DECIPHER DATA ACCESS AGREEMENT for Institutions

Between:

(1)   **GENOME RESEARCH LIMITED**, a company registered in England under number 2742969 and registered as a charity (number 1021457) whose registered address is 215 Euston Road, London NW1 2BE, UK, operating as the Wellcome Trust Sanger Institute ("**GRL**"); and

(2)   **[INSERT INSTITUTION DETAILS]** (the "**Recipient**").

In response to the Recipient's request for access to the Data (as defined below), GRL and the Recipient agree as follows:

1.   **Definitions**

   1.1   **"Consortium"** means the DECIPHER consortium established for the purposes of the project described in the Publications Policy set out in Schedule 1. A current list of Consortium members can be found on the study website https://decipher.sanger.ac.uk;

   1.2   **"Data"** means all and any human genetic data obtained from the Consortium. Explicitly, Data does **not** include samples or biological materials;

   1.3   **"Data Subject"** means the person (irrespective of state of health) to whom Data refers and who has been informed of the purpose for which the Data is held and has given his/her informed consent thereto;

   1.4   **"DECIPHER"** means the Database of Chromosomal Imbalance and Phenotype in Humans using Ensembl Resources;

   1.5   **"DECIPHER Data Access Committee"** means the committee (as amended from time to time) responsible for reviewing requests for access to the Data;

   1.6   **"Intellectual Property"** means (i) patents, designs, trade marks and trade names (whether registered or unregistered), copyright and related rights, database rights, know-how and confidential information; (ii) all other intellectual property rights and similar or equivalent rights anywhere in the world which currently exist or are recognised in the future; and (iii) applications, extensions and renewals in relation to any such rights;

   1.7   **"Publications"** means, without limitation, articles published in print journals, electronic journals, reviews, books, posters and other written and verbal presentations of research;

   1.8   **"Registered User"** shall mean a Researcher (or an individual conducting Research under the supervision of a Researcher) that is employed by the Recipient and is bound by confidentiality and non-use obligations in respect of Data and who has signed this Agreement and has received acknowledgement of its acceptance. For the avoidance of doubt, **"Registered User"** may also include students, visiting academics, contractors, sub-contractors or independent consultants provided that any such individual is bound by confidentiality and non-use obligations no less onerous then those binding the Recipient's employees;

   1.9   **"Research"** means research that is seeking to advance the medical and scientific knowledge, understanding and treatment of chromosomal rearrangements and disease gene discovery;

   1.10 **"Researcher"** means an individual who is carrying out Research who in the case of an individual seeking access to Data, has (i) authored a relevant peer-reviewed article that GRL can locate on PubMed and who is still working in the field; or (ii) been approved as a successful applicant by the DECIPHER Data Access Committee.

2. **Purpose**

   2.1 The Recipient agrees to use the Data only for Research.

3. **Confidentiality**

   3.1 The Recipient agrees to preserve, at all times, the confidentiality of information and Data pertaining to identifiable Data Subjects. In particular, the Recipient undertakes not to use, or attempt to use the Data to compromise or otherwise infringe the confidentiality of information on Data Subjects and their right to privacy.

   3.2 The Recipient agrees that it shall take all reasonable security precautions to keep the Data confidential, such precautions to be no less onerous than those applied in respect of the Recipient's own confidential information.

4. **Data Protection**

   4.1 The Recipient agrees that it and its Registered Users are covered by and shall comply with the obligations contained in the Data Protection Act 1998 as amended from time to time, or equivalent national provisions no less onerous then those contained in the Data Protection Act. In particular, the Recipient and its Registered Users understand their duties under such legislation in relation to the handling of Data and the rights of Data Subjects.

   4.2 The Recipient agrees that it and its Registered Users shall not analyse or make any use of the Data in such a way that has the potential to (i) lead to the identification of any Data Subject or (ii) compromise the anonymity of any Data Subject in any way.

5. **Access and Governance**

   5.1 The Recipient agrees that it shall only give access to the Data, in whole or part, or any identifiable material derived from the Data, to a Registered User. The Recipient agrees that before it gives any Registered User access to the Data it shall first show the Registered User a copy of this Agreement and shall inform the Registered User that he or she must comply with the obligations contained in this Agreement and sign up to the provisions of this Agreement in the form set out at the end of this Agreement. The Recipient shall provide GRL with a copy of the Registered User's acceptance form within thirty (30) days of the date of acceptance by the Registered User.

   5.2 In the event that the Recipient wishes to share the Data with a collaborator that is not a Registered User, the third party must make a separate application for access to the Data.

   5.3 The Recipient agrees that it shall only give Registered Users that are not Researchers (including but not limited to students or new researchers to the field) access to the Data if they are supervised by a Researcher who will take responsibility for such Registered Users' use of the data.

   5.4 GRL 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 that pertaining in the European Economic Area (EEA).

6. **Errors**

   6.1 The Recipient agrees to notify the DECIPHER administrators **(decipher@sanger.ac.uk)** of any errors detected in the Data.

7. **Data Reissue**

   7.1 The Recipient accepts that Data will be reissued from time to time, with suitable versioning. If the reissue is at the request of sample donors and/or as a result of other ethical scrutiny, the Recipient agrees to destroy all earlier versions of the Data.

8. **Publications and Reports**

8.1 The Recipient agrees to abide by the provisions set out in the Consortium 'Publications Policy' as set out in Schedule 1 to this Agreement in relation to all Publications.

8.2 The Recipient agrees 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 Consortium and the relevant primary collectors and their funders, in line with the sample wording provided in the Publications Policy given in Schedule 1 to this Agreement. The Recipient will also declare in any such work that those who carried out the original analysis and collection of the Data bear no responsibility for the further analysis or interpretation of it by the Recipient.

8.3 The Recipient agrees that it will submit a report to the DECIPHER Data Access Committee if requested, on completion of the agreed Research programme.

9. **Intellectual Property**

9.1 The Recipient acknowledges and agrees that the Data is protected by copyright and other intellectual property rights, and that duplication (except as reasonably required to carry out Research) or sale of all or part of the Data on any media is not permitted under any circumstances except with the prior written consent of GRL.

9.2 The Recipient recognises that nothing in this Agreement shall operate to transfer to the Recipient or its Registered Users any Intellectual Property rights in or relating to the Data.

9.3 The Recipient and its Registered Users shall have the right to develop Intellectual Property based on comparisons with their own data.

10. **Legal Statement**

10.1 The Recipient agrees that GRL, the Consortium, and all other parties involved in the creation, funding or protection of the Data:

10.1.1. make no warranty or representation, express or implied as to the accuracy, quality or comprehensiveness of the Data; and

10.1.2. 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.

11. **Termination**

11.1 This Agreement shall terminate immediately upon any breach of the provisions of this Agreement by the Recipient or by the Recipient's Registered User.

11.2 The Recipient accepts that the changing ethical framework of human genetic research may lead to: (i) alteration to the provisions of this Agreement, in which case the Recipient may accept such alterations or terminate this Agreement; or (ii) the withdrawal of this Agreement in extreme circumstances.

11.3 Either party shall have the right to terminate this Agreement with immediate effect upon giving written notice of termination to the other party.

11.4 In the event that this Agreement is terminated in accordance with this Clause 11 the Recipient shall return or destroy all Data at the direction of GRL.

12. **Governing Law**

12.1 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.

AGREED by the parties through their authorised signatories

GRL

Authorised Signature:	
Name:	
Title:	
Date:	

Recipient:

Recipient Name:	
Address:	
Telephone No:	
Email:	
Authorised Signature:	
Name:	
Title:	
Date:	

Registered Users:

The Registered Users acknowledge the contents of this Agreement and agree to comply with the obligations herein. For the avoidance of doubt the Registered Users are not a party to this Agreement.

Signature:	
Name:	
Title:	
Date:	

Signature:	
Name:	
Title:	

Date:	

Please send two signed copies of this Agreement to:

Matthew Hurles
DECIPHER Project
Wellcome Trust Sanger Institute
Hinxton, Cambridgeshire
CB10 1SA
United Kingdom

GRL complies with the requirements of the Data Protection Act 1998 with regard to the collection, storage, processing and disclosure of personal information and is committed to upholding the Act's core Data Protection Principles.

Information collected under this Agreement will be used for the purposes of maintaining this Agreement, and may be used for statistical reporting.

SCHEDULE 1

Publications Policy

The primary purposes of the DECIPHER project are to:

- Increase medical and scientific knowledge about chromosomal microdeletions/duplications

- Improve medical care and genetic advice for individuals/families with submicroscopic chromosomal imbalance

- Facilitate research into the study of genes which affect human development and health

The Consortium anticipates that data generated from the project will be used by others, such as required for developing new analytical methods, in understanding patterns of polymorphism and in refining critical intervals to map genes involved in specific phenotypes and diseases.

Authors who use data from the project must acknowledge DECIPHER using the following wording "*This study makes use of data generated by the DECIPHER Consortium. A full list of centres who contributed to the generation of the data is available from http://decipher.sanger.ac.uk and via email from decipher@sanger.ac.uk . Funding for the project was provided by the Wellcome Trust.*

The Recipient shall also declare in any published work that those who carried out the original analysis and collection of the Data bear no responsibility for the further analysis or interpretation of it by the Recipient or its Registered Users.