

**ST. JUDE CHILDREN'S RESEARCH HOSPITAL, INC.**

**AGREEMENT FOR ACCESS TO AND/OR DOWNLOAD  
OF CONTROLLED-ACCESS GENOMIC SEQUENCING DATA**

This Data Access Agreement ("Agreement") between You (including you individually and Your institution) and St. Jude Children's Research Hospital, Inc. ("St. Jude") governs the terms on which access will be granted and, in some cases, downloading will be allowed, to controlled access genomic sequencing Data generated by St. Jude Children's Research Hospital, Inc., or the St. Jude Children's Research Hospital – Washington University Pediatric Cancer Genome Project (PGCP).

By signing this Agreement, You agree to be bound by the terms and conditions set out in this Agreement. This Agreement (Part 1) permits You to access, and, consistent with additional terms and requirements (Part 2), in some instances, to download, St. Jude controlled access Data from the St. Jude Cloud Platform if performed in compliance with the terms of this Agreement.

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

**Definitions:**

Data or Data Set means genetic or genomic sequencing data or algorithms to which access is controlled and which may be accessed or downloaded only as allowed by this Agreement.

Data Access Committee means a committee that includes representatives of St. Jude and that is charged with making determinations about Data access, use, and download, and publications using or referring to Data.

Data Subject means a person from whose specimen Data was derived.

User means a researcher whose User Institution has completed a Data Access request and has received acknowledgement of its acceptance, and includes the individual's User Institution.

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

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

You and Your refer to and include User and User Institution.

**Terms and Conditions:**

**Part 1: Terms and Conditions for Access and Use of Data in the St. Jude Cloud Platform**

In signing this Agreement:

1. You agree to access and use the Data only for the advancement of medical or scientific research.
2. You agree that You are a laboratory head, principal investigator, or department Chair and take responsibility for the distribution restrictions defined in this Agreement, and for the use and protection of the Data by your User Institution and laboratory.

3. You represent and warrant that You have the authority to bind User Institution, and Your entry into this Agreement and acceptance of the Terms incorporated by reference in this Agreement will be deemed an acceptance by the User Institution and will not violate any other duty, law, or agreement.
4. All access and use of Data shall be and is subject to this Agreement, the St. Jude Cloud Platform Terms of Use (available at <https://platform.stjude.cloud/terms>), St. Jude Cloud Platform Privacy Policy (available at <https://www.dnanexus.com/privacy>), and relevant terms of DNAnexus and Microsoft Azure, as applicable, located at (<https://www.dnanexus.com/terms>, <https://www.dnanexus.com/privacy>, and <https://azure.microsoft.com/en-us/support/legal/>), and Your access constitutes agreement to all of these agreements, terms, and policies. If there is a conflict between this Agreement or other St. Jude terms or policies and the DNAnexus and/or Microsoft Azure terms, then this Agreement or the other St. Jude terms or policies will control with respect to St. Jude Data and the St. Jude Portal. You agree that the St. Jude Cloud Platform Privacy Policy and Terms of Use are incorporated by reference to this Data Access Agreement.
5. Consistent with the terms of this Agreement, You may access, use, and analyze the Data in the St. Jude Cloud Platform via or using, or sometimes directly on, the DNAnexus Platform. Your use of the St. Jude Cloud Platform constitutes agreement to all terms of the DNAnexus Platform.
6. You may not copy (except within the St. Jude Cloud Platform), download, or otherwise remove the Data from the St. Jude Cloud Platform or DNAnexus platform without specific permission as discussed below.
7. You agree that You will not share the Data with anyone, whether within or outside your Institution, without the prior written permission of an authorized representative of St. Jude.
8. Following Data availability after execution of this Agreement and, and consistent with and solely for so long as You comply with the terms of this Agreement and the St. Jude Cloud Platform Terms of Use, You have a limited license to use the Data for Your research. You may commercialize results or intellectual property that Your research produces so long as neither the Data or any portion thereof are part of the results or intellectual property that you commercialize. You shall not use the Data or any portion thereof in any product for sale or for any commercial purpose.
9. Data are de-identified. You agree to preserve at all times the confidentiality of information and Data pertaining to Data Subjects. In particular, You will not use or attempt to use the Data to compromise or otherwise infringe the confidentiality of information on or about Data Subjects and their right to privacy, and you will not attempt in any way to identify or re-identify Data Subjects in any manner.
10. 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 those with a need in the course of performing data and safety monitoring or program management. Should You wish to share the Data with a collaborator within or outside Your Institution, each collaborator must apply separately for access to the Data.
11. You will not rely on St. Jude to provide any further computational infrastructure or expertise.
12. You agree to submit an application providing a purpose and project for Your use of the Data. You agree that Your use the Data will be strictly limited to the approved purpose and project described in your application; You agree that Your use of the Data for any different, other, or new purpose or project will require a new application and approval.
13. You agree that the Data are made available for one (1) year from the date that you obtain the Data. You agree to destroy all Data and all copies that you make of the Data after one (1) year from obtaining the data, unless permission to extend time is given in writing by an authorized representative of St. Jude's Data Access Committee. If requested by St. Jude, you agree to provide a written certification that you have destroyed all copies of the Data that you have copied or downloaded pursuant to the terms in Part 2. You must re-apply to access the Data after this period.

14. You accept that Data will be reissued from time to time. If the reissue is at the request of sample donors and/or other ethical scrutiny, You will destroy earlier downloaded versions of the Data.
15. You agree to abide by the terms of the applicable Publication Policy corresponding the data set you seek to access, as attached in Schedule 1 hereto. In addition, by signing this agreement, You agree that You will not use the Data in a public presentation or publication for nine (9) months from the time of Data release, or until the Data is published by the St. Jude Children's Research Hospital, whichever occurs first.
16. You accept that the Data provided is provided "as is" and without associated phenotype data or data verifying and/or validating the presence of putative genetic alterations. St. Jude makes no warranty or representation about the Data.
17. You agree to acknowledge St. Jude Children's Research Hospital, Inc., or St. Jude Children's Research Hospital – Washington University Pediatric Cancer Genome Project, as applicable, and the version of the Data that You use in any work or invention based in whole or part on the Data and in any published paper from which the Data derives. Wording must be suitable to St. Jude and the same as or very similar to the suitable wording provided in the sample Publications Policy given in Schedule 1.
18. You agree that St. Jude Children's Research Hospital, the St. Jude Children's Research Hospital – Washington University Pediatric Cancer Genome Project, and any other Data Subjects, original data creators, depositors, or copyright holders, or the funders of the Data or any part of the Data supplied to You:
- a) bear no legal responsibility for the accuracy or comprehensiveness of the Data;
  - b) accept no liability for indirect, consequential, or incidental, damages or losses arising from use of the Data, or from the unavailability of, or interruption in or loss of access to the Data for any reason;
  - c) make no warranty regarding the Data, which is provided "as is," with User assuming all risk as to the Data;
  - d) do not allow the use of the Data in making patient-specific decisions regarding or guiding the clinical or medical management of anyone.
19. You understand and acknowledge that the Data is protected by copyright and other intellectual property rights, and that you may not duplicate, copy, modify, reproduce, reverse engineer or aid or assist in the reverse engineering of the Data, except as reasonably required to carry out Your research with the Data. You may not sell all or any part of the Data on any media or in any form.
20. You may not create a second or alternative storage repository, and You may not maintain, store, access, or use any Data for a second research project without written approval of an authorized representative of St. Jude.
21. You recognize that nothing in this agreement shall operate to transfer to You, including User Institution, any intellectual property rights relating to the Data.
22. You accept that this Agreement will terminate immediately upon any breach of this Agreement by You, including Your Institution, and You will be required to discontinue access and to destroy any Data that you have accessed or copied. If requested by St. Jude, you agree to provide a written certification in a form acceptable to St. Jude that you have destroyed all Data and any copies of the Data that you have copied.
23. You accept that it may be necessary for St. Jude or its appointed agent to alter the terms of this Agreement from time to time to address new concerns or new methods of access or for other reasons in their discretion. In this event, St. Jude or its appointed agent will contact You to inform You of changes, and You agree that You may continue to use the Data only if You enter into a new version of this Agreement on terms set forth by St. Jude.
24. You agree to complete fully and accurately and submit with your application the project description on the form attached following signature page of this Agreement, and you agree to update this information whenever your project changes. You agree that you will submit a report to the applicable Data Access Committee on which St. Jude representatives participate on completion of the project for which St. Jude has permitted you to access and use Data.

The applicable Data Access Committee will treat the report and all information, data, results, and conclusions contained within Your report as confidential information belonging to the User Institution. You further agree to provide a copy of any publication arising from the use of the Data to the applicable Data Access Committee within thirty (30) days of its publication.

25. This agreement shall be interpreted and construed in accordance with the laws of the United States of America and the State of Tennessee. 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.

26. If You wish to download or make copies of Data out of the St. Jude Cloud Platform (including via DNAnexus), You may only do so if you obtain written permission from St. Jude, and all such activities are governed by the Specific Terms for Downloading from or Copying of Data Outside the St. Jude Cloud Platform (set forth in Part 2 of this Agreement below). To the extent that you are granted express permission to download Data or otherwise copy it outside the Platform, the terms in the St. Jude Cloud Platform Terms of Use and in this Agreement prohibiting download or copying outside the St. Jude Cloud Platform would not apply (Part 1, Paragraph 6), but all other terms and restrictions of this Agreement and the St. Jude Cloud Platform Terms of Use and Privacy Policy apply to Your activities in full and to the maximum extent possible, and You agree to comply with them. Whether or not you have obtained permission or indicated your intent to download or copy Data out of the St. Jude Cloud Platform, if You download or make copies of Data outside the St. Jude Cloud Platform, You agree that You are bound by Part 2 of this Agreement.

## **Part 2: Specific Terms for Downloading from or Copying of Data Outside the St. Jude Cloud Platform (“Download Terms”)**

Indicate by putting Your initials here [CS] if You request permission to download or copy Data outside the St. Jude Cloud Platform. Your initials noted here mean that You agree to comply with all terms of this Agreement, including these Download Terms except those prohibiting download of Data or copying it outside the St. Jude Cloud Platform, in Part 1, Paragraph 6. (These Download Terms do not apply to those accessing Data but not downloading or copying it outside the Platform.) By signing this Agreement, You agree:

1. You will not share any Data that You download or copy with any other person or entity in or outside your Institution.
2. You accept that Data that You download or copy is subject to US laws and may be subject to laws of foreign jurisdictions. You are responsible for complying with, and You agree to comply with, any applicable law or requirement.
3. The applicable 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 United States and/or European Economic Area.
4. Although Data are de-identified, and You may not upload or use any identifiable Data on the St. Jude Cloud Platform, You must employ appropriate best practice security measures, and You agree to the following: You shall use, download, copy, and access the Data only in strict compliance with all applicable laws in the United States and your location, including but not limited to human subject protection and data privacy laws. You agree to use applicable U.S. and EU best practice administrative, logical, technical and physical security requirements to protect the availability, confidentiality, and integrity of the Data. All devices used to access or download the Data must meet commercially reasonable and industry standard security requirements for protected health information at the time of download or access, including without limitation: secure coding training, unique passphrase, separation of accounts controlled access based on need to know, encryption in transit, incident response training, secure configuration, privacy and security training, account monitoring and management, encryption on mobile devices and removable media, secure deletion upon decommission. User will notify St. Jude immediately in the event of unauthorized breach or access by others to Data via <http://stjude.cloud/contact>.

5. Data downloaded and copied must be stored in a secure, encrypted manner behind firewalls that block access from outside the institution, and restrict external access to cloud storage. Data must not be shared with anyone else including by sharing account access credentials. Data must not be posted on servers that will make the Data publicly available or discoverable.
6. You agree that You have the computation infrastructure and expertise to analyze the Data that you download.
7. You agree that the Data are made available for one (1) year from the date that you obtain the Data. You agree to destroy all Data downloaded or copied after one (1) year from obtaining the data, unless permission to extend time is given in writing by an authorized representative of St. Jude's Data Access Committee. If requested by St. Jude, you agree to provide a written certification that you have destroyed all copies of the Data that you have copied or downloaded. You must re-apply to access the Data after this period.
8. You agree that this Agreement will terminate immediately upon any breach of this Agreement by You or Institution, and You will be required to discontinue access and to destroy any Data that you have accessed or copied or downloaded. If requested by St. Jude, you agree to provide a written certification in a form acceptable to St. Jude that you have destroyed all Data and any copies of the Data that you have copied or downloaded.
9. By signing this Agreement, You agree to all applicable terms above for access to the Data in Part 1, Terms and Conditions for Access and Use of Data, so long as such terms do not conflict with the terms in these Download Terms.
10. If you download Data or copy Data outside the St. Jude Cloud Platform, You agree the terms and conditions in Part 2, Download Terms. You also will have your Chief Information Security Officer sign, and the signature of the Chief Information Security Officer indicates the ability and commitment to complying with the data protection and security measures stated herein.

Version 2, Effective April 2018

**SIGNATORIES BELOW AGREE WITH AND ACCEPT THIS AGREEMENT FOR ACCESS AND/OR DOWNLOAD OF CONTROLLED ACCESS GENOMIC SEQUENCING DATA (VERSION 1.0, September 11, 2017):**

**Dataset Title:**            ☒ **Pediatric Cancer Genome Project (PCGP)**  
                                  ☐ **Clinical Genomics and Genomes for Kids (G4K)**  
                                  ☒ **St. Jude Lifetime Cohort Study (SJLIFE)**  
                                  ☐ \_\_\_\_\_  
                                  ☐ \_\_\_\_\_

**For and on behalf of St. Jude Children's Research Hospital, Inc.**

**Signature:** \_\_\_\_\_

**Print name:** \_\_\_\_\_

**Title:** \_\_\_\_\_

**Institution:**

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**Email address:**

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**Telephone  
Number:**

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**For and on behalf of User\* and User Institution:**

**\* All who will have access to the data must be listed as an applicant below; please attach additional pages as needed. Signatories must include Laboratory Head, Principal Investigator, or Departmental Chair.**

**The Principal Investigator and other applicants and signatories agree to the terms in this AGREEMENT FOR ACCESS AND/OR DOWNLOAD OF CONTROLLED ACCESS GENOMIC SEQUENCING DATA, and shall inform other investigators and laboratories in his or her institution who may have or desire access to the Data as defined in this agreement of the restrictions of this Agreement, including but not limited to Section 11 in Part 1.**

**Read and Understood:**

**Principal Investigator**

**Signature:**



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**26 October 2018**



**Additional applicant(s) (add pages as needed):**

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Additional applicant(s) (add pages as needed):

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Date:

18 November 2018

**Institutional or Administrative Authority\*\***

**\*\* 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. The Institutional or Administrative Authority has authority to and does bind the User Institution.**

**Signature:**



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Research & Innovation Centre

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**Date:**

11/12/18

**Information Technology Director or Chief Information Security Officer of the Institution\*\*\***

**\*\*\*Signature required if St. Jude Data is to be copied and/or downloaded:**

**Signature:** John Lavelle

**Print name:** John Lavelle

**Title:** NUI Galway IT Security Officer

**Institution:** NUI Galway

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**Date:** 07/12/2018

Please use the following space to provide a project description, including contemplated use of the St. Jude Data, that constitutes biomedical research:

In recent years, genome and exome sequencing of tumour samples has become commonplace. This is at the heart of personalized cancer medicine, as mutations identified in cancer samples can inform treatment options and disease prognosis. In addition to distinct sets of driver mutations, different cancers are distinguished by different somatic mutation spectra. Rates of somatic mutation in human cancers have been shown to depend on the nucleotides being exchanged as well as on (at least) the -1 and +1 contexts of the nucleotide, giving rise to 192 triplet-specific mutation rates that comprise the cancer mutation spectrum. Existing methods to infer mutation rates or spectra from cancer samples first identify individual somatic mutations with high confidence. This requires high sequencing depth, in order to distinguish true somatic mutations, which may occur at relatively low frequencies, from sequencing errors and other sources of mismatches.

A statistical model that can learn the genome-wide mutation spectrum from much lower numbers of sequence reads by pooling information across mismatches has the potential to lead to a large reduction in sequencing depth required to infer the mutation spectrum. Our objectives are to 1) develop methods and provide computational tools to enable mutation spectra to be inferred from low-depth sequencing, thereby increasing the accessibility of sequencing-based cancer diagnosis/prognosis and 2) to assess inter-individual variation in somatic mutation rates and spectra through analysis of normal samples. Large population-scale sequencing projects have recently revealed differences in the germline mutation spectrum between human populations. Given that a large proportion of the somatic mutations in cancer samples accumulate prior to cancer initiation differences in mutation spectrum between normal tissues or between the same tissue in different individuals could be of extremely important for understanding tumorigenesis.

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



## SCHEDULE 1 - PCGP

### **Pediatric Cancer Genome Project (PCGP) Data Set 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: <https://pecan.stjude.org/permalink/pcgp>

**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.**

## SCHEDULE 1 – G4K

### Genomes for Kids (G4K) and Clinical Genomics Data Set Publication Policy

The primary purpose of the St. Jude Children's Research Hospital Genomes for Kids (G4K) research study is to identify all inherited and tumor-acquired (somatic) genome sequence and structural variants influencing the development and behavior of childhood tumors. Additional objectives include, but are not limited to, assessing the feasibility of a multiplatform next-generation sequencing test including whole genome sequencing in a clinical (CAP/CLIAA) environment and facilitating computational methods development to address important questions pertaining to tumor biology in general, and as specifically related to childhood malignancies.

St. Jude Children's Research Hospital anticipates that data generated from G4K and other clinical sequencing 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 G4K must acknowledge Genomes for Kids using the following wording "This study makes use of data generated by the St. Jude Children's Research Hospital Genomes for Kids Study" and cite the relevant primary G4K publication if one has been published. Details of these publications are at the below website: <https://pecan.stjude.org/permalink/g4k>.

Authors who use non-G4K clinical genomics data must acknowledge St. Jude Children's Research Hospital using the following wording: "This study make use of data generated by St. Jude Children's Research Hospital" and cite the relevant publication if one has been published. The publications can be found at the below website: <https://pecan.stjude.org/permalink/clingen>.

**Users should note that the St Jude Children's Research Hospital bears no responsibility for the further analysis or interpretation of these data, over and above that published.**

## SCHEDULE 1 – SJLIFE

### St. Jude Lifetime Cohort Study (SJLIFE) Data Set Publications Policy

The primary purpose of the St. Jude Lifetime Cohort Study (SJLIFE) is to identify all inherited genome sequence and structural variants influencing the development of childhood cancer and occurrence of long-term adverse outcomes associated with cancer and cancer-related therapy. 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 as specifically related to childhood malignancies.

The SJLIFE investigators anticipate 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 SJLIFE study using the following wording "This study makes use of data generated by St. Jude Children's Research Hospital as part of the St. Jude Life-time Cohort Study" and cite the relevant primary SJLIFE publication(s) if one has been published. Details of these publications are at the SJLIFE website:

<https://pecan.stjude.org/permalink/sjlife>

**Users should note that St. Jude and the SJLIFE investigators bear no responsibility for the further analysis or interpretation of these data, over and above that published by the SJLIFE study.**



