

## HipSci WTSI Data Access Agreement

WELLCOME TRUST SANGER INSTITUTE

### DATA ACCESS AGREEMENT (May 2014 v5)

#### Applicant

##### **Name of applicant (User), including affiliation and contact details**

**Name with Title:** Mrs Elizabeth Easthope

**Position:** Data Access and Regulatory advisor

**Affiliation:** Wellcome Trust Sanger Institute

**Institution's Legal Name (if differing from affiliation):**

**Institutional postal address:** Wellcome Trust Sanger Institute, The Genome Campus, CAMbridge, United Kingdom

**Institutional E-mail Address:** ems@sanger.ac.uk

#### Authorised Representative

##### **Name of authorised representative of the User Institution, including affiliation and contact details:**

**Name with Title:** Dr Carol Smee

**Position:** Regulatory Compliance Manager

**Affiliation:** The Wellcome Trust Sanger Institute

**Institutional postal address:** The Wellcome Trust Sanger Institute, The Genome Campus, Cambridge, United Kingdom

**Institutional E-mail Address:** cs14@sanger.ac.uk

#### Definitions

**Authorised Personnel:** The individuals at the User Institution to whom WTSI grants access to the Data. This includes the User, the individuals listed on the User Institution's initial request for access to the Data and any other individuals for whom

the User Institution subsequently requests access to the Data. Details of the initial Authorised Personnel are set out in Appendix I.

**Data:** The managed access datasets to which the User Institution has requested access.

**Data Producers:** WTSI and the collaborators listed in Appendix I responsible for the development, organisation, and oversight of the Data.

**External Collaborator:** A collaborator of the User, working for an institution other than the User Institution.

**Project:** The project for which the User Institution has requested access to the Data. A description of the Project is set out in Appendix II.

**Publications:** Includes, without limitation, articles published in print journals, electronic journals, reviews, books, posters and other written and verbal presentations of research.

**Research Participant:** An individual whose data form part of the Data.

**Research Purposes:** shall mean research that is seeking to advance the understanding of genetics and genomics, including the treatment of disorders, and work on statistical methods that may be applied to such research.

**User:** The principal investigator for the Project.

**User Institution(s):** The Institution that has requested access to the Data.

**WTSI:** Genome Research Limited, operating as the Wellcome Trust Sanger Institute

## Terms of the Agreement

1. The User Institution agrees to only use the Data for the purpose of the Project (described in Appendix II) and only for Research Purposes.
2. The User Institution agrees to preserve, at all times, the confidentiality of the Data. In particular, it undertakes not to use, or attempt to use the Data to compromise or otherwise infringe the confidentiality of information on Research Participants. Without prejudice to the generality of the foregoing, the User Institution agrees to use at least the measures set out in Appendix I to protect the Data.
3. The User Institution agrees to protect the confidentiality of Research Participants in any research papers or publications that they prepare by taking all reasonable

care to limit the possibility of identification.

4. The User Institution agrees not to link or combine the Data to other information or archived data available in a way that could re-identify the Research Participants, even if access to that data has been formally granted to the User Institution or is freely available without restriction.

5. The User Institution agrees only to transfer or disclose the Data, in whole or part, or any material derived from the Data, to the Authorised Personnel. Should the User Institution wish to share the Data with an External Collaborator, the External Collaborator must complete a separate application for access to the Data.

6. The User Institution agrees that the Data Producers, and all other parties involved in the creation, funding or protection of the Data: a) make no warranty or representation, express or implied as to the accuracy, quality or comprehensiveness of the Data; b) exclude to the fullest extent permitted by law all liability for actions, claims, proceedings, demands, losses (including but not limited to loss of profit), costs, awards damages and payments made by the Recipient that may arise (whether directly or indirectly) in any way whatsoever from the Recipient's use of the Data or from the unavailability of, or break in access to, the Data for whatever reason and; c) bear no responsibility for the further analysis or interpretation of these Data.

7. The User Institution agrees to follow the Fort Lauderdale Guidelines ([http://www.wellcome.ac.uk/stellent/groups/corporatesite/@policy\\_communications/documents/web\\_document/wtd003207.pdf](http://www.wellcome.ac.uk/stellent/groups/corporatesite/@policy_communications/documents/web_document/wtd003207.pdf)) and the Toronto Statement (<http://www.nature.com/nature/journal/v461/n7261/full/461168a.html>). This includes but is not limited to recognising the contribution of the Data Producers and including a proper acknowledgement in all reports or publications resulting from the use of the Data.

8. The User Institution agrees to follow the Publication Policy in Appendix III. This includes respecting the moratorium period for the Data Producers to publish the first peer-reviewed report describing and analysing the Data.

9. The User Institution agrees not to make intellectual property claims on the Data and not to use intellectual property protection in ways that would prevent or block access to, or use of, any element of the Data, or conclusion drawn directly from the Data.

10. The User Institution can elect to perform further research 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 User Institution agrees to implement licensing policies that will not obstruct further research and to follow the U.S. National Institutes of Health Best Practices for the Licensing of

Genomic Inventions (2005)

([https://www.icgc.org/files/daco/NIH\\_BestPracticesLicensingGenomicInventions\\_2005\\_en.pdf](https://www.icgc.org/files/daco/NIH_BestPracticesLicensingGenomicInventions_2005_en.pdf) ) in conformity with the Organisation for Economic Co-operation and Development Guidelines for the Licensing of the Genetic Inventions (2006) (<http://www.oecd.org/science/biotech/36198812.pdf> ).

11. WTSI is funded by the Wellcome Trust whose charitable objective is to improve health. If results arising from the User Institution's use of the Data could provide health solutions for the benefit of people in the developing world, the User Institution agrees to 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 license solely for uses within these territories.

12. The User Institution agrees to destroy/discard the Data held, once it is no longer used for the Project, unless obliged to retain the data for archival purposes in conformity with audit or legal requirements.

13. The User Institution will notify WTSI within 30 days of any changes or departures of Authorised Personnel.

14. The User Institution will notify WTSI prior to any significant changes to the protocol for the Project.

15. The User Institution will notify WTSI as soon as it becomes aware of a breach of the terms or conditions of this agreement.

16. WTSI may terminate this agreement by written notice to the User Institution. If this agreement terminates for any reason, the User Institution will be required to destroy any Data held, including copies and backup copies. This clause does not prevent the User Institution from retaining the data for archival purpose in conformity with audit or legal requirements.

17. The User Institution accepts that it may be necessary for the Data Producers to alter the terms of this agreement from time to time. As an example, this may include specific provisions relating to the Data required by Data Producers other than WTSI. In the event that changes are required, the Data Producers or their appointed agent will contact the User Institution to inform it of the changes and the User Institution may elect to accept the changes or terminate the agreement.

18. If requested, the User Institution will allow data security and management documentation to be inspected to verify that it is complying with the terms of this agreement.

19. The User Institution agrees to distribute a copy of these terms to the Authorised Personnel. The User Institution will procure that the Authorised Personnel comply

with the terms of this agreement.

20. This agreement (and any dispute, controversy, proceedings or claim of whatever nature arising out of this agreement or its formation) shall be construed, interpreted and governed by the laws of England and Wales and shall be subject to the exclusive jurisdiction of the English courts.

## APPENDIX I - DATASET DETAILS

### Cohort(s)

Normals, Bardet Biedl Syndrome, Monogenic diabetes, ES cells

### Minimum protection measures required

**File access:** Data can be held in unencrypted files on an institutional compute system, with Unix user group read/write access for one or more appropriate groups but not Unix world read/write access behind a secure firewall. Laptops holding this data should have password protected logins and screenlocks (set to lock after 5 min of inactivity). If held on USB keys or other portable hard drives, the data must be encrypted.

## APPENDIX II - LAY DESCRIPTION OF YOUR PROJECT

### Description of the project

Test application

### User Institution

**Affiliation:** Wellcome Trust Sanger Institute

**Institution's Legal Name (if differing from affiliation):**

**Mailing Address:** Wellcome Trust Sanger Institute, The Genome Campus, Cambridge, United Kingdom

**Principal Investigator:** Elizabeth Easthope

Individuals who the User Institution wishes to have access to the Data

### Registered User

Name: Test Application

Institutional Email Address: Test@application.com

Position: Post Doc

Affiliation: Wellcome Trust Sanger Institute

## APPENDIX III - PUBLICATION POLICY

WTSI are committed to the principles of rapid data release. WTSI intend to publish the results of their analysis of this dataset and do not consider its deposition into public databases to be the equivalent of such publications. WTSI anticipate that the dataset could be useful to other qualified researchers for a variety of purposes. However, some areas of work are subject to a publication moratorium.

The publication moratorium covers any publications (including oral communications) that describe the use of the data set for investigations related to variation in the cellular properties of induced pluripotent stem cell lines or cell lines derived from them. For research papers, this means that submission for publication should not occur until 12 months after the data were first made available on the relevant hosting database or until a paper using the data has been published by WTSI or as otherwise agreed with WTSI in writing.

Publications describing the use of the dataset to estimate population allele frequencies, for haplotype structure estimations, and for imputation and related projects, except if any of these analyses relate to the areas described above, can be freely submitted for publication.

In any publications based on this data, please describe how the data can be accessed, including the name of the hosting database (e.g., The European Genome-phenome Archive at the European Bioinformatics Institute) and its accession numbers (e.g., EGAS00000000029), and acknowledge its use in a form agreed by the User Institution with WTSI.

### EGA Account

Once your application has been approved an EGA account will be generated allowing access to the requested datasets. The account which is generated is a private account and login details must not be shared. Sharing Login details will be treated as a breach of security and could result in the account being blocked.

**Please add the name and email address of up to 2 people named in the application who will require an EGA account for the purpose of downloading the data.**

Test application

### Agreed for User Institution

**Agreed For** Wellcome Trust Sanger Institute

**Name:** Carol Smee

**Position:** Regulatory Compliance Manager

**Date:** 11 January 2017

## Agreement

**I have read and agree to abide by the terms and conditions outlined in the Data Access Agreement.**

Yes