

NIDDK CKD Biomarkers Consortium II Data Sharing Policy

The NIDDK CKD Biomarkers Consortium II (CKD BioCon II) seeks maximal scientific benefit from the data generated by the Consortium. Several NIH Institutes (e.g. NIDDK, NHLBI) have established repositories for study data and implemented sharing policies that seek to balance the scientific interests of the parent study investigators with those of the larger research community. The NIDDK CKD BioCon II Data Sharing policy establishes principles of data sharing to fulfill the requirements established by government supported repositories. The distribution of any NIDDK CKD BioCon II data by government repositories will be governed by the policies of those repositories. Typically, CKD BioCon II data will be constituted of biomarker data generated by the CKD Biomarker Consortium II along with necessary identifiers to link them to parent study data.

When data are generated by the NIDDK CKD BioCon II using samples from an ongoing study, those data will be provided to the parent study to be incorporated into the primary database maintained by that parent study. It will be the responsibility of the parent study to submit the BioCon II data to the government repository that houses that study's data (if applicable) within a timeframe that meets or exceeds the guidelines established by the entity funding that parent study.

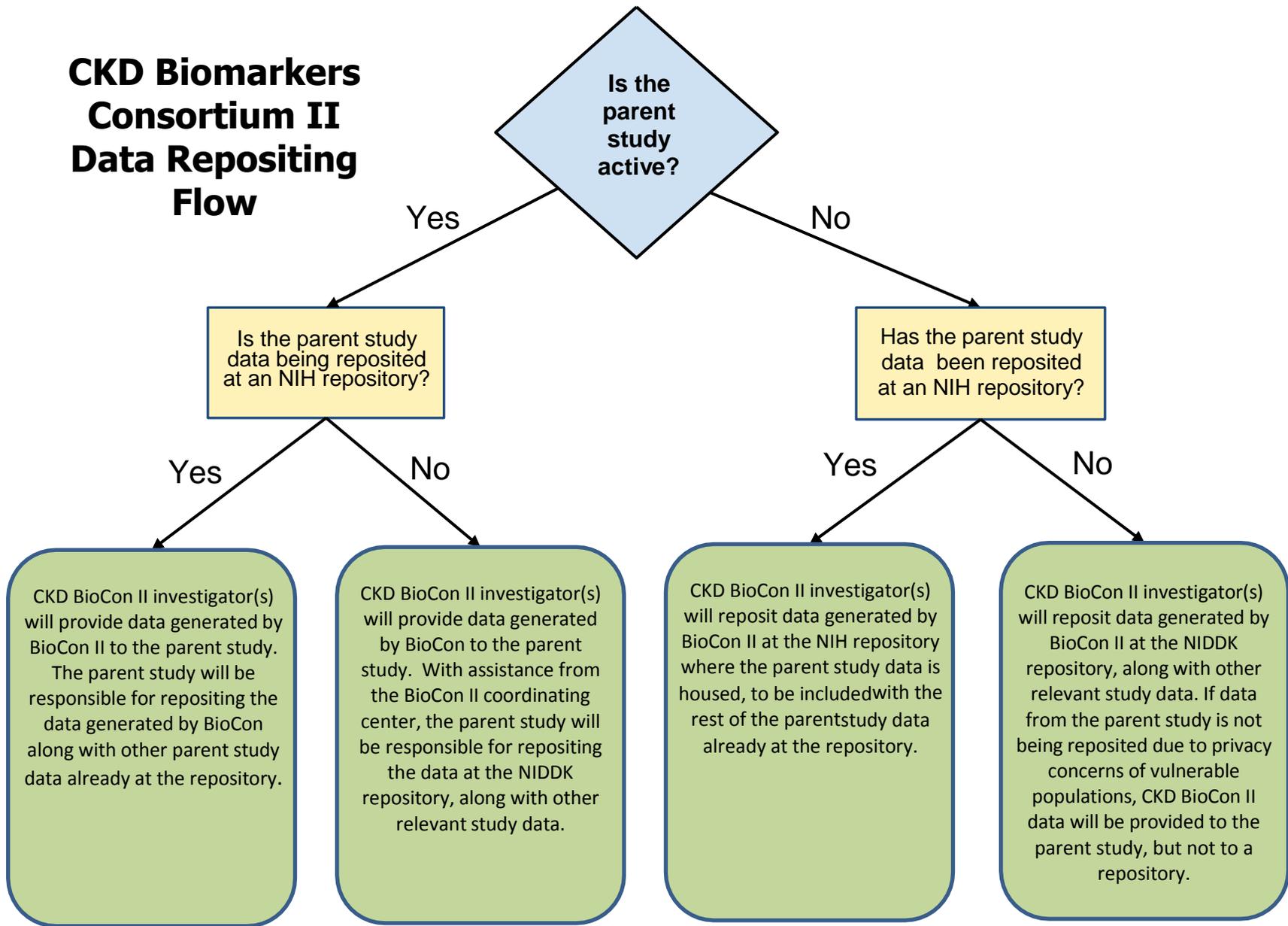
When data are generated by the NIDDK CKD Biocon II using samples from a parent study that is no longer ongoing and resources are not available to parent study investigator to fulfill data sharing responsibilities, the NIDDK CKD BioCon II will be responsible for sending them to the government repository housing the parent study's data within a timeframe that meets (or exceeds) the guidelines established by the funding entity for that parent study.

If the parent study's data are not at a government or other publicly accessible repository, the NIDDK CKD BioCon II will submit the new data generated by the NIDDK CKD BioCon II along with relevant parent study data to the NIDDK's data repository.

There may be rare instances where CKD BioCon II is not permitted by the parent study to submit data to a repository. In these cases, the NIDDK CKD BioCon II will only transmit the data it generates to the parent study.

Transfers of data to a repository will always be limited to data from participants whose informed consent permits such data sharing.

CKD Biomarkers Consortium II Data Repositing Flow



**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://www.fda.gov/oc/ohrt/transfer.html).

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, the industry partner may have time-limited, exclusive access to the study data in accordance with the terms negotiated in a collaboration agreement (e.g. the Clinical Trial Agreement (CTA) or a Cooperative Research and Development Agreement (CRADA)). This exclusive time-limited access to the study data will generally be granted to an industry partner for regulatory purposes or to protect its intellectual property rights. In such cases, the NIDDK may grant a waiver extending the timeframe for submission of these data to the Repository beyond the time limits specified above to account for special provisions negotiated in the collaboration agreement. If there are special provisions negotiated in existing collaboration agreements that preclude submission of study data prior to publication, the study data must be delivered to the Repository within 6 months after the publication date.

All CTAs or CRADAs negotiated subsequent to the effective date of this policy must include a provision that specifically addresses the NIDDK repository requirements. For example, CRADAs should include a statement that “all CRADA data will be available for sharing within 6 months of the primary outcome publication or within 6 months of expiration of the CRADA.”

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) If special circumstances dictate a longer period of exclusive data use for an individual study, a request for approval must be submitted in writing to the Deputy Director, NIDDK.
- 3) 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.
- 4) Each study must budget appropriately to ensure that there are adequate funds to carry out the activities required to prepare data for archiving.

Appendix B: NIDDK Data and Sample Sharing Form

Data and sample sharing form

Study name:

DCC PI and contact information:

Steering Committee chair/study PI and contact information:

NIDDK Project Officer:

Date study was funded:

Date of renewal(s):

Date(s) of end of intervention, if applicable:

Name of dataset	Dates included	Proposed date or time-line for sharing	Policy for when data will be shared with other investigators
Baseline data			<i>Two years after recruitment is complete (last initial visit) or within 6 months of publication date</i>
Primary outcome publication – analytic dataset			<i>Two years after database is locked for analysis or within 6 months of publication</i>
Secondary outcome(s) publication(s) – analytic set(s) - LIST			<i>Two years after the database is locked for analysis of these outcomes</i>
Entire dataset from intervention study			<i>Three years after last study contact (FDAAA’s primary completion date)</i>
All <u>complete</u> data elements on full cohort in observational study			<i>Two years after the end of each project period</i>
Analytic dataset from major papers			<i>6 months after publication appears on line</i>
Ancillary studies (list)			
Pilot studies (list)			

Samples

Current NIDDK policy is that samples will be shared no later than two years after the end of each project period.

Samples collected	Dates	Proposed date or time-line for sharing
DNA		
Urine		
Plasma		