

MalariaGEN Data Access Agreement

Background

This agreement governs the terms on which access will be granted to the data generated by the MalariaGEN consortium.

The MalariaGEN consortium has created a database containing comprehensive genetic data linked to epidemiological and clinical data, on human subjects (“Data Subjects”) living in malaria-endemic countries.

The MalariaGEN consortium members who contributed the Data are the custodians of that Data and hold such ownership rights as may exist in relation to such Data. The MalariaGEN consortium members have agreed to provide access to the Database for medical research uses in accordance with MalariaGEN’s **Data Release Policy for Genome-wide Association Data** which can be found with details of the MalariaGEN consortium at www.malariagen.net.

The University of Oxford manages the MalariaGEN database on behalf of the MalariaGEN consortium members and provides access to external Recipients who have received approval from MalariaGEN’s Independent Data Access Committee.

In signing this agreement, the Recipient agrees to be bound by the terms and conditions of access set out in this agreement, and agrees to ensure that the Recipient Institution’s Data Users comply with the terms and conditions of this agreement.

For the sake of clarity, the terms of access set out in this agreement apply both to the Recipient and the Recipient Institution (as defined below). The Recipient Institution and Recipient are referred to within the agreement as “You”, and “Your” shall be construed accordingly.

This Agreement is made the ____ day of _____ 20__ BETWEEN:

(1) The Chancellor, Masters and Scholars of the University of Oxford whose administrative offices are at Wellington Square, Oxford OX1 2JD, UK (“Oxford”)

(2)

_____ whose registered office/principal address is _____ (the “Recipient Institution”)

(3) (the “Recipient”)

Definitions:

“Recipient” means the principal researcher named above

“Recipient Institution” means the organisation named above at which the Recipient is employed, affiliated or enrolled

“Data Users” means those officers, employees and students of the Recipient Institution, who work directly with the Recipient and have a need to use the Data for the performance of their work with respect to the Agreed Purpose, and have agreed to comply with this Agreement, as named in Schedule 1.

“Agreed Purpose” means the medical research purpose(s) approved by the IDAC in writing.

“Publications” means, without limitation, articles published in print journals, electronic journals, reviews, books, posters and other written and verbal presentations of research.

“Database” the MalariaGen database containing comprehensive genetic data linked to epidemiological and clinical data, on Data Subjects

“Data Subjects” the individuals who have contributed their data to the Database

“Data” the data within the Database

“IDAC” MalariaGEN’s Independent Data Access Committee

IT IS AGREED:

1. You understand and acknowledge that the Data is experimental in nature, and that access to the Data is provided without any representations or warranties of any kind in relation to the Database or the Data. Neither Oxford nor the other members of the MalariaGEN consortium will be liable in any way for any use made of the Data or the Database. You agree to hold Oxford and the other members of the MalariaGEN consortium harmless from and to indemnify them against all and any losses, costs, fees, claims, demands and liabilities which may arise out of or in connection with Your use of the Data or the Database.
2. You will only access the Database and use the Data for the Agreed Purpose and shall not use the Data in such a way that damage or distress is or is reasonably likely to be caused to any Data Subjects.
3. The Data relates directly to individual Data Subjects and is strictly confidential. You shall only disclose the Data to your Data Users. You shall take all reasonable measures to ensure that your Data Users shall not make copies of the whole or any part of the Data without your consent, and shall keep a written record of any such copies sufficient to permit you to fulfil your obligations under clauses 3 and 7 of this Agreement. You shall not transfer or disclose any part of the Data to any other person or body.
4. You understand and acknowledge that the Data is protected by copyright and other intellectual property rights. Except as reasonably required to carry out Your research with the Data for the Agreed Purpose You shall not duplicate, or sell, or offer for sale or transfer or offer to transfer all or part of the Data, on any media.
5. You agree at all times to keep strictly confidential, and ensure that the Data Users keep confidential the information and Data pertaining to Data Subjects. In particular, You undertake not to use, or attempt to use, or permit anyone other than the Data Users to use the Data on its own or in conjunction with other data, to seek to discover the identity of any Data Subjects, to compromise or otherwise infringe the confidentiality of information on Data Subjects and their right to privacy.
6. You accept that the Data is protected by and subject to national and international laws, and that You are responsible for ensuring compliance with any applicable laws. The IDAC reserves the right to request and inspect data security and management documentation to ensure the adequacy of data protection measures in countries that have no national laws comparable to those which pertain in the EAA. If the IDAC makes any such request You agree to cooperate with it and to procure the cooperation of all your Data Users.
7. Upon termination of this Agreement you will permanently delete all copies of the Data from your computer systems and storage devices and will ensure that all Your Data Users shall also permanently delete such copies. You may

retain aggregate information on the proviso that such aggregate information does not allow any individuals or groups of individuals who are the subject of the Data to be identified with reasonable effort.

- 8 You accept that Data will be reissued from time to time, with suitable versioning. If the reissue is at the request of IDAC You and Your Data Users will destroy all earlier versions of the Data and Your use of the reissued version shall likewise be subject to the terms of this Agreement.
9. You may publish Your results arising from the use of the Data for the Agreed Purpose providing the Data itself is not disclosed. Aggregate or generic information generated from the Data may be published on the provisos that:
 - i. such aggregate or generic information does not allow Data Subjects or groups of Data Subjects to be identified with reasonable effort;
 - ii. no damage or distress is or is reasonably likely to be caused to any Data Subjects or groups of Data Subjects;
 - iii the Data will not be used in any way that could reasonably be expected to lead to ethnic stigmatisation; and
 - iv no attempt will be made to identify the Data Subjects.
10. You agree to acknowledge in any work based in whole or part on the Data, the published paper from which the Data derives, the version of the Data, and the role of the MalariaGen consortium and the relevant primary collectors and their funders. Suitable wording is provided in the Publications Policy given in Schedule 2.
11. You agree that you will submit annual reports and any other information reasonably requested to the IDAC for the purposes of monitoring data use on the understanding that IDAC will treat all the information, data, results, and conclusions contained within such materials as confidential information belonging to the Recipient Institution.
12. You agree that if your application is approved by IDAC, information about the proposed research use can be posted on MalariaGEN's public website. The information may include Your name and institution, the title of the project, and a non-technical summary of the research question.
13. You recognise that nothing in this Agreement shall operate to transfer to You any intellectual property rights relating to the Data. You have the right to develop intellectual property based on comparisons with Your own data.
14. The Data was generated using Grand Challenges in Global Health funding with the charitable objective of providing access to affordable health solutions for the benefit of people within the developing world and to ensure the broad availability of data and information. If results arising from Your use of the Data could provide health solutions for the benefit of people in the developing world, You agree to:

- i. offer non-exclusive licenses to such results on a reasonable basis for use in low income and low-middle income countries (as defined by the World Bank) to any party that requests such a licence solely for uses within these territories;
 - ii. on request, provide a non-exclusive, royalty-free licence with the right to sub-license to the Foundation of the National Institutes of Health, USA solely for uses in low income and low-middle income countries (as defined by the World Bank);
 - iii. provide preferential access to such results to the countries that contributed the samples from which the data in the MalariaGEN database is derived.
15. This Agreement is not transferable and You may not purport to assign it (in whole or in part) without the written consent of Oxford.
 16. If You commit a material breach of this Agreement or for any persistent breach of this Agreement, Oxford may terminate this Agreement immediately by notice in writing, without prejudice to its accrued rights and remedies.
 17. You accept that it may be necessary for Oxford or the MalariaGEN Consortium to alter the terms of this Agreement from time to time in order to address new concerns. In this event, Oxford will contact You to inform You of any changes and You agree that Your continued use of the Data shall be dependent on the parties entering into a variation of the Agreement.
 18. If requested to do so by the IDAC or the MalariaGEN consortium, Oxford may terminate this Agreement at any time by giving one month's notice in writing to You.
 19. Your duty to protect the confidentiality of the Data received under this Agreement shall survive termination of this Agreement and shall continue in full force and effect indefinitely.
 20. This Agreement shall be governed by English Law, and the parties submit to the exclusive jurisdiction of the English Courts for the resolution of any dispute which may arise out of this Agreement, save that Oxford may apply to any court having jurisdiction over the Recipient and/or Recipient Institution for an injunction or other order restraining the Recipient and/or Recipient Institution from any actual or threatened breach of its obligations of confidentiality.

AS WITNESS the hands of authorised signatories for the parties on the date first mentioned above.

SIGNED for and on behalf of the
Chancellor, Masters and Scholars of
the University of Oxford:

SIGNED for and on behalf of the Recipient
Institution

_____:

Name:-

Name:_____

Position:_____

Position:_____

Signature:_____

Signature:_____

Signed by the Recipient in acknowledgement of the terms of this Agreement:

Name:_____

Signature:_____

SCHEDULE 1

Data Users

Recipient: _____ Recipient Institution: _____

I have read the terms and conditions of this agreement and agree to be bound by them.

Name of Data User(s):

Signature of Data User(s):

SCHEDULE 2

Publications Policy

Authors who use data from MalariaGEN databases must acknowledge MalariaGEN using the following wording "*This study makes use of data generated by MalariaGEN. A full list of the investigators who contributed to the generation of the data is available from www.MalariaGEN.net. Funding for this project was provided by the Foundation for the National Institutes of Health and the Wellcome Trust. The funding for this project comes through the Grand Challenges in Global Health Initiative and cite the relevant primary MalariaGEN publication (details of which can be found on the MalariaGEN website).*

Recipients and Data Users should note that MalariaGEN bears no responsibility for the further analysis or interpretation of these data, over and above that published by the MalariaGEN.