

Accompanying information for:

A global network for investigating the genomic epidemiology of malaria
The Malaria Genomic Epidemiology Network
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Further information at <http://www.malariagen.net>

STANDARD OPERATING PROCEDURE FOR RE-LINKING GENETIC DATA WITH LOCAL CLINICAL DATABASES**Purpose**

This document describes the procedures to be followed when re-linking MalariaGEN genomic data with local clinical databases.

Applicability

The Oxford Co-ordinating 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 principal investigator (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 Co-ordinating Centre when the re-linking file is requested.

Responsibilities

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
- the consent given 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:

- 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.
- You receive ethical approval from your 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 Consortium Projects. You must also notify the Oxford Co-ordinating Centre and OXTREC of any such proposed research in advance.

The Oxford Co-ordinating Centre has the responsibility to:

1. 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).
2. Confidentially 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 preclude linking consortial data with local phenotypic databases. The ethicists at the Oxford Co-ordinating Centre are available to review and discuss these issues on a site-by-site basis when requested.
2. PIs develop or review 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 co-ordinating 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 Co-ordinating 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 named PIs and their Co-applicants conduct research covered in the ethical approval for the MalariaGEN Consortium 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 Co-ordinating Centre.
7. The named PIs notify the Oxford Co-ordinating 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);
 - 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 management of re-linked data

This agreement and the accompanying standard operating procedure are 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 agreement clarifies the respective responsibilities of Principal Investigators (PIs), Co-applicants, Institutional Representatives and the Oxford Co-ordinating 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 Co-ordinating Centre release the re-linking file to link their source codes with the MalariaGEN sample identifier (release key). Moreover, the Oxford Co-ordinating Centre can only release the re-linking file to PIs and their Co-applicants who confirm the following:

Releasing the re-linking file:

1. PI(s) confirm that you are satisfied that:

- appropriate ethical approval is in place for re-linking site-specific consortial genotype data with local phenotypic databases
- 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 you will comply with the attached standard operating procedure for re-linking genomic data with local clinical databases. In particular you take full responsibility for ensuring that:

- the re-linking file and re-linked data are securely stored and only available to the PIs and Co-applicants listed below.
- Ethical approval is received from your 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 Consortium Projects, and that the Oxford Co-ordinating Centre and OXTREC are notified of any such research in advance.

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

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

Date:

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:.....