

TEDDY Data Sharing Policy

Overview

The TEDDY study is committed to sharing data with the scientific community and has adopted the following data sharing policy. The policy is designed to enable the widest dissemination of data, while also protecting the privacy of participants through de-identification and masking of potentially sensitive data elements.

TEDDY investigators strive to perform analyses as the data are received; however, many analyses cannot begin until a complete dataset has been collected. Therefore, the members of the TEDDY Steering Committee retain control and primary rights to the data and biological specimens developed and obtained under NIH funding, subject to Government rights of access consistent with current HHS, PHS, and NIH policies.

Public Accessibility

All data submitted to public repositories will be accompanied with a data dictionary. In addition, the TEDDY Study Protocol will be available via the [NIDDK Central Repository](#) website to prevent any misuse or misinterpretation of the data.

Before data are made available to the public, the TEDDY group will ensure the data are cleaned and de-identified to protect participant's privacy. The timeline for making data publically available will vary based on the type of data and requirements from the funding agencies.

The following table contains the TEDDY study's current timelines for releasing data into public repositories.

Data Description	Timeline for Release to Repository
Manuscript datasets, including published pilot studies	NIDDK Central Repository: No later than 6 months after the manuscript is published online
Screening data to include: HLA screening genotype, family history of diabetes, country of residence	NIDDK Central Repository: No later than 6 months after the manuscript on TEDDY screening has appeared in print
Baseline clinical metadata for subjects enrolled in TEDDY follow-up: demographics, HLA confirmation genotype, family history of diabetes	NIDDK Central Repository: One year after the cleaned dataset becomes available
All lab data such as SNP, microbiome and viral metagenomics, dietary biomarkers, metabolomics and gene expression	dbGaP/SRA/Metabolomics Workbench: Up to 6 months after the cleaned dataset is available or at the time of acceptance of initial publication, whichever occurs first
All clinical metadata which have been collected on the cohort during the funding period	NIDDK Central Repository: Within two years after the end of each funding period

All clinical metadata at study close, when study investigators are no longer obtaining data directly from study participants	NIDDK Central Repository: By the end of the funding period
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* Genomics data will be submitted in accordance with the processing level described in the [NIH Genomic Data Sharing Policy](#).

Accessing TEDDY Data not Publicly Archived

Periodically, TEDDY receives data requests from the community of investigators currently working on the TEDDY Study or from others who would like to collaborate with the TEDDY Study. Investigators who would like to collaborate with TEDDY and access data not available in the above repositories can submit a request to TEDDY Publications at teddypublications@epi.usf.edu.

Additional information on accessing TEDDY data not publicly archived is available via the [TEDDY Study](#) website.

Journal Requirements

Manuscript data required by the journal to be made available at the time of publication will be accessible through the TEDDY Data Coordinating Center (DCC) in advance of release to a public repository as noted in the table above. Upon special approval by the TEDDY Publications Committee, the TEDDY DCC will submit data directly to the journals at the time of submission or publication when required by the receiving journal.

Investigators requesting access to manuscript datasets in advance of the release to a public repository will be asked to provide additional details regarding the request. In addition, investigators will be asked to sign the TEDDY Data and Materials Distribution Agreement (DMDA) to ensure compliance with TEDDY policies and procedures. All data requests should be submitted to the TEDDY DCC at teddypublications@epi.usf.edu.

Ancillary Studies

Additional information on the ancillary study process can be found in the TEDDY Ancillary Studies Guidelines, available via the [TEDDY Study](#) website.

TEDDY defines an ancillary study as research or data collection involving TEDDY subjects or the samples collected using any technique, procedure, questionnaire or observation other than those set forth in the TEDDY Study Protocol. The ancillary study investigator is a partner in the TEDDY Study and is therefore obliged to follow the rules and regulations governing the study as defined in the study protocol and by the Steering Committee.

Investigators interested in accessing TEDDY data and/or samples for an ancillary study can submit a proposal to the Ancillary Studies Committee at teddy@epi.usf.edu. The proposal should follow the National Institutes for Health (NIH) research grant (R01) format and include a description of the objectives, methods, significance, and plans for analysis. The proposal and the recommendations of the Ancillary Studies Committee will be forwarded to the Steering Committee for a final decision.