



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Date: January 6, 2014

To: Julie Wise
Office of Information and Regulatory Affairs (OIRA)
Office of Management and Budget (OMB)

Through: Seleda M. Perryman
NIH Report Clearance Officer

From: Anne Sperling
Health Science Policy Analyst
Office of Science Policy, Planning, & Communications
National Institute of Mental Health (NIMH)
National Institutes of Health (NIH)

Subject: **Change Request to a Currently Approved Form (OMB # 0925-0667, Expiration date 09/30/2016) for adding a DUC form for use by the Global Rare Diseases Patient Registry Data Repository (GRDR) to the approved clearance.**

WHEREAS the National Institute of Mental Health (NIMH) has applied for and obtained Paperwork Reduction Act clearance for the **NIMH Data Access Request/Use Certification** (OMB# 0925-0667, hereafter referred to as NIMH DUC) for the purpose of collecting information from qualified researchers seeking to obtain access to data held by NIMH;

WHEREAS the National Center for Advancing Translational Sciences (NCATS) has asked NIMH for temporarily authorization to use the NIMH DUC to collect information from qualified researchers seeking to obtain access to data held by NCATS—specifically, data from the Global Rare Diseases Patient Registry Data Repository (hereafter referred to as GRDR);

NIMH hereby grants NCATS temporary authorization to use the NIMH DUC for the GRDR. NCATS's intended usage of and purpose for the form is in line with the current NIMH usage and purpose, and burden hours for NCATS users matches that of NIMH users. NIMH provided NCATS with a customized version of the NIMH DUC, which shall be used without alteration, for up to a year/ (12) months, during which time NCATS will complete the Paperwork Reduction Act clearance process for a data collection form specifically for use by GRDR. NIMH temporary authorization will expire when that clearance is obtained.

NCATS approximately 1000 respondents will use the form to obtain access to data in GRDR over the course of the year.

Estimates of Annualized Burden Hours and Costs						
Form	Number of Respondents	Frequency of Response	Average Time Per Response (Hours)	Annual Hour Burden	Wage Rate per Hour	Cost
Data Access Request - GRDR	1,000	1	95/60	1,583	\$91.00	\$144,053
Total	1,000			1,583		\$144,053

Thank you for your consideration of this change request.