

TEDDY Data Sharing Policy

Overview

The TEDDY study is committed to sharing data with the scientific community. This data sharing policy is designed to enable the widest dissemination of TEDDY data, while also protecting the privacy of TEDDY participants.

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

TEDDY data are submitted to designated public NIH data repositories in segments that reflect the study's progress. These data releases are submitted at different time points and to various repositories, depending on funding agency requirements and the nature of the data. A document detailing [TEDDY repository data releases](#) is available on the TEDDY Study website.

The datasets comprising these releases are cleaned and de-identified to protect participants' privacy. Each submission is treated as an independent release, possessing uniquely masked subject and sample identifiers. All datasets are accompanied by data dictionaries. Various study documentation and metadata are also made available via the [NIDDK Central Repository](#) and [TEDDY Study](#) websites to aid in interpretation and use of the data.

The following table contains the TEDDY Study's current timelines for submitting data to public repositories.

Data Description	Timeline for Submission 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

* Genomics data will be submitted in accordance with the processing level described in the [NIH Genomic Data Sharing Policy](#).

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 externally funded (not TEDDY-funded) research involving TEDDY Study subjects' data that is not currently available through the NIH Data Repositories and/or samples. 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 that is not currently available through the NIH Data Repositories 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.