XIII. Data Sharing Policy

Rare Diseases Clinical Research Network
Data Sharing Policy

The National Institutes of Health (NIH) has supported data collection from participants in numerous clinical trials and epidemiologic studies as part of approved protocols under the Rare Diseases Clinical Research Network (RDCRN). These data constitute an important scientific resource. It is the view of the NIH that their full value can only be realized if they are made available, under appropriate terms and conditions consistent with the informed consent provided by individual participants, in a timely manner to the Rare Diseases Community and the largest possible number of qualified investigators. Accordingly, this document establishes the policy of the RDCRN for when data from these studies will be available for sharing with the scientific community for the purposes of scientific research. This policy adheres to the NIH data sharing policy (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html)

This policy does not include tissues or specimens collected in RDCRN studies. This policy relates to the transfer of data into an Office of Rare Diseases Research (ORDR)-governed repository. A separate policy will be developed with respect to access to the repository by qualified scientists.

Informed consents for RDCRN studies should include consent for sharing the data without personal identifiers with the scientific community for research purposes. Data sets without an informed consent permitting use by non-study researchers will be placed in the RDCRN repository only if the institutional review board (IRB) has approved a waiver of informed consent.

Data in the RDCRN Data Management and Coordinating Center (DMCC) under this policy will not include personal identifiers such as name, address, social security number, or medical record numbers. The identifiers will be held by the original investigators who collected the information.

Any publications arising from use of data must include reference(s) to relevant publications from the original investigators, if appropriate, and must in all cases acknowledge the RDCRN repository as the source of the data AND the depositing investigators of the utilized data.

Suggested Timing of Release of Data to Repository

a. *Clinical Trials* – Data sets should be made available to the scientific community after publication(s) of planned analyses (as set forth in the protocol) of the clinical trial results OR no later than 3 years after the final visit of the last participant to a clinical trial site, whichever comes first.

b. *Observational/Longitudinal/Natural History/Epidemiology Studies* – Available data will be released to the repository and will become available to the scientific community one year after publication of planned analyses, or after a period of 5 years from the date when the data were collected, whichever comes first.

c. *Ancillary Studies* – In those cases in which the timeline for an ancillary study differs from that of its parent study, the date of the release of data to the repository and availability to the scientific community will relate to the timeline of the ancillary study consistent with a and b above.

Rare Diseases Clinical Research Network Consortia
Data Sharing Policy

Each consortium is expected to maintain a data sharing policy which describes internal and consortium-specific data sharing procedures. The Consortium's policy shall be reviewed by ORDR, NIH Institute program staff and the DMCC.

Additional information on NIH Data Sharing requirements:
http://grants2.nih.gov/grants/policy/data_sharing/data_sharing_brochure.pdf