**H3Africa** **Data Access Agreement**

This agreement governs the terms on which access will be granted to the data generated by the H3Africa consortium.

**Background**

The H3Africa (Human Heredity and Health in Africa) consortium consists of principal investigators funded by the Wellcome trust/AESA or National Institutes of Health (NIH) through the H3Africa Initiative. The H3Africa consortium is generating comprehensive genotype and other sequence data linked to epidemiological and clinical data, on human subjects (“Data Subjects”) from African countries. The H3Africa consortium members who are contributing the data are the custodians of that data and hold such ownership rights as may exist in relation to such data. The H3Africa consortium members have agreed to provide access to the data for biomedical research uses in accordance with H3Africa’s **Data Sharing, Access and Release Policy** which can be found, along with details of the H3Africa consortium, at [www.h3africa.org](http://www.h3africa.org).

The H3Africa data is deposited in the European Genome-phenome Archive (EGA) and the European Nucleotide Archive (ENA). The EGA manages the data on behalf of the H3Africa consortium members and provides access to external Recipients who have received approval from H3Africa’s Data and Biospecimen Access Committee.

In signing this document:

1. The Recipient and Recipient Institution (as defined below) agree to be bound by the terms and conditions of access set out in this agreement, and also agrees to ensure that the Recipient Institution’s Data Users comply with the terms and conditions of this agreement.
2. The Recipient further acknowledges that he/she has shared this document, and the H3Africa data sharing policies, with any Approved Users named below.
3. Institutional Signing Officials acknowledge that they have reviewed the relevant H3Africa policies, have shared this document and the relevant policies and procedures with appropriate institutional organizations, and have assured compliance with local institutional policies related to technology transfer, information technology, privacy, and human subjects research.

This Agreement is made the \_\_\_\_day of\_\_\_\_\_\_\_\_\_\_\_\_20\_\_ BETWEEN:

(1) The H3Africa DBAC

(2) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ whose

registered office/principal address is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (the “Recipient Institution ”)

(3) ……………………………………………………………….. (the “Recipient”)

**Definitions:**

* “H3Africa consortium” means the consortium of Wellcome Trust/AESA and National Institutes of Health (NIH) funded project principal investigators.
* “Recipient” means the principal researcher named above; and “Recipient Institution” means the organisation named above at which the Recipient and other named data users are employed, affiliated or enrolled, and are also referred to as ‘You’ in the agreement).
* “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 research purpose(s) approved by the DBAC in writing.
* “Publications” means, without limitation, articles published in print journals, electronic journals, reviews, books, abstracts, posters and other written and verbal presentations of research.
* “Data” means the H3Africa data consisting of comprehensive genetic data which may be linked to epidemiological and clinical data on Data Subjects.
* “Data Set” means the specific data set from one of the individual H3Africa projects.
* “Data Subjects” means the individuals who have contributed their data or samples
* “DBAC” means H3Africa’s Data and Biospecimen Access Committee.

**IT IS AGREED:**

1. You, the recipient, 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 Data. Members of the H3Africa consortium will not be liable in any way for any use made of the Data. You agree to hold members of the H3Africa 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.

2. You will only use the Data for the Agreed Purpose (as set out in schedule 1) 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. The agreed purpose must be consistent with the consent obtained from sample donors and you will ensure compliance with such consent in your use of the data. New uses of these data outside those described in the request form will require submission of a new request; modifications to the research project will require submission of an amendment to this application (e.g., the addition of new aims related to the approved project, adding or deleting collaborators from the same institution, and the potential addition of new H3Africa genomic datasets to an approved project). You will recognize and abide by any restrictions on Data use delineated within the original informed consent agreements of contributing studies, as identified by the submitting institutions and stated on database websites.

3. 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.

4. 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.

5. You understand and acknowledge that the Data is protected by copyright and 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.

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. You will ensure that the data will always be physically secured (for example, through camera surveillance, locks on doors/computers, security guard); servers must not be accessible directly from the internet, (for example, they must be behind a firewall or not connected to a larger network); use of portable media, e.g., on a CD, flash drive or laptop, is discouraged, but if necessary then they should be encrypted consistent with applicable law. The DBAC reserves the right to request and inspect data security and management documentation to ensure the adequacy of data protection measures. If the DBAC makes any such request, you agree to cooperate with it and to procure the cooperation of all your Data Users. You agree to notify the H3Africa DBAC of any unauthorized data sharing, breaches of data security, or inadvertent data releases that may compromise data confidentiality within 24 hours of when the incident is identified.

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 DBAC 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 provided that you believe in good faith that:

i. the publication of such aggregate or generic information would not allow Data Subjects or groups of Data Subjects to be identified;

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 by any Data User 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 H3Africa 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 DBAC for the purposes of monitoring data use on the understanding that DBAC 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 DBAC, information about the proposed research use can be posted on H3Africa’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. The Recipient and the Recipient Institution agree not to make intellectual property claims on the Data, nor use the Data to make a related intellectual property claim, and not to use or encumber the results of the Planned Analysis in a manner that would prevent or block access to, or use of, any element of the Data, or conclusions drawn directly from the Data.

14. Subject to Clauses 13 and 15, the Recipient and the Recipient Institution can elect to perform further research with the results of the Planned Analysis that would add intellectual and resource capital to the Data and decide to obtain intellectual property rights on these downstream discoveries. In this case, the Recipient and the Recipient Institution agree to implement licensing policies that will not obstruct further research with the Data.

15. The Data was generated using Wellcome Trust or National Institutes of 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 you determine that 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 H3Africa database is derived.

16. This Agreement is not transferable and you may not purport to assign it (in whole or in part) without the written consent of the H3Africa DBAC. You and Approved Users agree to retain control over the data and further agree not to distribute data obtained through this Data Access Request to any entity or individual not covered in the submitted Data Access Request. You agree that if you change institutions during the access period, you will submit a new Data Access Request and Data Use Certification in which the new institution agrees to the H3Africa data use policy before data access resumes. Any versions of data stored at the prior institution for the approved use will be destroyed, unless prior request and approval has been granted to transfer responsibility for the approved research project.

17. If you commit a material breach of this Agreement or for any persistent breach of this Agreement, the H3Africa DBAC may terminate this Agreement immediately by notice in writing, without prejudice to its accrued rights and remedies.

18. You accept that it may be necessary for the H3Africa consortium to alter the terms of this Agreement from time to time in order to address new concerns. In this event, the H3Africa DBAC 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.

19. Research access to the requested dataset(s) is granted for a period of one (1) year from the date the dataset(s) are made accessible to you. At the end of the access period, Approved Users agree to destroy all copies of the requested dataset(s), except as required by publication practices or law to retain them. Consideration will be given to a renewal of this agreement upon submission of a new Data Access Request If requested to do so by the DBAC or the H3Africa consortium, the H3Africa DBAC may terminate this Agreement at any time by giving one month’s notice in writing to you.

20. 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.

21. This Agreement shall be governed by the Law of the country of the requesting institution, and the parties submit to the exclusive jurisdiction of the relevant Courts for the resolution of any dispute which may arise out of this Agreement, save that the H3Africa DBAC 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.

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| AS WITNESS the hands of authorised signatories for the parties on the date first mentioned above. SIGNED for and on behalf of the H3Africa DBAC: | SIGNED for and on behalf of the Recipient Institution  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_: |

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| Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Schedule 1**

Schedule 1 is the completed Data Access Request Form, which must be appended to the Data Access Agreement.

**Schedule 2**

**Publications Policy**

Authors who use data from the H3Africa consortium must acknowledge H3Africa using the following wording "*This study makes use of data generated by H3Africa. A full list of the investigators who contributed to the generation of the data is available from www.H3Africa org. . The funding for this project comes through the Human Heredity and Health in Africa (H3Africa) Initiative, which is funded by the National Institutes of Health and the Wellcome Trust through AESA.* Authors must also cite the relevant primary H3Africa publication (details of which can be found on the H3Africa website) and the information about which H3Africa datasets were used.

Recipients and Data Users should note that the H3Africa consortium bears no responsibility for the further analysis or interpretation of these data, over and above that published by the H3Africa consortium.