



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-Day comment request

The NIH/NCATS GRDRSM Program
Global Rare Diseases Patient Registry Data Repository (GRDR)

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 Center for Advancing Translational Sciences (NCATS), 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 Yaffa Rubinstein, Ph.D., Office of Rare Diseases Research (ORDR), National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH), 6701 Democracy Boulevard, Room 1004, Bethesda, Maryland 20892, or call non-toll free number (301) 402-4338, or E-mail your request including your address to yaffa.rubinstein@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 NIH/NCATS GRDRSM Program, 0925-NEW GRDR, 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, 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 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 RD 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 100.

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 Hour
Request for access	Individuals	1000	1	5/60	83
Request to submit	Individuals	100	1	10/60	17

Dated: July 17, 2014.

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