

Additional Standards for Accessing NDAR Data While a Study is Ongoing

The NIH is dedicated to the advancement of health through science. A goal of NDAR is to provide autism researchers with the capability to share data and collaborate at the earliest possible opportunity in order to speed discoveries in autism research. In some cases, data sharing prior to the completion of a study is possible and the NIH aims to facilitate such sharing through NDAR when appropriate.

When a study is ongoing, however, there are a number of reasons why data sharing for secondary or collaborative research may be limited. For example, an incomplete data set may not be a viable means to answer certain research questions. Relying upon it may engender bias or error. Furthermore, in many cases, new or secondary uses of a data set will be most effectively undertaken in collaboration with the original data Submitter. Synergies may be developed to improve both the ongoing study and the new research. NIH wishes to encourage collaboration whenever appropriate.

Submitters are in the best position to determine whether new uses of data are appropriate during the time that a study is ongoing, and collaboration requires communication between the Submitter and the potential Recipient. Therefore, the NIH wants Recipients who are seeking access to data from an ongoing study to coordinate with the Submitters. This coordination may result in a decision to collaborate, a decision to authorize access absent collaboration, or a decision to delay access until a study is complete. NIH may re-visit this policy in the future but believes, at this time, that a consultation process is an essential means to expand access to NDAR data in a timely fashion without compromising the valuable contribution and trust of NDAR Submitters.

Accordingly, data submitted to NDAR while a study is ongoing will become eligible for access after NIH and the submitter perform a data quality check that verifies that the information received by NDAR is complete, contains no identifying information, and displays correctly, and both NIH and the Submitter agree that the NDAR toolset functions as expected with the information. Researchers requesting access must specify which data set(s) are requested for access and provide other information via the Central Repository Access Request and Data Use Certification (DUC). In addition to submitting the Central Repository Access Request and signed DUC, those seeking ongoing study access are expected to consult with the Submitter(s) to determine if the proposed research use is appropriate. Submitters should notify NDAR staff of their agreement to authorize access to data from an ongoing study at ndar@mail.nih.gov or through the interface provided within the NDAR portal. The notification should identify the intended Recipients and note any agreements reached during the consultation process regarding publication and/or authorship.

Thereafter, data available from ongoing studies will become available as controlled access data at the time of publication or when the Primary Aims of the study are met (as determined through discussions with the Submitter's Program Officer), whichever occurs first. Controlled access data and Supporting

Materials submitted to NDAR may be accessed and used broadly by qualified researchers for research and other activities as authorized by and consistent with law. This period of time allows collaborators to complete data collection, allows for the careful and thoughtful analysis and interpretation of the data as it was planned in the study design, and allows NIH to perform final data quality and integrity checks. It also allows for completion of all documentation (e.g., full description of methods, data dictionary) necessary for reanalysis and reinterpretation, as necessary.