

# DATA SHARING POLICY FOR OUCRU STUDIES

## 1. Introduction

OUCRU recognizes the ethical obligation to ensure that optimal use is made of the data and specimens that we collect for our research and the value of sharing individual level data. We aim to ensure that data generated from all our research are collected, curated, managed and shared in a way that maximizes their benefit. When sharing data we have an obligation to ensure that the interests of research participants, researchers and other stakeholders are appropriately protected.

The purpose of this policy is to describe the principles and procedures for sharing of data from trials, observational studies and other research projects. This documents aims to:

- Outline the procedures for data sharing.
- Define the OUCRU roles and responsibilities involved in this process.

### 1.1 RATIONALE

There has been a move towards greater transparency in design, conduct and reporting in both the public and private sectors over recent years. Better registration of trials has led to a clearer understanding of ongoing research. There is more reporting of results and clearer presentation of data within those reports, e.g. CONSORT. Many funders and sponsors now insist on open access publication whereby results are free to the reader, either immediately or within a set time.

In parallel, a number of funders and sponsors have moved towards greater access to data from trials and other projects they have supported. They have done this by implementing policies that encourage or mandate access to results or data, either via the host institution or through appropriate data repositories. There are a number of advantages for research transparency including the ability to:

- (i) Place the results of the study in a larger context, e.g. as part of an individual patient data meta-analysis (IPD MA).
- (ii) Make secondary use of the dataset, e.g. using the trial or cohort as a convenience sample of high quality, prospectively collected data to address a different question.
- (iii) Collaborate directly with other researchers where data need to be transferred to an



alternative location for planned analyses, e.g. as part of biological sub-studies.

- (iv) Provide supporting evidence to plan a new trial, e.g. estimating the expected event on their control arm, or estimating rates of recruitment
- (v) Develop and validate new methodologies, e.g. new statistical methods or biomarker/prognostic indicators
- (vi) Independently verify the analyses that the trial team has published or presented.

## 1.2 SCOPE

The scope of this document is to cover data from any type of study, including RCTs, cohort studies and meta- analyses, and both individual patient data and aggregate data. It covers how studies led by the OUCRU network and sponsored by University of Oxford can be made discoverable and the process for sharing data. This includes studies run by the Hanoi Unit at the National Institute of Infectious & Tropical Diseases (NHTD), as well as the satellite research units in Kathmandu (Nepal) and Jakarta (Indonesia).

The scope of this data sharing policy is focused on data sharing requested by external parties (not including journals, sponsors or collaborators).

## 1.3 DEFINITIONS

Term	Working definition
Data	For this purpose, “data” covers raw data, processed data on individuals or aggregated, summarised data in the form of reports. The document also covers the release of stored samples. A dataset is a collection of data to be used for a specific purpose, as formulated in the proposal. Under some definitions (e.g. EMA), data has a broader definition, including files, test results, etc.
Data Monitoring Committee	The DMC, usually independent (→IDMC; can also be termed DSMB), is the only body to routinely see accumulating comparative data from a trial. The IDMC is considered the guardian of the interim analyses, and is well placed to consider the implications of <u>early requests</u> for data release.
Data Sharing	“Data sharing” encompasses data release and data transfer to



	external applicants.
“Data Sharing Plan”	The Data Sharing Plan is the term used here to describe a document, developed at an early stage, detailing some aspects of data sharing methods and principles.
Discoverability	The ability for the existence of a dataset or trial to be discovered.
Trial Management Group	TMG comprises the key internal and external people involved in running a trial, including the Principal/Chief Investigator. These members have been key in developing the trial protocol, conducting the trial and collecting and analysing the data.
Trial Steering Committee	The TSC is the trials’ executive body ensuring compliance to Good Clinical Practice (GCP), and is central to major decisions for the trial. The committee may be comprised of a number of independent members, including the chair, plus key members of the TMG.
Strategic Committee	The OUCRU SC determines the strategic objectives of OUCRU and defines the financial and managerial policies to achieve these objectives. The OUCRU SC has the final responsibility for reviewing and approving external data sharing requests.

## 1.4 SPONSOR INPUT

This policy sets out the principles for OUCRU-coordinated research and applies where OUCRU or Oxford University is the Sponsor. Explicit input should be sought at an early stage in the project where another organisation is the Sponsor. A data sharing or clinical trial agreement should be in place prior to any data collection.



## 2. Responsibilities and roles

The process of receiving and processing applications, developing agreements, producing and transferring data, and responding to subsequent requests for clarification of data involves a broad range of functions across the unit. In the order of the Standard Operating Procedures (SOP) training matrix, this could be:

CTU, Project lead, Research Scientists, Clinical Scientists	Recipient of requests
CTU	Involved in sending or receiving data release requests, as required
CTU	Take requests through review processes, Often lead contact for requests
Strategic Committee (SC)	Input and approval of requests
Data Management and IT Department (Statistics Group as required)	Extraction, cleaning and documentation of data, as required
Finance and Contracts team (CTU)	Work in conjunction with project/trial team to prepare and conclude a data disclosure and release agreement
Finance and Contracts team (CTU)	Engage in appropriate aspects of preparing the agreements where there are financial implications.
Data Management and IT Department	Data extraction, cleaning and documentation of dataset and Input to methods of secure transfer of data, as required
Data Management and IT Department	Input to methods of secure transfer of data



### 3. Principles

- (i) OUCRU employs a controlled access approach for data sharing requests by external parties.
- (ii) No data should be released that would compromise an ongoing trial or study.
- (iii) There must be a clear scientific or other legitimate rationale for the data to be used for the requested purpose.
- (iv) OUCRU's ability to share high-quality data in a timely manner will require considerable resources. We will therefore levy a charge on all external requests (independent from a standard scientific collaboration) for OUCRU data, which will be used to support the internal infrastructure required to share data effectively and efficiently.
- (v) Data exchange complies with Information Governance and Data Security Policies as well as relevant institutional and ethics regulations in all of the relevant countries.



## 4. Discoverability

A key issue for sharing is, knowing what information is available and when it will be available. To this end, OUCRU research should be “discoverable”.

### 4.1 CLINICAL TRIALS

All OUCRU clinical trials will be registered on an appropriate clinical trials register and will be discoverable through this process.

Trials will also be listed on the OUCRU website.

<http://www.oucru.org/trials-portfolio/>

### 4.2 OTHER STUDIES

OUCRU funded projects and studies other than randomised controlled trials (RCTs) may be found on the OUCRU website at:

:: [www.oucru.org](http://www.oucru.org)



## 5. Data Formatting and Standards

### 5.1 DATA SHARING PLANS

All applicants submitting funding proposals to the MRC, Wellcome and the Gates Foundation are required to include a Data Sharing Plan as an integral part of the application. Other funders may also ask or may be expected to follow suit in the future.

The Data Sharing Plan presents early information on data sharing principles and methods. It may also include a description of data collection, management, storage and curation, and covers security risks that would later be covered in a risk assessment and a Data Management Plan.

### 5.2 STANDARDISATION

Standardised terms and definitions should be used if appropriate and possible, including from the design stage of a study in order to facilitate future data sharing. For example:

- Data standards and data descriptions e.g. C-DISC.
- Standard tools for scoring and recording data should be used where possible e.g. quality of life and toxicity data.
- The COMET initiative makes efforts to determine standard outcome data items to collect for certain disease subsets, and this resource is growing. The aim is to help with standardisation of data sharing and, importantly, interpretation. Researchers should check the COMET initiative website early in trial development to see what information has already been agreed for the relevant disease or condition. More information can be found at:  
:: [www.comet-initiative.org](http://www.comet-initiative.org)



## 6. Procedures for Data Sharing

In line with journal and sponsor's regulations OUCRU has several options for data sharing, including but not limited to

(i) Online open access: e.g. as supplementary files to a journal article. With this method of access OUCRU has no oversight or control of secondary uses made of the data.

(ii) External repository without case-by-case assessment: With this method datasets submitted to a repository may be accessed by registered users who have agreed to the repository's terms and conditions of use. With this method OUCRU has no oversight or control over secondary uses made of the data by registered users. Uses made of the data will be restricted by the terms and conditions of the repository (such as ORA).

(iii) Data can be requested through application to the OUCRU Strategic Committee (SC). With this method applicants complete a request form and sign a data sharing agreement. Requests are considered by the SC on a case-by-case basis informed by the terms of reference and the request form. The type of agreement that applicants are asked to complete depends on the dataset requested. Additional specific conditions of access may be implemented including collaboration and cost- recovery for preparation of datasets.

### 6.1. DEVELOPING THE ASSESSMENT PROCESS

A number of stages may be required in the assessment process of data requested by external parties. The process for access to data should be made clear to potential applicants. A template request form is provided which includes a diagram of the default process.

### 6.2 STANDARD STEPS IN THE ASSESSMENT PROCESS

(i) Discussion with OUCRU project lead

This should scope the project, in terms of science, practicality and resources.

This may be before the application form has been completed.

Discussion of details of the project.

(ii) Review by the Strategic Committee

Discussion of the details of the project.

Is OUCRU being asked to undertake the analyses? This may have resource implications.



The executive body should reach a decision.

(iii) Review by the Data Monitoring Committee

Only for the use of intermediate or immature data.

### **6.2.1 OLDER STUDIES**

Data requests may continue to be received long after the trial has closed. The Principal/Chief Investigator should remain reachable for as long as is feasible in order to consider such requests.

## **6.3 KEY CONSIDERATIONS DURING REVIEW**

As with any application, there must be a strong scientific rationale or other legitimate reason (see section 1.1). Key points should be considered:

### **6.3.1 RATIONALE, MERIT AND CONDUCT OF PROJECT**

Questions here include:

- What is the scientific merit of the proposal
- Are the study data suitable for answering the proposed research question?
- What biases might be present? E.g. cohort selection
- Do the original researchers already have plans to use the data in the way proposed by the applicants?
- Are the analyses sufficiently well described to allow assessment of whether the proposal is fit for purpose?
- Is the team properly motivated and suitably qualified to perform the analyses?

### **6.3.2 PROTECTION OF PARTICIPANTS**

Questions here include:

- How would confidentiality be maintained?
- Does patient consent cover the proposal?

### **6.3.3 PROTECTION OF THE INTEGRITY OF THE ORIGINAL STUDY**

Questions here include:

- Would the proposed use of data jeopardise the conduct or results of the study from which the data are derived? If so, this is likely to be unacceptable.
- Is there duplication? Have these data already been requested for this purpose? Are there implications for the future conduct or interpretation of the trial?



#### 6.3.4 RESOURCE IMPLICATIONS

Questions here include:

- What resources would be required at OUCRU to:
  - help investigators to understand the data
  - prepare dataset
  - transfer dataset
  - perform analyses
- Are resources available at OUCRU?
- If not, could they be made available?
- What would be the opportunity costs?
- Are OUCRU staff considered providers of data or full collaborators?
- Are raw or summary data required?
- What version of the data set is required? Are new data chasing efforts needed?

#### 6.4 REQUEST FORM

The applicants should detail their request on a request form. A standard template is provided. Further items may be added to this if required and variations are acceptable for particular studies providing the process is well documented in the SC.

Completing the request form can be an iterative process, with updates from each stage of the review. The applicants can be asked to specify the information that will allow the reviewers to consider all relevant aspects.

- Objectives
- Study design
- Qualifications and suitability of the applicants
- Data/samples required
- Ethical approval and consent requirements
- Planned outputs
- Authorship and publication policy, and implications for OUCRU
- Timelines

A detailed protocol and statistical analysis plan should be provided, if available, and any other relevant documents.

#### 6.5 FEEDBACK AND UPDATE

The comments of the reviewers should be recorded at each stage. A form for this purpose is provided as a template, which may be sent out to reviewers. Feedback should be provided, as a summary, to the applicants.



## 6.6 AGREEMENTS

The contracts team should be notified at the appropriate stage of the review process so that suitable agreements can be drawn up promptly after a successful review. Agreements will be made at an institutional level rather than an individual level in all but the most exceptional circumstances.

Researchers in receipt of data must store it securely, according to Information Governance and Data Protection regulations. They are expected to process and publish reports according to their initial plans.

Agreements should specify the boundaries of use of the data, including, for example, that the data can only be used for the purposes for which they have been released.

Applicants should not use the data to identify individual patients, unless this is a pre-specified goal for the purpose of record linkage.

## 6.7 PREPARATION AND TRANSFER

The data protection legislation of all countries involved in the transfer must be considered. Particular care must be taken in preparing or releasing identifiable or sensitive data on individuals. Identifiers should be removed prior to disclosure wherever possible e.g. no names or detailed geographical locations; using ages or years of birth instead of full date of birth. Consideration should be given to further anonymising the data by including new ID numbers and breaking the link to the original dataset. This choice will largely depend on how the data are to be used and whether further linkage would be required. The time and effort required to prepare the appropriate dataset should not be under-estimated. Data should be transferred in an appropriately secure method, after discussion with the Data Management and IT department.

## 6.8 DATA RECEIPT

Recipients should acknowledge receipt of data and should check immediately for any problems.

## 6.9 REPORTING

The recipients of data should update OUCRU SC at time of completion of their project and share arising publications.



## 7. RECORDING AND REPORTING

An audit trail of applications and approvals is required. It is important to record in a tracking log that data have been requested and, if released: when, to whom and for what purpose. A Unit-wide database for requests will be developed and maintained by the CTU OUCRU.

## 8. FURTHER CONSIDERATIONS

### 8.1 ONWARD SHARING OF DATA

#### 8.1.1 DATA RECEIVED

OUCRU datasets may include linked data from other sources e.g. HTD data on hospital invoices. These are considered to be part of the dataset and can be included in data released from OUCRU, subject to agreement and approval by the original source.

#### 8.1.2 DATA PROVIDED

OUCRU data that are provided to other people may be subject to further requests for sharing. For example, a trial dataset may be released to Researcher B for inclusion in a meta-analysis, and Researcher C might then request access to the full dataset of Researcher B for a further analysis.

Onward sharing is not permitted without OUCRU consent. Generally, onward sharing to Researcher C will be permitted if Researcher C wishes to use the data in a project that has a purpose in line with the original release to Researcher B. If Researcher C wishes to use the data for a purpose that was not covered by the data release agreement, Researcher C should contact OUCRU directly for data.



## 9. FLOW CHART OF DEFAULT PROCESS

