

MORU Tropical Network Data Sharing Policy

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1. Introduction

The MORU Tropical Network recognizes 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.

MORU is committed to ensuring that data sharing is planned for in the inception of a study: including during negotiations with funders and collaborating sites, during evaluation of compliance with local and international ethics and regulatory requirements, and during the design and conduct of consent processes.

From January 2016 data management for all research studies will include preparation for data sharing. Data will be made available within six months of publication.

2. Background

MORU was established in 1979 as a research collaboration between Mahidol University in Thailand and University of Oxford in the United Kingdom. At any one time, MORU has around 60-70 active clinical studies ranging from small single site pharmacokinetic studies to large multi-country projects involving thousands of participants and generating vast amounts of data.

3. Scope

This policy applies to all clinical research data collected in studies led by the MORU network and sponsored by University of Oxford. This includes studies run by the Bangkok Unit, Shoklo Malaria Research Unit, Laos Oxford Mahosot Wellcome Trust Research Unit, Cambodia Oxford Medical Research Unit Kinshasa Oxford Medical Research Unit and Myanmar Oxford Research Unit.

4. Key Principles and Considerations

When sharing research data we aim to **maximise its scientific utility** through ensuring that data are high quality, shared in appropriate formats and accompanied by relevant and comprehensive associated information such as protocols, case report forms and data dictionaries. We aim to **minimize potential harms of sharing and protect the interests of relevant stakeholders** including research participants, communities and researchers by ensuring that data are released via governance methods with appropriate levels of oversight and conditions of use. MORU **remains the custodian of shared datasets** and

will monitor applicants' uses of data as appropriate. We aim to share data in a **fair manner** that does not exacerbate existing inequalities and will prioritise the health interests of those in low and middle income settings. Our data sharing governance is designed **to build and sustain stakeholders' trust** in data sharing. Our sharing policies and processes aim to be **fair, accountable and transparent as well as proportionate and responsive** to the contexts in which the data were collected.

5. Process

A. Data Access Committee

Oversight for data sharing within MORU is the function of the Data Access Committee (DAC). Members of the DAC are appointed by the Science & Strategy Committee.

The DAC on behalf of MORU is responsible for:

(i) Facilitating data access

(ii) Reviewing applications for sharing of datasets submitted to DAC

(iii) The custodianship and stewardship of the data, the oversight of the quality of the data shared, and compliance with funders' policies and this data sharing policy.

B. Data access routes

These include:

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

2. **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 MORU 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.

3. **Application to the Data Access Committee – for published and stand-alone datasets (e.g. PhD projects)**

With this method applicants complete an Application Form and data access agreement. Applications are considered by the DAC on a case-by-case basis informed by the terms of reference and the application checklist. The type of

agreement that applicants are asked to complete depends on the dataset requested.

4. Application to the Data Access Committee – for partially published, complex and sensitive datasets

With this method applicants complete an application form and data access agreement. Applications are considered by the DAC on a case-by-case basis informed by the terms of reference and the application checklist. The type of agreement that applicants are asked to complete depends on the dataset requested. Consideration is likely to involve consultation with principal investigators, relevant collaborators and other experts. Additional specific conditions of access may be implemented including collaboration and cost-recovery for preparation of datasets.

5. Limited release

Data may be judged as low priorities for release due to limited scientific value.

Queries and applications for datasets should be directed to Rita Chanviriyavuth, rita@tropmedes.ac