

EXP: 09/30/2016

Burden Disclosure Statement

Public reporting burden for this collection of information is estimated to vary from 15 min to 1.5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0667). Do not return the completed form to this address.

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NIMH Data Access Request/Use Certification—for use by GRDR

Date: _____

Data Requested: ___ Global Rare Disease Patient Registry Data Repository (GRDR)

Specify dataset (if applicable): _____

First Name: _____ Last Name: _____

Degree: _____ Academic Position (or Title): _____

Institution: _____ Department: _____

Street Address: _____

City: _____ State/Province: _____

Zip/Postal Code: _____ Country: _____

Telephone: _____ FAX: _____

E-mail Address: _____

Research Project (title):

By signing and dating this DUC as part of requesting access to the NCATS GRDR, my Institutional Officials and I certify that we will abide by the DUC and the NIH principles, policies and procedures for the use of NCATS GRDR data. I further acknowledge that I have shared this document and the NIH policies and procedures with any research staff who will participate in the use NCATS GRDR data. My Institutional Business Official(s) also acknowledges that they have shared this document and the relevant NIH policies and procedures with appropriate institutional organizations.

Signature: _____ Date: _____

Authorized Institutional Business Official (as registered in the NIH eRA Commons):<https://commons.era.nih.gov/commons/>

Name: _____

Title: _____

FWA#: _____

Signature: _____ Date: _____

Inquiries about NCATS GRDR should be sent to:

GRDR Program Director, Office of Rare Diseases Research

National Center for Advancing Translational Sciences, National Institutes of Health

6701 Democracy Boulevard, Suite 1004, MSC 4874

Bethesda, MD 20892

Phone: 301-402-4338; Email: yaffa.rubinstein@nih.gov

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Project Director/Principal Investigator Contact Information (if different from above)

First Name: _____ Last Name: _____
 Degree: _____ Academic Position (or Title): _____
 Institution: _____ Department: _____
 Street Address: _____
 City: _____ State/Province: _____
 Zip/Postal Code: _____ Country: _____
 Telephone: _____ FAX: _____
 E-mail Address: _____

Authorized Representative (Institutional Official)

First Name: _____ Last Name: _____
 Degree: _____ Academic Position (or Title): _____
 Institution: _____ Department: _____
 Street Address: _____
 City: _____ State/Province: _____
 Zip/Postal Code: _____ Country: _____
 Telephone: _____ FAX: _____
 E-mail Address: _____

Other Project Information:

1. Are Human Subjects involved? Yes No

If YES to Human Subjects

Is the Project Exempt from Federal regulations? Yes No

If yes, check appropriate exemption number. 1 2 3 4 5 6

If no, is the IRB review pending? Yes No

IRB Approval Date: _____

2. Research Use Statement/Project Summary:

Insert here.

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Senior/Key Person Profile (Collaborating Investigator at Same Institution)

First Name: _____ Last Name: _____
Degree: _____ Academic Position (or Title): _____
Institution: _____ Department: _____
Street Address: _____
City: _____ State/Province: _____
Zip/Postal Code: _____ Country: _____
Telephone: _____ FAX: _____
E-mail Address: _____
Project Role: _____ Other Project Role Category: _____

Senior/Key Person Profile (Collaborating Investigator at Same Institution)

First Name: _____ Last Name: _____
Degree: _____ Academic Position (or Title): _____
Institution: _____ Department: _____
Street Address: _____
City: _____ State/Province: _____
Zip/Postal Code: _____ Country: _____
Telephone: _____ FAX: _____
E-mail Address: _____
Project Role: _____ Other Project Role Category: _____

Senior/Key Person Profile (Collaborating Investigator at Same Institution)

First Name: _____ Last Name: _____
Degree: _____ Academic Position (or Title): _____
Institution: _____ Department: _____
Street Address: _____
City: _____ State/Province: _____
Zip/Postal Code: _____ Country: _____
Telephone: _____ FAX: _____
E-mail Address: _____
Project Role: _____ Other Project Role Category: _____

Use additional sheets for additional profiles as needed.