Mini Supporting Statement A

SCHARE Data Repository (SDR) Data Use Oversight System (DUOS)

Sub-study under OMB# 0925-0775,

Expiration Date: 11/30/2028

Generic Clearance for National Cancer Institute (NCI)

Resources, Software, and Data Sharing Forms

Date: February 12, 2026

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List of Attachments

Attachment 1 – Institutional Signing Official Approval Card Issuance
Attachment 2 – Data Access Request
Attachment 3 – DUOS homepage
Attachment 4 – Privacy Act System of Records Notice (SORN)

Mini Supporting Statement A

A.1 Circumstance Making the Collection of Information Necessary

The National Institutes of Health (NIH) Data Access Committees (DACs) play an important role in ensuring that controlled-access datasets (that contain potentially identifiable data and require approval prior to access) are used in a manner that is consistent with the informed consent of the study's participants. To balance data access and data security, access management systems collocate data use agreements with data access requests, providing DACs with all the information they need to make informed decisions as to whether to grant access to data requesters.

The Data Use Oversight System (DUOS) is one such access management system. DUOS captures information about controlled-access datasets that require oversight by a DAC. It also facilitates review by a DAC (data access - Attachment 2). DUOS is a proven system that has been previously approved for use by the AnVIL repository. For datasets stored on the Science Collaborative for Health and Artificial intelligence Reduction of Errors (SCHARE) Data Repository (SDR), the SDR DAC will operate through DUOS.

Collection and use of the data for these activities follow the Generic Clearance guidelines outlined in the Paperwork Reduction Act Program PRA; 44 U.S.C. 3501, et seq.

A.2 Purpose and Use of the Information Collection

Data Access (Attachment 2): The data collected includes Principal Investigator (PI) names, requesting institutions, lab staff, external collaborator names (as applicable), Institutional Signing Official names, intended Research Use, and Non-technical research use for controlled access data. These fields are required for all NIH data repository's management and security.

This information is critical to ensure a transparent and standardized process for accessing data and reviewing requests, while also ensuring that the privacy and confidentiality of study participants are protected. DACs can use the DUOS matching algorithm to advise their decision in their DAR reviews. This tool reduces the workload of the SDR DAC. The data collected will be used to assess the system's effectiveness and identify areas for improvement. Lack of access to this information can hinder the productivity and efficiency of researchers, Institutional Signing Officials, and DACs.

A.3 Use of Information Technology to Reduce Burden

DUOS allows investigators to submit the required information directly; thereby, minimizing the burden for investigators and institutions and NIH staff. The online system uses time-saving features, such as the use of pull-down and scrolling menus to fill data fields, "find as you type" (or "type ahead") functionality, and text fields that allow investigators and requesters to cut and paste information from other sources.

Where possible, data fields are automatically filled with information from different data sources, such as eRA Commons, which provides the investigator's or requester's name, institution, and Institutional Signing Official. Also, information from one online form can be used to pre-fill data fields on subsequent

forms. For example, information from an Institutional Certification will be used to pre-fill many data fields in the study registration system. Likewise, information in a DAR will be used to pre-fill many of the data fields on the Project Renewal and Project Close-out forms.

The NIMHD Privacy Act Coordinator was consulted, and it was determined that a Privacy Impact Assessment (PIA) is needed for every application system since personally identifiable information is collected and maintained. The PIA for the SDR is approved as of 12/15/2025.

A.4 Efforts to Identify Duplication

The SCHARE Team defines the methods used to securely control and grant access to controlled-access datasets hosted within the SDR, including managing automated credential handoff and developing streamlined processes for handling Data Access Requests. The SCHARE Team have reviewed these forms to find opportunities to simplify (including avoiding duplication) the data registration and data access request workflow with a unique submission format, hoping to expedite the onboarding of datasets and review of DARs. Due to the sensitive nature of the data contained in the SDR and in accordance with existing NIH policies, DUOS data access approvals are granted for one year and may be renewed thereupon.

A.5 Impact on Small Businesses or Other Small Entities

N/A

A.6 Consequences of Collecting the Information Less Frequently

Data Access: DUOS Data Access Requests (DARs) are collected as researchers are requesting datasets for their projects. This is a required mandate for security. Constraining or limiting these forms can slow down the progress of implementing and assessing improvements to the process of accepting and deciding whether to allow access to controlled-access datasets stored in the SDR and potentially minimize the benefits of improving efficiency for the researcher submissions, Institutional Signing Official approval, and DAC review.

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

This DUOS system will be implemented in a manner that fully complies with 5 C.F.R. 1320.5.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

N/A

A.9 Explanation of Any Payment of Gift to Respondents

No gifts or payments are to be offered regarding this information collection.

A.10 Assurance of Confidentiality Provided to Respondents

The names and institutional affiliations of the respondents (both data registration and data requesters) will be posted publicly on the DUOS website. It is a requirement to keep track of all data access requests. Thus, there is no assurance of confidentiality afforded to the respondents. However, it is important to emphasize that no personal information is requested from investigators registering datasets or accessing data beyond their name and institutional affiliation. Submitters of data to the SDR (and registering datasets in DUOS) are largely NIH-funded investigators whose names and institutional affiliations are already a matter of public record (see http://projectreporter.nih.gov/reporter.cfm). Requesters for the data are both NIH-funded and non-NIH-funded investigators. Making the names of submitters and requesters of the data publicly available is an important ethical underpinning of the NIH DMS Policy, as it allows NIH to be transparent in informing research participants, the scientific community, and the general public on how genomic data are being shared, with whom, and for what research purpose in addition to helping to foster future research collaborations.

SCHARE is supported through the Office of Data Science and Strategy (ODSS), the National Institute on Minority Health and Health Disparities (NIMHD) and other Institute, Centers, and Offices (ICOs) funds annually with a funding account in Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability (STRIDES). SCHARE operates at a FISMA Moderate rating and the SCHARE Data Repository's is cleared for production use under an Authority to Use (ATU).

The information collected is subject to the Privacy Act System of Records Notice, 09-25-0200 – "Clinical, Basic and Population-based Research Studies of the National Institutes of Health" (NIH) (Attachment 4).

A.11 Justification for Sensitive Questions

No questions of a sensitive nature are included in this data collection.

A.12.1 Estimated Annualized Burden Hours

There is an estimated total of 150 respondents: 50 respondents to complete the Institutional Signing Official Approval Issuance an average of twice per ISO (Attachment 1), and 100 respondents to complete the Data Access Request (Attachment 2). The estimated total annual burden is 58 hours.

A.12-1 Estimated Annualized Burden Hours

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Time Per Response (in hours)	Total Annual Burden Hours
Institutional Signing Official Issuance – Attachment 1	Individuals	50	2	5/60	8
Data Access Request – Attachment 2	Individuals	100	1	30/60	50
Totals			150		**58**

A.12-2 ANNUALIZED COST TO RESPONDENTS

The estimated total annualized cost to respondents amounts to a total of $2,893 with less than $50 per investigator, since it takes less than an hour to submit the Duos request.

A.12-2 Annualized Cost to the Respondents

Form Name	Type of Respondents	Total Annual Burden Hours	Hourly Wage Rate*	Respondent Cost
Investigator Submitting Request (DAR)	Individuals	50	$53.57	$2,678.50
Institutional Signing Official Approval Issuance	Individuals	4	$53.57	$214.28
Total		**54**		**$2,892.78**

*Source of the Hourly Wage Rate is provided by the Bureau of Labor Statistics, Occupation title "Medical Scientists" 19-1040 (or substitute another more appropriate occupation title), https://www.bls.gov/oes/current/oes_nat.htm#19-1040

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

Other than the respondent's time, no additional costs are associated with this data collection.

A.14 Annualized Cost to the Federal Government

The annualized cost to the government is $29,787.60 for federal employees. The other costs are accounted for as part of the SDR operating budget.

A.14-1 Annualized Cost to the Federal Government

Staff	Grade/Step	Salary**	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
Health Science Administrator	15/8	$197,200	10%		$19,720.00
Health Science Policy Analyst	13/02	$125,845	8%		$10,067.60
Total					**$70,543.00**

**The salary in the table above is cited from https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2026/DCB.pdf

A.15 Explanation for Program Changes or Adjustments

N/A.

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

Information submitted to DUOS to register studies data will be made available to the public via the SDR website once the registration is complete and the study has been released. The only submitted information that will not be publicly displayed on the website is the contact information of the submitting investigators and requesters (i.e., the investigator's email addresses and phone and fax numbers).

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

We are not requesting an exemption to the display of the OMB Expiration date.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

This request will comply with the requirements in 5 CFR 1320.9.