Supporting Statement A for

NIH/NCATS GRDR℠ Program: Global Rare Diseases Patient Registry Data Repository (GRDR)

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A.1 Circumstances Making the Collection of Information Necessary

This is a new request for data submission and data collection.

GRDR Program: The NIH created the GRDR Program https://grdr.ncats.nih.gov/ an informatics system and central data repository, housed at the NCATS/NIH Center to support and accelerate research in the cause, diagnosis, and treatment of rare diseases. The GRDR Program collects a wide range of data types, including phenotypic, clinical, and genomic, as well as medical images, derived from individuals who participate in rare disease patient registries, regardless of the source of funding. The GRDR Programs 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 patient clinical data is significant. However, genotype and phenotype information generated about individuals 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 GRDR data repository.

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.

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 to submit and access the data, as well as to notify interested recipients of updates, corrections, or other changes to the database. As part of the current Data submission and Data Access Request process for GRDR, NIH asks investigators to complete specific items on the request application form and submit it electronically. The type of information requested in GRDR Data Submission and Data Access Request and Use Certification satisfies the terms and conditions of the data sharing policies for these data. There are two levels of access to data. One is Open access that only summary of data and non-sensitive that is available to the public will be provided. The other level is Control Access where detailed information can be provided. In this case the applicant has to fill a form and provide some information for what the data is going to be used for. The

forms contain a section wherein investigators can provide a description of the research project they are proposing to perform with the data or data of which patient registry they would like to submit. The terms and conditions associated with GRDR remind investigators to provide notification of publications and presentation. 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, or submit data, an investigator must complete, sign, and upload the Data Access Request/Data Use Certification via the repository web portal and submit it electronically. The document must include the Federal Wide Assurance (FWA) of the investigator's Business/Institutional Official or Institutional Review Board (IRB).

The GRDR 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), Co-signatures from the Recipient Investigator and the Investigator's Institutional Official certifying that they will abide by the GRDR 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 with any research staff who will participate in the use of the repository.
- The institution's FWA number.
- The Institution IRB approval

Once completed, the request package is then sent for authority established to oversee submission and access to the shared data. When the investigator's request is approved, the investigator is notified by e-mail.

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 in the GRDR repository Submission and Access to Data Policy. Furthermore, each research project is unique, and collecting information about these projects through the GRDR Data Information and Certification Form, will enable NIH to document, track, monitor, and evaluate the use of the GRDR data, as well as to notify interested recipients of updates, corrections, or other changes to the database. The GRDR database is unique, for collecting de-identified patient data from different rare diseases registries. Similar form, (but not the same) for collecting information from investigators requesting access to data is used by NIMH for the NDAR program.

Although data collected into the GRDR data repository is de-identifies (coded), the GRDR program will operate in accordance with existing NIH policies and the Federal Privacy Act that ensures that no sensitive or personally identifiable information, located in federal systems of records (e.g., Recipient NIH records), is being shared. Data access is available to all approved investigators and is 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 GRDR 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 is collected on a needed basis. We anticipate no more than once a year per researcher/investigator request.

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 the careful screening of who may obtain access to the database, and ongoing monitoring of the use of that 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. The 60-Day Federal Register notice was published on July 30, 2014 (Vol. 79, No. 146, page 44185). No public comments were received.
B. GRDR Data Access/Data Submission Request and Use Certification has been reviewed by the GRDR working group see Attachment A

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

Data collected for the GRDR program will be stored and used according to the Federal Privacy Act. The Federal Privacy Act ensures that no sensitive or personally identifiable information, located in federal systems of records (e.g., Recipient NIH records), is being shared. The GRDR database maintains only de-identified data. Any approved investigator that is provided access to the datasets will have access to the data collected only for the purposes indicated by the investigators.

The information requested from the investigator seeking access to repository data, as part of the GRDR Data Access Request and Use Certification, may be made public in part or in whole for tracking and reporting purposes. The GRDR 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 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 GRDR Data Access Request and Use Certification, co-signed by the investigator and the designated Institutional Official(s). The GRDR Committee will review and approve all submission and data access requests.

A.11 Justification for Sensitive Questions

GRDR 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. GRDR 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). The wage rate was obtained from Bureau of Labor Statistics rates (DOL/civilians) website: http://www.bls.gov/oes/current/oes_nat.htm#15-0000. Occupational codes 15-1151 and 19-1020.

A. Estimates Annual Burden Hours

Type of Form	Estimated Number of Respondents	Estimated Frequency of Response	Average time per response (in hours)	Estimated Total Annual Burden Hour Requested
Request for Open Access	2000	1	2/60	67
Request for Controlled Access	1000	1	15/60	250
Request to Submit	100	1	10/60	17
Total				334

B. Estimates of Total Annual Cost Burden

Type of Form	Estimate Total Annual Burden Hours	Wage rate	Total Costs
Request for Open Access	67	$ 37.32	$ 2,500
Request for Controlled Access	250	$ 37.32	$ 9,330
Request to Submit	17	$ 37.32	6,344

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

This survey is estimated to cost the Federal Government $22,680 annualized (Table A.14-1).

Table A14-1. Cost to the Federal Government

Staffing	Task	Annualized Cost
NCATS	GS-14, Step 7, program director ($127,000 x 1% time for 12 months)	$75,240
Contractor	Web Management support, saving submitted information in specific folders of the web portal	$7,440

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 tracking purposes.

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

The OMB expiration date will be displayed in the upper-right hand corner of the questionnaire.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

These data are collected in a manner consistent with the certification statement. No exceptions are requested.