



## **MRC START Data sharing agreement**

This document specifies the data management and data sharing agreement between the MRC START study and *[name of host trial]*.

In this document, the 'START research team' refers to researchers named on the protocol. 'START collaborators' refers to those providing 'host' trials for the study.

## **MRC START roles and responsibilities**

*[Name of Trial]* team agrees to:

- (a) Randomly allocate *[specify sample size]* patients participating in *[specify trial]* to receive *[specify intervention]*.
- (b) Randomise patients to either the recruitment intervention or usual procedures on the basis of *[specify randomisation procedure]* over a *[specify time frame]* period
- (c) Collect data on the numbers of patients approached using each recruitment method, and data on the numbers recruited to the trial, and the number retained at each follow up point as follows *[specify as agreed in access negotiations]*
- (d) Collect data on the following patient demographic characteristics: *[if relevant, complete as agreed in access negotiations]*
- (e) Provide collected data in an anonymised form (labelled data set in SPSS or a data base suitable for import to SPSS) to the START research team for analysis by *[target date for data collection]*
- (f) Not introduce the recruitment intervention in a non-randomised fashion during MRC START
- (g) Seek permission from the MRC START research team to introduce them after the end of the MRC START study period.

It is possible that host trials may wish to withdraw from MRC START before the end of the study. In this case, data collected up to that point would still be provided to the MRC START research team.

### **Data Protection and publication issues in the START study**

The University of Manchester has strict guidelines for data storage, access to study data and adherence to the principles of data protection (including the Data Protection Act 1998). The link to relevant information is:

<http://www.staffnet.manchester.ac.uk/services/records-management/data-protection/data-protection-guidance/>

### **Data Transfer Policy**

Datasets will be accepted from MRC START collaborators in electronic format (the University of Manchester can translate datasets in various formats through *Stat Transfer*). In addition, MRC START collaborators will provide written details of the coding of variables in the dataset to allow consistent analysis (see study protocol).

All datasets will be anonymised by MRC START collaborators *before* transfer to the University of Manchester, removing all identifiable patient information such as names and addresses. Data may be encrypted before transmission to ensure security.

### **Data storage**

Datasets from MRC START collaborators will be transferred to a combined database on a secure server at the Health Sciences Research Group, University of Manchester. All data received will be treated in the strictest confidence. Analysis of the data will take place by Professor Peter Bower and Professor Sandra Eldridge. Professor Bower will act as custodian for the combined dataset. The combined

dataset will be stored by the University of Manchester in a secure location. Data from individual datasets will remain the property of MRC START collaborators.

## **Environment**

The NIHR School for Primary Care Research

(<http://www.haps.bham.ac.uk/primarycare/nspcr/index.shtml>) comprises the leading academic centres for primary care research in England, with a focus on research to improve everyday practice in primary care. The MRC START research project is led by the Centre for Primary Care, Institute of Population Health, the University of Manchester (<http://www.population-health.manchester.ac.uk/research/primarycare/>)