

## Human genetic data access agreement for institutions based in the United States of America

### 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 “**Cancer Genome Project**” (“**CGP**”) shall mean the project undertaken at the Wellcome Trust Sanger Institute in Cambridge to identify genetic sequence variants and mutations relevant to the development of human cancers;

1.2 “**Data**” shall mean all and any human genetic data obtained from the CGP including the Data Subjects’ age, sex and tumour pathology. Explicitly, Data does **not** include samples or biological materials;

1.3 “**Data Subject**” shall mean 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 “**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;

1.5 “**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 than those binding the Recipient’s employees;

1.6 “**Research**” shall mean research that is seeking to advance the understanding and treatment of cancer and closely related diseases, and work on statistical methods that may be applied to such research;

1.7 “**Researcher(s)**” shall mean an individual or individuals carrying out Research who:

- (a) in the case of an individual seeking access to Data held solely under the control of GRL and the CGP, has authored a relevant

peer-reviewed article that GRL can locate on PubMed and who is still working in the field; or

(b) in the case of an individual seeking access to Data held as part of a wider consortium, is a successful applicant to the consortium data access committee.

## **2 Purpose**

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

## **3 Confidentiality**

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

## **4 Data Protection**

4.1 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:

- (a) lead to the identification of any Data Subject; or
- (b) compromise the anonymity of any Data Subject in any way.

## **5 Access and Governance**

5.1 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.

5.2 The Recipient agrees to only give access to 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 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.

5.3 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 those applicable to the European Economic Area (EEA).

## **6 Errors**

6.1 The Recipient agrees to notify the CGP 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 Data is reissued at the request of sample donors and/or as the result of other ethical scrutiny, the Recipient agrees to destroy all earlier versions of the Data.

## **8 Intellectual Property**

8.1 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.

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

## **9 Publications**

9.1 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 CGP and its funders in its distribution. The Recipient agrees to use the acknowledgement wording provided for the relevant Data in its publication. 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.

## **10 Termination of Agreement**

10.1 This Agreement will terminate immediately upon any breach of the provisions of this Agreement by the Recipient or by the Recipient's Registered Users.

10.2 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 GRL shall notify the Recipient in writing of such alterations and the Recipient may choose to accept such alterations or to terminate this Agreement; or (ii) in extreme circumstances, the withdrawal of this Agreement.

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

10.4 In the event that this Agreement is terminated in accordance with this Clause 10 the Recipient shall return or destroy all Data at the direction of GRL.

## **11 Costs**

11.1 The Recipient acknowledges that GRL shall incur costs in providing the Data to the Recipient, including but not limited to administrative costs and the cost of obtaining appropriate data storage devices. The Recipient agrees to pay, on the request of GRL, such reasonable costs as GRL may incur in providing the Data, within thirty (30) days of GRL making such a request for payment.

## **12 Legal statement**

12.1 The Recipient acknowledges that GRL 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; and

(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.

12.2 The Recipient understands that all the Data is protected by copyright and other intellectual property rights, such that duplication or sale of all of or part of the Data on any media is not permitted under any circumstances, except with the prior written consent of GRL.

## **13 Governing Law**

13.1 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**

<b>Authorised Signature:</b>	
<b>Name:</b>	
<b>Title:</b>	
<b>Date:</b>	

**Recipient:**

<b>Recipient Name:</b>	
<b>Address:</b>	
<b>Telephone No:</b>	
<b>Email:</b>	
<b>Authorised Signature:</b>	
<b>Name:</b>	
<b>Title:</b>	
<b>Date:</b>	

**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.**

<b>Signature:</b>	
<b>Name:</b>	
<b>Title:</b>	
<b>Date:</b>	
<b>Email:</b>	

<b>Signature:</b>	
<b>Name:</b>	
<b>Title:</b>	
<b>Date:</b>	
<b>Email:</b>	

Please send completed forms to:

Andy Futreal  
Cancer Genome 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 the Agreement will be used for the purposes of maintaining the Agreement, and may be used for statistical reporting.