

Monday, December 08, 2014

## **National Center for Advancing Translational Sciences (NCATS)** ***Request for Patient Registry Template***

### Background

The NCATS and its Office of Rare Disease Research (ORDR) supports and coordinates rare diseases research, responds to research opportunities for rare diseases and provides information on rare diseases. ORDR serves the needs of patients who have any one of the thousands of rare diseases known today. To accomplish this, ORDR coordinates and fosters relationships with a variety of stakeholders, from patient advocacy groups to academic institutions as well as other NIH Institutes and Centers. For example, ORDR promotes and encourages the creation of patient registries and innovative programs that improve access to clinical research for rare disease patients and their families by aggregating and integrating coded patient clinical information from various rare disease patient registries into the NIH/NCATS/GRDR<sup>SM</sup> Program (Global Rare Diseases Patient Registry Data Repository). The GRDR<sup>SM</sup> is an NCATS program with the goal of establishing a data repository of de-identified patient data, aggregated in a standardized manner, using Common Data Elements and standardized terminology. This data will be available to all investigators to enable analyses across many rare diseases and to facilitate various biomedical studies, including clinical trials, in pursuit of developing drugs and therapeutics to improve the healthcare and the quality of life for the many millions of people who are diagnosed with rare diseases.

To help patient advocacy groups and other organizations to establish patient registries and collect data in a standardized manner, NCATS, through its GRDR program, develops tools and information that are available free of charge to the rare disease community. Examples of such tools are: the GRDR Common Data Elements (CDEs), the template informed consent for participating in the patient registry, and the Global Unique Identifier (GRDR-GUID).

NCATS, in agreement with the Marshfield Clinic, will distribute the software for the patient registry (developed by the Marshfield Clinic Research Foundation) to any advocacy group or organization that wishes to establish a patient registry and share their de-identified data with the GRDR program. This patient registry template utilizes the GRDR CDEs to increase interoperability with other registries and data bases.

Each potential user must first provide the requested information and sign the ***End User License Agreement*** (provided below). Requests will be reviewed by the GRDR program officials and notification of approval will be provided by email. For additional information please contact the GRDR program director [Yaffa Rubinstein, Ph.D.](#)

**End User License Agreement  
for  
Clinical Registry Development Software License**

Further to participation in the Global Rare Disease Registry (GRDR<sup>SM</sup>) program of the National Institute of Health's (NIH) National Center for Advancement of Translational Science (NCATS), End User hereby seeks a license to software from the Marshfield Clinic, Inc. to expedite development of a clinical registry (hereinafter "LICENSED SOFTWARE"). Benefits of widespread adoption of the SOFTWARE throughout the medical, scientific research, and healthcare communities include expanded opportunities for sharing of information across sites. Statistically speaking, the value of information is often a function of the volume of information. The capabilities of the LICENSED SOFTWARE to aggregate and de-identify data, create common data elements and standard terminologies, and other features make it suited specifically for satisfaction of medical, scientific research, and healthcare objectives dependent on Big Data.

As a condition precedent to receiving this end user license to use the LICENSED SOFTWARE for rare disease registry development, End User agrees to share its rare disease data with the NIH NCATS GRDR<sup>SM</sup> program (Global Rare Diseases Patient Registry Data Repository).

The LICENSED SOFTWARE represents a significant investment on the part of the Marshfield Clinic, Inc. The following terms and conditions shall apply:

1. License Grant

Marshfield Clinic, Inc. herein grants End User a license to use the LICENSED SOFTWARE in accordance with the following terms and conditions.

2. Restrictions

2.1.1 End User must be an organization focused on medical, scientific research, and/or healthcare.

2.1.2 End User shall only use the LICENSED SOFTWARE to develop a disease registry. Usage of the LICENSE SOFTWARE for any other purpose is not authorized.

2.1.3 End User shall not redistribute or sell the LICENSED SOFTWARE or disease registries developed therefrom.

3. Improvements / Modifications

3.1.1 End User shall communicate all improvements and modifications to the Marshfield Clinic, Inc. so that potential benefit to other End Users and/or further development may be assessed. Improvements and modifications include but are not limited to changes to the framework, support decision algorithms, etc.

3.1.2 If End User makes any changes whatsoever to the LICENSED SOFTWARE these changes shall be acknowledged in any presentations, publications, and/or packaging.

#### 4. Attribution

End User agrees to acknowledge in any presentations and/or publications regarding any registries developed with the LICENSED SOFTWARE that such LICENSED SOFTWARE was provided by the Marshfield Clinic Research Foundation and NIH/NCATS/GRDR<sup>SM</sup> Program by using the following statement: XXX registry was developed by using LICENSED SOFTWARE that was provided by the Marshfield Clinic Research Foundation and NIH/NCATS/GRDR<sup>SM</sup> Program.

#### 5. Warranties

Any LICENSED SOFTWARE delivered pursuant to this Agreement is understood to be experimental in nature and may have unknown properties and uncertain reliability with regard to storing, manipulating, or transferring any information or data entered into a registry generated using the LICENSED SOFTWARE. MARSHFIELD CLINIC, INC. MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE LICENSED SOFTWARE WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

#### 6. Limitation of Liability / Indemnification

As the LICENSED SOFTWARE is provided free of charge and without warranty for public interest purposes Marshfield Clinic, Inc. shall bear no liability whatsoever for consequences of any deficiencies. For example, Marshfield Clinic, Inc. shall bear no liability for lack of security, loss of data, violation of HIPAA and/or other regulations in connection with use of the LICENSED SOFTWARE by End Users. As a condition of downloading and using the LICENSED SOFTWARE End User hereby agrees to indemnify Marshfield Clinic, Inc. against any claim brought by a third party against Marshfield Clinic, Inc. in connection with use of the LICENSED SOFTWARE by third party or by End User.

#### 7. Governing Law

This Agreement is to be made under and shall be construed in accordance with Federal laws as applied by the Federal Courts in the State of Wisconsin and constitutes the entire understanding between the Parties hereto with respect to the subject matter hereof and merges any and all prior agreements, understandings and representations.

#### 8. Counterparts

This Contract may be executed in any number of counterparts which, when taken together, will constitute one original, and photocopy, facsimile, electronic or other copies shall have the same effect for all purposes as an ink-signed original.

#### 9. Severability

The invalidity or unenforceability of any provisions of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement, which shall remain in full force and effect.

End User information (**All fields are required**)

\_\_\_\_\_  
Name of organization

Type of organization; select one

Academia\_\_\_\_\_

Patient Advocacy \_\_\_\_\_

Industry \_\_\_\_\_

Others \_\_\_\_\_

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Disease(s) of interest

\_\_\_\_\_  
Full name

\_\_\_\_\_  
Title

\_\_\_\_\_  
Phone number

\_\_\_\_\_  
Email address

\_\_\_\_\_  
Country

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

**Individuals requiring technical assistance or with questions regarding the software application may contact directly the Marshfield Clinic main office at 715-389-7707 during working hours: Monday to Friday, 8 am to 5 pm CST.**