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THE CUSTOMIZED AGREEMENT FOR EXECUTION WILL BE GENERATED DURING THE REQUEST PROCESS

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**"), a component of the National Institutes of Health ("**NIH**"), and the Requesting Institution identified below.

This DUA sets all terms and conditions for the transfer of Data and Resources from NIDDK Central Repository ("NIDDK-CR"), and Materials to NIDDK-CR.

Requestor:

E-mail Address:

Requesting Institution:

Requested specimens, including amounts:

Requested Data:

Funding Source:

Introduction

NIDDK has supported the collection of phenotypic data and specimens from participants in numerous studies. The Data and Resources are held by NIDDK-CR. 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, under specific terms and conditions, to the largest possible number of qualified investigators.

Transfer of Data and Resources from NIDDK-CR, and Materials to NIDDK-CR is governed by NIH and NIDDK sharing policies and applicable federal, state, and tribal regulations.

NIDDK-CR receives Materials that do not include any direct personal identifiers or codes linking to the identifiable information and distributes these NIDDK-CR-held Data and Resources via controlled access.

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

By submitting a request to access Data and Resources, Requestors certify to have reviewed and understood the principles for responsible research use and data management as defined in the User Code of Conduct and NIH Security Best Practices for Users of Controlled-Access Data. A Requestor who is granted access to Data and Resources must adhere to the terms 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 Data and Resources available through NIDDK-CR.

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 federal and state laws, regulations, and any other applicable requirements.

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

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

"Materials": Include but are not limited to all data, specimens (human-derived specimens (biospecimens)), products, analytes, metadata, documentation, code, analytic tools, methods,

algorithms, workflows, results, summaries, analyses, or conclusions generated under the Research Project as a direct result of the use of NIH/NIDDK Data or Resources. The first generation of new Materials produced under the Research Project is addressed in section 2(c).

"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 any applicable regulations for research participant protections.

"Requestor": Research investigator(s) who is a permanent employee of the Requesting Institution, submitted a request for access to Data or 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 Data or 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, an analysis plan, as well as information on compliance with policies, documentation, data security, and proposed use of cloud computing or remote access as delineated in 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, including any private cloud computing, or any 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 NIDDK- CR.

"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 Data or Resources will only be used for the research purposes specifically described and approved in the Research Project, attached as Appendix A, and 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 Data or Resources and further agree not to transfer these to any third parties not under the direct supervision of the Requestor or an approved Requestor's Collaborator.

c) The Requestor and Requesting Institution understand that NIDDK is responsible for the Data and Resources under its custodianship, and that NIDDK-CR assumes this responsibility until the first generation of new Materials produced under the Research Project. The Requesting Institution agrees to control the first-generation Materials before submitting them to NIDDK-CR or an NIH/NIDDK-approved repository, and to notify NIDDK-CR of any third-party sharing before submitting the Materials to NIDDK-CR or an NIDDK-approved repository after the Research Project is completed.

d) New uses of the Data or 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 for approval, and an amendment to the Research Project. Appointment of a replacement or different Requestor requires submission of a request to amend this DUA. The Requesting Institution agrees to notify NIDDK-CR in writing prior to, or as soon as reasonably possible, following any changes in Requestor's employment status, institutional affiliation, or eligibility to serve as the responsible Principal Investigator (PI), including departure from the Requesting Institution.

e) The Requestor and Requesting Institution agree that they are responsible for ensuring that all their uses of the controlled access Data or Resources are consistent with federal law, including 45 CFR Part 46, and also state, tribal, local laws, and all applicable institutional policies, and NIH policies. The Requestor and Requesting Institution agree to protect controlled-access Data in accordance with the NIH Security Best Practices for Users of Controlled Access Data.

f) Requestor and Requesting Institution will comply with the limitations and conditions in the Institutional Review Board (IRB)-approved informed consents as provided to NIDDK-CR. By submitting a request for access, the Requestor acknowledges receiving and reviewing secondary use limitations and conditions for Data or Resources requested.

g) 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.

h) When applicable, Data and Resources at NIDDK-CR will be updated with additional information and will be identified by a corresponding version number. All terms under this DUA will apply to current and all future versions of the Data or Resources, and instructions provided by NIDDK-CR.

i) 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 as the Resources from NIDDK-CR, the Requestor and Requesting Institution assume full responsibility for their safe and appropriate handling.

j) The Requestor and Requesting Institution agree that specimens as the Resources 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 NIDDK-CR, subject to Articles 3, 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 Requestors 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 NIDDK-CR and follow NIDDK-CR'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 Requestors with access to personal identifying information from Study Participants in the original study at their institution, or through their Requestor's Collaborators, may also be required to have IRB approval.

c) Certificates of Confidentiality (Certificate) protect the privacy of research participants by prohibiting disclosure of protected information for non-research purposes to anyone not connected with the research except in specific situations. The data that are stored in and shared through the data repositories accessed under this agreement are protected by a Certificate. Therefore, the Requesting Institution and the Requestor(s) and Requestor's Collaborator, whether or not funded by the NIH, who are approved to access a copy of information protected by a Certificate, are also subject to the requirements of the Certificate of Confidentiality and subsection 301(d) of the Public Health Service Act. Under Section 301(d) of the Public Health Service Act and the NIH Policy for Issuing Certificates of Confidentiality, recipients of a Certificate of Confidentiality shall not:

> Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual whom the information, document, or biospecimen pertains; or

Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

Disclosure is permitted only when:

i. Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding.

ii. Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual.

iii. Made with the consent of the individual to whom the information, document, or biospecimen pertains; or

iv. Made for the purposes of other scientific research that is following applicable Federal regulations governing the protection of human subjects in research.

For more information see: Certificates of Confidentiality (Certificate) | Grants & Funding.

d) 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.

e) Requestors are not allowed to combine the Data or Resources received from NIDDK-CR with any other data or resources from an approved Requestor's Collaborator or any other individual not approved as a collaborating party unless specifically indicated and approved in the proposed Research Project.

f) The Requestor and Requesting Institution will promptly report to NIH/NIDDK any not permitted uses or disclosures of the Data and Resources not specifically approved under this DUA of which the Requestor or Requesting Institution becomes aware.

g) The Requestor and Requesting Institution agree to report to NIDDK-CR 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 NIDDK-CR 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-CR 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 Project'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 NIDDK-CR 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-CR approval of a Research Project, the contents of all requests for access are considered confidential information 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 certify that the appropriate administrative, technical, procedural, and physical safeguards are in place to protect the confidentiality and integrity of the Data and Resources and to prevent unauthorized access to them, in accordance with NIH Security Best Practices for Users of Controlled-Access Data.

a) The Requestor and Requesting Institution, including the Requestor's information technology (IT) director, 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 NIDDK-CR of all suspected or confirmed loss of control, compromise, unauthorized disclosure, violation of the terms of access, or similar occurrence without unreasonable delay, and no later than twenty-four (24) hours of discovery at NIDDK-CRsupport@niddk.nih.gov. Consistent with the applicable NIH and HHS policies and procedures, and as directed in writing by NIDDK-CR, the Requestor and Requesting Institution agree to notify the NIH Incident Response Team and NIH Office of Extramural Research Data Sharing Policy Implementation (OER/DSPI) Team of any unauthorized data sharing, breaches of data security, or inadvertent data releases that may compromise data confidentiality within 24 hours of when the incident is identified. For the NIH Incident Response Team, notifications can

be made by phone (301) 496-HELP (4357); Toll Free Number: (866) 319-4357 or TTY: (301) 496-8294 and can also be sent by email to NIHInfoSec@nih.gov or via the Report an Incident Link: https://irtportal.ocio.nih.gov/. For OER/DSPI Team, notifications can be sent to DMI_OER@mail.nih.gov.

As permitted by law, notifications should include any known information regarding the incident and a general description of the activities or process in place to define and remediate the situation in full. Within three (3) business days of notifying NIDDK-CR, the Requestor and Requesting Institution agree to submit to NIDDK-CR a detailed written report including the date and nature of the event, actions taken or to be taken to remediate the issue(s), and plans or processes developed to prevent future incidents, including specific information on timelines anticipated for action.

The Requestor and Requesting Institution agree to provide documentation verifying that the remediation plans have been implemented. Repeated violations or unresponsiveness to NIH/NIDDK requests may result in further compliance measures affecting the Requestor and Requesting Institution. Requesting Institution agrees that NIDDK-CR/NIH may designate another entity, as permitted by law, to investigate any data security incident or policy violation.

b) The Data and Resources, and resulted Materials, may be shared with the Requestor's Collaborator(s) listed in the attached Appendix A, 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 resulted Materials in the conduct of the approved Research Project.

c) Data and Resources will not be transferred to any third parties without the written authorization of NIDDK-CR and will also not be sold in whole or in part to any third party for any purpose. The Requestor and Requesting Institution agree that entering controlled access Data or Resources received from NIDDK-CR into public generative artificial intelligence (AI) tools (e.g., third-party tools) via prompts or other interfaces violates the provisions of Article 5 for non-transferability, and by extension, of this DUA.

d) 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 will apply to such copies. The Requestor will keep an accurate written account of all such copies and derivative files, which will be furnished to NIDDK-CR upon request. Upon completion of the Research Project or the termination of this DUA, the Requestor and Requesting Institution will destroy or return to NIDDK-CR all files received, and also any copies and derivatives, as instructed by NIDDK-CR.

e) Requesting Institution agrees to implement network access controls that ensure that remote devices and their users comply with security policies. When cloud computing is planned, Requesting Institution agrees to adhere to the security control and privacy expectations described in the NIH Security Best Practices for Users of Controlled-Access Data. If remote access or cloud computing is planned for Data or Resources storage or analyses, Requestor must describe in the Research Project 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 written statement in reference to the above in the Research Use Statement.

f) 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 interest for continued access or to closeout. If indicating interest for closeout, then a Certificate of Destruction/Disposition must be submitted to NIDDK-CR no later than thirty (30) business days from reporting closeout. The Requestor and Requesting Institution shall certify via established NIDDK-CR processes that all files received, and any copies and versions, have been returned to NIDDK-CR or deleted, or destroyed. Requestor and Requesting Institution agree to destroy all copies, and versions, of the Data and Resources received, on both local servers and hardware, and if cloud computing was used, delete the data and cloud images from cloud computing provider's storage, virtual and physical machines, databases, and random access archives, in accordance with NIH Security Best Practices for Users of Controlled-Access Data.

g) Requestor and Requesting Institution agree that if new genomic Materials meeting the threshold in scale or data types subject to the Genomics Data Sharing (GDS) Policy are generated, Requestor and Requesting Institution will comply with the GDS Policy expectations in accordance with NOT-OD-14-124. Requestor and Requesting Institution agree to deposit newly generated genomic Materials into an NIDDK-approved repository or other NIDDK-approved public resource per NIDDK-CR policy requirements.

h) Requestor and Requesting Institution may retain Data and Resources obtained under the Research Project for a period not to exceed five (5) years after completion of the Research Project, as required for applicable record retention policies and regulatory compliance purposes only. All DUA provisions relating to the management of such Data and Resources continue to apply during this period. At the end of this period, Requestor and Requesting Institution agree to manage Data and Resources as required in Article 5(f) and 7(b).

i) 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 NIDDK-CR's Code of Conduct, policies, procedures, and the terms of access in accordance with 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 either designate a new Requestor and will modify the DUA to continue the Research Project at their institution; or, if not, Requestor and Requesting Institution agree to close out the Research Project per Article 7 "Access Renewal and Closeout Period" prior to Requestor's departure from Requesting Institution.

6. Intellectual Property

By requesting access to Data and Resources from NIDDK-CR, 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/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 NIDDK-CR mechanisms should be considered pre-competitive.

b) NIDDK-CR does not explicitly prohibit the patenting and licensing of results generated by the Research Project. It is expected, however, that NIDDK-provided Data or Resources and conclusions and analyses 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) The first generation of new Materials resulting from 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 and, when applicable, the contributing study material transfer agreements with no conflicting terms regarding all of the above.

d) The Requestor and Requesting Institution agree to retain control over the Data and Resources and further agree not to distribute, sell, or license individual-level data in any form.

e) Requestor and Requesting Institution agree to inform NIDDK-CR of any intellectual property claims or patent applications resulting from the use of the Data or Resources. NIDDK-CR will consult with the NIDDK Technology and Advancement Office regarding the new intellectual property.

7. Access Renewal and Closeout 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 initiate Project Conclusion procedures to certify that all Data or Resources files received, and any applicable copies, have been returned to NIDDK-CR or deleted/destroyed as instructed by NIDDK-CR and certify when completed using the Certificate of Destruction/Disposition template provided by NIDDK-CR.

c) The Requestor and Requesting Institution agree that for requests granting access to specimens, the Resources, if access is not renewed within the Access Renewal period, Requestor and Requesting Institution will follow NIDDK-CR instructions for disposition of any remaining or unused specimens, the Resources, and will certify when completed in accordance with NIDDK-CR policy.

8. Research Progress Reporting and Dissemination of Research Results/Materials

It is NIH/NIDDK's intent to promote the dissemination of research findings from use of controlled-access Data and Resources as widely as possible through scientific publication or other appropriate public dissemination mechanisms. Requestor and Requesting Institution agree to public disclosure of the results, including negative results. The Requestor and Requestor's Collaborator are strongly encouraged to publish their results in peer-reviewed journals and to present research findings at scientific meetings.

a) Access to the requested NIDDK-CR provided Data or Resources is granted for a period of one (1) year, with the option to renew access or closeout at the end of that year. 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 NIDDK-CR 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) Requestor and Requesting Institution will manage Data and Resources in accordance with best practices and data standards per Article 5.

c) Materials generated in the conduct of the approved Research Project should be managed in accordance with best practices and data standards described in Article 5.

d) 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 NIDDK-CR via the request on NIDDK-CR 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 NIDDK-CR to review it for confidentiality requirements and compliance with research objectives as described in the Research Project. Citations of publications resulting from the Research Project will be posted publicly on the NIDDK-CR Resources for Research (R4R) website.

e) Requestor and Requesting Institution must agree to deposit Materials generated under the Research Project into NIDDK-CR or in a public repository at the discretion of NIH/NIDDK, in accordance with Article 5, as soon as possible after completion of the Research Project.

f) 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 or without the explicit approval of NIDDK. 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.

g) The Requestor and Requesting Institution agree to acknowledge the contribution of the Contributing Study Investigators and NIDDK-CR 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. No Warranties, Non-Endorsement, Non-Indemnification

The Data or Resources are supplied to the Requestor and Requesting Institution with NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. NIDDK AND NIDDK-CR make no representations that the use of the Data or Resources will not infringe on 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, NIH/NIDDK/NIDDK-CR of the Research Project or any resulting publications, opinions, any activities, or any commercial product(s) or services.

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. Termination, Disqualification, Enforcement, and Survivability

NIDDK may terminate the Research Project and the DUA, and immediately revoke or suspend access to

Data or Resources at any time, and initiate closeout procedures per Article 7, “Access Renewal and Closeout Period” if the Requestor or the Requesting Institution is found not to be in compliance with the terms of this DUA, the User Code of Conduct, the policies, principles, and procedures of NIH.

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 NIDDK-CR. All remedies under law or equity will be available to the United States Government in the enforcement of this DUA.

NIH may terminate this DUA in accordance with applicable NIH Policies, with written notice to the Requestor and Requesting Institution

The obligations of the Parties under this DUA, which by their nature should continue beyond the termination or expiration of this agreement, and provisions that provide meaning or context to any other provision, including, without limitation, Articles 2, 3, 5, 6, and 9, will survive the expiration or earlier termination of this DUA.

SAMPLE APPENDIX – FOR INFORMATIONAL PURPOSES

APPENDIX A IS AUTOGENERATED WITH THE CUSTOMIZED AGREEMENT BEFORE ROUTING FOR SIGNATURES

APPENDIX A

Research Project Title:

Requestor’s Name:

Requesting Institution’s Name:

Other Users under the PI:

Name of Independent Collaborators and their Institutions:

Data/Resources Requested:

Data/Resources Approved Uses/Restrictions (DUL):

Research Plan Details:

Information Security Details:

Signatures on the next page

I have read and understood that I am accountable for ensuring that all aspects of this Research Project align with 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:

I certify that the Requestor and the listed approved users under the Requestor are affiliated with the Requesting Institution, and that the Requestor has been approved by the Requesting Institution to request access and meets the minimum requirements to qualify to request Data and Resources from NIDDK-CR. Further, I certify that the minimum-security standards to safeguard and protect the confidentiality and integrity of the Data and Resources and to prevent unauthorized access to them as described in Article 5, "Security and Non-transferability," are in place at the Requesting Institution.

SIGNATURE for REQUESTING INSTITUTION: LEGALLY AUTHORIZED ORGANIZATION REPRESENTATIVE

Name of Requesting Institution: _____

Signature of Legally 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: Carolyn Buller, Ph.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 Diseases
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).