



Data Management Plan

Programme name: Building capacity for applied research to reduce tobacco-related harm in low- and middle-income countries (known as Tobacco Control Capacity Programme)

Funder: Medical Research Council (MRC) with funds from Global Challenges Research Fund (GCRF)

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Principal investigator: Professor Linda Bauld

Introduction

This document provides an overview of the approach that will be taken to data management within the Tobacco Control Capacity Programme. The nature of the programme is that individual research projects will be designed on an ongoing basis; as such, this should be treated as a live document that will be updated during the programme as necessary.

Compliance with Medical Research Council and University of Edinburgh policies

The principles and policies related to Medical Research Council (MRC) funded research programmes can be accessed here: <https://mrc.ukri.org/publications/browse/good-research-practice-principles-and-guidelines/> and <https://mrc.ukri.org/research/policies-and-guidance-for-researchers/data-sharing/>. All teams should make themselves aware of these MRC documents as well any specific data management policy created by their own university.

Some of the recommended actions and key points to note from the MRC guidance are as follows:

- All research data must be recorded and retained securely (for example, in electronic or hard copy laboratory notebooks) in a form that is original, legible, attributable and contemporaneous.
- Questionnaires, digital/audiotapes, etc should be retained in their original form within the research establishment that generated them.
- Where research data relating to a project are held in different formats (for example, completed questionnaires, machine readings, images and scans), these must be cross-referenced and recorded in the main record.
- The main record should be updated as soon as possible after data are collected; where the dates of collection and recording are different, this should be recorded.
- The main record should be approved by a supervisor to evidence that records are complete and accurate. Queries should be discussed as soon as possible and any changes resulting should be signed-off by the relevant parties.
- Information relating to participant consent should be held securely and subject to the same retention criteria as the primary/raw data.

Key additional points to note are as follows:

- Research data should be retained for a **minimum of ten years** after the study has been **completed**.

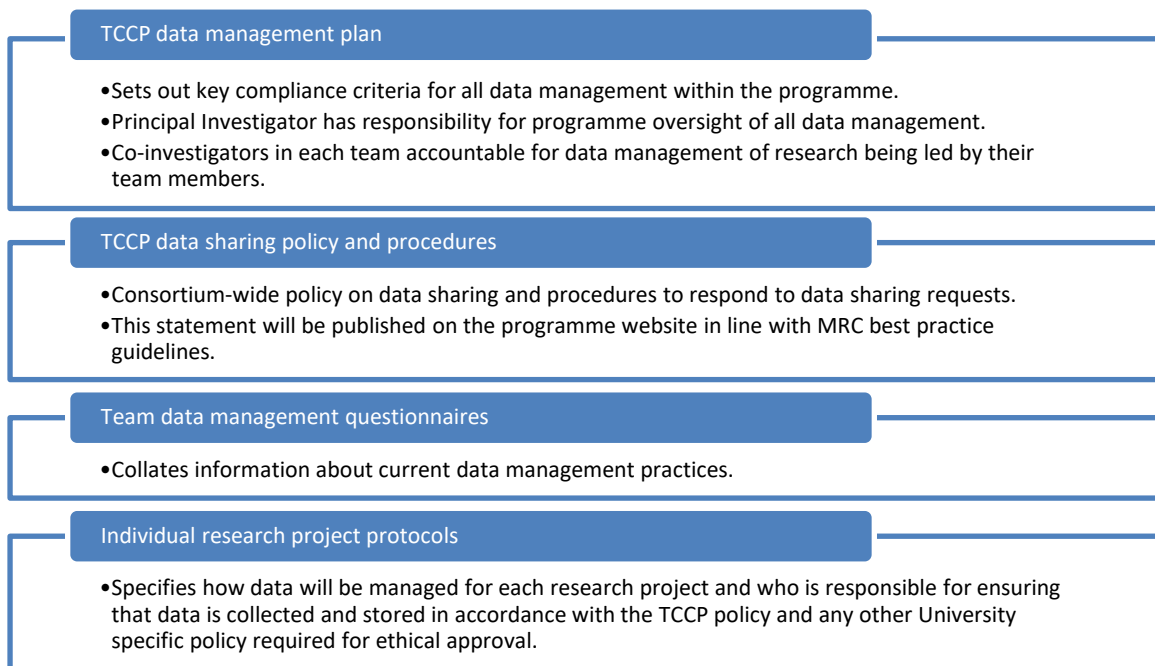


- A simple study policy on data-sharing must be readily discoverable by the research community on the study website, in a manner sensitive to the interests of participants.
- The summary (or whole) data sharing policy, or the link to a downloadable copy, is easy to find, and no more than one mouse-click from the home page on the study's website.
- MRC has defined categories of data availability. These are: 1) Unrestricted availability, 2) Independently viable, 3) Dependently viable and 4) Unavailable. Further information can be found in this document: <https://mrc.ukri.org/publications/browse/mrc-policy-and-guidance-on-sharing-of-research-data-from-population-and-patient-studies/>.

The lead partner for TCCP, the University of Edinburgh, has a research data management policy that can be found here: <https://www.ed.ac.uk/information-services/about/policies-and-regulations/research-data-policy>.

TCCP approach to data management

Our approach to data management is presented in the diagram below. This was discussed and agreed with the programme's allocated project officer from MRC.



Type of data

Within the programme, each of the eight LMIC research institutions are designing up to three research projects. In addition to these projects, the four UK-based Research Fellows will design research projects that are likely to have a more regional or global focus.

These research projects are likely to include the following types of studies: systematic reviews, policy analysis, media analysis, economic analysis and primary qualitative and/or quantitative research and secondary analysis of existing datasets.

Data standards

All data will be collected in compliance with the General Data Protection Regulation (GDPR) and any country specific data standard/regulations. This will be ensured through the submission of each



individual research project to ethical review in both the UK and the LMIC country where the research will be undertaken.

Managing and sharing data (within programme)

Researchers tasked with data collection will ensure that household and participants' anonymity is maintained and that their identities are protected from unauthorised parties. This will be achieved by delivering a study briefing prior to any data collection, where the Principal Investigator (PI) for each individual research project will explain the importance of confidentiality and how to store data appropriately. Households and participants will be assigned unique study identification numbers (study IDs) and these will be used on all data collection questionnaires, tools and other study records; households and participants will not be identified by their names. The individual research institutions leading research will keep and maintain a study log (including screening and enrolment logs) showing study IDs, names, dates of birth and other identifiable information of the participants securely under password protection (for electronic records) or lock and key (if hard copies).

Where data will be shared between different country teams, only the anonymized data will be shared. The co-investigator of the team sending the data will assess if there is any risk of persons being identified from the anonymized and accompanying documentation. Data for transfer will be password protected and transferred in accordance with the data transfer policy of the lead University conducting the study.

Quality assurance of data management

The Co-Investigator leading each individual research project will be responsible for the data being produced by their teams. Data management plans will be included with each research plan. Any specific issues related to data management will be raised with SMG for discussion during their quarterly meetings.

Sessions on data management and data sharing will be included in the annual team meetings to highlight key issues that have come up during the conduct of research within the programme, and to provide all consortium research fellows with guidance in this area.

Risks related to data management

Research is being undertaken within a large consortium of fifteen partners and is being co-created within multi-institution and multi-disciplinary working groups. As such, one of the main risks is that data security will be compromised during exchanges between different institutions. To mitigate against this, risk data management practices will be documented through questionnaires and individual research project documentation. All partners will be required to follow the data sharing principles outlines below.

Data sharing

A policy on data sharing will be published on the programme website in early 2019 (<http://ukctas.net/GCRF-TCCP>). Publications produced by the programme and connected external communications activities will be used to publicise the availability of data from the programme. The programme team will retain exclusive use of data until any planned publications have been published.

Anonymized data from the project, i.e. the quantitative data (including survey data) on which summary statistics and tables are based, will be made freely available while safeguarding the privacy of participants, and protecting confidential and proprietary data. We will make the data and



associated documentation available to users only under a data-sharing agreement that provides for: (1) a commitment to using the data only for research purposes and not to identify any individual participant; *bona fide* requests from researchers who have no connections to the tobacco industry; (3) a commitment to securing the data using appropriate computer technology; and (4) a commitment to destroying or returning the data after analyses are completed.

Requests to access data from the programme will be processed by the Research Project Manager and the Principal Investigator for the entire research programme (Professor Bauld). Where the request involves data produced by one or more other institution within the consortium, co-investigators situated within these institutions will also be consulted on the decision as to whether the data can be shared or not.

Plan details:

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Latest amendment: March 2019