NDAR Frequently Asked Questions (FAQs)

General FAQs

1. What is NDAR?

NDAR stands for the National Database for Autism Research. The National Database for Autism Research (NDAR) is a biomedical informatics system and research data repository developed by the National Institutes of Health (NIH) to support and accelerate the advancement of research on Autism Spectrum Disorders (ASD). NDAR provides the infrastructure to store, search across, and analyze various types of data. In addition, NDAR provides longitudinal storage of a research participant's information generated by one or more research studies. In other words, NDAR is able to associate a single research participant's genetic, imaging, clinical assessment and other information even if the data were collected at different locations or through different studies. By doing so, NDAR gives researchers access to more data than they can collect on their own and provides robust tools to analyze the information, making it easier and faster for researchers to gather, evaluate, and share autism research information from a variety of sources.

2. What is the purpose of NDAR?

The purpose of NDAR is to help accelerate autism research by creating an infrastructure that integrates heterogeneous datasets allowing access to much more quality research data than an investigator would be able to collect on their own. Generally, NDAR provides the following capabilities:

- Standards to enable cross site meta-analysis and data comparisons across bioinformatics systems
- Deployment of useful bioinformatics tools for researcher use
- Promotion of the sharing of quality research data with autism research community
- Query access to a repository of phenotypic, genomic, imaging and pedigree research data.

3. Is the NDAR policy available?

The approved NDAR policy is available at http://ndar.nih.gov/ndarpublicweb/policies.go. Questions related to the NDAR policy may be emailed to ndar@mail.nih.gov.

4. Where does NDAR get its data from?

NDAR currently holds "common measure" data from the NIH-funded Autism Centers of Excellence (ACE) grantees. Common measure data are the core of commonly collected assessments used by researchers who study autism as identified for the ACE initiative. These assessments include measures of cognitive, language, adaptive, physical and social functioning, physical exam results, and family medical history. Specific measures can be found at **http://ndar.nih.gov/ndarpublicweb/datasubmission.go**. These data will be available for researcher access in 2009.

In July 2009, NDAR will begin accepting data from up to 15 other research projects, irrespective of funding source. Researchers interested in submitting data should review the NDAR data submission request and procedures available at **http://ndar.nih.gov/ndarpublicweb/datasubmission.go** and contact NDAR staff at **ndar@mail.nih.gov** in preparation for data submission.

5. Who can submit data to NDAR?

Any researcher who has acquired research data related to ASD may apply for approval to submit data to NDAR. To initiate a data submission request, researchers complete the data submission request available at http://ndar.nih.gov/ndarpublicweb/accessingNDAR.go.

6. What type of data are in NDAR and will the data be expanded over time?

NDAR is set up to accept standard phenotypic data, images and genomic/pedigree data (see FAQ #26 for more information on the imaging and genomic formats supported by NDAR). For the specific data elements, refer to the NDAR Data Submission page at http://ndar.nih.gov/ndarpublicweb/datasubmission.go. In 2009, NDAR is approved to develop a data dictionary system that will allow investigators to help define additional ASD data elements. Having a data

dictionary, enhanced by both external investigators and NIH staff, will enable NDAR to recognize and accept most any type of structured research data.

7. If I am submitting an application to the NIH for funding, how should I include NDAR in my data sharing plans?

All ASD or ASD-related applications for NIH funding are strongly encouraged to share their data with NDAR. Investigators should include language describing their intent to share data with NDAR and the anticipated time frame for sharing data with NDAR in response to ASD-related Requests for Applications and Requests for Proposals. Any questions about whether and how your application should include a data sharing plan with NDAR should be directed to an NIH Program Officer.

8. If my NIH application is funded, what steps do I follow so that data I generate can be submitted to NDAR?

The first step is to speak with your Program Officer responsible for the funded grant or Project Officer responsible for contracts who can provide you with sample informed consent language for data sharing with NDAR. Next, you will need to complete the steps to submit data to NDAR as defined in the Data Submission sections at http://ndar.nih.gov/ndarpublicweb/datasubmission.go.

9. How is NDAR funded?

NDAR is a biomedical informatics system and data repository developed by the National Institutes of Health (NIH). NDAR is currently co-funded or receives other resource contributions from several institutes and centers at NIH, including:

- National Institute of Mental Health (NIMH)
- National Institute of Neurological Disorders and Stroke (NINDS)
- National Institute of Environmental Health Sciences (NIEHS)
- The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
- Center for Information Technology (CIT)

NDAR Capabilities

10. How does the research community provide input on the capabilities of NDAR?

NIH is keenly interested in meeting the needs of the ASD research community to help accelerate scientific discovery. To do so, NIH meets with researchers who study ASD, data managers, bioinformatics experts and many others to identify the capabilities needed by the ASD research community. Contact ndar@mail.nih.gov if you have questions about the process.

11. What does data “federation” mean and why is it important to NDAR?

The provision of access to data sources that exist outside of a central system such as NDAR is called data “federation”. NDAR uses technology developed by the Biomedical Informatics Resource Networks (www.nbirn.net) to access such data sources, allowing NDAR to provide simple, efficient access to ASD research data that may reside outside of the NDAR central repository. Autism research data exist in many such databases located around the world, but differing access processes for multiple sources and inconsistent data standards and formats often combine to create insurmountable barriers to data reuse and collaboration. Rather than moving data from their various sources into the NDAR Data Repository—which can invoke additional complications—NDAR is deploying data “federation” technology to allow researchers to access important research data directly, in a simple, consistent manner through the NDAR portal, regardless of where the data may reside. NDAR is piloting this capability in 2009.

12. What is the GUID and why is it so important to NDAR?

The NDAR GUID, or “Global Unique Identifier”, allows NDAR to associate a single research participant’s genetic, imaging, clinical assessment and other information even if the data were collected at different locations or through different studies. A GUID is a computer-generated alphanumeric code that is unique to each research participant. The process of assigning a GUID keeps direct identifiers from ever being

transmitted or stored in the NIH NDAR database. Use of the GUID minimizes risks to study participants because it keeps one individual's information separate from that of another person without NDAR having to contain names, addresses, or other identifying information. The unique code also allows NDAR to link together all submitted information on a single participant, giving researchers access to information that may have been collected elsewhere.

NDAR Governance

13. What is the NDAR Governance Structure?

The NIH has developed a governance structure for NDAR. The Director of the National Institute of Mental Health (NIMH) oversees NDAR, its policy and implementation. In carrying out this responsibility, the NIMH Director participates on a Governing Committee, with several other NIH Institute and Center Directors or their designees that fund NDAR. The NDAR Governing Committee is responsible for the on-going management and stewardship of NDAR policy and procedures. Reporting to the Governing Committee are several groups and teams charged with the implementation, communication, and development of specific procedures related to the conduct, submission and data release practices for NDAR. One of these groups, the NDAR Implementation Team, is responsible for overseeing NDAR policy and data access to promote consistent and robust participant protections in NDAR.

In consideration of the evolving scientific, ethical, and societal issues related to NDAR, the NIH NDAR Governing Committee:

- Ensures ongoing, high-level agency oversight; and
- Obtains regular input from public representatives, including those with expertise in bioethics, privacy, data security, and appropriate scientific and clinical disciplines; and
- Revisits and revises the NDAR policy as appropriate.

14. How does NIH control access to data within NDAR?

The NIH established a Data Access Committee (DAC) to oversee access to the data contained in NDAR. Investigators and institutions seeking data from the NDAR Data Repository meet data security measures (such as physical security, information technology security, and user training). In addition, researchers complete a data access request, including a Data Use Certification (DUC), which is co-signed by the investigator and the authorized Institutional Official(s). For information about the DAC procedures see FAQ #48. NDAR will begin accepting data access requests in May of 2009. Data access procedures, when available, will be posted at http://ndar.nih.gov/ndarpublicweb/accessingNDAR.go

15. What is the role of the NDAR Data Access Committee (DAC)?

Membership of the NDAR Data Access Committee (DAC) includes Federal staff with expertise in areas such as relevant scientific disciplines, research participant protection, and privacy protections. The NDAR DAC approves submission of data and/or images to the NDAR Central Repository and determines researcher access to NDAR resources.

The DAC approves access to data and/or images from the NDAR Central Repository for research purposes only. The DAC will review the Central Repository Access Request and the Data Use Certification (DUC) of each Recipient requesting data and provide access based on the expectations outlined in the NDAR policy. These expectations include the protection of data privacy, confidentiality, and security. In the event that requests raise concerns related to privacy and confidentiality, risks to populations or groups, or other concerns, the DAC will consult with other experts as appropriate.

16. What technical measures has NIH taken to ensure NDAR is secure and protected?

To ensure the security of the data held by the repository, the NIH Center for Information Technology employs multiple tiers of data security based on the content and level of risk associated with the data.

Datasets stored in the NDAR Data Repository are under strict security provisions, including but not limited to multiple firewalls, separate servers, and data encryption protocols. As a federal information system, NDAR follows the recommended security controls defined by the National Institutes of Standards 800-53r1 and related publications. NDAR undergoes an annual independent certification and assurance audit specific to the controls defined in 800-53r1 ensuring that the defined management, data recovery, procedural, and technical controls are followed.

17. What administrative and policy measures are taken to ensure that the data contained in NDAR are protected?

As detailed in the NDAR Policy, investigators and their sponsoring institutions seeking access to data in the NDAR Data Repository first submit a data access request that specifies both the data to which access is sought and the planned research use. The data access request, when available, will be posted at http://ndar.nih.gov/ndarpublicweb/accessingNDAR.go. In addition, the investigator agrees to the terms of access set forth in the Data Use Certification (DUC). NIH has established a Data Access Committee (DAC) to oversee and approve access to the NDAR Data Repository.

Data Submission

18. How do researchers submit data to NDAR?

Investigators interested in submitting data to NDAR should review the data submission procedures at http://ndar.nih.gov/ndarpublicweb/datasubmission.go and contact the NDAR team at ndar@mail.nih.gov to help plan for data submission. The general requirements to submit data to NDAR include:

- Software Transfer Agreement (STA) – This agreement available at http://ndar.nih.gov/ndarpublicweb/Documents/STA_for_CIT_and_GUID_CLIENT.pdf allows NDAR to provide the institution with the software to generate the Global Unique IDs (GUIDs).
- Data Submission Agreement – This document is completed by the investigator and an authorized institutional business official. The Submission Agreement (SA), available at http://ndar.nih.gov/ndarpublicweb/accessingNDAR.go, will be reviewed by the NDAR Data Access Committee (DAC). .
- NDAR Account – Once the Data Submission Agreement and GUID STA are completed, an NDAR portal account can be requested at http://ndarportal.nih.gov, attaching the electronic documents mentioned above to the request.

For technical details on submitting data to NDAR, please review the "NDAR Data Validation and Submission and User Guide" located on the NDAR website at the following link: http://ndar.nih.gov/ndarpublicweb/Documents/NDAR_DataValidationSubmissionlUserGuide.pdf

19. Does NDAR provide a test or training environment for data submission?

In preparation to submit data, any researcher may receive an account to the NDAR demonstration site to better understand the capabilities of NDAR. The NDAR Demonstration site allows researchers planning to submit or access data in NDAR to understand better the capabilities of the system within an area that demonstrates NDAR's capabilities. The demonstration environment allows individuals to query fictitious sample data containing no identifiers or any real research data to better understand the capabilities available within NDAR. To request an NDAR demonstration account, visit https://ndardemo.nih.gov.

20. Does the NIH have reference materials for IRBs or research participants about NDAR?

Yes. The NDAR Policy addresses informed consent concerns for both prospective studies and retrospective studies using existing data. In addition, NIH has obtained a Certificate of Confidentiality and developed sample informed consent language for NDAR that can be requested through NDAR@mail.nih.gov. NIH has also prepared a brochure for research participants, which can be found at http://ndar.nih.gov.

21. What is considered a valid signature for institutional signoff on an NDAR submission agreement?

A valid signature for these certifications is the Institutional Business Official. In general, an Institutional Business Official is the person working in a research organization's business office who has signature or other authority. For Grants.gov that person is called an authorized organizational representative; for the NIH eRA Commons it is a signing official.

22. Are data within NDAR subject to a Freedom of Information Act (FOIA) request?

As an agency of the Federal Government, the NIH is required to release Government records in response to a request under the FOIA, unless they are exempt from release under one of the FOIA exemptions. Although NIH held data is coded and NIH does not hold direct identifiers to individuals within the NDAR Data Repository, the agency recognizes the personal and potentially sensitive nature of the genotype-phenotype data. Further, NIH takes the position that technologies available within the public domain today, and technological advances expected over the next few years, make the identification of specific individuals from raw genotype-phenotype data feasible and increasingly straightforward.

The agency believes that the release of un-redacted NDAR datasets in response to a FOIA request would constitute an unreasonable invasion of personal privacy under FOIA Exemption 6, 5 U.S.C. § 552 (b)(6). Therefore, among the safeguards that NIH foresees using to preserve the privacy of research participants and confidentiality of genetic data is the redaction of individual-level genotype, phenotype, and other data from disclosures made in response to FOIA requests as well as the denial of requests for un-redacted datasets.

23. As stated in the NIH NDAR policy, the NIH expects that all submissions to the NIH NDAR data repository will include a certification by the responsible Institutional Official(s) of the submitting institution that the expectations of the policy have been met for submission to the NIH NDAR data repository. For multi-site studies, is the submitting institution expected to certify data that are contributed by data collection centers at other institutions?

No. The submitting institution need not certify that the expectations of the Policy are met for data collected by other institutions within its multi-site arrangement. The NIH understands that the submitting institution is not necessarily the local institution or IRB of record for all data collected in a multi-site trial. However, the submitting institution should assure the NIH through the submission of the certification document—within the Submission Agreement—that it believes, based on either its own review or assurance from other institutions, that the expectations of the Policy are met for the entire dataset. In obtaining assurance from other sites in a multi-site study, the submitting institution should retain copies of any information it receives from other data collecting sites.

24. Are submitting institutions expected to certify that data submission is consistent with applicable laws and regulations in effect at any and all locations at which data were collected?

No. Submitting institutions are expected to certify that data submission is consistent with applicable laws and regulation relevant to their specific activities, e.g., home state law, home institutional policies, etc. Submitting Institutions may assume that all prior data transfers from data collection sites to the submitting institution (e.g., a data coordinating center) were conducted according to any applicable laws relevant to the those organizations at the time of the original data transfer. The NIH, however, does expect that all data were collected in accord with 45 C.F.R. Part 46. As discussed in a separate FAQ, this assurance in multi-site studies can be made on the basis of a direct review of study materials by the submitting institution or based on information or assurance provided to the submitting institution by data collecting organizations.

25. What technology does a researcher need to contribute data to NDAR?

NDAR supports submissions of clinical assessment data through the CDISC (www.cdisc.org) format. Imaging data are supported for submission in the MIPAV XML format, and genomic data submissions are supported through Excel templates. The procedures, sample files, and detail data definitions are defined at http://ndar.nih.gov/ndarpublicweb/datasubmission.go. Additionally, NDAR has provided tools to convert tab and comma delimited data into CDISC format (contact ndar@mail.nih.gov for more information).

26. Can imaging and genomic data be submitted to NDAR?

Yes, NDAR is able to accept both imaging and genomic data along with common measure data and phenotypic data. For imaging data, NDAR supports DICOM, NIFTI, AFNI, MINC 1.0, MINC 2.0, Analyze, SPM, GE, Siemens, and MIPAV formats. NDAR has adopted the MIPAV XML format for gathering metadata on images to be submitted to NDAR. The MIPAV (Medical Image Processing, Analysis, and Visualization) (http://mipav.cit.nih.gov) application enables quantitative analysis and visualization of medical images of numerous modalities such as PET, MRI, CT, or microscopy. MIPAV contains a module that processes images and generates the MIPAV XML required for imaging data submission to NDAR. Similar to clinical assessments, the NDAR Data Dictionary defines the field names and acceptable values for image metadata which the MIPAV XML data file(s) must adhere to. The data dictionary also has a sample imaging MIPAV XML file for reference. See the "Submitting Data to NDAR" section of the NDAR website for more detailed information on imaging submissions.

For the information about the experiment (metadata), NDAR supports Templates which is an implementation of the Minimum Information about a Microarray Experiment (MIAME) standard. This implementation was selected for its flexibility allowing NDAR to support information about other types of genomics experiments.

The field of genomics is working on common formats for the actual data measurements by various technologies. For each specific technology, NIH will work with the users to make sure we are getting both the raw data and typical processing expected by the community. For example, for Affymetrix® data, we will accept raw data in the .dat format; preprocessed data in the .cel files, and processed data in .chp files. NDAR can also accept the .exp and .rpt files.

NIH welcomes comments on NDAR specifications and standards at ndar@mail.nih.gov.

27. What is a data dictionary and where can I find the NDAR Data Dictionary?

The data dictionary is a document that defines the data supported for submission to NDAR. The NDAR Data Dictionary as well as the other steps needed to submit data to NDAR are defined at http://ndar.nih.gov/ndarpublicweb/datasubmission.go.

28. Does NDAR accept all types of phenotypic data?

Currently, NDAR supports only the assessments defined in the NDAR Data Dictionary (http://ndar.nih.gov/ndarpublicweb/datasubmission.go). NIH is expanding this list to include additional assessments. In 2009, NDAR will develop a system to allow the research community to define phenotypic data, thereby allowing NDAR to accept virtually any phenotypic data available from researchers.

29. Should data be submitted to NDAR cumulatively or in installments?

Except for imaging and genomic data that are unchanged, all data should be submitted to NDAR cumulatively. By receiving data cumulatively, it greatly simplifies data analysis and querying capabilities and allows researchers to more easily compare data longitudinally.

30. How should NIH intramural staff submit data to NDAR and request access to the NDAR Data Repository?

NIH intramural ASD research projects approved on or after April 15, 2008 are expected to address the submission of research information to NDAR. The procedures for submitting data to NDAR and requesting access to the NDAR Data Repository for both intramural and extramural researchers will be the same. To provide data to NDAR, complete the NDAR data submission request available at http://ndar.nih.gov/ndarpublicweb/accessingNDAR.go.

Data Availability in NDAR

31. When will the data submitted into NDAR be made available to researchers approved to access the NDAR Data Repository?

Data submitted to NDAR for broad research access are expected to be made available to other researchers within nine months of submission. This period allows the investigator and NIH to undertake quality control efforts described in the NDAR policy. Researchers should consult their funding agency and the terms and conditions of award to determine an appropriate data submission schedule.

32. How are data organized in NDAR?

When an investigator is authorized to submit data to NDAR, he or she has the ability to organize one or many datasets into a single entity called a "collection." In general terms, a "collection" is a virtual container for the data that is submitted, allowing an investigator to describe in detail the collected data. Once data is contained in a collection, a researcher may then link that data to an NDAR study hypothesis, defining population and subpopulations specific to the aims of an investigator's research.

Refer to the Data Validation and Submission Guide available on the NDAR website at http://ndar.nih.gov/ndarpublicweb/Documents/NDAR_DataValidationSubmissionlUserGuide.pdf for more information on data submission and organization procedures.

33. What is the process for making data available?

The investigator is able to query all data he or she has submitted to NDAR. At first, data submitted for broad research access is held in a location that only the investigator, and the NDAR staff, can access to perform quality control procedures. Within nine months, the investigator is expected to initiate a request to make the data available for research use. The NDAR DAC then reviews the request before the data are moved to a shared state. If existing data are already shared, those data will be remain available but identified in NDAR as not being the most current. In other words, NDAR will retain and display prior versions of data but will indicate to researchers the datasets that may have been updated.

34. How will updates to data within NDAR be handled?

Once data are made available in the shared repository, those data can not be changed. Data are expected to be refreshed with cumulative data according to the defined submission schedule. Previous versions of data remain available in NDAR, allowing for analysis of changes from one submission to the next.

35. What quality control processes and measures are in place in NDAR?

The NIH is implementing a two-tiered data control procedure for information and images submitted to NDAR. Such efforts help to ensure that the information submitted has undergone reviews for accuracy, completeness, and availability.

The first level of quality control is performed by the researcher who is expected to certify the accuracy of the information prior to submission. Additionally, all data provided to NDAR undergoes automated validation using the NDAR data validation tool before it is even received into the NDAR Data Repository. The NDAR Validation Tool checks the data proposed for submission against the NDAR Data Dictionary to

ensure that the data comply with the standards established in the data dictionary. Currently, this tool provides item-level validation.

The second level of quality control occurs when data and/or images are submitted to NDAR for broad research access. The NIH provides a period of up to nine months to allow the submitter and the NIH to undertake activities to review the completeness of the submission. Such efforts include verifying that the information received by NDAR is complete (i.e., not missing records intended for submission), contains no identifying information, displays correctly, and that the NDAR toolset functions as expected with the information. During this timeframe, access to data and brain images for research is temporarily suspended to help ensure that NDAR makes available only carefully reviewed information. Should the NIH determine that additional time is necessary to ensure the quality of the submitted information (e.g., time necessary to remedy concerns), the NIH may opt to extend the quality control period as necessary in the interest of science. After quality control measures are satisfied, the submitted information will be certified as accurate by the submitting researcher and will be available for sharing.

36. Is NDAR a repository for biological samples (e.g. tissues, DNA, cell lines)?

No, NDAR does not accept, store or access biological samples. However, NDAR provides reference to biological samples located elsewhere enabling researchers to contact such biological repositories to gain access such samples.

37. Can non-research entities (e.g., law enforcement agencies, insurance companies, employers) request access to identifiable information corresponding to phenotype and genotype data held in the NIH NDAR Data Repository?

The NIH acknowledges that legitimate requests for access to data made by law enforcement offices to the NIH may be fulfilled. The NIH does not possess direct identifiers within the NDAR Data Repository, nor does the NIH have access to the link between the data code and the identifiable information that may reside with the primary investigators and institutions for particular studies. The release of identifiable information may be protected from compelled disclosure by the primary investigator's institution if a Certificate of Confidentiality is or was obtained for the original study (please see http://grants2.nih.gov/grants/policy/coc/). The NIH strongly encourages investigators to consider obtaining a Certificate of Confidentiality as an added measure of protection against future compelled disclosure of identities for studies planning to collect genome-wide association data.

38. Is a Certificate of Confidentiality necessary for data submitted to NDAR?

No. The NIH strongly encourages, but does not require, institutions to obtain a Certificate of Confidentiality for eligible studies that plan to contribute research subject data to NDAR.

The NIH considers a Certificate of Confidentiality to be an important but not mandatory research tool, available to assist research organizations in protecting the privacy of their research participants. Congress designed these certificates as a way of encouraging potential research participants to participate in studies, given a common concern that public knowledge of their participation could lead to potentially negative consequences.

39. What data should an investigator provide to NDAR?

The NIH strongly encourages the submission of ASD-related phenotype, imaging, genotype, and pedigree data, and other data as appropriate, to the NIH NDAR Data Repository. To learn more about the type of data that NDAR can accept, refer to the data submission area of the NDAR website at http://ndar.nih.gov/ndarpublicweb/datasubmission.go or contact NDAR staff at ndar@mail.nih.gov.

40. Can a parent provide his or her child's medical and assessment data directly to NDAR?

No. Only researchers with an approved data submission request may submit data to NDAR. If, however, the child's health care provider is also a researcher, the health care provider could request to submit data to the NDAR Data Repository.

41. Can NDAR compile all information about a single research participant, even if it was submitted by different researchers and at different times?

Yes. Although data submitted to the NIH NDAR Data Repository are de-identified such that the identities of research participants cannot be readily ascertained or otherwise associated with the data by the repository staff or secondary users, research participants should be made aware during the informed consent process that other researchers will have access to their coded research data in NDAR, and what, if any, privacy risks exist. In fact, investigators approved to submit data to NDAR and their institutional officials certify that an IRB and/or Privacy Board have considered the risks to privacy prior to submitting the data. In addition, investigators granted access to NDAR data and their institutions sign a Data Use Certification (DUC), agreeing not to make any attempt to re-identify individual participants, to use the data only for approved purposes, and to protect data confidentiality, among other stipulations.

Data Access

42. Who may access shared NDAR research data?

NIH will provide access to NDAR data to scientific investigators for research purposes. Researchers who have completed a Data Use Certification (DUC) and received approval from the NDAR Data Access Committee (DAC) may be approved to access broadly shared data in NDAR. Additionally, the DAC and NDAR support staff at NIH have access to NDAR data.

43. How do I request access to NDAR data?

Shared data will be available to approved researchers in NDAR beginning in 2009. Investigators requesting and receiving NDAR data are expected to:

- Submit a description of the proposed research project;
- Submit a Data Access Request, including a Data Use Certification co-signed by the authorized Institutional Official(s) at their sponsoring institution;
- Protect data confidentiality;
- Ensure that data security measures are in place;
- Notify the Data Access Committee of policy violations; and
- Submit annual progress reports detailing significant research findings.

44. What is a Data Use Certification?

To promote the responsible use of NDAR data, all investigators seeking access, and their institutions, acknowledge their agreement with the NDAR Policies and Procedures by signing a Data Use Certification. The NDAR Data Use Certification articulates that investigators will agree, among other things, to:

- Use the data only for the approved research;
- Protect data confidentiality;
- Follow appropriate data security protections;
- Follow all applicable laws, regulations and local institutional policies and procedures for handling NDAR data;
- Not attempt to identify individual participants from whom data within a dataset were obtained;
- Not sell any of the data elements from datasets obtained from the NIH NDAR data repository;

- Not share with individuals other than those listed in the request any of the data elements from datasets obtained from the NIH NDAR data repository;
- Agree to the listing of a summary of approved research uses within the NIH NDAR data repository along with his or her name and organizational affiliation;
- Agree to report, in real time, violations of the NDAR policy to the DAC;
- Acknowledge the NDAR policy with regard to publication; and
- Provide annual progress reports on research using NDAR data.

See http://ndar.nih.gov/ndarpublicweb/accessingNDAR.go for more information.

45. Can the researcher who contributed the data to NDAR be identified?

Yes. When data are submitted, the researcher provides information related to the data, including his or her name, an overview of the data and how it was acquired, and other pertinent information associated with the research. This information is made available to other researchers, in accordance with the NDAR policy and procedures.

46. What technology does a researcher need to access data?

NDAR currently supports an interface with Microsoft Internet Explorer, Version 6.0 or higher. In addition, the Java Runtime Environment (JRE) version 1.5 or greater is required to submit data.

47. Will only data collected from NIH-funded studies be made available through NDAR?

NDAR will accept data from other researchers, regardless of funding source, in 2009. Currently, only data from the NIH Autism Centers of Excellence awardees and NIH Intramural researchers are being included in NDAR. However, NIH encourages others to complete the steps defined at http://ndar.nih.gov/ndarpublicweb/datasubmission.go and contact NDAR staff at ndar@mail.nih.gov to plan data submissions.

48. Which data in the NDAR Data Repository can researchers use if they are approved for access?

Researchers approved for access will be granted access to the entire collection of shared data in the NDAR Data Repository. This includes access to data contributed by NIH-funded extramural researchers and intramural researchers, as well as research institutions or organizations that are not necessarily funded by NIH. Please refer to the NDAR policy at http://ndar.nih.gov/ndarpublicweb/policies.go.

49. What is the process for deciding who will gain access to the data I submit to NDAR for broad research access?

The NDAR Data Access Committee (DAC) will review requests from research investigators seeking access to NDAR datasets. The DAC will review requests to determine whether the proposed use of the dataset is scientifically and ethically appropriate.

The access request process involves submission of a Data Use Certification (DUC) that is co-signed by the investigator and the authorized Institutional Official(s). Data Access Requests should include a brief description of the proposed research use of the requested NDAR. (See FAQ # 44 for details about the DUC).

50. Does a researcher need to pay a fee to access NDAR data?

No, there are no fees to access data stored within NDAR. NDAR is a resource funded by the NIH.

51. When can the data I submit be accessed by approved researchers?

Data provided to NDAR for broad research access are expected to be made available within nine months of submission to allow sufficient time for data quality checks. The timing of access, however, may differ depending on the type of data submitted (i.e. common measures, other phenotypic data, imaging, and

genomics). A specific schedule for submission to NDAR is best determined between the investigator and the funding agency.

52. As a researcher, I may have data that would be of value to NDAR and the ASD research public. Is there funding available for submitting data to NDAR?

No funding assistance is currently available for retrospective studies. However, exceptions may be considered. For prospective studies that would be of benefit to NDAR and other researchers, we encourage investigators to include NDAR in your response to ASD-related Requests for Applications and Requests for Proposals and budget.

53. As a researcher, I have a grant application that proposes to use data made available in NDAR. When will NDAR data be available for research use?

NDAR will begin to provide data available for broad research access in 2009. However, investigators interested in using this data for prospective studies funded by the NIH are encouraged to complete the NDAR Data Access Procedures and include the request within their application.