Use Certification 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 09-25-0216 “Administration: NIH Electronic Directory, HHS/NIH” (FR Citation 83, FR 6591).

A.11 Justification for Sensitive Questions

No sensitive information about Users is collected. However, aggregate race and ethnicity of study participants are recorded in the **Data and Biospecimen Catalog Submission** form (*Attachment A.2-2*). The information is collected to provide potential Users with a description of study participant characteristics to determine whether the data or biospecimens are relevant to their research.

Because DASH is an archive, race and ethnicity reporting preserves the originally collected study and/or biospecimen data 'as is' and does not manipulate any fields. This principle has been vetted via 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 to 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 enlist customer support for direction. We estimate that translating the information into new categories and potentially seeking assistance could add 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.

A.12 Cost and Burden Calculations

The total burden has increased by 928 hours annually (from 433 to 1,361). Details are provided below.

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	1,500	1	5/60	125
Data and Biospecimen Catalog Submission	100	1	2	200
Institutional Certification Template	100	1	5/60	8
Data Access Request (New Request)	500	1	1	500
Data Access Request (Renewal)	380	1	10/60	63
Biospecimen Access Request (New Request)	60	1	1	60
Biospecimen Access Request (Renewal)	3	1	10/60	1
Annual Progress Report/ Closeout Report (Data & Biospecimen Access)	606	1	40/60	404
Total	**3,249**	**3,249**		**1,361**

A.12.2 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	1,361	$56.18	$76,460.98

Salary/Wage Source: Bureau of Labor Statistics/Occupational Employment and Wages, May 2025: 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

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	$186,207	2.0		$3,724.14
Contractor Cost – IT Project Support		$138.92/hr	208 annual hrs (10% effort)	N/A	$28,895.36
Total Cost					**$32,619.50**

Salary/Wage Source: Office of Personnel Management 2026 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

Current OMB-approved NICHD DASH forms have an expiration date of July 31, 2027. Two events necessitated submission of revisions 6 months earlier than anticipated:

1. NICHD DASH migration to the BRICS repository platform required form changes to adopt the BRICS' platform structure (modules and webforms where certain types of information are collected and stored) and to adapt to BRICS information collection (data and metadata) standards.

2. The Required Security and Operational Standards for NIH Controlled-Access Data Repositories (NIH CADRs) Guidebook (released under NOT-OD-25-159) required the addition of new information fields and the modification of form language to ensure that NICHD DASH and its Users are in compliance with standard data submission and access processes and security standards and practices.

Regarding User burden calculations: The total User burden increased from 2024 to 2026, due to two primary factors. Additional attestation information and data are required to comply with NOT-OD-25-159 and NICHD DASH is supporting a significant increase in User numbers due to NIH-wide data sharing expectations under the NIH DMS Policy. The increased respondent estimates for the User Registration (from 900 to 1,500), Data Access Request (from 150 to 500), and Biospecimen Access Request (from 4 to 60) forms were calculated from NICHD DASH form submission metrics in 2024 and 2025 and data sharing projections based on the NICHD research portfolio and NIH DMS Policy expectations.

Where forms were revised to support more than one information collection workflow, the number of respondents was updated accordingly. Specifically, the **Data Access Request** respondent count was adjusted to include two workflows: new requests and request renewals. Whereas users previously submitted the **Data Request Renewal** form once every three years, users must now annually renew their **Data Access Request** and annually submit a Progress or Closeout Report to comply with NOT-OD-25-159. Users with an approved **Biospecimen Access Request** renew their request every three years using the new **Biospecimen Access** Request renewal workflow and will now also need to annually submit a Progress or

Closeout Report, which were not previously supported in NICHD DASH forms. Therefore, the total number of respondents for the **Annual Progress Report/Closeout Report** Form increased from 240 to 606.

No (0) forms are added for the 2026 submission.

Three (3) forms are removed from the 2024 OMB-approved package: The External Resource Catalog Submission, the Study Catalog Submission, and the Data Request Renewal. The Data Request Renewal was removed as information in this form will now be collected in the revised **Data Access Request**. As such, one question was added to the **Data Access Request** form to identify if the request is a renewal or a new request. NICHD DASH is no longer collecting external catalog submissions (information about studies and resources hosted in external repositories); hence removal of the Study Catalog Submission and External Resource Catalog Submission forms. The **Annual Progress Report** was revised to support information collection for annual progress and closeout reports from both data and biospecimen requests.

To calculate the User burden for the six (6) updated forms (Attachments A.2-1 through A.2-6), we identified the number of fields and/or questions which were added, removed, or changed for each of the current OMB-approved NICHD DASH Forms. In situations where an equal number of questions were added or removed, we describe a net-neutral (no change) burden. Minor wording updates did not impact the User burden. Specific changes to each form are described below:

i. In the **User Registration form** (Attachment A.2-1), five (5) fields were removed that are not collected with BRICS' existing account creation process. With NIH Researcher Auth Service (NIH RAS) as an identity broker for User authentication, Users do not need to create NICHD DASH login credentials (email, password). One (1) new field was added to collect a username, which is required for account creation in the BRICS platform. The overall User burden did not change.

ii. The **Data and Biospecimen Catalog Submission** form (Attachment A.2-2) was revised to remove four (4) policy questions, as submitting institutions will now attest to relevant policy compliance with a single question in the **Institutional Certification Template** (Attachment A.2-3) as required by NOT-OD-25-159. Two (2) fields were removed for collecting Institutional Division information and nine (9) informational fields were removed for NICHD Point of Contact. The form structure was revised to streamline information collection about study team members into one section. Two (2) questions related to use limitations (study approval and IRB approval) were removed, as this information will be collected in a single Data Use Limitation field. Finally, all form sections for file upload (e.g. Institutional Certification) were removed to align with the BRICS platform workflow. New field additions include five (5) questions to facilitate NICHD DASH review of biospecimen catalog submissions, one (1) field to clarify Project Role for study team members, one (1) field for persistent identifiers of external studies (to facilitate findability of related data for secondary users), one (1) field to indicate if the person entering the data is the submitter, and three (3) fields for Recruitment Status, Data Submission and Estimated Follow Up Submission timing, all of which

provide information needed for NIH data sharing policy milestone tracking. The overall User burden did not change.

iii. The **Institutional Certification Template** (Attachment A.2-3) was revised to align with data submission requirements per standard language in Appendix D of NOT-OD-25-159. Twelve (12) checkboxes for attestation of each individual requirement were removed and replaced with a single attestation checkbox. Three (3) new questions were added (grant number, sensitive data, and Certificate of Confidentiality applicability questions) and language was updated to comply with NOT-OD-25-159. The overall User burden did not change.

iv. The Data Request form title was updated to **Data Access Request** (Attachment A.2-4). Two (2) fields were removed related to Division information, as revised in all forms. Nine (9) fields related to Affiliates were removed, as this type of collaborator is not compliant with NOT-OD-25-159. Four (4) fields related to Associates were renamed to Institutional Research Team fields, to align with language in NOT-OD-25-159. All contact information about the Data Requester will be auto-populated from information in the User Registration form, and details about studies being requested will now be auto-populated from the Data and Biospecimen Catalog Submission form. Six (6) questions were added to collect information about the IT system where data will be stored and accessed, for compliance with NOT-OD-25-159. One (1) field was added to indicate each Institutional Research Team member's Project Role. The form was revised to accommodate data request renewals, adding two (2) questions to determine if the request is a renewal, and if so, the reason for renewal. When the Data Access Request is used to renew an existing request, all fields within the form will be auto populated, except for the reason for renewal. In sum, the overall User burden did not change.

v. The Biospecimen Request form title was updated to **Biospecimen Access Request** (Attachment A.2-5). Four (4) fields were removed for information that is no longer collected related to the Institution Division and the Principal Investigator. Eight (8) fields were added to collect information about the Institutional Research Team collaborating on research use of requested biospecimens. The form was revised to accommodate biospecimen request renewals, adding two (2) questions to determine if the request is a renewal and, if so, the reason for renewal. When used to renew an existing request, all fields within the form will be auto populated except for the reason for renewal, resulting in a burden of 10 minutes. The overall User burden for a new request is unchanged.

vi. The Data Request Annual Report form was revised to support four information collection and reporting processes: Data Request Annual Progress Report, Data Request Closeout Report, Biospecimen Request Annual Progress Report, and Biospecimen Request Closeout Report, all required per the terms of access. The resulting, broader form has been updated and retitled: **Annual Progress Report/Closeout Report** (Attachment A.2-6) and has two (2) new fields to determine which type of report is being submitted. User, Signing Official, Institutional Research

Team, and Research Plan information will be auto-populated with data from the Data Access Request or Biospecimen Access Request. For a Closeout Report, one (1) question was added to provide the reason for a closeout. If a User is submitting a Progress Report, one (1) new field was added to provide a description of changes to the Research Plan, if changes are requested. Two (2) questions were added to enable reporting of data access violations, as required in NOT-OD-25-159. Despite significant auto-population of data fields, the additional questions required in this consolidated form result in a 10-minute increase to the User burden, (from 30 minutes to 40 minutes). Additionally, the total number of respondents increased to accommodate new biospecimen request reporting workflows, resulting in an overall increase to the User burden.

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

All data collected from use of NICHD DASH is for the purpose of internal administrative management, except for certain information that may be shared publicly as stipulated in the terms of the Data Use Certification (DUC) and Materials Transfer Agreement (MTA). 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 Report/Closeout Report such as publications, patents, presentations and significant findings. Information gathered through the Annual Progress Report/Closeout 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.