SPIROMICS
SubPopulations and InteRmediate Outcome Measures In COPD Study

SOURCE
SPIROMICS Study of Early COPD Progression

NHLBI Supplement to the NIH Policy for Data Management and Sharing

Effective May 25, 2023 | Revised December 15, 2023

Frequently Asked Questions

General Information

Q. Where can I find information about NHLBI data sharing?

A. The NHLBI Supplement to the NIH Policy for Data Management and Sharing (effective May 25, 2023) is available on the NHLBI website. That webpage links to the Final NIH Policy for Data Management and Sharing (NIH DMS Policy), related policies, and additional resources.

Q. How do I prepare clinical Research Study Datasets for Submission to the NHLBI?

A. Visit the Instructions for Preparing Clinical Research Study Datasets for Submission to the NHLBI webpage for information about the preparation of datasets and associated documentation from NHLBI-funded clinical research studies for submission to NHLBI repositories, such as NHLBI BioData Catalyst® (BDC), including datasets to be submitted with corresponding biospecimen collections.

Related Resources

- NHLBI Supplement to the NIH Policy for Data Management and Sharing (effective May 25, 2023)
- Data Sharing Policy Comparison Table
- Instructions for Preparing Clinical Research Study Datasets for Submission to the NHLBI
- Instructions for Data Submission to BDC

Data Repositories

Q. How do I select a data repository?

A. NIH provides general guidance on selecting a data repository. NHLBI applicants should review their Notices of Funding Opportunities (NOFOs) carefully, as some may indicate data deposition into a specific repository. If NOFOs do not stipulate a specific repository, NHLBI strongly encourages depositing human data into NHLBI's BioData Catalyst (BDC).

For other data types, NHLBI encourages depositing scientific data in the most appropriate repository for the type of data generated. Existing domain-specific repositories (e.g., Gene Expression Omnibus (GEO), National Sleep Research Resource (NSRR), and other NIH-supported repositories) may be suitable choices.

If you are unsure which repository to select for your data, please contact your Program Official(s), Contracting Officer, Scientific Program Director, or Protocol Navigator for guidance.

Q. What is human data, and what repositories are recommended for sharing human data that need access controls?
A. Human data are derived from human research participants, which the NIH defines in the Definition of Human Subjects Research. If a dataset contains both human and non-human data, it is considered human data. NHLBI strongly encourages using BDC for human data that require controlled access. For more information on when access controls may be warranted, see Designating Data for Controlled Access.

Q. What if my data include identifiable data, such as patient names, addresses, dates of birth, etc.?
A. Please follow the NIH Principles and Best Practices for Protecting Participant Privacy. If more guidance is needed, please contact your Program Official(s), Contracting Officer, Scientific Program Director, or Protocol Navigator.

Q. Can I use a generalist repository?
A. If BDC or another repository is not required by the NOFO or the data are not associated with an NHLBI Strategic Biomedical Data Asset (e.g., longitudinal cohort studies), a generalist repository may be appropriate for data lacking a suitable domain-specific repository. Please consult NIH guidance on generalist repositories and the generalist repository comparison chart. If more guidance is needed, please contact your Program Official(s), Contracting Officer, Scientific Program Director, or Protocol Navigator.

Q. What is a globally unique and persistent identifier, and why should I use one?
A. A globally unique and persistent identifier must be globally unique, meaning it cannot be reused or reassigned without referring to your data, and persistent, meaning the link may not become invalid over time. Datasets are assigned a citable, unique persistent identifier, such as a digital object identifier (DOI) or accession number, to support data discovery, reporting, and research assessment. The identifier points to a persistent landing page that remains accessible even if the dataset is de-accessioned or no longer available.

Q. How do I obtain a globally unique and persistent identifier, such as a Digital Object Identifier (DOI), for my data?
A. NHLBI strongly encourages using a Digital Object Identifier (DOI), which has become a standard globally unique persistent identifier. Many data repositories already use a registry service to generate a DOI automatically. For example, BDC and FigShare generate a DOI through the DataCite registration agency. If your repository does not create a DOI for you, you can use a registration agency to create one (see this link for such agencies). If you wish to use a globally unique and persistent identifier other than a DOI, please provide strong justification for doing so in your Data Management and Sharing (DMS) Plan.

Q. What is the master index, and how can I share my globally unique persistent identifier within it?

A. The NHLBI has a master index that uses DOIs to create a comprehensive list of all data generated from NHLBI support, published or not, and where it resides. The intent is to enable findability, accessibility, interoperability, and reusability (FAIR) data-sharing principles. The DOIs generated as part of NHLBI requirements help support the population of this master index, which is a resource available to the research community to search and browse through NHLBI-supported datasets. Submitting data through BDC or NIH-supported generalist repositories will automatically add your DOI to the master index. If you submit data to a non-NIH repository, please contact your Program Official(s), Contracting Officer, Scientific Program Director, or Protocol Navigator to add your DOI to the master index manually.

Q. How do I prepare and submit data to BDC?

A. Visit the Instructions for Preparing Clinical Research Study Datasets for Submission to the NHLBI webpage for information about the preparation of datasets and associated documentation and visit the Instructions for Data Submission to BDC for information about the steps for submitting data and making it available through BDC.

Ancillary Studies

Definitions	
"Parent Study"	An NHLBI-funded parent study is a grant, contract, or other transaction (OT) award in which NHLBI is the sole or primary funder and the NIH Institute issuing the award.
"Ancillary Study"	A project that is funded by a grant, contract, OT, Industry, Foundation, or other award would be ancillary to an NHLBI-funded parent study if the investigator collects new information beyond what has been proposed under the parent study or derives new information from existing resources by leveraging data, biospecimens, images, interaction with participants, or other resources directly from the NHLBI administered parent study.

Q. What are the responsibilities of the NHLBI parent study in sharing data collected or derived from ancillary studies?

A. The parent study coordinating center or data management center will deposit ancillary study data into an approved NIH repository. This includes data from ancillary studies and data collected from parent study activities such as clinical/home/remote visits, follow-up contacts, adjudicated or derived outcomes, or assays directly funded under the main award. If an ancillary study award extends past the project period for the parent study AND the parent study does not receive renewal funding, then the ancillary study investigator will submit the data collected from the ancillary study directly to the repository the parent study was using.

The parent study will develop ancillary study and publications and presentations (P&P) policies that conform with the approved Data Management and Sharing Plan and clearly communicate to internal and external investigators the expectations for complying with NIH/NHLBI data sharing policies. These ancillary and P&P policies will define timelines for the submission by ancillary studies of scientific data and appropriate documentation to the parent study so the parent study can ensure their integration into its database for deposition into the approved repository according to its approved Data Management and Sharing Plan.

NHLBI-administered parent studies must comply with the data management and sharing policies and supplements effective when the funding application was submitted and the data management and sharing terms and conditions included in their awards unless directed otherwise by NHLBI.

- For parent studies with new or renewal applications submitted prior to January 25, 2023, refer to the NHLBI Policy for Data Sharing from Clinical Trials and Epidemiological Studies.
- For parent studies with new or renewal applications submitted between January 25, 2023, and May 24, 2023, refer to the NIH Data Management and Sharing Policy.
- For parent studies with new or renewal applications submitted on or after May 25, 2023, refer to the NHLBI Supplement to the NIH Policy for Data Management and Data Sharing.

Q. What are the responsibilities of the ancillary study investigator in sharing data derived from ancillary studies?
A. NHLBI expects ancillary studies to adhere to NIH and NHLBI data-sharing policies regardless of funding source, as outlined in the agreement between the parent and ancillary study. Any limitation on sharing must be communicated to the parent study and strongly justified (for example, Tribal sovereignty, consent restrictions). Ancillary studies funded through an NIH application submitted on or after January 25, 2023, are subject to the NIH DMS Policy and require a Data Management and Sharing (DMS) Plan. DMS plans will be reviewed by the NIH. Ancillary study DMS Plans must clearly reference the relevant parent study approved repository and parent study policies, as well as the ancillary study investigator's planned adherence to those policies. Changes to an NIH DMS Plan for an ancillary study must be discussed with the parent study before NIH submission and approval.

Ancillary studies that are subject to the NIH DMS Policy prior to the parent study are not expected to share scientific data if it would conflict with the sharing policies or plans of the parent study or agreements entered into with the parent study, as noted in the ancillary study FAQ for the NIH DMS Policy.

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Data Freeze Approach

Definitions	
"Data freeze"	A "data freeze" is defined here as a comprehensive database of all "locked datasets" that have been received or prepared by a study's data management group prior to any associated publications being published. A "data freeze" encompasses data newly generated or updated since the previous repository submission.
"Locked datasets"	A "locked dataset" is defined as individual datasets (e.g., specific biomarker assay) or a group of related datasets (e.g., clinical event follow-up files, data files associated with a clinical exam) that have been prepared and are suitable for publication purposes.
High publication volume studies	Studies with an average of 25 or more publications per year

Q. For NHLBI-funded clinical studies, is there an alternative to per-publication sharing for complying with the expectations and requirements of the NIH Data Management and Sharing Policy?

A. To maximize the value of data sharing with the biomedical research community and control study and repository costs, NHLBI allows Institute supported studies to use a comprehensive data freeze approach to meet NIH Data Management and Sharing policy requirements. This approach requires sharing comprehensive data freezes of scientific data throughout the funded project periods in advance of publications rather than sharing small subsets of extensive data on a per-publication basis.

Q. What are the specific elements of the comprehensive data freeze approach?

A. The specific elements of the comprehensive data freeze approach include the following:

- Throughout the study's project period, the comprehensive data freezes will incorporate existing datasets (as necessary) and any newly collected or updated versions of datasets that have been locked and made available to study investigators for within-study analyses.
- Data being submitted must be complete and include all scientific data, for example, participant examination data, annual or biannual participant follow-up contact, adjudicated events of clinical significance and vital status, and ancillary study data finalized for analysis whether derived from existing biospecimens, images, data, or from participant contact.

- A final, updated comprehensive data freeze will be submitted at or before the end of the project period.
- To meet the reproducibility goals of the NIH Data Management and Sharing Policy, a library of meta-data from study- and collaborator-initiated, peer-reviewed scientific publications will be maintained on the study's public website and transferred to the approved repository at or before the end of the project period.

Q. When should clinical studies using the comprehensive data freeze approach share their data freezes externally and internally?
A. The comprehensive data freeze should be submitted to the repository identified in the study's approved Data Management and Sharing Plan before any associated publications are published. Consideration should be given to factors such as the timeline for closure of annual follow-up, surveillance for clinical events, and/or typical exam closure dates.

Q. What studies are eligible to propose the comprehensive data freeze approach to fulfill data sharing requirements?
A. NHLBI anticipates research investigative teams to follow the NIH Data Management and Sharing Policy, the NHLBI Supplement to the NIH Policy for Data Management and Sharing, and all other applicable policies and guidance, including requirements on the timing for sharing data.

The NHLBI is making the comprehensive data freeze approach available to all NHLBI funded studies that have approved Data Sharing and Management Plans specifying comprehensive data freezes. The comprehensive data freeze approach is encouraged for studies anticipating high publication volume.

Q. How should principal investigators of eligible studies propose using the comprehensive data freeze approach to fulfill their data-sharing requirements?
A. Principal investigators of eligible studies who wish to propose using the comprehensive data freeze approach to fulfill their data-sharing requirements should include it in their Data Management and Sharing Plans.

Principal investigators are strongly encouraged to seek guidance from their NHLBI Program Official/Contracting Officer's Representative in advance of submitting funding applications and new or revised Data Management and Sharing Plans.

Q. Is the comprehensive data freeze approach optional or required for ancillary study data collected from parent studies using the comprehensive data freeze approach?
A. Unless superseded by terms and conditions specified in contracts, Other Transactions (OT), or NIH notices of funding opportunities (NOFOs), ancillary study investigators should follow the data-sharing policies as determined by their parent studies. Therefore, if a parent study uses the comprehensive data freeze approach, so should its ancillary studies.

Parent Studies: NHLBI expects parent study policies to abide by applicable aspects of the NIH Data Management and Sharing Policy, the NHLBI Supplement to the NIH Policy for Data Management and Sharing, and the NHLBI Comprehensive Data Freeze Approach.

Ancillary Studies: Principal investigators of solicited or unsolicited NIH grants ancillary to parent studies must submit Data Management and Sharing plans consistent with the parent study.

For the purpose of inclusion in each data freeze submission, principal investigators with studies ancillary to parent studies that are using the comprehensive data freeze approach are required to submit finalized data to the respective coordinating centers or the applicable data management groups once locked for analysis.

Each ancillary study Data Management and Sharing Plan must include a provision to submit the scientific data it generates directly to the repository approved for the parent study. This is required because the ancillary study principal investigators will be responsible for submitting data to the repository approved for the parent study in the event the coordinating center or data management group for the parent study is no longer funded and cannot submit the ancillary study data.

Refer to the NIH Data Management and Sharing Policy, NHLBI Supplement to the NIH Policy for Data Management and Sharing, and the NHLBI Ancillary Studies FAQ for more information.