

Policy Comparison Table:

National Heart, Lung, and Blood Institute (NHLBI) Supplement to the NIH Policy for Data Management and Sharing (2023) vs. NIH Policy for Data Management and Sharing (2023) vs. NHLBI Policy for Data Sharing from Clinical Trials and Epidemiological Studies (2006)

Purpose: This document compares three data sharing policies: 1) NIH Policy for Data Management and Sharing (2023), 2) NHLBI Supplement to the NIH Policy for Data Management and Sharing (2023), and 3) NHLBI Policy for Data Sharing from Clinical and Epidemiological Studies (2006). The NHLBI Supplement to the NIH Policy for Data Management and Sharing is harmonized with the NIH Policy for Data Management and Sharing (2023) and replaces the narrower-in-scope NHLBI Policy for Data Sharing from Clinical and Epidemiological Studies (2006). Several relevant provisions found in each of these policies are summarized, along with descriptions of their key differences. The policy provisions compared are Scope and Definitions, Effective Date, What Data Types are Expected to be Shared, Exceptions for Data Sharing, Data Management and Sharing Plan Submission and Review, Consent, Data Management and Sharing Plan Elements, Timeline for Sharing Data, Enforcement and Compliance, Ancillary Studies, Repository Specifications, and Interaction with Other NIH Data Sharing Policies.

Policy Provision	NIH Policy for Data Management and Sharing (2023) (NIH DMS Policy)	NHLBI Supplement to the NIH Policy for Data Management and Sharing (2023)	NHLBI Policy for Data Sharing from Clinical and Epidemiological Studies (2006)	Key Differences
<p>Scope and Definitions</p>	<p>All NIH-supported research generating scientific data.</p> <p><u>Scientific Data</u>: "The recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications."</p> <ul style="list-style-type: none"> - <u>Does not include</u> lab notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects. <p>Genomic data sharing considerations described in the <u>NIH Genomic Data Sharing Policy</u> are expected to be addressed in a single data sharing plan, the Data Management and Sharing (DMS) Plan required under the <u>NIH DMS Policy</u>. NIH is no longer collecting this information in a separate Genomic Data Sharing Plan.</p>	<p>Defers to the <u>NIH DMS Policy</u> Scope and Definitions in general but explicitly indicates scientific data include human and non-human data. This policy also sets additional NHLBI-specific expectations for compliance timelines, NIH-supported data repositories, and ancillary studies to NHLBI-funded parent studies.</p>	<p>Applies in general to studies meeting at least one of the following:</p> <ul style="list-style-type: none"> - Research applications/proposals requesting \$500,000 direct costs or more in any one year - Research studies that have 500 or more participants - Ancillary studies based on NHLBI-funded parent studies - Applications/proposals submitted in response to Funding Opportunity Announcements (FOAs) that specify the inclusion of data sharing plans - Other research studies deemed appropriate for data sharing by NHLBI Program Officials <p>Does not apply to research projects after they become subject to the <u>NIH DMS Policy</u>.</p> <p>All studies conducting genomic research, regardless of cost, should refer to the <u>NIH Genomic Data Sharing Policy</u> for additional requirements.</p>	<p>The <u>NIH DMS Policy</u> and <u>NHLBI Supplement to the NIH Policy for Data Management and Sharing</u> generally provide a broader scope for sharing all scientific data, human or non-human, generated by NIH-supported research. However, the <u>NHLBI Supplement to the NIH Policy for Data Management and Sharing</u> goes beyond the <u>NIH DMS Policy</u> to set expectations for NIH-funded ancillary studies and inform non-NIH-funded ancillary studies on data sharing agreement requirements between NHLBI-funded parent studies and their respective ancillary studies.</p> <p>The <u>NHLBI Policy for Data Sharing from Clinical and Epidemiological Studies</u> specifies monetary or participant thresholds that trigger the policy and leaves the discretion to FOAs and program staff. As a result, this policy has been mainly applied to a subset of research involving human participants.</p> <p>All three policies indicate that researchers conducting genomic research are subject to the expectations of the <u>NIH Genomic Data Sharing Policy</u>. Furthermore, the <u>NIH DMS Policy</u> has been harmonized with the <u>NIH Genomic Data Sharing Policy</u>; both <u>NIH DMS Policy</u> and the <u>NHLBI Supplement to the NIH Policy for Data Management and Sharing</u> provide additional guidance on complying with the harmonization guidance (see <u>NOT-OD-22-198</u>).</p>

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Effective Date	<p>The effective date of the NIH DMS Policy is January 25, 2023, including for:</p> <ul style="list-style-type: none"> - Competing grant applications that are submitted to NIH for the January 25, 2023 and subsequent receipt dates; - Proposals for contracts that are submitted to NIH on or after January 25, 2023; - NIH Intramural Research Projects conducted on or after January 25, 2023; and - Other funding agreements (e.g., Other Transactions) executed on or after January 25, 2023, unless otherwise stipulated by NIH 	<p>The effective date for the NHLBI Supplement to the NIH Policy for Data Management and Sharing is May 25, 2023, including for:</p> <ul style="list-style-type: none"> - Competing grant applications that are submitted for NHLBI funding or for ancillary studies to NHLBI parent studies on or after May 25, 2023 - Proposals for contracts that are submitted for NHLBI funding or for ancillary studies to NHLBI parent studies on or after May 25, 2023 - NIH Intramural Research Projects conducted on or after May 25, 2023 - Other funding agreements (e.g., Other Transactions) that are executed on or after May 25, 2023, unless otherwise stipulated by the NHLBI <p>However, the NHLBI may set the expectations for certain ongoing research that it supports to comply with the updated NHLBI Supplement to the NIH Policy for Data Management and Sharing. This will be done in advance of any renewal on or after May 25, 2023, as determined by specific programmatic needs, and will be communicated to individual awardees.</p>	<p>This Policy will remain in effect for NHLBI-funded clinical trials and epidemiological studies via applications submitted prior to January 25, 2023. Adopting the NIH DMS Policy and NHLBI Supplement to the NIH Policy for Data Management and Sharing after their respective effective dates is encouraged for awards not yet subject to the NIH DMS Policy and NHLBI Supplement to the NIH Policy for Data Management and Sharing.</p>	<p>The effective dates are January 25, 2023, for NIH DMS Policy and May 25, 2023, for the NHLBI Supplement to the NIH Policy for Data Management and Sharing. The NHLBI Policy for Data Sharing from Clinical and Epidemiological Studies may stay active for a limited time period on and after May 25, 2023, to provide guidance for applications and awards not yet subject to the NIH DMS Policy and NHLBI Supplement to the NIH Policy for Data Management and Sharing. After all NHLBI-supported research projects that generate scientific data are subject to the NIH DMS Policy, the NHLBI Policy for Data Sharing from Clinical and Epidemiological Studies will be retired and replaced by the NHLBI Supplement to the NIH Policy for Data Management and Sharing.</p> <p>The NHLBI Supplement to the NIH Policy for Data Management and Sharing goes beyond the NIH DMS Policy by setting expectations for early compliance of certain ongoing NHLBI-funded research.</p>
What Data Types are Expected to be Shared	<p>Scientific data, the recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether used to support scholarly publications, should be shared. This includes research resulting in null or negative findings.</p>	<p>Defers to the NIH DMS Policy on data expected to be shared.</p>	<p>This policy did not express expectations on what data types should be shared; however, this policy leaves room for specific requirements to be included in the FOA, Notice of Award (NOA), or contract.</p>	<p>The NIH DMS Policy and NHLBI Supplement to the NIH Policy for Data Management and Sharing set expectations on what data should be shared.</p> <p>The NHLBI Policy for Data Sharing from Clinical and Epidemiological Studies does not provide guidance on what data types should be shared.</p>

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Exceptions for Data Sharing	<p>NIH DMS Policy recognizes ethical, legal, or technical factors that may necessitate limiting sharing to some degree.</p>	<p>Defers to the NIH DMS Policy on limitations for data sharing.</p>	<p>Exceptions are considered to safeguard the rights of individuals and communities.</p>	<p>All three policies allow exceptions to sharing to be described in their data sharing plans.</p>
<p>Data Management and Sharing Plan Submission and Review</p>	<p>Researchers planning to generate scientific data are required to submit a DMS Plan to the funding NIH Institute, Center, or Office (ICO) as part of the Budget Justification section of the application for extramural awards, as part of the technical evaluation for contracts, as determined by the Intramural Research Program for Intramural Research Projects consistent with the objectives of this Policy, or prior to release of funds for other funding agreements.</p> <p>NIH peer reviewers will not be asked to comment on the DMS Plan or factor the DMS Plan into the funding application score unless data sharing is integral to the project design and specified in the FOA. Peer reviewers may comment on the reasonableness of the DMS budget, but these comments will not affect the project score.</p> <p>NIH program staff will review the DMS Plan for acceptability and may request modifications prior to award as appropriate.</p>	<p>Defers to the NIH DMS Policy on the Plan Submission and Review requirement.</p>	<p>For studies meeting at least one of the above-specified scope criteria, investigators are required to provide a data sharing plan, which will be reviewed and approved by the relevant NHLBI program officer.</p>	<p>While all policies expect that a data sharing plan be provided, the NIH DMS Policy and NHLBI Supplement to the NIH Policy for Data Management and Sharing provide more detailed and specific provisions on when and where the DMS Plan should be submitted and how the DMS Plan will be reviewed.</p>

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<p>Consent</p>	<p>“NIH strongly encourages researchers to plan for how data management and sharing will be addressed in the informed consent process, including communicating with prospective participants how their scientific data are expected to be used and shared.”</p> <p>Additional consent guidance is also provided in the Supplemental Information to the NIH Policy for Data Management and Sharing: Protecting Privacy When Sharing Human Research Participant Data, NOT-OD-22-213:</p> <p>“2. Clear communication of data sharing and use in consent forms. Researchers and institutions should develop robust consent processes that prioritize clarity regarding future sharing and use of scientific data, including limitations on future use, and general aspects regarding how data will be managed (see Informed Consent for Secondary Research with Data and Biospecimens: Points to Consider and Sample Language for Future Use and/or Sharing).[7] While informed consent is not itself a privacy protection, it does provide the opportunity to establish the conditions for sharing and using scientific data (including whether data can be shared openly or should be shared through controlled access). Scientific data that are collected, shared, or used without informed consent also deserve privacy considerations.”</p>	<p>Defers to the NIH DMS Policy on consent expectations.</p>	<p>“These data must only be made available under terms and conditions consistent with the informed consent provided by individual participants, and as approved by the awardees’ Institutional Review Board and any local, state and Federal laws and regulations.”</p>	<p>All policies expect that data be shared appropriately, given informed consent, IRB review, and laws and regulations.</p> <p>The NIH DMS Policy and NHLBI Supplement to the NIH Policy for Data Management and Sharing take a proactive approach to encourage investigators to plan ahead for how data management and sharing will be addressed in the informed consent process.</p>

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<p>Data Management and Sharing Plan Elements</p>	<p>NIH recommends addressing all the following elements for any NIH-funded or conducted research that will generate scientific data:</p> <ul style="list-style-type: none"> - Data type - Related tools, software, code - Standards - Data preservation, access, and associated timelines - Access, distribution, and reuse considerations - Oversight of data management <p><i>See further details in the supplemental document.</i></p> <p>The DMS Plan Elements should address the expectations described in the NIH Genomic Data Sharing Policy for genomic research projects.</p>	<p>Defers to the NIH DMS Policy on Plan elements. Additional elements to be included in the Plans submitted to the NHLBI may be specified in an NHLBI FAQ or supplemental information.</p>	<p>No Plan elements were specified; however, any changes to the data sharing plan must be discussed in advance with the relevant program officer.</p>	<p>The NIH DMS Policy and NHLBI Supplement to the NIH Policy for Data Management and Sharing, via the supplemental information and possibly FAQs, generally recommend a more structured Plan to be submitted to NIH compared to the NHLBI Policy for Data Sharing from Clinical and Epidemiological Studies. Applicants and awardees should look for additional guidance from NHLBI’s FAQs on any NHLBI-specific, recommended DMS Plan elements in addition to those described in the NIH DMS Policy supplemental information on recommended DMS Plan elements.</p>

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<p>Timeline for Sharing Data</p>	<p>WHEN TO SHARE: “Shared scientific data should be made accessible as soon as possible, and no later than the time of an associated publication, or the end of performance period, whichever comes first.”</p> <p>HOW LONG TO SHARE: “Researchers are encouraged to consider relevant requirements and expectations (e.g., repository policies, retention requirements, journal policies) for minimum time frames.”</p>	<p>Defers to the NIH DMS Policy on the timeline for sharing data.</p>	<p>Various approaches to sharing data are allowed, and timelines for data from clinical trials, observational epidemiology studies, and ancillary studies submitted to NHLBI-supported repositories are delineated:</p> <ul style="list-style-type: none"> - Clinical trial data sets must be submitted to the study NHLBI project officer no later than 3 years after the end of the clinical activity or 2 years after the main paper of the trial has been published, whichever comes first. - Observational epidemiology studies data from each cycle of an examination or follow-up component are to be submitted to the NHLBI project officer no later than 3 years after the completion of each examination or follow-up cycle or 2 years after the baseline, follow-up, genetic, ancillary study, or other data set is finalized for use in publication, whichever comes first. - Ancillary studies – if the timeline for an ancillary study differs from the timeline of its parent study, the release date of data will relate to the timeline of the ancillary study. Requirements will be outlined in the agreement between the parent and ancillary study. <p>While no timeline is explicitly specified for data shared through a non-NHLBI repository, this policy refers investigators conducting genomic research to the NIH Genomic Data Sharing Policy, which specifies the expectations of data sharing timelines for different types of genomic data deposited into any repositories.</p>	<p>All three policies specify data sharing timelines regardless of where the data will be made accessible. Additional NIH guidance on the NIH DMS Policy states, “In the event that another applicable policy has more detailed expectations than that of the DMS Policy, those expectations should be followed in addition to the DMS Policy.”</p>

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<p>Enforcement and Compliance</p>	<p>The DMS Plan will become a Term and Condition of the Award. The NIH ICO will determine compliance with the Plan. Failure to comply with the Terms and Conditions may result in an enforcement action and may affect future funding decisions.</p> <p>Compliance and enforcement of projects also subject to the NIH Genomic Data Sharing Policy will be carried out under the provisions of the NIH DMS Policy as described in NOT-OD-21-013 Section VIII and NOT-OD-22-198.</p>	<p>Defers generally to the NIH DMS Policy on enforcement and compliance.</p>	<p>For studies subject to this policy, investigators must submit a data sharing plan that is reviewed and approved by a relevant NHLBI program officer. Investigators must also address adherence to their plan in their annual progress report and discuss any changes to their data sharing plan in advance with the relevant program officer. Data sharing expectations may also be included in the FOA and therefore be a Term and Condition of the Award. Failure to comply with the Terms and Conditions may result in an enforcement action.</p>	<p>All policies are similar in language about enforcement and compliance. The NIH DMS Policy and NHLBI Supplement to the NIH Policy for Data Management and Sharing further specify that noncompliance could affect future funding decisions.</p>
<p>Ancillary Studies</p>	<p>The NIH DMS Policy did not include provisions/expectations on ancillary studies. An NIH FAQ on ancillary studies was published, providing additional guidance on ancillary studies' definitions and compliance expectations which provides additional guidance on definitions and compliance expectations for ancillary studies.</p>	<p>“Ancillary Studies – the NHLBI defines ancillary studies as studies that collect new data or derive data for purposes that are separate from the main “parent” study. Ancillary studies’ goal is to extend scientific knowledge beyond the parent study’s original scope. NHLBI ancillary studies are primarily supported by NIH funds but may also be funded, in part or whole, by other sources such as non-profit and private sector organizations. Studies approved as ancillary, regardless of funding sources, to an NHLBI-funded parent observational study or clinical trial (including studies co-funded by multiple institutes, centers, and offices or to which NHLBI provides administrative oversight) are required to adhere to the parent study’s data sharing policies as a condition of approval. The requirements of data sharing agreements between NHLBI-funded parents and their ancillary studies should be consistent with the principles of the NIH DMS Policy.”</p>	<p>“Ancillary Studies - In those cases in which the timeline for an ancillary study differs from that of its parent study, the release date of data will relate to the timeline of the ancillary study. Requirements will be outlined in the agreement between the parent and respective ancillary study. It is the responsibility of the ancillary study Principal Investigator to state in writing to the parent study Steering Committee any special circumstances that would preclude data sharing.”</p>	<p>The NHLBI Supplement to the NIH Policy for Data Management and Sharing is consistent with the NHLBI Policy for Data Sharing from Clinical and Epidemiological Studies, but the former spells out more specific expectations and provides a clear definition of Ancillary Studies from the NHLBI.</p> <p>The NHLBI Supplement to the NIH Policy for Data Management and Sharing goes beyond the NIH DMS Policy in defining ancillary studies, including any such studies to NHLBI-funded parent studies, regardless of funding source. As such, the NHLBI Supplement to the NIH Policy for Data Management and Sharing sets NHLBI-specific expectations for NIH-funded ancillary studies and informs non-NIH-funded ancillary studies on data sharing agreements between parent and ancillary studies. Additional expectations for data sharing agreements will be specified in an NHLBI SOP.</p>

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<p>Repository Specifications</p>	<p>Encourages the use of established repositories. NIH ICOs may designate a specific data repository or repositories and consider <u>desirable characteristics for all data repositories</u>:</p> <ul style="list-style-type: none"> - Unique persistent identifiers - Long-term sustainability - Metadata - Curation and quality assurance - Free and easy access - Broad and measured reuse - Clear use guidance - Security and integrity - Confidentiality - Common format - Provenance - Retention policy <p><u>Additional considerations for repositories storing human data</u>:</p> <ul style="list-style-type: none"> - Fidelity to consent - Restricted use compliant - Privacy - Plan for breach - Download control - Violations - Request review <p><i>Further details are provided in a supplemental <u>document</u>.</i></p>	<p>NHLBI-supported researchers are expected to share scientific data through existing NIH-supported data repositories, such as NHLBI BioData Catalyst® (BDC).</p> <p>Generally discourages but allows for the deposition of the same data in multiple repositories with justification in the DMS Plan.</p>	<p>Investigators should consider various approaches to sharing data, including examples provided on the NIH Scientific Data Sharing website. This policy recommends sharing NHLBI-funded data through an NHLBI data repository, including NHLBI BioData Catalyst® (BDC), Biologic Specimen and Data Repository Information Coordinating Center (BioLINCC), and National Sleep Research Resource (NSRR). The policy also refers investigators conducting genomic research to the NIH Genomic Data Sharing Policy, which lists frequently used repositories for such data.</p>	<p>The NIH DMS Policy does not specify a particular repository or repositories but rather provides supplementary information with characteristics to consider when choosing one.</p> <p>The NHLBI Supplement to the NIH Policy for Data Management and Sharing sets a strong expectation for any data generated with NHLBI support to be shared via NIH-supported data repositories, such as BDC. Data deposition to other repositories would need a strong justification and needs to be approved by the NHLBI.</p> <p>The NHLBI has an updated expectation for scientific data to be deposited in BDC – especially for data from studies that must comply with NHLBI’s Accrual of Human Subjects (Milestones) Policy and for those projects supported by funding opportunity announcements that encourage data deposition into BDC.</p>

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<p>Interaction with Other NIH Data Sharing Policies</p>	<p>Replaces the 2003 NIH Data Sharing Policy. The NIH DMS Policy sets the minimum policy requirements and expectations concerning data management and sharing across the NIH to which ICOs can add ICO-specific guidance/expectations.</p> <p>Harmonizes with the data sharing plan requirements of the NIH Genomic Data Sharing (GDS) Policy. After January 25, 2023, “Plans for sharing genomic data as expected by the GDS Policy are to be described in the DMS Plan submitted at the time of application, and not in a separate GDS Plan or at Just-in-Time.” (See Implementing Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023, NOT-OD-22-198.)</p>	<p>Replaces the NHLBI Policy for Sharing Data from Clinical and Epidemiological Studies. Aligns with and refers to the NIH DMS Policy in the scope, definitions, effective dates, requirements, compliance, etc., and sets additional NHLBI-specific expectations for compliance timelines, NIH-supported data repositories, and ancillary studies.</p>	<p>Will stay effective for research previously subject to the NHLBI Policy for Data Sharing from Clinical and Epidemiological Studies and not yet required to comply with the NIH DMS Policy and the NHLBI Supplement to the NIH Policy for Data Management and Sharing during the transition period after January 25, 2023, and May 25, 2023, respectively. After the transition period, the NHLBI Policy for Data Sharing from Clinical and Epidemiological Studies will phase out and be replaced by the NHLBI Supplement to the NIH Policy for Data Management and Sharing.</p>	<p>The NHLBI Supplement to the NIH Policy for Data Management and Sharing has the same policy requirements as the NIH DMS Policy but goes beyond the NIH DMS Policy to set additional expectations on compliance timelines, NIH-supported data repositories, and ancillary studies. The NHLBI Supplement to the NIH Policy for Data Management and Sharing also sets expectations for NIH-funded ancillary studies and informs non-NIH-funded ancillary studies to NHLBI-funded parent studies. Non-NIH-funded ancillary studies are not subject to any NIH policy, including the NIH DMS Policy.</p> <p>The NHLBI Supplement to the NIH Policy for Data Management and Sharing provides updated information and expectations on data deposition into NIH-supported data repositories and more specific guidance on ancillary studies, compared to the NHLBI Policy for Data Sharing from Clinical and Epidemiological Studies.</p>