

graduate medical education (GME) to freestanding children's hospitals, similar to Medicare GME support received by other, non-children's hospitals. The legislation indicates that eligible children's hospitals will receive payments for both direct and indirect medical education. Direct payments are designed to offset the expenses associated with operating approved graduate medical residency training programs and indirect payments are designed to compensate hospitals for expenses associated with the treatment of more severely ill patients and the additional costs relating to teaching residents in such programs.

The CHGME Payment Program statute Public Law 109-307 requires that CHGME-participating hospitals provide information about their residency training programs in an annual report to HRSA that will be an addendum to the hospitals' annual applications for funds. Data are required to be collected on (1) the types of training programs that the hospital provided for residents such as

general pediatrics, internal medicine/pediatrics, and pediatric subspecialties including both medical subspecialties certified and non-medical subspecialties; (2) the number of training positions for residents, the number of such positions recruited to fill, and the number of positions filled; (3) the types of training that the hospital provided for residents related to the health care needs of different populations such as children who are underserved for reasons of family income or geographic location, including rural and urban areas; (4) changes in residency training including: (i) Changes in curricula, training experiences, and types of training programs, and benefits that have resulted from such changes, and (ii) changes for purposes of training residents in the measurement and improvement of the quality and safety of patient care; and (5) the numbers of residents (disaggregated by specialty and subspecialty) who completed their training at the end of the academic year

and care for children within the borders of the service area of the hospital or within the borders of the State in which the hospital is located.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

Total Estimated Annualized burden hours:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Screening Instrument (HRSA 100-1)	56	1	56	9.2	515.2
Annual Report: Hospital and Program-Level Information (HRSA 100-2 and 3)	56	1	56	78.7	4,407.2
Total	56	4,922.4

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Dated: May 21, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request: National Institute of Mental Health Data Access Request and Use Certification

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Mental Health (NIMH), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the

agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and for Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Keisha Shropshire, NIMH Project Clearance Liaison, Science Policy and Evaluation Branch, OSPPC, NIMH, NIH, Neuroscience Center, 6001 Executive Boulevard, MSC 9667, Rockville Pike, Bethesda, MD 20892, or call 301-443-4335 or Email your request, including your address to: kshropsh@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: The National Institute of Mental Health Data Access Request and Use Certification (previously National Database for Autism Research Data Access Request), 0925-0667, Revision, Expiration Date: 01/31/2016; NIMH, NIH.

Need and Use of Information Collection: NIMH recently received OMB approval for use of the National Database for Autism Research (NDAR)

Data Use Certification (DUC) Form. 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. The NIMH DUC form is necessary for “Recipient” Principal Investigators and their organization or corporations with approved assurance from the DHHS Office of Human Research Protections to access data or images from NIMH repositories and datasets for research purposes. The primary use of this information is to document, track,

monitor, and evaluate the use of the NIMH repositories/datasets, as well as to notify interested recipients of updates, corrections or other changes to the database. 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).

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 380.

ESTIMATED ANNUALIZED BURDEN HOURS

Form	Type of respondent	Number of respondents	Frequency of response	Average time per response (in hours)	Annual hour burden
NIMH Data Access Request and Use Certification.	Principal Investigators/Research Assistant.	240	1	95/60	380

Dated: May 16, 2013.
Sue Murrin,
Executive Officer, NIMH, NIH.
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BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301-496-7057; fax: 301-402-0220. A signed Confidential Disclosure Agreement will

be required to receive copies of the patent applications.

Assay for Quantifying Fragile X Mental Retardation-1 Gene Product

Description of Technology: The invention is directed to a fluorescence based assay to quantify the protein product of the Fragile X Mental Retardation-1 (FMR1) gene in a biological sample.

Fragile X syndrome (FXS) is an X-linked genetic disease that is responsible for intellectual disability and is also the most common single gene cause of autism. FXS is typically caused by loss of expression of the FMR1 gene, which codes for an RNA-binding protein called FMRP. FXS patients exhibit a wide spectrum of symptoms with varying degrees of cognitive and psychosocial impairment. The severity of these symptoms correlates well with the levels of FMRP present in the FXS patient. Because the FMR1 gene is silenced in varying degrees, the levels of FMRP in any particular FXS patient could vary greatly.

Scientists at NIDDK and NCATS have developed a sensitive, time resolved fluorescence based assay to quantify FMRP levels in a biological sample. Unlike other assays, the invention assay utilizes two highly-specific antibodies that bind to different sites of FMRP so as to enable precise and reliable quantification. Currently, there is no approved drug to treat FXS. The invention assay can be used as a high throughput screen to identify and evaluate candidate drugs. In addition,

the invention assay can be used to assess and/or predict the severity of a patient’s condition based on the amount of FMRP present.

Potential Commercial Applications:

- Diagnosis assay
- High throughput screen of drug libraries
- Optimization assay to further develop potential drug candidates

Competitive Advantages:

- Fast, accurate, and reliable assay to quantify FMRP in easy-to-use fluorescence based format
- Adaptable for high throughput use

Development Stage:

- Prototype
- Pilot
- In vitro data available

Inventors: Wei Zheng (NCATS), Karen P. Usdin (NIDDK), Manju Swaroop (NCATS), Daman Kumari (NIDDK)

Intellectual Property: HHS Reference No. E-083-2013/0—US Application No. 61/793,577 filed 15 March 2013

Licensing Contact: Lauren Nguyen-Antczak, Ph.D., J.D.; 301-435-4074; lauren.nguyen-antczak@nih.gov.

Collaborative Research Opportunity: The National Center for Advancing Translational Sciences (NCATS) is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Assay for Quantifying Fragile X Mental Retardation-1 Gene Product. For collaboration opportunities, please contact the NCATS Technology Development Coordinator at NCATSPartnerships@mail.nih.gov.