

National Database for Autism Research (NDAR)

Central Repository Data Submission Request

Contents

NDAR Central Repository Data Submission Request	1
Steps to Request to Submit Data and/or Images to NDAR	1
Data Submission Agreement for the National Database for Autism Research Central Repository.....	2
NDAR Information Security Best Practices.....	5
Best Practices.....	5
Security Standards	5
Submitter Information and Certifications.....	6

NDAR Central Repository Data Submission Request

The NDAR Data Access Committee (DAC) approves submission of data and/or images to the NDAR Central Repository. The DAC will review the Central Repository Data Submission Request from each Submitter submitting data and will decide whether to permit the submission based on the expectations outlined in the NDAR policy. In the event that submissions raise concerns related to privacy and confidentiality, risks to populations or groups, or other concerns, the DAC will consult with other experts as appropriate.

Submitters may use this Central Repository Data Submission Request to 1) only submit data to NDAR or 2) submit data to NDAR and for subsequent analysis with NDAR tools by the Submitter. Both types of requests are subject to approval by the DAC. Completing this Central Repository Data Submission Request is a necessary step to submit data to NDAR. Access to other data within NDAR for analysis purposes may be subject to the NDAR Central Repository Access Request and procedures.

Steps to Request to Submit Data and/or Images to NDAR

1. Contact NIH through NDAR@mail.nih.gov. The NDAR staff meets with Submitters to discuss: a) data submission expectations; b) data access preferences; c) technical specifications; and d) data accuracy. Contacting NIH two months before the desired date of submission is preferable to provide ample time to resolve technical and other issues.
2. If NDAR can accommodate the data per discussions with the NDAR staff, the Submitter should read the NDAR Central Repository Data Submission Agreement (SA) and complete and sign the SA on the Submitter Information and Certifications page.
3. Obtain the Institutional Official(s) signature/date.
4. Submit the SA and accompanying documents to NDAR@mail.nih.gov.
5. Data submission review: The DAC will review requests to submit data to the NDAR Central Repository. Such reviews are generally completed within 10 business days.
6. The DAC will notify NDAR officials if the submission request has been approved. NIH then notifies the requester that he/she may request an NDAR account.
7. Obtain an NDAR account through the NDAR account request link at <http://ndar.nih.gov/>. This link brings up an e-mail request for an account. NIH creates the user account within 2 business days. The user will receive an automated notification of his/her account activation with user name, passwords, and instructions for accessing the NDAR portal.
8. Contact the NDAR Technical Specialist at NDAR@mail.nih.gov to obtain access to the Global Unique Identifier (GUID) Client software and the requisite certifications and procedures to submit data to NDAR.
9. Submit data to NDAR. You should receive a submission confirmation within 2 business days. If not, contact the NDAR Technical Specialist at NDAR@mail.nih.gov.
10. Begin data-quality activities, as specified in the NDAR policy.

Data Submission Agreement for the National Database for Autism Research Central Repository

I request approval to submit data and/or images to the National Database for Autism Research (NDAR) Central Repository for the purpose of sharing data for research purposes. I agree to the following terms:

1. Research Project. These data will be submitted solely in connection with the "Research Project", specifically indicated and described in the Submitter Information and Certifications section.

Data submitted to NDAR may be made available by NIH for either collaborative research (i.e., to accelerate research on ongoing studies) or general research purposes (i.e., meta-analyses and other secondary uses of the data).

This Submission Agreement (SA) covers only the Research Project as contemplated in the Submitter Information and Certifications section. Submitter will submit a completed SA (this document) for each research project for which submission is requested.

2. Non-transferability of Agreement. This SA is not transferable. Submitter agrees that substantive changes Submitter makes to the Research Project requires execution of a new SA, in which the new Research Project is designated. If the Submitter changes institutions and wishes to retain submission privileges to NDAR, a new SA in which the new institution acknowledges and agrees to the provisions of the SA is necessary.

3. Use of NIH Global Unique Identifier Client. Submitter has used the software program provided free-of-charge by NIH to assign Global Unique Identifiers (GUID) to each participant as described in the Policy for the National Database for Autism Research (NDAR Policy) (see http://ndar.nih.gov/ndarpublicweb/Documents/NDAR_Policy_02152008.pdf) and have re-sorted the data according to GUID.

4. Non-Identification of Subjects. Submitter agrees the data and/or images have been 'de-identified' according to the following criterion: the identities of subjects cannot be readily ascertained or otherwise associated with the data by the repository staff or secondary data users (45 C.F.R. 46.102(f)). Submitter further agrees not to disclose the identities of research participants to NDAR in the future and to verify that data and/or images lack identifiers after submission. Submitter agrees to notify NIH as soon as possible if, upon review of NDAR data, the Submitter discovers identifying information in that data.

5. Data Disclaimers. Submitter agrees that NIH does not and cannot warrant the results that may be obtained by using any data or data analysis tools included in NDAR. NIH disclaims all warranties as to the accuracy of the data in NDAR or the performance or fitness of the data or data analysis tools for any particular purpose.

6. Supporting Data Materials. At a minimum, submitter agrees to attach the following supporting information and documentation ("Supporting Materials"):

- Research protocol(s)
- Questionnaire(s)
- Study manuals
- Description of variables measures
- Other supporting documentation, as appropriate

7. Data Accuracy. Submitter certifies to the best of his/her knowledge and belief that the data submitted to NDAR are accurate. Submitter also agrees to perform the specified quality control activities within a timeframe specified by the NDAR Policy (see above). Submitter further agrees to notify NIH as soon as possible if, upon review of NDAR data, the Submitter discovers data quality concerns.

8. Notification to NIH of Publication. Prompt publication or other public disclosure of the results of the Research Project is encouraged. Submitter agrees to notify NIH via email at NDAR@mail.nih.gov as to when and where a publication (or other public disclosure) of a report from the Research Project will appear. Notification of such publications can occur by sending to NIH an updated biographical sketch or CV of the publishing author.

9. Data Access for Research. Submitter agrees that data and Supporting Materials submitted to NDAR may be accessed and used broadly by qualified researchers for research and other activities as authorized by and consistent with law. This access may result in duplication of research data.

10. Non-Research Access. Submitter acknowledges that data and Supporting Materials submitted to NDAR become U.S. Government records that are subject to the Freedom of Information Act (FOIA). NIH is required to release Government records in response to (FOIA) requests unless they are exempt from release under one of the FOIA exemptions. Submitter further acknowledges that data and Submitting Materials may be used or released consistent with law.

11. Acknowledgments. Submitter agrees to acknowledge the contribution of the NDAR bioinformatics platform in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of Data using the NDAR tools. The manuscript should include the following acknowledgement:

Data and/or research tools used in the preparation of this article were analyzed using the NIH-supported National Database for Autism Research (NDAR). NDAR is a collaborative biomedical informatics system created by the National Institutes of Health to provide a national resource to support and accelerate research in autism. This manuscript reflects the views of the authors and does not reflect the opinions or views of the NIH or of the Submitters submitting original data to NDAR.

In addition, Submitters agree to include a reference to NDAR datasets analyzed and to cite NDAR and the Submitters' federal research funding sources in abstracts as space allows.

12. Non-Endorsement; Liability. Submitter agrees not to claim, infer, or imply endorsement by the United States Government, the Department of Health & Human Services, the National Institutes of Health, or the National Institute of Mental Health of the Research Project, the entity, or personnel conducting the Research Project or any resulting commercial product(s). The United States Government assumes no liability except to the extent provided under the Federal Tort Claims Act (28 U.S.C. § 2671-2680).

13. Submitter's Compliance with Institutional Requirements. Submitter acknowledges that these data were collected in manner consistent with all applicable laws and regulations, as well as institutional policies. Submitter further acknowledges that the data were collected pursuant to an informed consent that is not inconsistent with the data submission, and that the data submitted were collected in accordance with 45 CFR Part 46, or applicable foreign law concerning the protection of human subjects, and other applicable U.S. federal and state laws, if any.

14. Submitter's Permission to Post Information Publicly. Submitter agrees to permit NIH to summarize and release for public use on the NDAR Web site the Supporting Materials along with the Submitter's name and organizations/institutional affiliation.

15. Privacy Act Notification. The Submitter agrees that information collected from the Submitter, as part of the SA and submission certification, may be made public in part or in whole for tracking and reporting purposes. This Privacy Act Notification is provided pursuant to Public Law 93-579, Privacy Act of 1974, 5 U.S.C. Section 552a. Authority for the collection of the information requested below from the Submitter comes from the authorities regarding the establishment of the National Institutes of Health, its general authority to conduct and fund research and to provide training assistance, and its general authority to maintain records in connection with these and its other functions (42 U.S.C. 203, 241, 2891-1 and 44

U.S.C. 3101), and Section 301 and 493 of the Public Health Service Act. These records will be maintained in accordance with the Privacy Act System of Record Notice 09-25-0200 (<http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm>) covering "Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD." The primary uses of this information are to document, track, and monitor and evaluate the submission of data from clinical, basic, and population-based research activities and to notify Submitters in the event a potential error in the dataset is identified or in the event of updates or other changes to the database.

The Federal Privacy Act protects the confidentiality of the Submitter's NIH records. NIH will use the data collected for the purposes described above. In addition, the Act allows the release of some information in the Submitter's records without the Submitter's permission; for example, if it is required by members of Congress or other authorized individuals. The information requested is voluntary, but necessary for submitting data to NDAR.

16. Security. Submitter acknowledges the expectations set forth by the attached "NDAR Information Security Best Practices" for the use and security of data.

17. Annual Update. When requested, Submitter will provide to NDAR@mail.nih.gov an annual summary of research accomplishments from using NDAR in an updated biographical sketch or CV.

18. Amendments. Amendments to this SA must be made in writing and signed by authorized representatives of both parties.

19. Termination. Either party may terminate this SA without cause provided 30 days written notice to the other party. NDAR will retain a copy of all data already submitted to NDAR for which data quality activities have been completed, except in the event that research participants withdraw consent for sharing of their data through the NDAR repository and NIH is informed by the Submitter to withdraw the data. Submitters agree to immediately report violations of NDAR Policy to the NDAR DAC. Additionally, the NIH may terminate this agreement with 5 days written notice if the NIH determines, in its sole discretion, that the Submitter has committed a material breach of this SA. The NIH may, in its sole discretion, provide Submitter with 30 days notice to remedy a breach before termination. Closed accounts may be reactivated upon submission of an updated Submission Request and SA.

20. One-Year Term and Access Period. Researchers who are granted permission to submit data to NDAR receive an account that is valid for a period of one year. This SA will automatically terminate at the end of one year. An account may be renewed upon recertification of a new SA. Accounts that remain inactive for 12 consecutive months may be closed at the discretion of NIH.

NDAR Information Security Best Practices

The purpose of these Security Best Practices is to provide minimum security standards and best practices for individuals who use NDAR to submit, access, and analyze data. Keeping NDAR information secure through these best practices will help to ensure Submitter access to the system. Submitters agree to immediately report breaches of data confidentiality to the NDAR DAC.

Best Practices

- 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.
- Ensure that anyone directed to use the system has access to, and is aware of, NDAR Information Security Best Practices and all existing policies and procedures relevant to the use of NDAR, including but not limited to, the NDAR policy at <http://ndar.nih.gov> and 45 CFR Part 46.
- Follow the NDAR password policy which includes:
 - Choose 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.
 - Change your passwords every six months.
 - Protect your NDAR password from access by other individuals—for example, store it electronically in a secure location.
- Notify NDAR staff at ndar@mail.nih.gov of security incidents, or any incidents of suspected fraud, waste or misuse of NDAR or when access to NDAR is no longer required.

Security Standards

- Protect the data, providing access solely to authorized researchers permitted access to such data by your institution.
- When you download NDAR data, download the data to a secured computer or server with strong password protection.
- For the computers hosting NDAR 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, destroy the data or otherwise dispose of it properly.

Submitter Information and Certifications

1. Submitter Information:

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: _____
Institution's NDAR Point of Contact Name (if different from the Submitter): _____
Institution's NDAR Point of Contact Phone: _____ E-mail: _____

2. Certificate of Confidentiality: (applied / obtained / does not have, please circle one)

3. Attachments:

Attach copies of the study protocol, questionnaires, study manuals, variables measured, and other supporting documentation, as appropriate.

4. Signatures

By signing and dating this SA as part of submitting Data to NDAR, my Institutional Officials and I certify that we will abide by the SA and the NIH principles, policies and procedures for the use of the NDAR Central Repository. I further acknowledge that I have shared this document and the NIH policies and procedures with any research staff who will participate in the use of NDAR. My Institutional Business Official(s) also acknowledges that they have shared this document and the relevant NIH policies and procedures with appropriate institutional organizations.

Signature: _____ Date: _____

Authorized Institutional Business Official

Name: _____

Title: _____ FWA#: _____

Signature: _____ Date: _____

Inquiries and Requests to Submit Data to NDAR should be sent to:

Office of the NDAR Program Director

National Institute of Mental Health, National Institutes of Health

6001 Executive Boulevard, Room 81178252, MSC 9649

Rockville, MD 20892-9649 (if overnight delivery): Rockville, Maryland 20852

Telephone: 301-443-3879 Email: NDAR@mail.nih.gov