Supporting Statement A for

National Institute of Mental Health
Data Access Request and Use Certification
(Previously the NDAR Data Access Request)

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A.1 Circumstances Making the Collection of Information Necessary

This is a revision to the currently approved ICR (Title: NDAR Data Access Request; OMB Control Number: 0925-0667; Expiration Date: 01/31/2016). Several National Institutes of Health (NIH) data repositories require applicants to complete a data access request form, generally consisting of an abbreviated Standard Form 424 and a data use certification. The use of this previously OMB-approved information collection form was an expedient measure to jumpstart the use of these databases. The National Institute of Mental Health (NIMH) recently received OMB-approval for use of the National Database for Autism Research (NDAR) Data Use Certification Form (Title: NDAR Data Access Request; OMB Control Number: 0925-0667; Expiration Date: 01/31/2016). NIMH is interested in renaming this form the "NIMH Data Access Request and Use Certification (DUC) Form" and using it to meet the unique data access needs of all NIMH data repositories. There are currently three data repositories/sets positioned to use the NIMH DUC form: NDAR, the NIH Pediatric MRI Data Repository (PedsMRI), and the NIMH Clinical Research Datasets (NCRD).

NDAR: The NIH created 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.

PedsMRI: The PedsMRI (www.pediatricmri.nih.gov) was created by four NIH institutes (NICHD, NIMH, NIDA and NINDS) using a contract mechanism to collect brain magnetic-resonance imaging data (anatomic MRI, supplemented by proton spectroscopy and diffusion tensor imaging) and correlated clinical/behavioral data from over 500 healthy, psychiatrically normal children, ages newborn to late adolescent/young adult. The goal of PedsMRI is to provide a normative reference that might be used to study healthy brain development as a basis for studying child and adolescent brain disorders and diseases, and for developing tools (e.g., image processing tools, atlases, etc.) that might be used to study brain development. PedsMRI has been moved to the NIH (housed at the Center for Information Technology (CIT) and into the infrastructure provided by NDAR.

NCRD: The data from NIMH-supported clinical trials are an important scientific resource (http://www.nimh.nih.gov/trials/datasets/index.shtml). It is the view of NIMH that their full value can only be realized if they are made available, under appropriate terms and conditions, in a timely manner to the wider scientific community, provided that the confidentiality and privacy of study participants are protected.

The potential for public benefit to be achieved through sharing autism, pediatric MRI, and clinical trials research data is significant. However, genotype and phenotype information generated about individuals, such as data related to the presence or risk of developing brain disorders 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 NIMH data repositories/sets.

The information requested from the investigator seeking access to repository/set data, as part of the Data Access Request for these repositories and datasets, may be made public in part or in whole for tracking and reporting purposes. Each 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 repository 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 for PedsMRI and NCRD, 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 the repositories/sets. The type of information requested in the new NIMH Data Access Request and Use Certification satisfies the terms and conditions of the data sharing policies for these data. The revised form contains a section wherein investigators can provide a description of the research project they are proposing to perform with the data. The terms and conditions associated with NDAR remind investigators to provide an annual summary of research accomplishments from using the repository/set in an updated biographical sketch or CV, and the terms for PedsMRI and NCRD ask for notification of publications. 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 repositories/datasets in the research community.

A.3 Use of Information Technology and Burden Reduction

To gain access to data, an investigator must obtain data access privileges. To obtain these privileges, an investigator must complete, sign, scan, and upload or email the Data Access Request/Data Use Certification to the repository web portal (or mailing address in the case of NCRD). The document 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 the repository is designed to be both electronic (information may be typed into the form and the form is uploaded via a web portal/emailed) and mechanical (signatures are requested on the form, which is then scanned and uploaded/emailed):

The NIMH Data Access Request and Use Certification requests the following pieces of information:

- The title and a brief summary/abstract of the Research Project for which repository data are sought. A single paragraph is sufficient.
- Contact information for the investigator seeking access (the 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 the repository/dataset. 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 the repository. 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 relevant Data Access Committee or authority (for NDAR, Pediatric MRI, and NCRD) established to oversee access to the shared data. When the investigator's request is approved, the investigator is notified by e-mail.

A Privacy Impact Assessment (PIA) for NIMH Data Access Request and Use Certification (previously NDAR DUC) 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 the repositories, investigators who seek access to these data are expected to adhere to the specifications of the principles outlined the repository Data Sharing Policy (for NDAR, see http://ndar.nih.gov/ndarpublicweb/Documents/NDAR_Policy.pdf, section entitled, "Data Access"; for PedsMRI, see http://pediatricmri.nih.gov/nihpd/info/irb.html; for NCRD, see http://www.nimh.nih.gov/trials/datasets/nimh-policy-for-distribution-of-data.shtml). Furthermore, each research project is unique, and collecting information about these projects, through the new NIMH Data Information and Certification Form, will enable NIH to document, track, monitor, and evaluate the use of the NDAR, PedsMRI, and NCRD data, 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 the repositories/datasets, and in accordance with existing NIH policies, such as that for NDAR, PedsMRI, and genome-wide association studies (GWAS, see http://grants.nih.gov/grants/gwas/index.htm), 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 NIMH Data Information and Certification Form 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 NIMH Data Information and Certification Form states that data recipients may be asked to provide an annual summary of research accomplishments

from using the repositories in an updated biographical sketch or CV (as noted above, 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. NIMH Data Access Request and Use Certification has been reviewed and approved by the NDAR Data Access Committee (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 NIMH Data Access Request and Use Certification (previously NDAR Data Access Request).

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 repository data, as part of the NIMH Data Access Request and Use Certification, may be made public in part or in whole for tracking and reporting purposes. The NIMH Data Information and Certification Form 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 repository data will be coded (or de-identified) and the NIH will not hold direct identifiers to individuals within the NIH 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 the repository are expected to meet data security measures and to submit a NIMH Data Access Request and Use Certification, co-signed by the investigator and the designated Institutional Official(s) (see http://ndar.nih.gov/ndarpublicweb/Documents/NDAR_Policy.pdf, http://pediatricmri.nih.gov/nihpd/info/irb.html, and http://www.nimh.nih.gov/trials/datasets/nimh-policy-for-distribution-of-data.shtml). The NDAR Data Access Committee reviews and approves all submission and access requests. (see http://ndar.nih.gov/ndarpublicweb/policies.html#AccessCommittee). PedsMRI and NCRD have their own separate, independent Data Access Committees or authorities.

A.11 Justification for Sensitive Questions

NDAR and PedsMRI do 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, do no need to provide a justification for this type of information. NCRD does not distribute sensitive data.

Upon submission of data, the repository 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**
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**	
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	Repository Operations Time	Repository Operations Cost*
Repository Operations Staff Tier 1	1 hour	$17.50
Repository Operations Staff Tier 2	1.25 hour	$87.50
Data Access Committee (DAC) 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*		
Repository Staff (T1) = $17.50/hr		
Repository Staff (T2) = $70/hr		
DAC = $85/hr		

A.15 Explanation for Program Changes or Adjustments

This is a revision of a currently approved ICR. Several National Institutes of Health (NIH) data repositories require applicants to complete a data access request form, generally consisting of an abbreviated Standard Form 424 and a data use certification. The use of this previously OMB-approved information collection form was an expedient measure to jumpstart the use of these databases. The National Institute of Mental Health (NIMH) recently received OMB-approval for use of the National Database for Autism Research (NDAR) Data Use Certification Form (Title: NDAR Data Access Request; OMB Control Number: 0925-0667; Expiration Date: 01/31/2016). NIMH is interested in renaming this form the "NIMH Data Access Request and Use Certification (DUC) Form" and using it to meet the unique data access needs of all NIMH data repositories.

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.