



## **Data sharing policy for The EPIcure Studies**

**4 January 2021**

### **Background**

This data sharing policy is based on that of the MRC (who funded both EPIcure and EPClure2) with the expectation that 'valuable data arising from MRC-funded research is to be made available to the scientific community with as few restrictions as possible. Such data must be shared in a timely and responsible manner'.

New studies that result from this data sharing should meet the high standards of all MRC research regarding scientific quality, ethical requirements and value for money; new studies should also add recognisable value to the original dataset.

Currently, electronic copies of all EPIcure data are held by Neil Marlow (CI), and Professor Joan Morris (Study Statistician). Whilst study analyses are ongoing data are also held by co-investigators and research staff, on the understanding that they are confidential to the EPIcure Studies group. Subsequent to the completion of the study, data will be archived and migrated appropriately to maintain their usefulness. The full range of study analyses completed are in the publications from the study but at present active analysis is ongoing for both cohort studies and thus data sharing that conflicts with proposed analyses is not appropriate. Data have already been shared for comparator studies.

Once the study is complete and funding ceases the CI and co-investigators will ensure that data are held securely, that a list of completed analyses are made available electronically via the website, and access to the data will be via a route openly advertised on the website. ([www.epicure.ac.uk](http://www.epicure.ac.uk))

### **Data sharing policy**

Proposals will be then considered by a Data Sharing Committee (DSC; see composition later). To safeguard the scientific integrity and validity of any new studies that request data sharing must receive approval from the DSC.

This process will include:

- The responsibilities and rights of all parties should be agreed at the outset.
- The DSC will perform a review of the protocol for the proposed analysis, which will need to contain clear scientific justification for the particular project; anticipated outputs and timelines will be required.
- Independent peer review of the specific project will be required.
- Funds may be required to support the data extract and transfer.
- The appropriate regulatory permissions – ethical, legal and institutional – must be in place before data can be shared.
- In accordance with MRC policy, requests for sharing data that are currently still the subject

of analysis and writing up by the original co-applicants will be deferred until such time as the work has been accepted for publication.

There is an expectation that a data extract will be provided rather than a copy of the full data set. Extraction of the data will be undertaken by the study team and adequate resources will be required to reflect the complexity of the data extract. To comply with the Data Protection Act, only an anonymised data extract will be provided, and with the expectation that only durations and summary scores will be required rather than exact dates and raw data.

The Chief Investigator (Neil Marlow) will be responsible for coordinating applications for use of the data generated by the EPICure Studies. This will ensure that the Chief Investigator is aware of all planned analyses and publications and can prevent duplication occurring and co-ordinate the dissemination of information most effectively. The CI will not have right of veto over agreement to use the data nor over publication of studies arising from this but will pass all proposals for further analyses and publications from interested parties to the DSC.

### **Publication of agreed studies**

Researchers who are using the data should send the penultimate draft to the DSC to ensure correct contextual interpretation of the data sets.

A standard acknowledgement should be included in any publication: 'The EPICure Studies were funded by the MRC. The EPICure Data Sharing Committee approved the proposal. Data were extracted from the original dataset for this study by the EPICure investigators'.

### **Composition of the DSC**

The DSC will be chaired by Professor Neil Marlow and will also include those co-investigators, who have access to the data currently (Prof Joan Morris, Prof Sam Johnson at present). The DSC will only be required to meet on an ad hoc basis, in response to applications for data sharing and review of studies prior to publication.

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UCL 15 August 2011, updated January 2021

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