

**Information for Potential Grant Applicants and Awardees**  
**National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)**  
**Data Sharing Policy**  
**July, 2013**

NIDDK seeks maximal scientific benefit from the data and samples collected from multi-center and large single-center clinical studies in which it has invested substantial resources, and study investigators and participants have invested substantial effort. NIDDK has established repositories for study data, and biologic and genetic samples to foster the use of these resources. The NIDDK Data Sharing policy was established to balance the interests of the study investigators with those of the larger scientific research community by setting a defined period of exclusive access by study investigators; after that time data will become “publicly” available through the NIDDK Data Repository (referred to hereafter as “the Repository”). There is a separate sharing policy for biologic and genetic samples obtained from NIDDK supported studies.

Exclusive access by study investigators must be time-limited so that other investigators have access to data following the completion of a study. Many studies will also have defined intermediate phases and milestones after which their data should also be made available. Access to data obtained as soon as feasible provides the opportunity to increase its use. It also encourages timely analysis to address questions of importance to study investigators. This staged approach to data release is especially important for observational studies and for long-term clinical trials that continue for many years before the primary results are known. This policy does not supersede or conflict with legal requirements such as transferring composite results to [clinicaltrials.gov](http://clinicaltrials.gov).

Prior to enrollment of the first study participant, the study’s steering committee must develop and approve a plan for data release to the Repository. The written plan must include specific data elements to be provided as well as a schedule of their release.

NIDDK has established milestones specific to the type of study (see below) which determine the time points at which data should be made “publicly” available. NIDDK recognizes that study designs differ; hence, variations and flexibility may be required to meet the goals of this policy. For networks conducting multiple studies, milestones should be defined for each individual study.

For interventional studies:

- 1) Baseline data - will be provided to the Repository so that it can be shared within two years after study recruitment is complete or within six months of the publication date of the baseline data, whichever comes first. An analytic data set for the baseline publication should be provided within 6 months of the publication date (when the publication appears on line).
- 2) Primary and secondary outcome data - All study data analyzed for publication of the primary study outcome(s) will be provided to the Repository so that it can be shared within six months of the publication date for the primary outcome publication or within two years of the date that the database is locked for analysis, whichever occurs first. However, the release of specific data in the primary outcome publication dataset related to one or more secondary outcomes may be delayed if the data are part of an analysis that is being prepared for a separate publication. All data analyzed for publication of the

secondary outcome(s) will be provided to the Repository so that it can be shared within two years of the date that the database for these outcomes is locked for analysis.

- 3) Complete dataset - If the study ends and data are no longer being obtained directly from study participants by study investigators, all study data will be provided to the Repository by the end of the funding period (which may include no-cost extensions). If the study continues with follow-up of participants after the intervention has been stopped, the period of exclusive use of the entire dataset from the interventional study will be for three years after the last study contact (corresponding to the “primary completion date” defined by FDAAA; the Food and Drug Administration Amendments Act (FDAAA) of 2007) for collection of intervention outcomes. Study investigators are expected to send the intervention phase data set to the Repository within that three year period.

For interventional studies conducted with industry partners:

When an industry partner serves as the regulatory sponsor and/or provides its proprietary drug, submission of study data will be governed by the relevant collaboration agreement (e.g. the Clinical Trial Agreement (CTA) or a Cooperative Research and Development Agreement (CRADA)), which will address the NIDDK Repository requirements.

For observational studies:

- 1) Baseline data will be provided to the Repository so that it can be shared within two years after completion of study recruitment for each identifiable cohort or within six months of the publication date of the baseline data, whichever comes first.
- 2) When a study ends (study investigators are no longer obtaining data directly from study participants), all data will be provided to the Repository by the end of the funding period, which may include no-cost extensions.
- 3) For studies that continue for more than one funding period, all data elements which have been collected on the cohort will be provided to the Repository so that it can be shared within two years after the end of each funding period.

For all studies:

- 1) Analytic datasets from study publications selected by NIDDK in consultation with the study, including reports of pre-specified primary and secondary outcomes, will be provided to the Repository so that they can be shared within six months of the publication date (when publication appears on line).
- 2) Discussions between the study’s data coordinating center and the Repository should begin as early as possible so that the data coordinating center can plan appropriately for data archiving, and allow for completion of all validity and quality control checks that need to be conducted by the Repository.
- 3) Each study must budget appropriately to ensure that there are adequate funds to carry out the activities required to prepare data for archiving.