MalariaGEN
GENOMIC EPIDEMIOLOGY NETWORK

# Standard operating procedure for re-linking genomic data with local clinical databases

## Purpose

This SOP describes the procedures to be followed and the responsibilities of the parties involved when re-linking MalariaGEN genomic data with local clinical databases.

## Applicability

The Oxford Coordinating Centre and all MalariaGEN principal investigators (PIs), co-applicants, and institutional representatives.

## Introduction

Due to the on-going and iterative nature of genomic epidemiological research, it is important for contributing PIs to be able to re-link genomic and phenotypic data from consortial databases with their own locally-held clinical databases, which may contain personal identifiers. In such circumstances MalariaGEN recognises that it is essential to protect research participants' privacy. When joining the consortium, each PI and his/her institution signed a contract requiring compliance with relevant international and national ethical guidance on research ethics and with Good Clinical Practice standards, which require that the privacy of research participants and the confidentiality of their information be protected. Moreover, PIs are already entrusted with protecting the privacy of their research participants and, in many cases, are already participating in other studies which join up genomic and clinical data. This SOP clarifies the respective roles and responsibilities of PIs, co-applicants, institutional representatives and the Oxford Coordinating Centre when the re-linking file, which enables re-linking of genomic and phenotypic data from consortial databases with locally-held clinical databases, is requested.

## Reponsibilities

The **PI** has the responsibility to ensure that:

- appropriate ethical approval is in place for re-linking site-specific consortial genotypic data with local phenotypic databases; and
- the consent given by participants for samples to be included in the study does not prevent linking site-specific consortial data with local phenotypic databases.

The **PI(s), co-applicant(s)** and their **institutional representative** have the responsibility to ensure that:

- procedures are in place to maintain the privacy of participants and the confidentiality of re-linked data;
- the re-linking file and re-linked data are securely stored and only available to the PIs and co-applicants listed in the agreement at Appendix A; and
- they receive ethical approval from their local research ethics committee for any additional research on the re-linked data that is not covered by the ethical approval given for the MalariaGEN consortial projects. They must also notify the Oxford Coordinating Centre and OXTREC of any such proposed research in advance.

The **Oxford Coordinating Centre** has the responsibility to**:**

- liaise with sites requesting the re-linking file and provide appropriate support (particularly in the fields of data analysis, secure storage of information, and ethics); and
- securely supply the re-linking file to sites making applications to re-link data, after appropriate liaison has taken place.

## Procedures for re-linking data

1. PIs review their local ethical approval to ensure that it allows the re-linking of consortial genotypic data with local phenotypic databases and that the consent given for samples to be included in the study does not prevent linking consortial data with local phenotypic databases. The ethicists at the Oxford Coordinating Centre are available to review and discuss these issues on a site-by-site basis when requested.
2. PIs preserve patients' privacy by developing or reviewing procedures to restrict access to the re-linking file and re-linked data to the named individuals at Appendix A. The IT staff at the Oxford Coordinating Centre are available to review and discuss these issues on a site-by-site basis when requested.
3. PIs, co-applicants and an institutional representative apply for the re-linking key using the agreement at Appendix A.
4. The Oxford Coordinating Centre responds and discusses the points outlined in procedures 1 and 2 above, as well as ways of providing the re-linking file in a secure manner.

5. PIs receive the re-linking file and store the file and any re-linked data securely.

6. The PIs and their co-applicants conduct research covered by the ethical approval for the MalariaGEN consortial projects. It is recommended that researchers maintain a log of who accesses the data on which dates and for what research purposes. Research support is always available from the analysis team at the Oxford Coordinating Centre.

7. The PIs must notify the Oxford Coordinating Centre of:

    a. upcoming publications based on the re-linked data;

    b. any proposed research not covered in the original ethical approvals (including plans to seek the necessary additional ethical approval); and

    c. proposals to extend or amend the list of PIs and co-applicants who have access to the data (accompanied by completed agreements listing the new applicants (see Appendix A)).

# Appendix A

## Agreement about the requirements for management of re-linked data

This SOP is not designed to add to investigators' responsibilities as outlined in the **Agreement to Govern Collaborations funded under the Grand Challenges in Global Health Initiative** between the University of Oxford and the MalariaGEN collaborating institutions. Instead, for the avoidance of doubt, this operating procedure clarifies the respective responsibilities of **PIs, co-applicants, institutional representatives** and the **Oxford Coordinating Centre** when managing re-linked data.

### Requesting the re-linking file:

Because of the sensitive nature of the re-linked data only **PIs** can request that the **Oxford Coordinating Centre** release the re-linking file to link their source codes with the MalariaGEN sample identifier (released key). Moreover, the **Oxford Coordinating Centre** can only release the re-linking file to **PIs** and their **co-applicants** who meet the following requirements:

### Releasing the re-linking file:

1. **PI(s)** confirm that:

- appropriate ethical approval is in place for re-linking site-specific consortial genotype data with local phenotypic databases; and
- the consent given for samples to be included in the study does not prevent linking site-specific consortial data with local phenotypic databases.

2. **PI(s), co-applicant(s) and their institutional representative** confirm that they will comply with the MalariaGEN **Standard operating procedure for re-linking genomic data with local clinical databases.** In particular they take full responsibility for ensuring that:

- procedures are in place to maintain the privacy of participants and the confidentiality of re-linked data;
- the re-linking file and re-linked data are securely stored and only available to the **PIs** and **co-applicants** who have agreed to comply with these requirements (see overleaf); and
- ethical approval is received from their local research ethics committee for any additional research on the re-linked data that is not covered by the ethical approval given for the MalariaGEN consortial projects, and that the **Oxford Coordinating Centre** and OXTREC are notified of any such research in advance.

**We, the undersigned, agree to comply with the MalariaGEN SOP for re-linking genomic data with local clinical databases.**

**Principal Investigator(s):…….Signature:.....**

**Principal Investigator(s):……..……Signature:.....**

**Date: ……..**

**Co-applicant(s):…….....Signature:.....**

**Co-applicant(s):…….....Signature:.....**

**Co-applicant(s):…….....Signature:.....**

**Date……..**

**For and on behalf of User Institution:……**

**Signature:…….Date……**

**For and behalf of Oxford Coordinating Centre: .....**

**Signature:.....Date:……...**