



Enhanced Nathan Kline Institute-Rockland Sample (NKI-RS)

Data Access Request

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NKI-RS ACCESS REQUEST: OVERVIEW

Access to the Enhanced Nathan Kline Institute – Rockland Sample (NKI-RS) requires successful completion and execution of a Data Use Agreement (DUA). While the NKI-RS team's goal is to provide the least restrictive requirements for access to and usage of shared datasets, protection of participant privacy must be the highest priority. In this regard, the need for a DUA arises from two factors: 1) while permitted in a Limited Data Set (LDS), knowledge that participants in the NKI-RS live in Rockland County, New York precludes full de-identification in accord with Health Insurance Portability and Accountability Act (HIPAA), and 2) the robust phenotypic and psychometric data engender an increased risk of identification beyond the 18 traditional HIPAA protected health identifiers. The Enhanced NKI-RS Sample DUA incorporates several key components from that of the National Database for Autism Research (NDAR; <http://ndar.nih.gov/>).

The NKI-RS team will approve access to data and/or images from the NKI-RS for research purposes only. The NKI-RS team will review the Access Request and the proposed Data Use Agreement (DUA) of each Recipient requesting data and determine whether to provide access based on the expectations outlined in the following pages. These expectations include the protection of data privacy, confidentiality, and security. In the event that requests raise particular concerns related to privacy and confidentiality, risks to populations or groups, or other concerns, the NKI-RS team will consult with other experts as appropriate. The NKI-RS team reserves the right to suspend or revoke approved Access Requests at any time if concerns arise regarding the appropriateness of data usage by Recipient or Recipient's compliance with the Data Use Agreement..

Recipients seeking access to data or images from NKI-RS are expected to submit their DUA, certified and co-signed by the Principal Investigator and the designated Institutional Official(s), a Scope of Work, and an up-to-date CV or biosketch for the Principal Investigator. Completing this NKI-RS Access Request is a necessary step to access data or images from NKI-RS.

Steps to Request General Access to the Enhanced NKI-RS

1. Read the Enhanced NKI-RS Data Use Agreement (DUA) and sign the Recipient Information and Certifications page, and obtain your Institutional Official's signature and date.
2. By submitting an individual's name on the form, you and your Institutional Official affirm that the collaborators have read and agreed to the terms and conditions within the Data Use Agreement. Your collaborators at different organizations must complete separate requests for the data.
3. Provide a scanned copy of the signed DUA Recipient Information and Certifications page, an addition to the Standard Scope of Work, if applicable(max = 500 words), and an up-to-date CV or biosketch of the Principal Investigator to request an account or to request access renewal.
4. Access Request Review: Requests to access the Enhanced NKI-RS will be reviewed to ensure completeness of the application and scientific appropriateness of the intended project.
5. After review and approval, an account will be created and the user will receive notification of their account update with any modified user name, passwords, or instructions for accessing the NKI-RS.

DATA USE AGREEMENT FOR THE ENHANCED NATHAN KLINE INSTITUTE-ROCKLAND SAMPLE

Introduction

The Enhanced NKI-RS is a large cross-sectional sample of brain development, maturation and aging (ages 6 - 85 yrs), that is currently funded by the NIMH (BRAINS R01MH094639-01; PI Milham) and Child Mind Institute (PI Milham) to characterize 1000 community-ascertained participants using state-of-the-art multiplex imaging-based resting state fMRI (R-fMRI) and diffusion tensor imaging (DTI), genetics, and a broad neurobehavioral phenotypic characterization protocol. Designed as an open-access community resource, the NKI-RS will provide researchers with data for the testing of existing hypotheses, as well as the generation of novel hypotheses through the application of data exploration techniques. Imaging datasets will be shared through the Collaborative Informatics and Neuroimaging Suite and the Neuroimaging Tools and Resources Clearinghouse (NITRC) and genetic samples will be processed and made available through the NIMH Genetics Repository.

Data collected in this study are stripped of all individual identifiers prior to sharing, but the unique and intrinsically personal nature of the phenotypic, imaging, and genetic data coupled with the specific geographic localization in Rockland County, New York has altered the framework through which “identify-ability” can be defined and this data is therefore being provided in the form of a Limited Data Set. To protect and assure the confidentiality and privacy of all participants, the Recipient granted access to these data is expected to adhere to the specifications of this DUA. Failure to do so could result in withdrawal of prior permissions and denial of further access to data.

Definitions

For purposes of this agreement, “data” refers to the information that has been collected and recorded from participants in the Enhanced Nathan Kline Institute-Rockland Sample herein after Enhanced NKI-RS study.

The Principal Investigator and his/her affiliated institution or organization (“Institution”) are jointly referred to as “Recipient.” The Recipient Principal Investigator may be a researcher at a non-profit or for-profit organization or corporation.

The “Recipient Parties” shall mean Recipient Institution, Recipient Principal Investigator, Recipient’s research team members and Recipient Institution’s employees, officers, director and agents.

Terms and Conditions

Recipient requests approval to access data and/or images from the Enhanced Nathan Kline Institute-Rockland Sample for research purposes. Recipient agrees to the following terms:

1. Scope of Work. A Standard Scope of Work that covers most anticipated uses of the data is provided on the Recipient Information and Certifications page. Data access requests may include additions to the Standard Scope of Work if desired by attaching a page(s) to this application with detailed information describing the request.

a. Any data obtained under this DUA will be used by Recipient solely in connection with the “Scope of Work” submitted with the Access Request and for no other purpose.

b. Recipient agrees that any data obtained under this DUA will not be used in any research that is not within the approved Scope of Work. Should the intended use of Enhanced NKI-RS data exceed the limits of the approved Scope of Work or should Recipient make a material change or changes to the Scope of Work, the Recipient will submit a revised DUA (this document) and Scope of Work, and shall not use any Enhanced NKI-RS data for such additional purpose unless and until it is approved by the NKI-RS.

2. Non-transferability of Agreement. This DUA is not transferable. If the Recipient Institution appoints another Principal Investigator to complete the Research Project, Recipient Institution must submit a new DUA together with the new Recipient Principal Investigator. If the Recipient Principal Investigator changes Institutions and wishes to retain access to NKI-RS data, the Recipient Principal Investigator must submit a new DUA together with the new Recipient Institution. In either case, Recipients shall not use Enhanced NKI-RS data pending approval of a new DUA.
3. Non-Identification of Subjects. Recipient agrees that data will not be used, either alone or in conjunction with any other information, in any effort whatsoever to establish the individual identities of any of the subjects from whom data were obtained. Recipient agrees to promptly notify the Nathan Kline Institute-Rockland Sample team if, upon use of Enhanced NKI-RS data, the Recipient discovers identifying information (protected health information, as defined by HIPAA), other than County, in that data.
4. Data Disclaimers. All data provided under this DUA is provided “AS IS” and without any representations or warranties of any kind, whether express or implied, including accuracy or completeness and implied warranties of merchantability or fitness for a particular purpose. Recipient agrees that NKI does not and cannot warrant the results that may be obtained by using any data included therein.
5. Assumption of Risk: Recipient Institution shall be fully responsible for the acts and omissions of its employees, officers, directors, students and agents with respect to their failure to adhere to the terms of the Scope of Work, applicable regulations, and this Agreement.
6. Notification of Publication. Prompt publication or other public disclosure of the results of the Scope of Work is encouraged. Recipient agrees to notify via email at rocklandsample@nki.rfmh.org as to when and where a publication (or other public disclosure) of a report from the Scope of Work will appear.
7. No Distribution of Data. Recipient agrees to retain control over data, and further agrees not to transfer data, with or without charge, to any other entity or any individual. Recipient agrees not to sell the data in any form to any entity or individual or to distribute the data to anyone other than his/her research staff who will also agree to the terms within this DUA. This applies to all versions of NKI-RS data.
8. Non-Endorsement. Recipient agrees not to claim or imply endorsement by NKI, OMH or RFMH of (a) the project or projects being conducted under the Scope of Work, (b) the Recipient Parties or any other entities or personnel related to or involved in the project(s), or (c) any resulting commercial product(s).
9. Recipient's Compliance with Institutional Requirements. Recipient agrees to comply with all Recipient Institution's applicable rules for the protection of human subjects, which may include Department of Health and Human Services regulations at 45 C.F.R. Part 46, and other federal and state laws for the use of this data This DUA is made in addition to, and does not supersede, any of Recipient Institution's institutional policies or any local, State, and/or Federal laws and regulations that provide additional protections for human subjects.
10. Recipient's Compliance with Scope of Work, Law and the DUA. Recipient agrees that any access, receipt and use of data obtained under this Agreement shall be in accordance with the Scope of Work, all applicable state and federal law and regulations (including HIPAA) and this DUA. Recipient agrees to report promptly to the NKI-RS team any material change in the Scope of Work and any unanticipated problems involving risks to subjects. Recipient agrees to promptly report any

violations of NKI-RS Policy or the terms of this DUA to the NKI-RS team.

11. Recipient's Permission to Post Information Publicly. Recipient agrees to permit NKI to summarize on the NKI-RS Web site the Recipient's research use of NKI-RS along with the name of the Recipient and the Recipient Institution. .

12. Privacy Act Notification. In order to access the NKI-RS, the Recipient agrees to provide the information requested below in Recipient Information and Certifications. The Recipient agrees that information collected from the Recipient, as part of this DUA, may be made public in part or in whole for tracking and reporting purposes. The primary uses of this information are to document, track, and monitor and evaluate the use of the NKI-RS datasets, as well as to notify interested recipients of updates, corrections or other changes to the database.

13. Security. Recipient shall comply with the Best Practices and Security Standards set forth in the attached "Information Security Best Practices" in connection with its access, receipt and use of the data.

14. Amendments. Amendments to this DUA must be made in writing and signed by authorized representatives of the Recipient Institution, the Recipient Principal Investigator and NKI.

15. Termination/Survival of Obligations.

a. Recipient or NKI may terminate this DUA without cause upon 30 days prior written notice to the other party.

b. NKI or the NKI-RS team may terminate this agreement with 5 days prior written notice if the Nathan Kline Institute determines, in its sole discretion, that the Recipient has committed a material breach of this DUA. The Nathan S. Kline Institute for Psychiatric Research may, in its sole discretion, provide Recipient with an opportunity to remedy a breach before termination but is not obligated to do so. Closed accounts may be reactivated upon submission of an updated NKI-RS Access Request and DUA.

c. This DUA shall automatically terminate:

(i) as provided in paragraph 18 below;

(ii) if the Recipient completes the work provided for in the Scope of Work or terminates the work prior to completion; or

(iii) if the Recipient Principal Investigator disaffiliates or is disaffiliated from the Scope of Work or the Recipient Institution.

d. Notwithstanding termination of the DUA, all obligations of the DUA with respect to any data accessed by Recipient prior to termination shall survive and remain in effect.

e. Recipient agrees that upon termination of this DUA, or completion of the use of the data under this DUA, all copies of the data will be destroyed or otherwise disposed of properly as permitted by law, except that Recipient may retain one copy of the data solely for archival and compliance purposes.

16. Seven-Year Term and Access Period. Recipients who are granted permission to access data from NKI-RS receive an account that is valid for a period of seven years. This DUA will automatically

terminate at the end of seven years..

17. Accurate Representations. Recipient expressly certifies that the contents of any statements made or reflected in this document are truthful and accurate.

18. Governing Law. This Agreement shall be governed by the laws of New York, except where the Federal Supremacy Clause requires otherwise.

INFORMATION SECURITY BEST PRACTICES

The purpose of these Security Best Practices, which are subject to applicable law, is to provide minimum security standards and best practices for individuals who use NKI-RS to submit, access, and analyze data. Keeping NKI-RS information secure through these best practices is important. Subject to applicable law, Recipients agree to promptly report breaches of data confidentiality that are known or that should reasonably have been known to the NKI-RS team.

Best Practices

We require that you:

- Do not attempt to override technical or management controls to access data for which you have not been expressly authorized.
- Do not use your trusted position and access rights to exploit system controls or access data for any reason other than in the performance of the proposed research within the Scope of Work.
- Ensure that anyone directed to use the system has access to, and is aware of, Information Security Best Practices and all existing policies and procedures relevant to the use of the NKI-RS.
- Follow the NKI-RS password policy which includes:
 - Choosing passwords of at least seven characters including at least three of the following types of characters: capital letters, lower case letters, numeric characters and other special characters.
 - Changing your passwords every six months.
 - Protecting your NKI-RS password from access by other individuals—for example, store it electronically in a secure location.
- Notify NKI-RS staff, as permitted by law, at rocklandsample@nki.rfmh.org of security incidents, or any incidents of suspected fraud, waste or misuse of NKI-RS or when access to NKI-RS is no longer required.

Security Standards

- Protect the data, providing access solely to authorized researchers permitted access to such data by your institution or to others as required by law.
- When you download NKI-RS data, download the data to a secured computer or server with strong password protection.
- For the computers hosting NKI-RS data, ensure that they have the latest security patches and are running virus protection software.
- Make sure the data are not exposed to the Internet or posted to a website that may be discovered by Internet search engines such as Google or MSN.
- If you leave your office, close out of data files or lock your computer. Consider the installation of a timed screen saver with password protection.
- Avoid storing data on a laptop or other portable medium. If storing data on such a device, encrypt the data. Most operating systems have the ability to natively run an encrypted file system or encrypt portions of the file system. (Windows = EFS or Pointsec and Mac OSX = File Vault)
- When finished using the data, Recipient may retain one copy of the data with access permitted solely for archival and compliance purposes. Any other copies of the data must be destroyed, or otherwise disposed of properly, as permitted by law.

RECIPIENT INFORMATION AND CERTIFICATIONS

First Name: _____ Last Name: _____
 Degree: _____ Academic Position (or Title): _____
 Institution: _____ Department: _____
 Street Address: _____
 City: _____ State/Province: _____
 Zip/Postal Code: _____ Country: _____
 Telephone: _____ FAX: _____
 E-mail Address: _____

Research Project (title):

Standard Scope of Work: Exploration of brain structure and function, including its phenotype relationships, using a combination of morphometric, functional and diffusion MRI data, as well as medical, physical, laboratory, psychiatric, cognitive and behavioral phenotyping measures.

** To request any additions to Standard Scope of Work specified above, please attach a page(s) to this application with detailed information regarding your request.*

By signing and dating this DUA as part of requesting access to data in Nathan Kline Institute-Rockland Sample (NKI-RS), my Institutional Official and I certify that Recipient will abide by the DUA and the NKI-RS principles, policies and procedures for the use of the NKI-RS. We further acknowledge that Recipient Investigator has shared this document and the NKI-RS policies and procedures with any research staff who will participate in the use of NKI-RS data. My Institutional Official(s) also certifies that they have shared this document and the relevant NKI-RS policies and procedures with appropriate institutional entities and individuals.

Recipient Principal Investigator

Signature: _____ Date: _____

Recipient Authorized Institutional Official

NKI Authorized Institutional Official

Name: _____

Name: _____

Title: _____

Title: _____

Signature: _____ Date: _____

Signature: _____ Date: _____