Supporting Statement A for

National Institute of Mental Health
NDAR Data Access Request

(October 19, 2012)

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A.1 Circumstances Making the Collection of Information Necessary

The National Institutes of Health (NIH) created the National Database for Autism Research (NDAR, http://ndar.nih.gov), an informatics system and central data repository, housed at the NIH Center for Information Technology, to support and accelerate research in the prevention, cause, diagnosis, and treatment of autism spectrum disorder (ASD). NDAR collects a wide range of data types, including phenotypic, clinical, and genomic, as well as medical images, derived from individuals who participate in ASD research, regardless of the source of funding. NDAR provides the infrastructure to store, search across, retrieve, and analyze these varied types of data.

The potential for public benefit to be achieved through sharing autism research data is significant. However, genotype and phenotype information generated about individuals, such as data related to the presence or risk of developing autism and information regarding paternity or ancestry, may be sensitive. Therefore, protecting the privacy of the research participants and the confidentiality of their data is critically important. Risks to individuals, groups, or communities should be balanced carefully with potential benefits of the knowledge to be gained through NDAR.

The information requested from the investigator seeking access to NDAR data, as part of the Data Access Request, may be made public in part or in whole for tracking and reporting purposes. The Data Access Request provides a Privacy Act Notification pursuant to Public Law 93-579, Privacy Act of 1974, 5 U.S.C. Section 552a. Authority for the collection of the information requested from the recipient investigators 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, 289l-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 09-25-0156, (http://oma.od.nih.gov/ms/privacy/pa-files/0156.htm) covering "Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the Public Health Service, HHS/PHS/NIH/OD." The NIH System of Record Notice was previously published in the Federal register on September 26, 2002, Volume 67, No 187, page 60742.

A.2 Purpose and Use of the Information Collection

The primary uses of this information are to document, track, monitor, and evaluate the use of the NDAR datasets, as well as to notify interested recipients of updates, corrections, or other changes to the database. As part of the **current** Data Access Request process, NIH asks investigators to complete specific items on the Grants.gov SF 424 Form. The use of this previously OMB-approved information collection form was an expedient measure to jumpstart the use of the database in its infancy. As data submission and access procedures are maturing, NIH is interested in developing a Data Access

Request Form more tailored to the unique needs of NDAR. The type of information requested in the new NDAR Data Access Request Form satisfies the terms and conditions of the NDAR Data Sharing Policy. The new form contains a section wherein investigators can provide a description of the research project they are proposing to perform with NDAR data. The form also reminds investigators to provide an annual summary of research accomplishments from using NDAR in an updated biographical sketch or CV. As investigators typically update their sketches and CVs on a regular basis, this is unlikely to be an undue burden when requested. This valuable information will help NIH understand and evaluate the use of NDAR in the ASD research community.

A.3 Use of Information Technology and Burden Reduction

To gain access to NDAR data, an investigator must obtain NDAR data access privileges. To obtain these privileges, an investigator must complete, sign, scan, and upload the Data Access Request/Data Use Certification to the NDAR web portal. Both documents must include the Federal-wide Assurance (FWA) number of the investigator's affiliated institutions, and be co-signed by an NIH-recognized Business/Institutional Official. Thus, the process for obtaining access to data within NDAR is designed to be both electronic (information may be typed into the form and the form is uploaded via a web portal) and mechanical (signatures are requested on the form, which is then scanned and uploaded):

The NDAR Data Access Request form requests the following pieces of information:

- The title and a brief summary/abstract of the Research Project for which NDAR data are sought. A single paragraph is sufficient.
- Contact information for the investigator seeking access (the NDAR Data Recipient), as well as for key/senior personnel in the Recipient's laboratory who will also require access as part of the Research Project.
- Co-signatures from the Recipient Investigator and the Investigator's Institutional Official certifying that they will abide by the DUC and the NIH principles, policies and procedures for the use of NDAR. Investigators also acknowledge that they have shared the Data Access Agreement document and the NIH policies and procedures with any research staff who will participate in the use of NDAR. The Institutional Business Official(s) also acknowledges that they have shared this document and the relevant NIH policies and procedures with appropriate institutional organizations.
- The institution's FWA number.

Once completed, the request package is then sent for adjudication to the Data Access Committee (DAC) established to oversee access to the NDAR shared data. When the investigator's request is approved, the investigator is notified by e-mail and explained the conditions under which the approval is granted.

A Privacy Impact Assessment (PIA) for NDAR was approved on September 28, 2012.

A.4 Efforts to Identify Duplication and Use of Similar Information

To protect and assure the confidentiality and privacy of all research participants whose data have been submitted to NDAR, investigators who seek access to these data are expected to adhere to the specifications of the principles outlined the NDAR Data Sharing Policy (see http://ndar.nih.gov/ndarpublicweb/Documents/NDAR_Policy.pdf, section entitled, "Data Access"). Furthermore, each research project is unique, and collecting information about these projects, through the new NDAR Data Access Request Form, will enable NIH to document, track, monitor, and evaluate the use of the NDAR datasets, as well as to notify interested recipients of updates, corrections, or other changes to the database.

Due to the sensitive nature of the data contained in NDAR, and in accordance with existing NIH policies, such as that for NDAR and genome-wide association studies (GWAS, see http://grants.nih.gov/grants/gwas/index.htm), NDAR data access approvals are granted for one year and may be renewed thereupon.

A.5 Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study.

A.6 Consequences of Collecting the Information Less Frequently

The information requested in the NDAR Data Access Request does not ask investigators to generate any new information, because the type of information being requested is fundamental to conducting any research study. The data are collected on a needed basis. We anticipate no more than once a year per researcher/investigator request.

Additionally, the NDAR Data Access Request states that data recipients may be asked to provide an annual summary of research accomplishments from using NDAR in an updated biographical sketch or CV (as noted above, NDAR data access approvals are granted for one year and may be renewed thereupon). As investigators typically update their sketches and CVs on a regular basis, this is unlikely to be an undue burden when requested.

As stated before, protecting the privacy of the research participants and the confidentiality of their data is critically important. Essential aspects of that protection are careful screening who may obtain access to the database, and ongoing monitoring of the use of those data.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

Not Applicable.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

A Federal Register Notice was published on June 22, 2012, Vol 77 FR 37683 (https://www.federalregister.gov/articles/2012/06/22/2012-15334/proposed-collection-comment-request-ndar-data-access-request). No public comments were received.

The Data Access Request has been reviewed and approved by the NDAR Data Access Committee (DAC)
(DAC). The DAC represents a diverse group of NIH scientific and programmatic staff.. Both the DAC and the NIH Autism Coordinating Committee contributed their input during the development of the Data Access Request Form.

A.9 Explanation of Any Payment of Gift to Respondents

No payment or gift will be provided to respondents.

A.10 Assurance of Confidentiality Provided to Respondents

The Federal Privacy Act protects the confidentiality of the Recipient's NIH records. The NIH and any sites that are provided access to the datasets will have access to the data collected from the Recipient for the purposes described above. In addition, the Act allows the release of some information in the Recipient's records without his/her permission; for example, if it is required by members of Congress or other authorized individuals. The information requested is voluntary, but necessary for obtaining access to data.

The information requested from the investigator seeking access to NDAR data, as part of the Data Access Request, may be made public in part or in whole for tracking and reporting purposes. The Data Access Request provides a Privacy Act Notification pursuant to Public Law 93-579, Privacy Act of 1974, 5 U.S.C. Section 552a. Authority for the collection of the information requested from the recipient investigators 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, 289l-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 09-25-0156, September 26, 2002, 67 FR 60742-60794 (http://oma.od.nih.gov/ms/privacy/pa-files/0156.htm) covering "Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the Public Health Service, HHS/PHS/NIH/OD."

Although the NDAR data will be coded and the NIH will not hold direct identifiers to individuals within the NIH NDAR data repository, the agency recognizes the personal and potentially sensitive nature of the genotype-phenotype data. Investigators and institutions seeking access to data or images from NDAR are expected to meet data security measures and to submit a Data Access Request, including a Data Use Certification, co-signed by the investigator and the designated Institutional Official(s) (see http://ndar.nih.gov/ndarpublicweb/Documents/NDAR_Policy.pdf). The NDAR Data Access Committee reviews and approves all submission and access requests. (see http://ndar.nih.gov/ndarpublicweb/policies.html#AccessCommittee).

A.11 Justification for Sensitive Questions

The National Database on Autism Research does not ask any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are

commonly considered private; and therefore, does no need to provide a justification for this type of information.

Upon submission of data, NDAR staff performs a quality control review to ensure that no personally identifiable information (PII) is contained in the dataset or supporting documentation. Only data that have undergone a quality control review are approved for sharing with the research community.

A.12 Estimates of Hour Burden Including Annualized Hourly Costs

There are two scenarios for completing the form. Sometimes the Principal Investigator completes the whole document, and other times he/she has a Research Assistant complete it (after which the Investigator reviews and signs it).

A. Estimates Annual Burden Hours				
Form	**Estimated Number of Respondents**	**Estimated Frequency of Response**	**Average time per response (in hours)**	**Estimated Total Annual Burden Hour Requested**
NDAR Data Access Request	40	1	95/60	63
Total	40			63
B. Estimates of Total Annual Cost Burden				
Form	**Estimate Total Annual Burden Hours**	**Wage rate**	**Total Costs**	
NDAR Data Access Request	63	$ 91.00	$ 5,733	

A.13 Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no additional costs other than the respondents' burden given in A12**.**

A.14 Annualized Cost to the Federal Government

Staff	NDAR Operations Time	NDAR Operations Cost*
NDAR Operations Staff Tier 1	1 hour	$17.50
NDAR Operations Staff Tier 2	1.25 hour	$87.50
Data Access Committee Staff	1.25 hour	$106.25
Total per Data Access Request Form		$211.25
Annual # of Data Access Requests		40
Total Annualized Cost		$8,450.00
Estimated salaries*		
NDAR (T1) = $17.50/hr		
NDAR (T2) = $70/hr		
DAC = $85/hr		

A.15 Explanation for Program Changes or Adjustments

This is a new data collection.

A.16 Plans for Tabulation and Publication and Project Time Schedule

There is no specific plan to publish the data collected from this form. These data are for internal monitoring purposes.

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

Not applicable.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

Not applicable.