Example Data Management Protocol

1. Introduction

This protocol covers the management of data generated through the XX Trial and YY Trial. Although the first trial concluded in XX and the second trial is scheduled to conclude in YY, the protocol will apply beyond those dates for as long as the data is being used. Further information about the protocols for each trial can be found in Appendix A.

2. The purpose of this document

This document outlines procedures for utilising data collected as part of the XXYY Trials. Specifically, the document aims to do the following:

1. Ensure the accuracy of final data;
2. Describe the process for data use by program members;
3. Describe a process for data use by external users.

3. Trial team

Trial data will used to evaluate the effectiveness of the intervention. The trial will be conducted and evaluated under the collaborative arrangement between X, Y, G and Z. Oversight of the trial is the responsibility of the Advisory Group.

4. Accuracy of data

4.1 Data subgroups

Once data collection (baseline or follow-up) has been completed, a data sub-group will be formed and comprised of members of the X research team with representatives from the Y, G and Z. The group will be responsible for the overseeing following tasks performed by a trial statistician:

1. Cleaning and documenting changes to databases according to an agreed data cleaning protocol;
2. Initial variable classification/creation giving consideration to the importance of comparisons with other surveys; and,
3. Producing descriptive statistics, cross-tabulations, and summaries to present to the Advisory Group.
4. Ensure appropriate use of data adhering to ethics approvals (e.g de-identification and management of data)

Sign-off on the dataset regarding data cleaning and the readiness of the data for analysis and dissemination will be required by the Research Fellow or X Program Manager.

4.2 Describe a process for data use by program members

For internal implementation purposes

Release of data in a timely and efficient manner is vital to meeting objectives of the trial. Following the completion of data cleaning processes of data subgroups, Advisory Group members will be able

to conduct analyses on data sets to plan the development or delivery of interventions and inform and engage stakeholders. Such analyses will not require approval i) if the use of the data is not disseminated/shared beyond the partner organisation members ii) if the data is being used to engage a stakeholder but remains confidential between the stakeholder and a study partner or ii) if the data has already been approved for external dissemination.

For external dissemination

The research team will seek to manage the analyses, release and publication of research data via a paper dissemination process, organised by the trial Director and monitored at each Advisory Group meeting (See also authorship guidelines). In this way, all Advisory Group members will be presented with an opportunity to comment on planned dissemination activities and discuss research findings well before dissemination.

Nonetheless, any data to be used by non-members of the Advisory Group, that is shared or disseminated beyond the partners without confidentiality provisions (e.g media, conference presentation, publication) should first be cleared with the General Manager of X, Grant CIA, Policy Agency Director and University representative. A final version of the dissemination out-put (e.g paper) must be submitted to each organisation representative to approve. It is expected that a decision regarding approval is made within 2 weeks. Once analyses for public dissemination have been approved the analyses can be used in other outputs, without re- approval.

4.3 Describe a process for data use by external users

Requests for data by organisations or individuals external to the program (including external students) will be managed by the Research Fellow. On receipt of a request for external use of the data, the Research Fellow will:

1. Review external requests for data made using a standard proforma.
2. Ensure that the planned use of data does not compromise study dissemination priorities.
3. Ensure that the individual/organisation has sufficient knowledge and skills to appropriately report data.
4. Ensure that the data will be reported in a way consistent with the values of the collaborators.

If the Research Fellow approves the release of data to external groups/individual he/she is to seek the approval of the General Manager of X, Grant CIA, Policy Agency Director and University, and inform Advisory Group prior to data release. All external use of study data should include an appropriate acknowledgement of the project (See author guidelines document)

5. Data custodian

The Research Fellow will be responsible for the data. Program databases will be managed by an assigned Data Manager who will release data when authorised, and keep a log for data requests.