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NIDDK Central Repository
DATA and RESOURCES USE AGREEMENT

Contact: NIDDK-CRsupport@niddk.nih.gov

This Data and Resources Use Agreement ("**DUA**") is made and entered into as of the last date of signature by the Parties ("**Effective Date**"), by and between the National Institute of Diabetes and Digestive and Kidney Diseases ("**NIDDK**"), and the Requesting Institution identified below. This DUA sets all terms and conditions to transfer Resources from, and Materials to NIDDK Central Repository for the specified approved Research Project in "**Appendix A**."

Requestor:

E-mail Address:

Requesting Institution:

Requested Data:

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

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

Introduction

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

Transfer of Resources from, and Materials to the Repository is governed by NIH and NIDDK sharing policies and applicable federal regulations.

The Repository receives only data and specimens that do not include direct personal identifiers or codes linking to the identifiable information and distributes these Resources via controlled access.

In the event that investigators from more than one institution will be collaborating on a Research Project using the Resources transferred under this DUA, an investigator from each Requesting Institution is required to complete a separate DUA.

It is the intent of NIDDK that Requestors must follow the limitations imposed by the contributing study's informed consent agreements.

NIDDK has established policies and processes to make Data and Resources available through appropriate terms and conditions to qualified Requestors. The Repository requires the Requestor and Requesting Institution to read, understand, and sign this DUA and to agree to abide by the terms and conditions of this DUA, and sign as a condition of access. A Requestor who is granted access to Resources must adhere to the specifications of this DUA as executed in its final form. Failure to do so may result in denial of further access by the Requestor's Institution to Resources available through the Repository.

Terms of Access

1. Definitions:

"Access Renewal": Renewal of controlled access for continued research use of previously approved Resources.

"Authorized Organization Representative (AOR)": Individual, named by the Requesting Institution, who is authorized to act for the Requestor and to assume the obligations imposed by the federal laws, regulations, and requirements.

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

"Data": Controlled access data provided by NIH/NIDDK in limited data set format (do not contain direct identifiers, are sensitive, and must be protected), that may also be available from repositories other than the Repository (for example, dbGaP).

"Materials": Include but are not limited to all data, specimens, products, analytes, metadata,

documentation, code, analytic tools, methods, algorithms, workflows, results, summaries, analyses, or conclusions generated under the Research Project as a direct result from the use of NIH/NIDDK Resources.

"Progress Report": Non-confidential information provided during the annual Access Renewal or at Project Conclusion summarizing accomplishments with specific information on how the Resources have been used, including any publications or public disclosures releases and resulting from the use of the Resources, a summary of any plans for future research use, any violations of the terms of access and the implemented remediation, and information on any intellectual property generated from the Resources.

"Project Conclusion": The closeout or termination of a Research Project that used controlled access Resources obtained through an NIH/NIDDK approved Research Project under a signed DUA and after a Certificate of Destruction/Disposition has been received.

"Requesting Institution": An institution, organization, or corporation that is the employer of the Requestor. The Requesting Institution assumes responsibility for the Requestor's compliance with the terms and conditions of this DUA and is responsible for complying with all NIH/NIDDK policies, applicable federal, state, tribal, and local laws and regulations for research participant protections.

"Requestor": Research investigator(s) who submitted a request for access to Resources, is primarily responsible for the Research Project, has been approved by the applicable NIH oversight committee, and has a fully- executed DUA for the requested Resources. Personnel working on the Research Project under the direct supervision of the Requestor, including trainees, employees, or fee-for-service contractors, are considered approved users under the Requestor.

"Requestor's Collaborator": Investigator(s) at a different institution than the Requestor who is independently approved to have access to the Data or Resources or Materials and has a fully executed DUA for the same request.

"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 Collaborator(s) and their institutions, a one to two-paragraph Research Use Statement, a description of the research objectives and design, and an analysis plan, as well as information on compliance with policies, documentation, data security, and proposed use of cloud computing or remote access. (Appendix A).

"Research Use Statement": Statement of the proposed research to be conducted in plain language, 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 Data and Resources, and includes any proposed use of cloud computing/private cloud computing or remote access.

"Resources": Include but are not limited to Data, specimens, products, analytes, metadata, documentation, code, methods, analytic tools, algorithms, workflows, results, summaries, analyses, or conclusions provided by the Repository.

"Study Participant": An individual who participated in the clinical research protocol.

2. Research Project: Use of Data, Resources, and Materials

a) The Requestor and Requesting Institution agree that the Resources will only be used for the research purposes specifically described and approved in the Research Project, attached as Appendix A, by the Requestor at their location under suitable conditions, as outlined in Article 5. The Resources shall not be used in any research that is not disclosed and approved as part of the Research Project.

b) The Requestor and Requesting Institution agree to retain control over the Resources and Materials and further agree not to transfer the same to any third parties not under the direct supervision of the Requestor or an approved Requestor's Collaborator.

c) New uses of the Resources outside those described and approved in the Research Project require the execution of a new DUA. Modification to an approved Research Project requires submission to the applicable oversight committee and an amendment to the Research Project. Appointment of a replacement or different Requestor requires submission of a request to amend this DUA.

d) The Requestor and Requesting Institution agree that they are responsible for ensuring that all their uses of the controlled access Resources are consistent with federal law, including 45 CFR Part 46, and also state, tribal, local laws, and all applicable institutional policies.

e) Requestor and Requesting Institution will comply with the limitations and conditions in the Institutional Review Board (IRB)-approved informed consents.

f) The Requestor and Requesting Institution will only use the Data and Resources in accordance with the individual studies' IRB-approved informed consent documents and approved Research Project in Appendix A.

g) When applicable, Data or Resources at the Repository will be updated with additional information and Data will be so identified by a corresponding version number. All

statements herein will apply to current and all future versions of the Data or Resources, and instructions provided by the Repository.

h) *The Requestor and Requesting Institution acknowledge that specimens 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 specimens under laboratory conditions that afford adequate biohazard containment. By accepting specimens, the Requestor and Requesting Institution assume full responsibility for their safe and appropriate handling.*

i) *The Requestor and Requesting Institution agree that:*

i. *Specimens will not be used in Humans. When the Research Project is completed, the unused specimens will either be returned or discarded in compliance with all applicable practices, policies, statutes, and regulations as directed by the Repository, subject to Articles 5, 7, and 8 of this DUA.*

3. Human Research Protections: Compliance with Requirements

a) The Requestor and Requesting Institution acknowledge that the conditions for the use of these Data and Resources may require the review and subsequent approval or a determination of "Not Human Subjects Research" by the Requestor's and Requesting Institution's IRB or other ethics 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 their IRB or other ethics body. Approved users who access data that were originally protected under a certificate of confidentiality acknowledge they are subject to the requirements of the certificate and Public Health Service Act subsection 301(d)(1).

b) In order to respect the privacy of the Study Participant, the Requestor and Requesting Institution agree not to contact or make any effort to identify individuals, families, communities, tribes, or populations that are or may be the source of the Data and Resources. Should the Requestor or Requesting Institution inadvertently receive identifiable information or otherwise identify a Study Participant, the Requestor shall promptly notify the Repository and follow the Repository's written instructions, which may include the return or destruction of the identifiable information. This condition does not apply to Contributing Study Investigators who provided the phenotypic data used to generate the Data and Resources if they have appropriate IRB approval to retain the Study Participant identities or to re-contact Study Participants. Approved users with access to personal identifying information from Study Participants in the original study at their institution or through their collaborators may be required to have IRB approval.

c) The Requestor and Requesting Institution will not combine or link the Data and Resources provided with any other collection or source of information that may contain information specific to Study Participants and other individuals, unless specifically indicated and approved in the proposed Research Project (Appendix A).

d) Requestors are not allowed to combine the Resources received from the Repository with any other resources from an approved collaborator or any other individual not approved as a collaborating party unless specifically indicated and approved in the proposed Research Project (Appendix A).

e) The Requestor and Requesting Institution will promptly report to NIDDK any use or disclosure of the Data and Resources not provided for under this DUA of which it becomes aware.

f) The Requestor and Requesting Institution agree to report to NIDDK in advance of the implementation of any proposed modifications in the Research Project and any unanticipated issues involving risk to Study Participants or others via their request on the Repository website or by emailing NIDDK-Crsupport@niddk.nih.gov. The Requestor and Requesting Institution agree to this provision in addition to any of the Requestor's and Requesting Institution's institutional policies or any federal, state, tribal, and local laws and regulations that provide additional protections for human subjects. Such agreement to report to 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 information about the approved Research Project may be posted on a public website that describes the Data and Resources requested from the Repository and the proposed use. 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. Security and Non-transferability

The Requestor and Requesting Institution agree to store the Data and Resources in a secure manner and environment with adequate security controls and to maintain appropriate control over the Data and Resources. The Requestor and Requesting Institution agree to establish the appropriate administrative, technical, procedural, and physical safeguards to protect the confidentiality of the Data and Resources and to prevent unauthorized access to them. The Requestor and Requesting Institution agree to ensure that the Data and Resources are 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 or suspected. Best practices for computer security and data control are available online at https://repository.niddk.nih.gov/static/NIDDK-CR_Security_Best_Practices.pdf.

a) Data and Resources from the Repository represent a significant investment on the part of NIDDK. Therefore, the Requestor and Requesting Institution agree to retain control over the Data and Resources and further agree not to transfer or distribute the Data and Resources in any form to any third party or entity, or individual not under the Requestor's direct supervision. The Data and Resources may be shared with the Requestor's Collaborator(s) listed in the attached Research Project, who are also approved users with a secondary, fully executed DUA for this Research Project. The Requestor and Requesting Institution are responsible for ensuring the appropriate use of these Data and Resources in accordance with the terms of this DUA. Requestor and Requesting Institution agree to disclose all personnel under the direct supervision of the Requestor and Requestor's Collaborator(s), who will have access to the Data, Resources, and Materials in the conduct of the Research Project.

b) The Requestor agrees to retain control over the Resources 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 and Resources except as necessary for the purposes authorized in this DUA. The Requestor and Requesting Institution acknowledge that if any copies of the Data and Resources are generated, the terms and conditions of this DUA apply to such copies. The Requestor shall keep an accurate written account of all such copies and derivative files, which will be furnished to NIDDK upon request. Upon completion of the Research Project or the termination of this DUA, the Requestor shall destroy or return to the Repository all files received and any copies and derivatives.

c) Requesting Institution agrees to implement network access controls that ensure that remote devices and their users comply with security policies. If remote access or cloud computing is planned for Data or Resources storage or analyses, Requestor must describe in the Research Project (Appendix A) the type of cloud service provider(s) or private cloud system and how it will be used to carry out the proposed Research Project and include a statement, written in plain language, in the Research Use Statement.

d) Subject to Article 7, the Data or Resources transferred under this DUA will be safely maintained by the Requestor for the duration of the Research Project and contingent on annual progress reporting requirements from the Effective Date. At the time of Access Renewal, Requestor will indicate the desire for continued access or to closeout. If indicating interest to closeout, then a Certificate of Destruction/Disposition must be submitted to the Repository no later than ten (10) days from reporting closeout. The Requestor and Requesting Institution shall certify via established Repository processes that all files received, and any copies, have been returned to the Repository or deleted.

e) Requestor and Requesting Institution may retain Materials generated under the Research Project that are required for policy and regulatory compliance for a period not to exceed five (5) years after completion of the Research Project. At the end of the five-year period, Requestor and Requesting Institution agree to deposit Materials into the Repository or in a public repository (at NIDDK's discretion) per Article 8(b).

f) The Requestor agrees that if they change institutions and wish to continue the Research Project at the new institution, a new DUA must be executed in which the new Requesting Institution agrees to the Repository's Code of Conduct, policies, procedures, and the terms of access per this DUA in order for the Requestor to continue the Research Project at the new institution. If the Research Project continues at the original institution, then that Requesting Institution agrees to designate a new Requestor and modify the DUA to continue the Research Project at their institution or else close out the project.

6. *Intellectual Property*

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

a) Achieving maximum public benefit is the ultimate goal of data distribution through NIH-designated repositories. NIH and NIDDK encourage the broad use of NIH/NIDDK-generated resources consistent with a responsible approach to the management of intellectual property. Data and Resources distributed through the Repository mechanisms should be considered pre-competitive.

b) The Repository does not explicitly prohibit the patenting and licensing of results generated by the Research Project. It is expected that NIDDK-provided Data or Resources and conclusions and analysis and results, including Materials derived therefrom, will remain freely available without the requirement for licensing. Basic sequence data and certain related information (e.g., genotypes, haplotypes, p-values, allele frequencies), and all conclusions derived directly from them are considered pre-competitive and should remain freely available without any licensing requirement.

c) Any and all Materials generated as a direct result of the use of Data and Resources must remain freely available and adhere to NIH sharing policies and may not be sold in whole or in part in accordance with the informed consent documents.

d) Data and Resources will not be transferred to any third parties without the written authorization of NIDDK and will also not be sold in whole or in part.

e) Requestor and Requesting Institution agree to inform NIDDK Repository of any intellectual property claims resulting from the use of the Data and Resources, and the Repository will consult with the NIDDK Technology and Advancement Office.

7. *Access Renewal Period*

a) The Requestor and Requesting Institution agree to submit a request for Access Renewal or closeout the Research Project no more than thirty (30) days prior to the one (1) year anniversary of the Effective Date of this DUA and no later than thirty (30) days after the anniversary of the Effective Date. Requestor and Requesting Institution also agree to submit a Progress Report at this time and annually thereafter, per Article 8(a). Questions regarding this process may be directed to NIDDK-Crsupport@niddk.nih.gov.

b) The Requestor and Requesting Institution agree that if access is not renewed within the Access Renewal period, access will be suspended and Requesting Institution will be asked to certify that all Data or Resource files received, and any applicable copies, have been returned to the Repository or deleted as instructed by the Repository and certify when completed using a Certificate of Destruction/Disposition template as located at Information for Requestors using NIDDK-CR R4R page.

c) *The Requestor and Requesting Institution agree that for requests granting access to specimens, if access is not renewed within the Access Renewal period, Requestor and Requesting Institution will follow Repository instructions for disposition of any remaining or unused specimens and will certify when completed using the template located at Information for Requestors using NIDDK-CR R4R.*

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 Effective Date, at the time of Access Renewal or Project Conclusion, a Progress Report on the Research Project via the Repository website. The Progress Report should include a non-confidential summary of accomplishments with specific information on how the Data or Resources have been used, including any publications or public disclosures resulting from the use of the Data or Resources, a summary of any plans for future research use, any violations of the terms of access described within this DUA and the implemented remediation, and information on any intellectual property generated from the Data or Resources.

b) The Materials and supporting documentation may be included in the Repository at the discretion of NIDDK. Requestor and Requesting Institution agree to manage Data, Resources, and Materials in accordance with best practices and data standards per Article 5.

c) 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 Data or Resources, the Requestor will submit a copy of the Materials to the Repository via the request on the Repository website or by emailing 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.

d) The Requestor and Requesting Institution agree not to publish or otherwise disclose the

Data or Resources to any person or organization unless the Data or Resources 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 the Data or Resources that identify individual providers or facilities, or from which such identities could be inferred.

e) 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 Data or Resources. A sample statement to be used in acknowledgments can be found at: https://repository.niddk.nih.gov/pages/acknowledgements/. The Requestor agrees to include a data availability statement in all public releases.

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 Data and Resources in the Repository, the Data or Resources are provided as a service to the research community. The Data or Resources 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 Data or Resources will not infringe any patent or proprietary rights of third parties.

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

No indemnification for any loss, claim, damage, or liability is intended or provided by any party to this DUA. Each party shall be liable for any loss, claim, damage, or liability that the party incurs as a result of its activities under this DUA, except that 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*. (https://uscode.house.gov/view.xhtml?path=/prelim@title28/part6/chapter171&edition=pre lim)

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 Data or Resources from the Repository. All remedies under law or equity will be available to the United States Government in the enforcement of this DUA.

Signatures on the next page

I have read and understood the conditions outlined in this DUA and I agree to abide by them in the receipt and use of the Data or Resources.

SIGNATURE of REQUESTOR

Name of Requestor: _____

Signature of Requestor: _____

Date: _____

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

SIGNATURE for REQUESTING INSTITUTION: LEGALLY AUTHORIZED ORGANIZATION REPRESENTATIVE

Name of Requesting Institution:

Signature of Authorized Official for Requesting Institution:

Name of Authorized Signatory:

Title of Authorized Signatory:

NIDDK INFORMATION and AUTHORIZED SIGNATURE

Program Official:
Name of Program Official: Rebecca M. Rodriguez, Ph.D.
Title of Program Official: Director, Repository Program

Authorized Signatory:

Name of Authorized Official: Agnieszka Eley, M.S., J.D.
On Behalf of Charles Niebylski, Ph.D., J.D.
Title of Authorized Official: Director, Technology Advancement Office
Address: National Institute of Diabetes and Digestive and Kidney Disease
31 Center Drive, Bethesda, MD 20892

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