NIDDK Central Repositories
Sample and Data Use Agreement

Version date 01 December 2009
Contact: niddk-dac@mail.nih.gov

Requestor: _____

E-mail Address: _____

Requesting Institution: _____

Requested Samples ("Samples"), including amounts: _____

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 and Samples 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 Samples or Dataset.

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

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

Terms of Access

1. Definitions:

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

Contributing Study Investigators: Means research investigators who provided the phenotypic data and samples to the NIDDK Central Repositories.

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: Means a statement of proposed research to be conducted which may be made publicly available. The Research Use Statement is submitted by Requestor as a part of Requestor's Research Project request for access to Samples and Dataset(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 Samples and Dataset(s)

a) Requestor and Requesting Institution agree that NIDDK Central Repositories Samples and 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 Samples and 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 Samples and Dataset(s) and further agree not to transfer the Samples and Dataset(s) to other people not under the direct supervision of the Requestor.

b) Requestor and Requesting Institution acknowledge that Samples have the potential for carrying viruses, latent viral genomes, and other infectious agents in a dormant state. Requestor and Requesting Institution agree to treat the Samples under laboratory conditions that afford adequate biohazard containment. By accepting Samples, Requestor and Requestor Institution assume full responsibility for their safe and appropriate handling. **The Requestor and Requesting Institution agree that the Samples may not be used in Humans.**

c) New uses of the Samples or Dataset(s) outside those described in the Research Project require submission of a new Sample and Data Use Agreement 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 Agreement request.

d) Requestor and Requesting Institution acknowledge that other researchers have access to NIDDK Central Repositories resources and that duplication of research is a distinct possibility.

e) Requestor and Requesting Institution further acknowledge that they are responsible for ensuring that all their uses of the Samples and 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.

f) When the Research Project is completed, the unused Samples either will be returned at Requestor or Requesting Institution's expense or discarded in compliance with all applicable statues and regulations as directed by the NIDDK Central Repositories.

g) Requestor and Requesting Institution shall use the Samples and Dataset(s) only for purposes related to biomedical research, cost-effectiveness, or other economic research. Purposes for which 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).

3. Human Subject Protections: Compliance with IRB Requirements

a) Requestor and Requesting Institution acknowledge that the conditions for use of these Samples and 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 Samples or Dataset(s). (This condition is not applicable to Contributing Study Investigators who provided the Samples and Data and used to generate the Dataset(s) at and from the NIDDK Central Repositories, if they have appropriate IRB approval to retain the Study Subject identities or re-contact Study Subjects.)

c) 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-dac@mail.nih.gov, 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 Samples and Dataset(s) from the NIDDK Central Repositories. The information may include the Requestor's and Requesting Institution's names, project title, and Research Use Statement.

5. Data Security/Non-transferability

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 http://www.ncbi.nlm.nih.gov/projects/gap/pdf/dbGaPLevel2SecurityProcedures.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 Repositories at the following e-mail address: niddk-dac@mail.nih.gov as soon as a security breach is discovered.

a) These Dataset(s) represent a significant investment on the part of NIDDK. 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 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 Agreement 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 Agreement.

b) 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 Sample and Data Use Agreement. Requestor and Requesting Institution acknowledge that if any copies of the Samples or Dataset(s) are generated, the terms and conditions of this Agreement 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 Sample and Data Use Agreement may be kept for no longer than five years from the date of receipt,

c) Requestor agrees that if he/she changes institutions, a new Sample and Data Use Agreement 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 Samples and Dataset(s) from the NIDDK Central Repositories, the Requestor and Requesting Institution acknowledge the guidelines outlined below:

- Achieving maximum public benefit is the ultimate goal of data and sample distribution through the NIDDK Central Repositories mechanisms. The NIDDK believes that NIDDK Central Repositories data should be considered as pre-competitive, and urges Requestors, Requesting Institutions and others accessing the Samples and Dataset(s) to avoid making intellectual property (IP) claims on the Samples and Dataset(s) and their analyses. However,

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 Repository and conclusions derived therefrom 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.
- 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 one-year from the date of the Sample and Data Use Agreement approval. Renewal of access may be granted if requested of the NIDDK Central Repositories by submission of a request to the following e-mail address: niddk-dac@mail.nih.gov.

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) Requestor and Requesting Institution agree to submit, one year from the date of the Data Use Agreement approval or renewal of access being granted, a report to the NIDDK on the Research Project that includes all analyses conducted with the Samples and Dataset(s) and related manuscripts submitted for publication. The analyses conducted with the Samples and Dataset(s) may then be included in the NIDDK Central Repositories' Database at the discretion of NIDDK.

b) Before 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 Sample and Data Use Agreement. NIDDK reserves the right to delete or modify information that might reasonably be viewed as offensive to the Study Subjects involved.

c) 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. 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) Requestor and Requesting Institution agree to acknowledge the contribution of the Contributing Study Investigators and the NIDDK Central Repositories 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

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 Repositories, the Samples and Dataset(s) are provided as a service to the research community. The Samples and 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 Repositories make no representation that the use of the Samples and Dataset(s) will not infringe any patent or proprietary rights of third parties.

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 samples or data from the NIDDK Central Repositories. All remedies under law or equity will be available to 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:

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 Samples and Dataset(s).

_____Date: _____
Signature of Requestor

_____ _____Date: _____

Authorized Signature for Requesting Institution

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

NIDDK INFORMATION and AUTHORIZED SIGNATURE

Program Official: _____Date: _____
Rebekah Rasooly, PhD, KUH_
National Institute of Diabetes and Digestive and Kidney Diseases

_____ _____Date: _____
Authorized Signature

Name of Authorized Official: Cindy Fuchs, JD
Title of Authorized Official: Director, Office of Technology Transfer and Development
Address: 6707 Democracy Blvd., Rm. 778
Bethesda, MD 20817

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.