



DATE: December 15, 2014

TO: Yaffa Rubinstein, Ph.D.,
National Center for Advancing Translational Services (NCATS)

FROM: NIH Privacy Act Officer

SUBJECT: Applicability of the Privacy Act: Global Rare Diseases Patient Registry Data Repository (GRDR)

I have reviewed the NCATS submission to OMB for the central informatics system which will support and accelerate research into the cause, diagnosis, and treatment of rare diseases. The NIH Global Rare Diseases Patient Registry Data Repository will document, track, monitor, and evaluate the use of repository datasets to submit and access data, as well as notify interested recipients of updates, corrections, or other changes to the database.

The GRDR database stores de-identified patient data from different rare diseases registries. Although the repository data will be coded and the NIH will not hold direct identifiers to individuals within the data repository, the agency recognizes the personal and potentially sensitive nature of the genotype-phenotype data. Investigators seeking access to the GRDR database will complete an access request and use certification form. The form will collect the business contact information of the Investigator seeking access to the database, the title and brief summary of the research project for which repository data are sought, co-signatures from the Investigator and his/her Institutional Official, the Institution's Federal Wide Assurance (FWA) number, and the approval of the Institutional Review Board (IRB). Once completed, the Investigator will scan and upload the form to the repository for approval of the GRDR Committee. The information requested from the Investigator may be made public for tracking and reporting purposes.

Upon submission of data, the repository staff will perform a quality control review to ensure that no PII is contained in the dataset or supporting documentation. Only data that have undergone a review will be approved for sharing with the research community.

I have determined that the Privacy Act will not apply to this information collection because the GRDR will not store personally identifiable information and is not designed to retrieve information about the Investigator or Participant. If you have questions, please contact me at (301) 402-6201.

Karen Plá

Enclosure

Copy w/o enclosure: Mikia Currie, Project Clearance Branch, OD