National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Central Repository

Resource Archival and Sharing Policy

Executive Summary

Program and Policy

- The program was established as a centralized resource to support the receipt, storage, and distribution of data and biospecimens generated by current and previous clinical studies within the NIDDK mission areas.
- The policy defines relevant aspects of the program operations, resource management, user terms of engagement, and governance structure.
- The policy aligns with National Institutes of Health (NIH) Data Management and Sharing (DMS) Policy and NIDDK DMS Guidance.

Submitting Resources

- NIDDK-funded or other clinical studies with significant programmatic involvement relevant to the NIDDK research areas and of considerable scientific value to the broader community may be eligible to submit study-generated resources to NIDDK Central Repository (NIDDK-CR).
- What to submit
    - A written protocol-level Resource Archival and Sharing request before participants are enrolled.
    - Resources include raw data, analytic datasets, metadata, digital images, computational data sets, and accompanying documentation and codebooks, as well as a representative archival set of biospecimens.
- When to submit
    - Time of publication.
    - End of study (submit resources within 12 months of the end of study).
    - End of period of performance (submit resources no later than 3 months prior).
- When to share
    - Time of publication (no embargo period).
    - End of study (within 12 months following submission of resources).
    - End of period of performance.

Resource Privacy

- Resources must be properly consented for future secondary use.
- Resources must be free of direct personal identifiers.
- Resources must include sufficient metadata to allow proper management and distribution.

Requesting Resources

- NIDDK-CR has decision authority for the distribution of resources under the custodianship of NIDDK.
- Resources are available for request to qualified investigators independent of their institutional affiliation or geographical location, only limited by informed consent or applicable NIH or U.S. Government policy use restrictions.
- Access is granted based on scientific merit, feasibility, and appropriateness.
- Requestors must seek approval and execute a Data and Resources Use Agreement.
- Requestors must share results and any new materials generated via NIDDK-CR or an NIDDK-approved public repository.

Table of Contents

1. INTRODUCTION

Overview of NIDDK Central Repository

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Central Repository (NIDDK-CR) was established in 2003 as a centralized research resource supporting the receipt, storage, and distribution of data and biospecimens from current and previously funded NIDDK multi-center clinical studies (or studies within the NIDDK mission areas).

NIDDK-CR 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 multi-center and large single-center clinical studies in which NIDDK, study investigators, and participants have invested considerable efforts. Data and biospecimens from these well-characterized studies 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.

The mission of NIDDK-CR, aligned with NIDDK mission, is to facilitate the sharing of resources for secondary uses and encourage work by junior and established investigators, investigators with novel approaches, and others not included in current collaborations to test new hypotheses without the need to collect new data or biospecimens. These secondary research uses help to maximize research participants' contributions and decrease duplicative sampling efforts, increasing the scientific value and impact of the originating study.

NIDDK-CR Resource Archival and Sharing Policy defines relevant aspects of the program operations, resource management, user terms of engagement, and governance structure. NIDDK-CR policy does not supersede the legal requirements to submit composite results to clinicaltrials.gov per the Final Rule for Clinical Trials Registration and Results Information Submission.

In January 2023, National Institutes of Health (NIH) implemented a Data Management and Sharing (DMS) Policy to promote the management and sharing of scientific data generated from NIH-funded or conducted research. NIDDK-CR policy harmonizes with NIH DMS Policy, and other NIH Scientific Data Sharing policies, and NIDDK DMS Guidance. Failure to comply and abide by the NIH DMS Policy or NIDDK-CR policy may impact future NIDDK funding decisions or the use of NIDDK-CR held resources.

Purpose of the Policy

NIDDK-CR balances the interests of study investigators with those of the larger scientific research community by accepting and distributing resources in an ethical and equitable manner. All resources transferred to and shared via NIDDK-CR are held under the guardianship of the NIDDK-CR and custodianship of NIDDK for a set portion of the resource lifecycle as specified in section 2.4.1 Distribution Authority, with an established preservation strategy.

Applicability of the Policy

NIDDK-CR policy applies to all resources held under the guardianship of the repository and all users (direct and indirect) of NIDDK-CR program and its Resources for Research (R4R) website platform(s), including projects that submit resources to NIDDK-CR and secondary research directly resulting from the use of NIDDK-CR resources.

Expectations of the Policy

All users, including submitters and requestors, are expected to comply and abide by NIH, NIDDK, and NIDDK-CR policies, practices, and procedures. Projects planning to submit resources to NIDDK-CR are expected to comply with NIH DMS Policy and NIDDK DMS Guidance for public sharing of scientific data. Individuals interested in accessing resources held under the guardianship of NIDDK-CR are expected to abide by the terms and conditions of the Data and Resources Use Agreement (DUA) and any use limitations set forth by the study participants' informed consent. All NIDDK-CR R4R users must abide by the User Code of Conduct.

Additional information about NIDDK-CR expectations, submission and access request guidelines, and preservation practices can be found on the NIDDK-CR website.

2. RESOURCE ARCHIVAL AND SHARING

2.1 Repository Usage

2.1.1 Support for NIDDK-Funded Studies

NIDDK-CR supports the storage and sharing of study-generated resources from active and completed NIDDK-funded clinical studies with significant programmatic involvement and other NIDDK-funded or supported clinical studies deemed to be of considerable scientific value to the broader scientific community, including ancillary clinical studies and secondary research directly resulting from the use of NIDDK-CR held resources. NIDDK-CR reserves the right to decline to accept resources deemed not representative of the enrolled population, lack appropriate consent to facilitate future reuse, or not of scientific value to the broader research community. Acceptability determinations are made in collaboration with NIDDK Program Directors and, when necessary, Division Directors.

2.1.2 Support for non-NIDDK Funded Studies

NIDDK-CR will, under certain circumstances, provide support to non-NIDDK funded multi-center clinical studies that are highly relevant to NIDDK's mission, benefit the broader scientific community, have appropriate informed consent language, and are feasible to transfer. Non-NIDDK-funded studies meeting these general criteria may request to share biospecimens and associated clinical data or data only via NIDDK-CR. Submission of these resources may be authorized based on the overall scientific value of the collection, likelihood of future use, and availability of funds to support the transfer of the study-generated resources.

2.1.3 Biomedical Repositories Services and Support

NIDDK-CR does not accept resources intended for exclusive use by the study group. NIDDK-CR strongly encourages using centralized outside facilities to store collected biospecimens during the active phase of a study and to transfer a representative archival set to NIDDK-CR (along with biospecimen-specific data attributes and metadata) at regular intervals. NIDDK-CR may exercise discretion and provide additional services or support to a given study when it deems necessary or in the best interest of NIDDK.

2.2 Resource Submission and Sharing

2.2.1 Resource Archival and Sharing Request

Projects that intend or are required to submit resources to NIDDK-CR must submit a written, protocol level, Resource Archival and Sharing Request to NIDDK-CR for approval before enrollment of the first study participant. The written Request to onboard a protocol must align with NIH DMS Policy and NIDDK DMS Guidance and include timelines for submitting and publicly sharing data and biospecimens per NIDDK-CR submission and sharing schedules and must: (a) describe resources proposed for submission, (b) clearly define terms of use in accordance with participant's informed consent, and (c) provide a justification for the proposed resource archival submission and sharing schedule. NIDDK-CR expects resources to be submitted and shared regardless of whether a publication is produced and that the biospecimens archival set be made available when associated data are shared per pre-approved Resource Archival and Sharing Request. Participant-level resources are expected, unless reasonable justification is provided and approved by NIDDK. NIDDK-CR must approve protocol-level requests before studies are permitted to submit resources for archival and sharing. No resources may be submitted without prior NIDDK-CR approval. The Resource Archival and Sharing Request does not supersede the requirement to submit and update the NIH DMS plan as needed and when appropriate.

2.2.2 Resource Submission Schedules

Study-generated resources must be submitted to NIDDK-CR for curation in accordance with pre-approved Resource Archival and Sharing requests and according to the submission and sharing schedules outlined below by the primary party responsible for managing and submitting the resources or their designee.

2.2.2.1 Submission at the time of publication

Study data analyzed for publications (raw data and analytic datasets) must be submitted to NIDDK-CR when the manuscript is accepted for publication or at the time of publication. Relevant documentation and codebooks must be submitted along with the data following NIDDK-CR submission guidelines.

2.2.2.2 Submission at the end of the study

Study protocols that end during the period of performance must submit resources to NIDDK-CR as soon as possible and no later than twelve (12) months following the end of the study (when study investigators are no longer obtaining data directly from study participants or the conclusion of any follow-up monitoring and data collection provided in the protocol).

2.2.2.3 Submission at the end of the period of performance

Study protocols that continue across multiple periods of performance before primary results are known must submit representative snapshots (point-in-time copy) of the resources prior to the end of each period of performance. All resources must be submitted no later than three (3) months before the end of each period of performance.

All studies must submit a complete and clean copy of all study data (including, but not limited to: raw data, analytic datasets, metadata, digital images, and computational data sets) and accompanying documentation and codebooks, as well as a representative archival set of biospecimens.

2.2.3 Resource Sharing Schedules

Resources submitted to NIDDK-CR will be made publicly available per the approved Resource and Archival Sharing Request and sharing timelines detailed below. NIDDK-CR recommends a staged resource-sharing approach for studies that continue for many years before the primary results are known, and encourages studies to share data and biospecimens via NIDDK-CR or other NIDDK-approved repository(ies) per NIH/NIDDK guidelines. To that end, NIDDK-CR sharing timelines are as follows:

2.2.3.1 Sharing at the time of publication

Study data analyzed for publications must be shared with the broader scientific community at the time of publication. There is no embargo period for data associated with a publication.

2.2.3.2 Sharing at the end of the study or period of performance

NIDDK-CR requires a complete set of resources (data and biospecimens, including corresponding supporting materials) to be shared with the external research community as soon as feasible following the submission of resources to NIDDK-CR or per sharing timeframes specified in the approved Resource and Archival Sharing Request. At the discretion of study leadership, resources may be shared earlier, but no later than the end of the period of performance.

NIDDK-CR respects embargo periods defined in the approved Resource and Archival Sharing requests. By the end of the funding or embargo period, a study group may not continue to exclusively use or share study-generated resources until those resources are available to the public via NIDDK-CR or an NIDDK-approved repository. Limited exemptions to sharing schedules may be identified by study leadership and authorized in consultation with NIDDK and NIDDK-CR and with the approval of NIDDK's Deputy Director.

2.3 Resource Privacy

2.3.1 Protection of Participant's Privacy

Resources must be submitted free of direct personal identifiers so that the identities of study participants cannot be readily ascertained. Resources must be accompanied by sufficient metadata and linkages to allow appropriate management and distribution of the resources long-term, and NIDDK-CR will share resources in a de-identified manner. To further protect study participants' privacy, NIDDK-CR recommends the use of global unique identifiers. NIDDK-CR supports the generation and assignment of global unique identifiers.

2.3.2 Consent for Secondary Research

Studies contributing resources to NIDDK-CR must include appropriate language in the informed consent documents to allow for future secondary use through NIDDK-CR, and study participants must explicitly consent to sharing resources for secondary research. NIDDK-CR encourages broad informed consent with minimal restrictions and limitations, if any, for future use in accordance with any federal, state, tribal, and local laws or regulations.

NIDDK-CR strongly encourages using standardized data use limitations and consent clauses ontologies in the informed consent language that ensures study participants have a clear understanding of how study-generated resources will be used during the active phase of the study and how these may be shared and re-used in future secondary research. Before resources are submitted, NIDDK-CR must confirm that informed consent language permits the storage and sharing of resources via NIDDK-CR without any intellectual property or other restrictions for the purpose of future research by secondary investigators. Contributing studies should provide NIDDK-CR with a clear statement identifying all restrictions or limitations on the use or sharing of the resources specified in the study participants' informed consent documents.

2.4 Resource Access

2.4.1 Distribution Authority

NIDDK-CR assumes responsibility and has final decision authority for the distribution of resources under the custodianship of NIDDK for a set portion of the resource lifecycle, from acquisition of resources and ending after the first generation of new materials, where any and all new materials generated from the use of NIDDK-CR resources are required to be made publicly available. Resources distributed through NIDDK-CR are considered pre-competitive and should remain freely available without any licensing requirement. All NIDDK-CR held resources, renewable and non-renewable, are available for request to qualified investigators independent of their institutional affiliation or geographical location, only limited by informed consent or applicable NIH or U.S. Government policy use restrictions.

2.4.2 Request for Access

Access to NIDDK-CR-held resources is granted based on scientific merit, feasibility, and appropriateness. All requestors must seek approval to gain access to resources from NIDDK-CR through the R4R platform and execute an NIDDK-CR DUA. NIDDK may require the requestor to submit resulting analyses and any new data or materials generated to NIDDK-CR or another NIDDK-approved repository to be shared publicly.

2.4.2.1 Renewable resource request

Access to renewable resources, including data and biospecimens, may be granted via an internal review process if the request is considered to have a reasonable likelihood of achieving the proposed research aims.

2.4.2.2 Non-renewable resource request

Access to non-renewable resources may be granted via two pathways. Requests for highly abundant-modestly depleting, non-renewable resources may be granted access via an internal review process if the request is considered to have a reasonable likelihood of achieving the proposed research aims. Requests for more than modestly depleting non-renewable resources require a full grant-like application (NIH or non-NIH) and independent scientific merit review.

3. REPOSITORY ORGANIZATION, MANAGEMENT and GOVERNANCE

3.1 Resource Preservation and Sustainability

3.1.1 Preservation

NIDDK-CR is committed to ensuring long-term preservation and access to resources under the custodianship of NIDDK. Resources submitted to NIDDK-CR will be preserved for use by the broader scientific and research

community until these are used up or to the end of their scientific utility. NIDDK-CR will periodically assess the ongoing scientific utility of held resources. NIDDK-CR will routinely review resource utilization rates to assess the value of data and biospecimen resources and options for resource management or deaccessioning per established practices.

3.1.2 Sustainability

NIDDK-CR is an NIH/NIDDK sustained repository and funding decisions are based on annual U.S. Government appropriations. In the event that scientific priorities change or funding is discontinued, under the written direction of NIDDK, resources will be temporarily transitioned to ensure continued public availability and accessibility via alternative mechanisms or their permanent archival. NIDDK is responsible for all decisions on the sustainability of NIDDK-CR and the long-term preservation of the held resources. NIDDK's responsibility does not expire even in the event of funding discontinuation.

3.2 Costs Associated with Submitting and Accessing Resources

3.2.1 Submitting Resources

Submitters are responsible for the costs of collecting and preparing resources to be deposited into NIDDK-CR. NIDDK-CR will cover the costs of shipping resources to NIDDK-CR and the storage and redistribution of resources.

3.2.2 Accessing Resources

NIDDK-CR makes resources available for request by the research community at no or modest costs to the requestor under a cost-recovery model that recovers only the costs of preparing resources for the request.

3.2.3 Other Services and Support

Additional services or support under a fee-for-service structure may be requested with a reasonable justification and must be approved by NIDDK-CR before services are rendered.

3.3 Governance and Oversight

NIDDK-CR is under the direct oversight of NIDDK Office of the Director within the Office of Clinical Research Support (OCRS) and under the direct supervision of NIDDK Deputy Director. Ongoing operations management and stewardship of NIDDK-CR resource utilization, sharing, and archival policies, practices, and procedures are the responsibility of the NIDDK-CR Program Director and the NIDDK-CR Executive Committee.

The Executive Committee is composed of members of NIDDK extramural divisions who serve on a rotating basis for set intervals and are responsible for establishing best practices, promotion of resource utilization, and ensuring that NIDDK-CR is aligned with NIDDK's mission goals. NIDDK Repository Program Directors (RPD) Committee and designated NIDDK Program staff are responsible for the review of resource access requests.

4. REFERENCES AND ADDITIONAL RESOURCES

- Details about the final NIH Data Management and Sharing Policy described in NOT-OD-21-013
- Details about NIDDK Data Management and Sharing Guidance located at https://www.niddk.nih.gov/research-funding/research-resources/data-management-sharing
- See NIDDK Central Repository Data Preservation and Access Practices for information on data submission and access requirements.
- NIDDK Central Repository User Code of Conduct
- NIDDK Central Repository Data and Resources Use Agreement (DUA)
- See considerations for Informed Consent for Secondary Research with Data and Biospecimens from the Office of Science Policy (OSP) and the Office of Extramural Research (OER).
- See supplemental information to the NIH DMS Policy on responsible management and sharing of American Indian and Alaskan Native Participants' data in NOT-OD-22-214