

**NIDDK Central Database Repository
Data Use Agreement**

Version date 20 August 2015
Contact: niddk-cr@imsweb.com

Requestor: _____

E-mail Address: _____

Requesting Institution: _____

Requested Dataset(s) ("Dataset(s)": _____

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

_____.

Introduction

The National Institute of Diabetes and Digestive and Kidney Disease (NIDDK) has supported collection of Data from participants in numerous studies. 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, on appropriate terms and conditions, to the largest possible number of qualified investigators in a timely manner.

The NIDDK Central Database Repository does not receive personally identifiable information or codes linking such information to Dataset(s).

In the event that investigators from more than one institution will be collaborating on a project using the Dataset(s) transferred under this Certification, an investigator from each institution is required to complete a separate Data Use Agreement request.

It is the intent of the NIDDK that Approved Users of NIDDK Central Repository Dataset(s) recognize the limitations imposed by the original informed consent agreements of contributing studies as described on the NIDDK Central Repository website.

Terms of Access

1. Definitions:

Approved Users: Means research investigators who submitted a request for access to NIDDK Central Database Repository Dataset(s) that have been approved by the NIDDK Data Access Committee and who have a fully-executed Data Use Certification for the requested Dataset(s)

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

NIDDK Central Database Repository Dataset: contains the relevant data from a specific project. Access to this resource may be managed for NIDDK by the National Center for Information via dbGaP.

Research Project: Attached as Appendix A, includes the project title, the Requestor's name and Requesting Institution's name, the names of any independent collaborators and their institutions,



a one to two paragraph Research Use Statement, a description of the research objectives and design, and an analysis plan.

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 Requestor's Research Project request for access to Data set(s).

Study Subject: means an individual who participated in the clinical research, either as a recipient of a test article or as a control. A Study Subject may be either a healthy human or a patient.

2. Research Project: Use of Dataset(s)

- a) Requestor and Requesting Institution agree that the NIDDK Central Database Repository Dataset(s) 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 Research Project will include the project title, the Requestor's name and Requesting Institution's name, the names of any independent collaborators and their institutions, a one to two paragraph Research Use Statement, a description of the research objectives and design, and an analysis plan. The Dataset(s) 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 Dataset(s) and further agree not to transfer the Dataset(s) to other people not under the direct supervision of the Requestor.
- b) New uses of these Dataset(s) outside those described in the Research Project require submission of a new Data Use Certification request. Modification to an approved Research Project requires submission to the NIDDK Data Access Committee of an amendment to the Research Project. Appointment of another or different Principal Investigator to complete an approved Research Project is a modification and requires submission of an amendment to this Data Access Certification request.
- c) The Requestor and Requesting Institution acknowledge that other researchers have access to NIDDK Central Database Repository resources and that duplication of research is a distinct possibility.
- d) The Requestor and Requesting Institution further acknowledge that they are responsible for ensuring that all their uses of the Dataset(s) are consistent with Federal (including 45 CFR Part 46), state, and local laws and any relevant institutional policies and that limitations in the informed consents set out on the NIDDK Central Repositories web site will be observed..
- e) The Requestor and Requesting Institution shall use the Dataset(s) only for purposes related to biomedical research, cost-effectiveness, or other economic research. Purposes for which the Dataset(s) may not be used include but are not limited to:
 - identification and targeting of under- or over-served health service markets primarily for commercial benefit;
 - obtaining information about health care providers or facilities for commercial benefit;
 - insurance purposes such as redlining areas deemed to offer bad health insurance risks; and
 - adverse selection (e.g., identifying patients with high risk diagnoses).

It is anticipated that, at least in some cases, the Dataset(s) at the NIDDK Central Database Repository will be updated with additional information and will be so identified by an appropriate version number. Unless otherwise indicated, all statements herein are presumed to be true and applicable to the access and use of all versions of the Dataset(s) at and from the NIDDK Central Database Repository.

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

- a) Requestor and Requesting Institution acknowledge that the conditions for use of these Dataset(s) require the review and subsequent approval or waiver of approval 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. Requestor agrees to comply fully with all such conditions.
- b) In order to respect the privacy of the Study Subjects, 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 Dataset(s). (This condition is not applicable to Contributing Study Investigators who provided the data used to generate the Dataset(s) at and from the NIDDK Central Database Repository, if they have appropriate IRB approval to retain the Study Subject identities or re-contact Study Subjects.)
- c) The Requestor shall not combine or link the Dataset(s) provided with any other collection or source of information that may contain information specific to individuals.
- d) Requestor and Requesting Institution agree to report promptly to the NIDDK, at the following e-mail address: niddk-cr@imsweb.com, any proposed modifications in the Research Project and any unanticipated problems involving risk to Study Subjects or others. Requestor and Requesting Institution agree to this provision in addition to any of Requestor's and Requesting Institution's institutional policies or any local, State, and/or Federal laws and regulations which provide additional protections for human subjects. Such agreement does not supersede the applicable laws, regulations and policies.

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

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 Dataset(s) from the NIDDK Central Database Repository. The information may include the Requestor's and Requesting Institution's names, project title, and Research Use Statement.

5. *Data Security/Non-transferability*

The Requestor and Requesting Institution agree to store the Dataset(s) on a computer with adequate security controls, and to maintain appropriate control over the Dataset(s). Best practices for computer security and data control are available online at <https://www.niddkrepository.org/static/bestpractices.pdf>. The Requestor and Requesting Institution agree to establish appropriate administrative, technical, procedural, and physical safeguards to protect the confidentiality of the Dataset(s) and to prevent unauthorized access to it. The Requestor and Requesting Institution agree to ensure that the Dataset(s) is protected by reasonable safeguards against loss, unauthorized access, use, modification or disclosure, and

against any misuse and agree to notify the NIDDK Central Database Repository at the following e-mail address: niddk-cr@imsweb.com as soon as a security breach is discovered.

- a) These Dataset(s) represent a significant investment on the part of NIDDK. The Requestor and Requesting Institution therefore agree to retain control over the Dataset(s), and further agree not to transfer or distribute the Dataset(s) in any form to any entity or individual not under the Requestor's direct supervision. The Dataset(s) may be shared with independent collaborating investigators listed in the attached Research Project who are also Approved Users who have a fully-executed Data Use Certification for the purposes of this Research Project. The Requestor and Requesting Institution acknowledge responsibility for ensuring appropriate use of these Dataset(s) in accordance with the terms of this Certification.
- b) The Requester agrees to retain control over the data and further agrees not to distribute individual-level data in any form. No copies or derivatives shall be made of the Dataset(s) except as necessary for the purposes authorized in this Data Use Certification. Requestor and Requesting Institution acknowledge that if any copies of the Dataset(s) are generated, the terms and conditions of this Certification 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. At the completion of the activities in the Research Project, all files containing Dataset(s) or any portion thereof will be destroyed or returned to the NIDDK at the Requestor's and Requesting Institution's expense, and any derivative files and copies shall be destroyed. Subject to Article 7, the Dataset(s) transferred under this Data Use Certification may be kept for no longer than five years from the date of receipt.
- c) The Requestor agrees that if he/she changes institutions, a new Data Use Certification in which the new Requesting Institution acknowledges and agrees to NIDDK principles, policies, procedures and the terms of access will be required in order for the Requestor to continue the Research Project at the new institution.

6. *Intellectual Property*

By requesting access to Dataset(s) from the NIDDK Central Database Repository, the Requestor and Requesting Institution acknowledge the guidelines outlined below:

- Achieving maximum public benefit is the ultimate goal of data distribution through NIDDK Central Database Repository mechanisms. The NIDDK believes that NIDDK Central Database Repository data should be considered as pre-competitive, and urges Requestor's, Requesting Institutions and others accessing the Dataset(s) to avoid making intellectual property (IP) claims on the Dataset(s) and their analyses. However, the NIDDK also recognizes the importance of the later development of IP on downstream discoveries, especially in therapeutics, which will be necessary to support full investment in products that the public needs.
- In this spirit, it is expected that Dataset(s) from the NIDDK Central Database Repository and conclusions derived there from will remain freely available, without requirement for licensing, for applications such as, but not necessarily limited to, the following: the use of markers in developing assays or diagnostic tools; the use of combinations of markers in multiplex assays; and the use of markers as guides toward identification of new drug targets.
- The NIDDK encourages licensing practices consistent with the recommendations cited in NIH's [Best Practices for the Licensing of Genomic Inventions](#) and in the [NIH Research Tools Policy](#).



7. *Data Access Renewal Period*

Initial access is granted for two (2) years from the date of the Data Use Agreement approval. Renewal of access may be granted if requested of the NIDDK Central Repositories by submission of a letter through the original online request. The letter should be signed by the PI and an authorized representative of their institution in the same manner as this agreement the Data Use Agreement . An example template is located at <http://niddkrepository.org/static/extension.doc>. Questions regarding this process may be directed to niddk-cr@imsweb.com.

8. *Research Reporting and Dissemination of Research Results - Acknowledgment of NIDDK*

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

- a) The Requestor and Requesting Institution agree to submit, one year from the date of the Data Use Certification approval or renewal of access being granted, a report to the NIDDK on the Research Project that includes all analyses conducted with the Dataset(s) and related manuscripts submitted for publication. The analyses conducted with the Dataset(s) may then be included in the NIDDK Central Repositories Database at the discretion of NIDDK.
- b) Before the Requestor or the Requesting Institution submits a paper or abstract for publication or otherwise intends to publicly disclose information about the Samples and Dataset(s), Requestor and the Requesting Institution shall ensure that NIDDK has at least thirty (30) days to review the proposed publication or disclosure and agree to provide NIDDK a copy of any manuscript or other disclosure document thirty (30) days in advance of submission for publication, in order to ensure compliance with the confidentiality requirements set forth in this Data Use Certification. NIDDK reserves the right to delete or modify information that might reasonably be viewed as offensive to the Study Subjects involved.
- c) The Requestor and Requesting Institution agree not to publish or otherwise disclose the Dataset(s) to any person or organization unless the Dataset(s) 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 individuals or fewer than five providers or facilities. The Requestor and Requesting Institution shall not publish or otherwise disclose Dataset(s) 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 NIDDK Central Database Repository in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of the Dataset(s).

A sample statement to be used in acknowledgements can be found at:
<https://www.niddkrepository.org/niddk/jsp/public/acknowledgements.jsp>

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 Dataset(s) in the NIDDK Central Database Repository, the Dataset(s) are provided as a service to the research community. The Dataset(s) 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 NIDDK CENTRAL DATABASE REPOSITORY makes no representation that the use of the Dataset(s) 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 US Government of the Research Project, the entity, or personnel conducting the Research Project or any resulting commercial product(s).

No indemnification for any loss, claim, damage or liability is intended or provided by any party to this agreement. 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 Requestor or Requesting Institution from receiving additional data from the NIDDK Central Database Repository. All remedies under law or equity will be available to the The United States Government in the enforcement of this agreement

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

REQUESTOR INFORMATION and REQUESTING INSTITUTION AUTHORIZED SIGNATURE

Requestor: _____
Requesting Institution: _____

_____ Date: _____
Authorized Signature for Requesting Institution

Name of Authorized Signatory: _____
Title of Authorized Signatory: _____

Certification of Requestor: I have read and understood the conditions outlined in this Certification and I agree to abide by them in the receipt and use of the Dataset(s).

_____ Date: _____
Signature of Requestor



NIDDK INFORMATION and AUTHORIZED SIGNATURE

Program Official: _____ Date: _____
Beena Akolkar, PhD,
National Institute of Diabetes and Digestive and Kidney Diseases

Authorized Signature Date: _____

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 any independent collaborators and their Institutions:

Description of Research:

For detailed instructions on preparation, see www.niddkrepository.org

Research objectives and design:

Analysis Plan:

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