

POLICY ON THE RELEASE OF TEDDY DATA

The TEDDY study is committed to sharing data with the scientific community and has adopted a data sharing policy that is posted on its public website. Recognizing that the TEDDY study is ongoing and its data bank is still accumulating information as cases are identified and TEDDY subjects are being followed, the TEDDY Study has established procedures to submit data to the NIDDK Data Repository in segments that reflect the study progress. This reflects study milestones, such as the completion of screening and assembling the study cohort or the publication of interim results.

Periodically, the TEDDY study will release other data to the NIDDK Data Repository in a timely fashion relative to its progress as defined by the TEDDY data sharing policy.

Access and availability of data submitted to the NIDDK Data Repository is determined by the NIDDK.

From time to time there may be other requests for TEDDY data that come from the community of investigators currently working on the TEDDY Study itself or from others who would like to collaborate with the TEDDY study. Access to the TEDDY data will be reviewed by the Data Access Committee of the study group.

The purpose of this document is to establish a policy for the release of TEDDY data not in the NIDDK Data Repository.

1. The request for TEDDY data must be based on a specific intended purpose and the requestor must agree that the use of the data is limited to solely that purpose.
2. Publication or presentation of the results of any analysis of the TEDDY data must follow the current rules and review of the TEDDY Publication Committee with respect to scientific merit, authorship, and funding attribution.
3. The requestor explicitly agrees that no attempt will be made to link the TEDDY data to any other data source that could potentially violate the confidentiality of any TEDDY Subject or in any way violate the explicit and implied consent under which TEDDY data has been collected.
4. If the data request comes from completely outside the community of TEDDY investigators, there must be a member of the TEDDY Steering Committee willing to serve as a sponsor and liaison with the TEDDY Study group who agrees to be responsible to TEDDY and to the funding agency (i.e., NIDDK) to ensure compliance with these guidelines and those contained in the funding Notice of Grant Award.

Procedures:

If the intended use of the TEDDY data requested is consistent with the goals and objectives of TEDDY, the request can be submitted as a manuscript proposal (using the existing proposal form) to the TEDDY Publications committee. The requestor will append a signed document attesting to the agreement with the above stipulations. The TEDDY Publications Committee will conduct such reviews as it feels necessary before approving the request as it currently does with all other manuscript proposals that are submitted.

If the intended use of the TEDDY data requested is outside the scope of the TEDDY Study, the request can be submitted as an Ancillary Study to the Ancillary Studies Committee using the appropriate application form. The requestor will append a signed document attesting to the agreement with the above stipulations. The TEDDY Publications Committee will conduct such reviews as it feels necessary before approving the request as it currently does with all other ancillary study proposals that are submitted.

Following approval by the appropriate TEDDY Committee, the TEDDY Data Coordinating Center will work with the requestor to evaluate the opportunity to conduct the analyses as delineated for the approved intended use itself or to produce a data set that allows the requestor to conduct such analyses themselves. As there are many factors that go into fulfilling a request (e.g., freezing the data as of a specific time point, recoding data to protect confidentiality, access to other TEDDY data sources such as dietary coding dictionaries, etc.) this will be decided on a case by case basis; the goal being the timely successful conclusion of the planned, approved, data analysis.