

**NIDDK Central Repository
Sample and Data Use Agreement**
Contact: NIDDK-CRsupport@niddk.nih.gov

Requestor: _____

E-mail Address: _____

Requesting Institution: _____

Requested Samples, including amounts: _____

Requested Data: _____

If Requestor is funded by NIH for this Research Project, the grant number is: _____

If Research Project is associated with X01 access mechanism, the number is: _____

Introduction

The National Institute of Diabetes and Digestive and Kidney Disease (NIDDK) has supported collection of samples and data from participants in numerous studies. The samples and data are held by the NIDDK Central Repository (hereinafter referred to as the "Repository"). In order to maximize the benefits of these resources collected with public funds and maximize their research value, it is important that these resources be made available, with appropriate terms and conditions, to the largest possible number of qualified investigators in a timely manner.

Transfer of resources to and from the Repository is governed by the NIH and NIDDK sharing policies.

The Repository does not receive personally identifiable information or codes linking such information to Samples or Data.

In the event that investigators from more than one institution will be collaborating on a project using the Samples or Data transferred under this Agreement, an investigator from each institution is required to complete a separate Sample and Data Use Agreement (SDUA).

It is the intent of the NIDDK that Requestors of Repository held resources recognize the limitations imposed by the original informed consent agreements of contributing studies.

NIDDK has established policies and processes to make these Repository held resources available through appropriate terms and conditions to qualified requestors. The Repository requires the Requestor to read, understand, and sign this SDUA and their institution to acknowledge and agree to abide by the terms and conditions of this SDUA as a condition of access. A Requester who is granted access to Samples and Data must adhere to the specifications of this SDUA as executed in its final form. Failure to do so shall result in denial of further access by the Requestor's Institution to resources available through the Repository.

Terms of Access

1. Definitions:

Contributing Study Investigators: Research investigators who provided the phenotypic data and samples to the Repository.

Materials: Include but are not limited to data, biospecimens, products, analytes, metadata, documentation, code, analytic tools, algorithms, workflows, results, summaries, or analyses provided by the NIDDK or generated by the Research Project.

Requestor: Research investigator(s) who submitted a request for access to Repository held resources, have been approved by the appropriate NIH oversight committee, and have a fully-executed agreement for the requested resources.

Requesting Institution: An institution, organization, or corporation who is the employer of the Requestor. The Requesting Institution assumes responsibility for the Requestor's compliance with the terms and conditions of this agreement, and is responsible for complying with all applicable federal, state, and local laws and regulations for research participant protections.

Repository Samples and Data (referred to as "Samples and Data"): The relevant samples and data from a specific project(s). Access to these resources may be available from repositories other than the Repository (for example, dbGaP).

Research Project: A summary of the proposed research that includes the project title, the Requestor's name and Requesting Institution's name, the names of any Requestor's collaborators and their institutions, a one to two paragraph Research Use Statement, a description of the research objectives and design, and an analysis plan. (Appendix A)

Research Use Statement: Statement of proposed research to be conducted which may be made publicly available. The Research Use Statement is submitted by the Requestor as a part of the Research Project request for access to samples and data.

Study Participant: An individual who participated in the clinical research protocol, as either a healthy human or a patient in a specific area of study.

2. Research Project: Use of Samples and Data

- a) Requestor and Requesting Institution agree that Repository Samples and Data shall be used only for research purposes by the Requestor in his/her laboratory under suitable conditions, as outlined in Article 5 for the research described with specificity in the Research Project attached as Appendix A. The Samples and Data shall not be used in any research that is not disclosed and approved as part of the Research Project. The Requestor and Requesting Institution agree to retain control over the Samples and Data and further agree not to transfer the Samples and Data to any third parties not under the direct supervision of the Requestor.
- b) New uses of the Samples or Data outside those described in the current Research Project require submission of a new SDUA request. Modification to an approved Research Project requires submission to the appropriate NIH oversight committee of an amendment to the

Research Project. Appointment of another or different Requestor requires completion of an approved new Research Project and requires submission of a request to amend this SDUA.

- c) The Requestor and Requesting Institution acknowledge that other researchers have access to Repository resources, and that duplication of research is a distinct possibility.
- d) The Requestor and Requesting Institution further acknowledge that Samples have the potential for carrying viruses, latent viral genomes, and other infectious agents in a dormant state. The Requestor and Requesting Institution agree to treat the Samples under laboratory conditions that afford adequate biohazard containment. By accepting Samples, the Requestor and Requesting Institution assume full responsibility for their safe and appropriate handling. **The Requestor and Requesting Institution agree that the Samples will not be used in Humans.**
- e) The Requestor and Requesting Institution further acknowledge that they are responsible for ensuring that all their uses of the Samples and Data are consistent with federal (including 45 CFR Part 46), state, and local laws and any applicable institutional policies and that limitations in the informed consents delineated by the Repository will be complied with.
- f) When the Research Project is completed, the unused Samples either will be returned at the Requestor or Requesting Institution's expense or discarded in compliance with all applicable practices, policies, statutes, and regulations as directed by the Repository.
- g) The Requestor and Requesting Institution shall use the Samples and Data only in accordance with the individual studies' IRB approved informed consents and Approved Research Plan in Appendix A.

It is anticipated that, at least in some cases, the Sample and Data at the Repository will be updated with additional information and will be so identified by an appropriate version number. All statements herein will apply to current and all future versions of the Data, and instructions provided by the Repository.

3. ***Human Subject Protections: Compliance with Requirements***

- a) The Requestor and Requesting Institution acknowledge that the conditions for use of these Samples and Data may require the review and subsequent approval or a determination of "Not Human Subjects Research" by the Requestor's and Requesting Institution's Institutional Review Board (IRB) or other approval body operating under an Office of Human Research Protections (OHRP) - approved Assurance and in accordance with Department of Health and Human Services regulations at 45 CFR Part 46. The Requestor and Requesting Institution agree to comply fully with all such conditions as instructed by the Repository.
- b) In order to respect the privacy of the Study Participants, the Requestor and Requesting Institution agree not to contact or make any effort to identify individuals, families, communities, tribes, or populations which are or may be the source of the Samples or Data. Should the Requestor inadvertently receive identifiable information or otherwise identify a participant, Requestor shall promptly notify the Repository and follow the Repository's reasonable written instructions, which may include return or destruction of the identifiable information. (This condition is not applicable to Contributing Study Investigators who provided the Samples and Data to generate the Data at and from the Repository, if they

have appropriate IRB approval to retain the Study Participant identities or re-contact Study Participants.)

- c) The Requestor and Requesting Institution shall not combine or link the resources provided with any other collection or source of information that may contain information specific to individuals, unless specifically indicated and approved in the proposed research (Appendix A).
- d) The Requestor and Requesting Institution shall promptly report to the Repository any use or disclosure of the Data not provided for by this Agreement of which it becomes aware.
- e) The Requestor and Requesting Institution agree to report to NIDDK in advance of implementation of any proposed modifications in the Research Project and any unanticipated issues involving risk to Study Participants or others, at the following e-mail address: NIDDK-CRsupport@niddk.nih.gov. The Requestor and Requesting Institution agree to this provision in addition to any of Requestor's and Requesting Institution's institutional policies or any federal, state, and local laws and regulations which provide additional protections for human subjects. Such agreement to report to the NIDDK does not supersede Requestor and Requesting Institution's responsibilities to comply with applicable laws, regulations, and policies related to protections for human subjects.

4. *Public Posting of Approved User's Research Use*

The Requestor and Requesting Institution agree that if the attached Research Project is approved, information about the proposed research use may be posted on a public web site that describes the Samples and Data requested from the Repository. The information may include the Requestor's and Requesting Institution's names, project title, and Research Use Statement. Prior to NIDDK Repository approval of a Research Project, the contents of all requests for access are considered confidential and are not published or shared with any third party.

5. *Data Security/Non-transferability*

The Requestor and Requesting Institution agree to store the Data in a secure manner and environment with adequate security controls, and to maintain appropriate control over the Data. Best practices for computer security and data control are available online at <https://repository.niddk.nih.gov/static/bestpractices.pdf>. The Requestor and Requesting Institution agree to establish appropriate administrative, technical, procedural, and physical safeguards to protect the confidentiality of the Data and to prevent unauthorized access to it. The Requestor and Requesting Institution agree to ensure that the Data is protected by reasonable safeguards against loss, unauthorized access, use, modification, or disclosure, and any misuse, and agree to notify the Repository at the following e-mail address NIDDK-CRsupport@niddk.nih.gov as soon as a security breach is discovered.

- a) Data from the Repository represent a significant investment on the part of NIDDK. The Requestor and Requesting Institution therefore agree to retain control over the Data, and further agree not to transfer or distribute the Data in any form to any third party or entity or individual not under Requestor's direct supervision. The Data may be shared with Requestor's collaborating investigators listed in the attached Research Project who are also approved users who have a fully-executed SDUA for the purposes of this Research Project. The Requestor and Requesting Institution acknowledge responsibility for ensuring appropriate use of these Data in accordance with the terms of this Agreement.

- b) The Requester agrees to retain control over the Data and further agrees not to distribute, sell, or license individual-level data in any form. No copies or derivatives shall be made of the Data except as necessary for the purposes authorized in this SDUA. The Requestor and Requesting Institution acknowledge that if any copies of the Samples or Data are generated, the terms and conditions of this SDUA apply to such copies. The Requestor shall keep an accurate written account of all such copies and derivative files, which will be furnished to the NIDDK upon request. Upon completion of the Research Project or the termination of this SDUA, the Requestor shall destroy all files received or return any copies and derivatives to the Repository, if requested.
- c) Subject to Article 7, the Data transferred under this SDUA will be safely maintained by the Requestor for no longer than five (5) years from the date of receipt. No later than the end of the five (5) year period the Requestor and Requesting Institution shall send the Repository contact person an email at NIDDK-CRsupport@nidk.nih.gov certifying that all data, copies, and derivatives have been returned and deleted.
- d) The Requestor agrees that if he/she changes institutions, a new SDUA must be executed in which the new Requesting Institution agrees to NIDDK principles, policies, procedures and the terms of access per this SDUA in order for the Requestor to continue the Research Project at the new institution.

6. *Intellectual Property*

By requesting access to Samples and Data from the Repository, the Requestor and Requesting Institution acknowledge the guidelines outlined below:

- a) Achieving maximum public benefit is the ultimate goal of Sample and Data distribution through the Repository mechanisms and it should be considered pre-competitive.
- b) The Repository does not explicitly prohibit the patenting and licensing of results generated by the Research Project. In view of the current law (*Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. (2013)), naturally occurring DNA sequences and their use as a biomarker of disease or biological function are not patentable in the United States. Therefore, basic sequence data and certain related information (e.g., genotypes, haplotypes, p-values, allele frequencies), and all conclusions derived directly from them are pre-competitive and should remain freely available, without any licensing requirement in accordance with the NIH sharing policies.
- c) New Materials generated from use of NIDDK Central Repository resources must remain freely available and adhere to NIH sharing policies.

7. *Data/Sample Access Renewal Period*

Initial access is granted for two (2) years from the date of approval of the SDUA. Renewal of access may be granted, if requested of the Repository, by submitting a letter through the original online Repository request. The letter should be signed by the Requestor and an authorized representative of their institution in the same manner as this Sample and Data Use Agreement. An example template is located at https://repository.nidk.nih.gov/pages/agreement_forms/. Questions regarding this process may be directed to NIDDK-CRsupport@nidk.nih.gov.

8. *Research Progress Reporting and Dissemination of Research Results*

Prompt publication or any public disclosure of the results of the Research Project is encouraged. The Requestors are strongly encouraged to publish their results in peer-reviewed journals.

- a) The Requestor and Requesting Institution agree to submit, one (1) year from the date of the SDUA approval or renewal of access being granted, a progress report to the Repository on the Research Project. The progress report should include all annotated data associated with any publications submitted for publication, any unpublished or published analyses and summaries, and all published references conducted with the Samples and Data. The aforementioned Materials, documents, and progress report may then be included in the Repository at the discretion of NIDDK.
- b) Before the Requestor or the Requesting Institution submits any publication, abstract, or other Materials for publication or intends to publicly disclose any information about the Samples and Data, they will send a copy of the Materials to the Repository (NIDDK-CRsupport@niddk.nih.gov) at least thirty (30) days in advance of submitting for publication or otherwise publicly disclosing the Materials, in order for the Repository to review it for confidentiality requirements and compliance with research objectives as described in Appendix A.
- c) The Requestor and Requesting Institution agree not to publish or otherwise disclose the Data to any person or organization unless the Data have been aggregated (that is, combined into groupings of data such that the data are no longer specific to any individuals within each grouping), and no cells (aggregates of data) contain information on fewer than ten (10) individuals or fewer than five (5) providers or facilities. The Requestor and Requesting Institution shall not publish or otherwise disclose Data that identify individual providers or facilities, or from which such identities could be inferred.
- d) The Requestor and Requesting Institution agree to acknowledge the contribution of the Contributing Study Investigators and the Repository in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of the Samples and Data. A sample statement to be used in acknowledgements can be found at: <https://repository.niddk.nih.gov/pages/acknowledgements>

9. ***Non-Endorsement, Non-Indemnification***

The Requestor and Requesting Institution acknowledge that although all reasonable efforts have been taken to ensure the accuracy and reliability of the Samples and Data in the Repository, the Samples and Data are provided as a service to the research community. The Samples and Data are supplied to Requestor and Requesting Institution with NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. NIDDK AND THE REPOSITORY makes no representation that the use of the Samples and Data will not infringe any patent or proprietary rights of third parties.

The Requestor and Requesting Institution agree not to claim, infer, or imply endorsement by the United States Government or NIH/NIDDK of the Research Project, the Requestor or Requesting Institution, or any resulting publications or commercial product(s).

No indemnification for any loss, claim, damage or liability is intended or provided by any party to this SDUA. Each party shall be liable for any loss, claim, damage, or liability that the party incurs as a result of its activities under this agreement, except that the NIDDK, as an agency of the United States, assumes liability only to the extent provided under the Federal Tort Claims Act, 28 U.S.C. 2671 *et seq.*

10. Disqualification, Enforcement

Failure to comply with any of the terms specified herein may result in disqualification of the Requestor or Requesting Institution from receiving additional resources from the Repository. All remedies under law or equity will be available to the United States Government in the enforcement of this agreement.

I have read and understood the conditions outlined in this agreement and I agree to abide by them in the receipt and use of the Samples and Dataset(s)

SIGNATURE of REQUESTOR

Name of Requestor: _____

_____ Date: _____

Signature of Requestor

Agreeing to be bound by the terms of this agreement, the parties hereby affix their signatures:

AUTHORIZED SIGNATURE for REQUESTING INSTITUTION

Name of Requesting Institution: _____

_____ Date: _____

Authorized Signature for Requesting Institution

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

NIDDK INFORMATION and AUTHORIZED SIGNATURE

Program Official: _____ Date: _____

Rebecca M. Rodriguez, Ph.D.
National Institute of Diabetes and Digestive and Kidney Diseases

_____ Date: _____

Authorized Signature

Name of Authorized Official: Charles Niebylski, Ph.D., J.D.
Title of Authorized Official: Director, Technology Advancement Office
Address: 31 Center Drive
Bethesda, MD 20892

Any false or misleading statements made, presented, or submitted to the Government, including any relevant omissions, under this Agreement and during the course of negotiation of this Agreement are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§ 3801-3812 (civil liability) and 18 U.S.C. § 1001 (criminal liability including fine(s) and/or imprisonment).



Appendix A Research Project

Project title:

Requestor's name:

Requesting Institution's Name:

Names of all Requestor's collaborators and their Institutions:

Description of Research:

For detailed instructions on preparation, see <https://repository.niddk.nih.gov>

Research objectives and design:

Analysis Plan:

Please include a one-two (1-2) paragraph Research Use Statement which may be made publicly available.