

# Data Sharing Considerations for the TiME Trial

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**TiME**

# ***Have your research partners expressed concerns about how the data will be shared?***

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- Concern 1: Masking the identities of the provider organization, dialysis units, and patients
- Concern 2: Preserving the value of the data

## ***How will individual health systems be identified in shared data sets?***

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- Data elements will not be linked to dialysis provider
- Data elements that are unique to a provider will be removed prior to sharing
  - e.g., 24 hour urine collection
- Dialysis units will not be identified

# *Are there legal/regulatory obstacles to sharing your data sets?*

## **1. HIPAA Regulations**

### Requirements for Waiving or Altering Authorization for disclosing PHI

- The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
  - an adequate plan to protect the identifiers from improper use and disclosure;
  - an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
  - adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;
- The research could not practicably be conducted without the waiver or alteration; and
- The research could not practicably be conducted without access to and use of the protected health information.

# *Are there legal/regulatory obstacles to sharing your data sets?*

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## **2. Clinical Trial Agreement with Dialysis Providers**

Prime recipient:

- (i) shall not use, disclose, or further disclose any protected health information (“PHI”), as defined under HIPAA Regulations, in a manner that would violate HIPAA or HIPAA Regulations.
- (ii) shall utilize the limited data set provided by Subrecipient hereunder only in compliance with the terms of the Protocol and this CD Agreement and for no other purpose.
- (iii) shall ensure that data submitted to the NIH pursuant to this Subaward Agreement is de-identified pursuant to Section 45 CFR § 164.514 and in compliance with HIPAA and HIPAA Regulations.

# *How/where will you will be sharing your data?*

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- NIDDK Data Repository
  - Data made available to investigators through formal request and data use agreement between requestor and NIDDK

# *Can the analysis be replicated using the shared data sets?*

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- Not entirely
  - Provider will be removed
  - Dates will be removed

# NIDDK Data Sharing Policy

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