THE ST. JUDE CHILDREN'S RESEARCH HOSPITAL – WASHINGTON UNIVERSITY PEDIATRIC CANCER GENOME PROJECT

DATA ACCESS AGREEMENT

This agreement governs the terms on which access will be granted to the genotype data generated by the St. Jude Children's Research Hospital – Washington University Pediatric Cancer Genome Project.

In signing this agreement, You are agreeing to be bound by the terms and conditions of access set out in this agreement.

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

Definitions:

PCGP means the St. Jude Children's Research Hospital – Washington University Pediatric Cancer Genome Project.

Data means all and any human genetic data obtained from the PCGP.

Data Subject means a person, who has been provided informed consent for the use of biologic material for research.

User means a researcher whose User Institution has previously completed this Data Access Agreement and has received acknowledgement of its acceptance.

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

User Institution means the organization at which the User is employed, affiliated or enrolled.

Terms and Conditions:

In signing this Agreement:

1. You agree to use the Data only for the advancement of medical research.

2. You agree that You are a laboratory head, principal investigator or departmental chair and take responsibility for the distribution restrictions defined in Section 4 of this Agreement, and use and, protection of the Data by your laboratory.

3. You agree that You cannot (1) share the Data without St. Jude's prior written permission, (2) use the Data to create a commercial or open source product that includes the data in the product.

4. You understand and acknowledge that You may use the Data for research that could produce results or intellectual property that might be commercialized.

5. You agree not to use the data from the PCGP or any part thereof for the creation of products for sale or for any commercial purpose.

6. You agree to preserve, at all times, the confidentiality of information and Data pertaining to Data Subjects. In particular, You undertake 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.

7. You agree not to transfer or disclose the Data, in whole or part, or any identifiable material

derived from the Data, to others, including other investigators and laboratories in your institution, except as necessary for data/safety monitoring or programme management. Should You wish to share the Data with a collaborator within or outwith the same Institution, the third party must make a separate application for access to the Data.

8. You agree that you have the computation infrastructure and expertise to analyse the Data.

9. You agree to use the data for the approved purpose and project described in your application; use of the data for a new purpose or project will require a new application and approval.

10. You agree that the Data are made available for one (1) year. You agree to destroy the Data after one (1) year. You must re-apply to access the Data after this period.

11. You accept that Data will be reissued from time to time, with suitable versioning. If the reissue is at the request of sample donors and/or other ethical scrutiny, You will destroy earlier versions of the Data.

12. You agree to abide by the terms outlined in the PCGP publication policy: By signing this agreement, you are agreeing that you will not use the PCGP data in a public presentation or publication for 9 months from the time of data release, or until the data is published by the PCGP, whichever occurs first.

13. You accept that the genomic sequence data provided in this initial 9 month period following deposition is provided "as is" without associated phenotype data or data verifying and/or validating the presence of putative genetic alterations.

14. 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 PCGP. Suitable wording is provided in the Publications Policy given in Schedule 1.

15. You accept that the PCGP, the original data creators, depositors or copyright holders, or the funders of the Data or any part of the Data supplied:

    a) bear no legal responsibility for the accuracy or comprehensiveness of the Data; and
    b) accept no liability for indirect, consequential, or incidental, damages or losses arising from use of the Data, or from the unavailability of, or break in access to, the Data for whatever reason.

16. You understand and acknowledge that the Data is protected by copyright and other intellectual property rights, and that duplication of the Data, except as reasonably required to carry out Your research with the Data, or sale of all or part of the Data on any media is not permitted.

17. You recognize that nothing in this agreement shall operate to transfer to the User Institution any intellectual property rights relating to the Data. The User Institution has the right to develop intellectual property based on comparisons with their own data.

18. You accept that this agreement will terminate immediately upon any breach of this agreement by You and You will be required to destroy any Data held.

19. You accept that it may be necessary for the PCGP or its appointed agent to alter the terms of this agreement from time to time in order to address new concerns. In this event, the PCGP or its appointed agent 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 new version of the Agreement.

20. You agree that you will submit a report to the PCGP Data Access Committee, on completion of the agreed purpose. The PCGP Data Access Committee agrees to treat the report and all information, data, results, and conclusions contained within such report as confidential information belonging to the User Institution. You further agree to provide a copy of any publications arising from the use of the Data to the PCGP Data Access Committee within thirty (30) days of its publication.

21. You accept that the Data is protected by and subject to international laws, including but not limited to the UK Data Protection Act 1998, and that You are responsible, as applicable to ensure compliance with any such applicable law. The PCGP Data Access Committee 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 which pertain in the EAA.

22. This agreement shall be interpreted and construed in accordance with the laws of the country of the defending party, in cases where your Institution is the defending party, or the laws of the United States, in cases where the PCGP, St. Jude Children's Research Hospital, and/or Washington University are the defending parties. Unless specified otherwise, reference in this agreement to a statute refers to that statute as it may be amended, or to any restated or successor legislation of comparable effect.

SCHEDULE 1

Publications Policy

The primary purpose of the St. Jude Children's Research Hospital – Washington University Pediatric Cancer Genome Project (PCGP) is to identify all inherited and tumor-acquired (somatic) genome sequence and structural variants influencing the development and behaviour of childhood tumors. Additional objectives include, but are not limited to, the acquisition and analysis of additional genomic data, including epigenetic and gene expression data, data integration, and the development and validation of informatic and analytical solutions appropriate to the scale and nature of the project, as well as use of the data generated to answer important methodological and biological questions studies of tumor biology in general, and as specifically related to childhood malignancies.

The PCGP anticipates that data generated from the project will be used by other researchers (scientists who are employed by, or a student enrolled at or legitimately affiliated with, an academic, non-profit, or government institution, or a commercial company) to develop new analytical methods, validate results, and identify additional genetic variations and alterations in the data.

Authors who use data from the project must acknowledge the PCGP using the following wording "*This study makes use of data generated by the St. Jude Children's Research Hospital – Washington University Pediatric Cancer Genome Project*" and cite the relevant primary PCGP publication if one has been published. Specifically, authors using data for a given tumor type(s) must cite the publications arising from the PCGP that have described the results of the analyses of primary genomic data for the tumor type(s). Details of these publications are at the PCGP website:

http://explore.pediatriccancergenomeproject.org.

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

For and on behalf of User:

EBI Dataset ID: _____

(*Please note that you need one application per dataset)

Name of Applicant(s)*: _____

_____

_____

Signature of Applicant(s): _____

_____

_____

E-mail address of Applicant(s): _____

_____

_____

Telephone number Applicant(s): _____

_____

_____

Date: _____

For and on behalf of User Institution:

Read and Understood: _____

User Name

_____

User Signature

Date: _____

Name of the Information Technology Director of the Institution: _____

Signature of Institutional or Administrative Authority:** _____

Print name: _____

User Institution: _____

Date: _____

*** Must include Laboratory Head, Principal Investigator or Departmental Chair**

**** The Institutional or Administrative Authority is equivalent to the individual with the organizational authority to sign for a grant application, otherwise known as the Authorized Organizational Representative (AOR) or the Signing Official.**

Please utilize the following space to provide a project description that constitutes biomedical research:

WHEN SUBMITTING THIS DOCUMENT, PLEASE INCLUDE ALL PAGES OF THE AGREEMENT WITH THIS SIGNATURE PAGE.