

Principal Investigators:

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Professor David Celermajer

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Guide for Study Specific Statistical Analysis Plan Version 2 (18Mar2019)

This document is intended for use alongside the NEDA Master Statistical Analysis Plan V1.2 (8May2018)

1. MASTER ANALYSIS PLAN

The NEDA Master Statistical Analysis Plan (SAP) V1.2 describes the broad principles for each researcher involved in the analysis of the NEDA database. The NEDA MASTER SAP V1.2 conforms to the STROBE guidelines and is useful for preparing publications, and is available at www.neda.net.au.

2. STUDY DESIGN

Each new study within NEDA requires approval by the NEDA Steering Committee. Application for studies is made using the Project Proposal Template (FRM 1.0) available by emailing admin@neda.net.au.

The a priori study hypothesis is described Project Proposal. Researchers should be aware of the scope, advantages and limitations of the NEDA database when designing their study. The Steering Committee will confirm the feasibility of addressing the study hypothesis from the data available in NEDA.

3. STATISTICAL ANALYSIS PLAN

An individual statistical analysis plan, specific to that study, should be created that compliments the MASTER NEDA SAP V1.2. (Template for study specific SAP is available at admin@neda.net.au).

This plan should document each relevant analysis for their study, and should be housed in the root directory of the Dropbox location described below. This plan should remain available after the study is completed, to allow for auditing and compliance purpose, and for results to be reproduced if required.

4. NEDA DATABASE

The NEDA database provided to each researcher will be a compressed version of the master NEDA database that contains all of the relevant data points for their research study.

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The database will be housed in a Dropbox folder, with specific sharing privileges. It is a NEDA requirement that the database remains in that Dropbox location at all times and is not shared with other researchers that do not have access to the Dropbox.

The naming convention of the folder and database will be as follows:

1. The folder name will start with three numbers, followed by three letters, then the name of the research project, and finally the name of the principal investigator for that study. This can only be altered by the Principal Investigators.
2. The database will follow a similar naming convention, with V1.0 at the end of the file name.
3. As the researchers alter the database, the file name should be changed to V1.1, V1.2 and so on. If a new copy of the database (e.g. a new mortality linkage) is provided by the Principal Investigators, the file name will change to V2.0.

5. NEDA DATABASE ANALYSIS

Each analysis of the NEDA database should also include the relevant SYNTAX, which should be saved along with the output logs.

These SYNTAX files should be saved along with the database in the Dropbox location, to allow for auditing, compliance and future verification of results should this be required.

6. REPORTING OF RESULTS

For each research study, accurate reporting of the results of analysis is the responsibility of the researcher.

Each senior author on each project must be involved in a logic check of data in including concordance with previous NEDA outputs.

Each author in the study is required to provide input into the analysis and reporting of the study, however the order of authorship is the responsibility of the principal investigator for that study (1).

The Authorship should be based on the guidelines provided by the NEDA Rules for Authorship.

References

1. Brennan PM, Jubb A, Baillie JK, Partridge RW. Deciding authorship order. *BMJ (Clinical Research Ed)*. 2013;347:f7182-f.