NIDDK Supplement to the 2023 NIH Policy for Data Management and Sharing

Introduction

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) supports and conducts research on some of the most common, chronic, costly, and consequential diseases, along with research on diseases and disorders that are less widespread but nonetheless devastating in their impacts. The NIDDK disseminates knowledge gained from its research to healthcare providers, people affected by disease and their families, and the public. Resources generated by these studies (study, network, consortia) constitute an important scientific resource, and the full value of these resources can only be realized if they are made available promptly for use by other researchers. Data sharing for the purpose of secondary research is a fundamental component of and essential to the fulfillment of NIDDK mission to engender public trust and seek maximal benefit from the resources collected from studies in which NIDDK, investigators, and participants have invested considerable effort.

In January 2023, National Institutes of Health (NIH) implemented the NIH Policy for Data Management and Sharing (NIH DMS Policy) to promote the management and sharing of scientific data generated from NIH-funded or conducted research.

This NIDDK Supplement harmonizes with the NIH DMS Policy and other NIH Scientific Data Sharing policies and clarifies expectations for NIDDK-funded studies subject to the NIH policies, including consortia and ancillary studies. NIDDK-specific guidance to assist investigators implementing the NIH DMS Policy can be found at NIDDK DMS Guidance.

NIDDK Supplement to the NIH DMS Policy affirms the expectation that scientific data generated from NIDDK-funded studies will be shared publicly per NIH and NIDDK policies via an NIDDK-approved repository or other NIDDK-approved public source.

NIDDK Central Repository (NIDDK-CR) was established in 2003 as a centralized research resource supporting the receipt, storage, and distribution of data and specimens from select NIDDK-funded multi-center clinical studies or studies within the NIDDK mission areas. Projects that are eligible and are required or intend to submit data or specimens to NIDDK-CR must also comply with the NIDDK-CR Resource Archival and Sharing Policy (NOT-DK-24-003).

Applicability

This NIDDK Supplement is applicable to NIDDK-funded institutions and investigators, ancillary studies to NIDDK-funded parent studies, and NIDDK program staff and intramural investigators.

Policy

The effective date of the NIH DMS Policy is January 25, 2023.

In accordance with the NIH DMS Policy the NIDDK-approved Data Management and Sharing Plan (DMS Plan) will become a term and condition of award and be routinely monitored during the award period. Compliance with the DMS Plan, as well as NIH and NIDDK policies, may factor into future funding decisions. When NIH or NIDDK data sharing policies expect sharing of data, an NIDDK-funded investigator or study may not continue to exclusively use or share study generated data until those data (and associated specimens when applicable) are available to the public via an NIDDK-approved repository or other NIDDK-approved public source per the NIDDK-approved DMS Plan. These data (and associated specimens when applicable) must be available to the wider scientific community in accordance with NIH Scientific Data Sharing policies and this NIDDK Supplement per the NIDDK-approved DMS Plan.

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NIDDK-funded investigators and studies are expected to share scientific data through existing NIH-supported Scientific Data Repositories or domain-specific or generalist repositories that have characteristics consistent with those described in the Supplemental Information to the NIH Policy for Data Management and Sharing: Selecting a Repository for Data Resulting from NIH-Supported Research or other NIDDK-approved public source.

Specific Expectations:

Ancillary Studies: NIDDK defines ancillary studies as studies that use data, specimens, or other resources generated by an actively funded parent study, collect new data, or derive data for purposes that are separate from or beyond the original scope of the parent study. Ancillary studies may be funded by other sources via third-party collaborations (including interactions with organizations from industry, academia, and nonprofit institutions). Studies approved as ancillary to an NIDDK-funded parent study (including studies co-funded by multiple NIH institutes, centers, or offices or to which NIDDK provides administrative oversight) are required to comply with NIH, NIDDK, and the parent study's sharing policies as a condition of approval. The requirements of data sharing agreements between an NIDDK-funded parent study and ancillary study should be consistent with the principles of NIH DMS Policy, other applicable NIH Scientific Data Sharing policies, and this NIDDK Supplement. Ancillary studies should be governed by a research collaboration agreement (e.g., Clinical Trial Agreement, Clinical Study Agreement, etc.) or any third-party contract mechanism(s) between study investigator and the investigator's institution and a third-party with terms and conditions that ensure that the collaboration is conducted in accordance with the applicable NIH and NIDDK policies and procedures, and study governance policies.

Specimens: NIDDK defines specimens as both biological and non-biological materials. Projects that are subject to the NIH DMS Policy and will be submitting data or other resources to the NIDDK-CR (e.g., select multi-center clinical studies) should also plan to share associated specimens using the same timelines as in the DMS Plan, consistent with this NIDDK Supplement and the NIDDK-CR Resource Archival and Sharing Policy. Any additional expectations regarding specimens will be specified in a Notice of Funding Opportunity or Notice of Award.

NIDDK-funded cooperative agreements or consortia: Any third-party agreements related to NIDDK-funded studies between study investigator and the investigator's institution and a third-party will be provided to the NIDDK program staff and NIDDK Technology Advancement Office for review, comment, and approval to assure compliance with NIH and NIDDK policies and procedures, and study governance policies. Further, at the request of the NIDDK program staff, any other applicable study-relevant third-party agreements must be shared with NIDDK. Failure to comply with this NIDDK Supplement may be considered as noncompliance and will be considered by NIDDK for future funding and support decisions and may result in termination of the award.

NIDDK-funded clinical cooperative agreements or consortia: NIDDK-CR supports the receipt, storage, and distribution of data, specimens, and other resources generated by select multi-center clinical studies funded by the NIH and NIDDK. Studies that are eligible and are required or intend to submit resources to NIDDK-CR must adhere to NIDDK Central Repository Resource Archival and Sharing Policy. Per NIDDK-CR policy the investigator or designee must develop and submit a written, protocol level, Resource Archival and Sharing Request proposal to NIDDK-CR for approval before enrollment of the first study participant for resources that will be held under the guardianship of NIDDK-CR and custodianship of NIDDK. These resources will be available to the wider scientific community in accordance with the NIDDK Central Repository Resource Archival and Sharing Policy and the NIH DMS Policy per the NIDDK-approved DMS Plan.