

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; The NIH/NCATS GRDRSM Program: Global Rare Diseases Patient Registry Data Repository (GRDR)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the *Federal Register* on July 17, 2014, page 44185 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202-395-6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project contact: Dr. Yaffa Rubinstein, Director of Patient Resources for Clinical and Translational Research at the Office of Rare Diseases Research (ORDR), NCATS, NIH, Suite 1004, 6701 Democracy Boulevard, Bethesda, MD 20892-4874, or call non-toll-free number (301) 402-4338 or Email your request, including your address to: *yaffa.rubinstein@nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: NIH/NCATS GRDRSM Program: Global Rare Diseases

Patient Registry Data (GRDR), The National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH).

Need and Use of Information Collection: 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 and clinical information, as well as medical images, derived from individuals who participate in rare disease patient registries, regardless of the source of funding. The GRDR program provides the infrastructure to store, search across, retrieve, and analyze these varied types of data. This valuable information will help NIH understand and evaluate the use of repositories/datasets in the research community. The GRDR program will support: (1) Mapping data to standards; (2) increased visibility for participating registries; (3) opportunity for cross-disease research; (4) better and faster rare disease clinical research.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 334.

ESTIMATED ANNUALIZED BURDEN HOURS

| Form name | Type of respondent | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total annual burden hours |
|-------------------------------------|--------------------|-----------------------|------------------------------------|--|---------------------------|
| Request for Open access | Individuals | 2000 | 1 | 2/60 | 67 |
| Request for Controlled access | Individuals | 1000 | 1 | 15/60 | 250 |
| Request to Submit | Individuals | 100 | 1 | 10/60 | 17 |

Dated: January 9, 2015.

Pamela McInnes,

Deputy Director, NCATS, 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. 209 and 37 CFR part 404 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.

SUPPLEMENTARY INFORMATION: Technology descriptions follow.

Highly Sensitive Tethered-Bead Immune Sandwich Assay

Description of Technology: This technology is a highly sensitive tethered-bead immune sandwich assay. Analyte molecules are captured between two antibodies, a capture antibody and a detection antibody. The capture antibody on a micron-size bead binds analyte from a sample fluid. The bead-captured analyte is then exposed to a "detection" antibody that binds to the bead-captured analyte, forming a "sandwich". The sandwiched analyte-bead complex then connects to a flexible polymer (such as DNA)