

INTERACTIVE AUTISM NETWORK (IAN) RESEARCH DATABASE DATA ACCESS AGREEMENT

Part I. APPLICATION INSTRUCTIONS

The Principal Investigator must complete the following steps in order to qualify for access to IAN Research Database data:

1. Submit a current Online IAN Data Access Application, located at (www.IANCommunity.org/cs/for_researchers/application).
2. Include a copy of the letter from the Principal Investigator's current Institutional Review Board (IRB) indicating that the proposed data analysis plan was either approved by the IRB, granted an exemption by the IRB, or determined to be non-Human Subject Research by the IRB..
3. Sign and mail an original copy of this IAN Research Database Data Access Agreement to:

IAN Research, Department of Medical Informatics
Kennedy Krieger Institute
1st Floor Painter Building
3825 Greenspring Avenue
Baltimore, MD 21211

Part II. DEFINITIONS

1. Institution – The institution that has executed this Agreement and employs or retains the Principal Investigator (whether the Principal Investigator is in an employee/employer relationship or an independent contractor relationship with the institution).
2. Principal Investigator – The researcher employed/retained by Institution and approved by the IRB as Investigator of the Research Project, for which Principal Investigator has sole responsibility.
3. Recipient – Collectively, Institution and Principal Investigator.
4. Online IAN Data Access Application – The online application for access to IAN Research Database data.
5. Research Project – The scientific investigation that proposes to use any portion of the IAN Research Database data.

Part III. RIGHTS TO USE OF DATA

Recipient requests access to data collected by the Interactive Autism Network (IAN) for the purpose of scientific investigation, teaching, or the planning of clinical research studies, and agrees to the following terms:

1. Recipient will receive access to deidentified data in which all specific identifiers have been removed. The recipient will not attempt to establish the identity of any IAN participant. Any prior knowledge or additional information the recipient may possess or obtain will not be used in combination with IAN data to identify an individual. The recipient will not attempt to contact any of the IAN participants.
2. Recipient will not further disclose the IAN Research Database data beyond the uses outlined in this agreement and the Online IAN Data Access Application. Principal Investigator will not share the data with any party not associated with the Research Project for which they obtained access to the data.

3. Recipient will require anyone who utilizes the IAN Research Database data, or anyone with whom Recipient shares the data, to comply with this Agreement.
4. Recipient will accurately provide the requested information about persons who will use the data and the analyses that are planned using the data.
5. Recipient will respond promptly and accurately to annual requests from the IAN Project to update the information provided under this Agreement.
6. Recipient will comply with any rules and regulations imposed by Institution and its Institutional Review Board in using the data.
7. Recipient will ensure that Investigators who utilize IAN data use appropriate administrative, physical, and technical safeguards to prevent use or disclosure of the data other than as provided for by this Agreement.
8. Recipient will report in writing to IAN Research (address noted above) any use or disclosure of the data not provided for by this Agreement of which Recipient becomes aware within 15 days of becoming aware of such use or disclosure.
9. Recipient understands that failure to abide by these guidelines will result in termination of privileges to access IAN data and to use any IAN data already acquired.

Part IV. ATTRIBUTION

If Recipient publishes manuscripts using IAN Research Database data, Recipient agrees to the following:

1. Recipient will include language similar to the following in the methods section of manuscripts in order to accurately acknowledge use of IAN Research Database data. Depending upon the length and focus of the article, it may be appropriate to include more or less than the example below, however, inclusion of some variation of the language shown below is mandatory.

“Data used in the preparation of this article were obtained from the Interactive Autism Network (IAN) Research Database at the Kennedy Krieger Institute and Johns Hopkins Medicine – Baltimore, sponsored by the Autism Speaks Foundation, version dated _____. For up-to-date information see www.ianproject.org.”

2. Recipient will take reasonable measures to include the database version or date stamp of the IAN Research Database data used in the text of the manuscript, as well as in descriptions of figures and tables where appropriate.
3. Recipient will submit all manuscripts to the IAN Research Program Director prior to publication. This review will not be a scientific review, but is intended to ensure that the attribution requirement above is correctly implemented. IAN will maintain confidentiality of the manuscript.

Part V. RESTRICTIONS

1. Institutional Review Board (IRB) Compliance – Recipient certifies that the Institution provides IRB approval or exemption for the conduct of the research, or the IRB has determined the study to be non-Human Subjects Research. Recipient certifies that the Principal Investigator is in full compliance with the regulations and policies of said IRB. Recipient agrees to report promptly to IAN any proposed changes in the research project. The IRB reviewing the research described in this application must have a Federal Wide Assurance (FWA) issued by the U.S. Department of Health and Human Services (HHS) Office of Human Research Protections (OHRP).

2. NO WARRANTY AND LIMITATION OF DAMAGES – The IAN Research Database data is provided as a service to the research community. The database is provided “as is.” IAN Research does not make, and expressly disclaims, any express or implied warranties, including, without limitation, any implied warranties of merchantability, fitness for a particular purpose, and non-infringement. In no event shall either party be liable for any incidental, special, indirect, punitive or consequential damages arising out of or relating to this agreement, even if such party has been advised of the possibility of such damages.
3. Nothing in this indemnification shall authorize the sale or distribution of the IAN Research Database data.
4. The terms and conditions of this Agreement are binding upon Recipient, including any and all research associates, graduate students, and collaborators working on the Research Project.
5. If the terms of this Agreement contradict the terms of any other IAN document, the terms of this Agreement shall supersede the terms of any other document.
6. Recipient understands that IAN has the sole discretion as to whether to approve or disapprove the Online IAN Data Access Application and this Data Access Agreement. IAN shall notify Principal Investigator when action has been taken on said Application.
7. The Parties agree and acknowledge that the relationship of Recipient and IAN is in the nature of an independent contractor. This Agreement shall not be deemed to create a partnership, joint venture or franchise, and neither party is the other’s agent, partner, employee or representative.
8. Neither Recipient nor IAN may use the name, trade name, trademark, domain name, or other designation of the other party in connection with any products, promotion, marketing or advertising without the prior written consent of the other party.
9. The waiver or failure of either party to exercise any right in any respect provided for herein shall not be deemed to be a waiver of any further right hereunder.
10. This Agreement shall be binding upon and inure to the benefit of each of the Parties, including their respective heirs, legal representatives, successors, and assigns. Institution may not assign this Agreement or any of its rights or obligations hereunder without the prior written consent of IAN.
11. This Agreement constitutes the entire understanding of the Parties with respect to the matters referred to herein and supersedes all prior negotiations, commitments and understanding with respect thereto. No variation or modification of this Agreement or waiver of any terms of provisions hereof shall be deemed valid unless in writing and signed by authorized representatives of both Parties.

ACKNOWLEDGED AND UNDERSTOOD BY PRINCIPAL INVESTIGATOR:

_____	_____
Signature of Principal Investigator	Date
_____	_____
Printed Name of Principal Investigator	Title

ACCEPTED AND AGREED BY INSTITUTION:

Name of Principal Investigator's Institution

Signature of Institutional Officer

Date

Printed Name of Institutional Officer

Title

By signing this Agreement, the Principal Investigator certifies that the IAN ID provided below is the correct IAN ID for the Principal Investigator for the IRB approved Research Project.

IAN ID of Principal Investigator