

ST. JUDE CHILDREN'S RESEARCH HOSPITAL, INC.**AGREEMENT FOR ACCESS TO AND/OR DOWNLOAD
OF CONTROLLED-ACCESS GENOMIC SEQUENCING DATA*****Not Negotiable***

This Data Access Agreement ("Agreement") is between You (including you individually and Your institution) and St. Jude Children's Research Hospital, Inc. ("St. Jude"). This Agreement sets the terms You and Your Institution must comply with if You access or download controlled access genomic sequencing Data generated by St. Jude or St. Jude and other institutions as indicated in the applicable Schedule 1 (Publication Policy) for that dataset, located at <https://www.stjude.cloud/docs/citing-stjude-cloud/>.

Overview of This Agreement

Part 1 of this Agreement permits You to access St. Jude controlled access Data and to analyze and copy it within the St. Jude Cloud Platform if performed in compliance with this Agreement.

Part 2 of this Agreement permits You to download, or copy St. Jude controlled access Data from the St. Jude Cloud Platform if performed in compliance with both Part 1 and Part 2 of this Agreement.

Schedule 1 to this Agreement provides the applicable publications policy for each Data Set, located at <https://www.stjude.cloud/docs/citing-stjude-cloud/>, and is incorporated into this Agreement.

By signing this Agreement, You (all Users) agree to be bound by this Agreement. Through its signatory, Your Institution also agrees to be bound by this Agreement and binds the Institution. You and Your Chief Information Security Officer or person in a similar role agree that Your institution can and will provide the security levels stated in this Agreement. Where prohibited, Investigators do not bind the Institution.

The terms of access, use, and where applicable, download or copying, 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, except as or where stated otherwise.

Definitions

Data or *Data Set* means all data provided to you through St. Jude Cloud which is still comprised of its fundamental data elements OR in a form to which no or minimal intellectual contribution is added. This includes the original genetic or genomic sequencing or variant data directly provided to You (e.g., data contained in the provided FASTQ, BAM, VCF, or any other file or database), any subset of the provided genetic or genomic sequencing data (e.g., any of the aforementioned files sliced down to genomic regions of interest or in any other way of decomposing the original data), any derivatives of the data still comprised of its fundamental elements (e.g., reprocessing data through a different alignment algorithm, reprocessing data using different reference files, reprocessing data using a different variant calling algorithm, or any other processing pipeline), and any algorithms which are fundamentally a part of data to which access is granted to you under this Agreement.

Data Access Committee means a committee that includes representatives of St. Jude and sometimes other institutions (as indicated in the applicable Schedule 1) 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.

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

User means a researcher who has, and whose User Institution also has, completed a Data Access request and has received acknowledgement of its acceptance, and anyone accessing or downloading Data.

User Institution or *Institution* means the organization at or with which the User is employed, affiliated, contracted, or enrolled and the organization whose facilities and systems are used to access, copy, or download the Data.

You and *Your* refer to and include User and User Institution except as or where stated otherwise.

Terms and Conditions

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

1.1. **Use of Data Only for Advancement of Research:** You agree to access and use the Data only for the advancement of medical or scientific research and only as approved by the Data Access Committee for the Data Set.

1.2. **User Representations:** User agrees that User is a laboratory head, principal investigator, or department Chair with authority to sign this Agreement. You take responsibility for compliance with the distribution restrictions defined in this Agreement, and for the use and protection of the Data by your laboratory and User Institution. You represent and warrant that You have not altered any of the terms of this agreement in any way, before or after signing.

1.3. **User Institution Representations:** User Institution and its signatory or signatories represent and warrant that You have the authority to sign this Agreement and to bind User Institution, and Your and Your Institution's entry into this Agreement, including 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. You represent and warrant that You have not altered any of the terms of this agreement in any way, before or after signing.

1.4. **Applicable Terms:** 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://stjude.cloud/terms-of-use.html>), St. Jude Cloud Platform Privacy Policy (available at <https://stjude.cloud/privacy-policy.html>), 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. Access to the Data and tools on the St. Jude Cloud Platform is governed by the St. Jude Cloud Platform Privacy Policy and Terms of Use.

1.5. **Platform Terms:** 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.

1.6. **Copy and Download Prohibition:** 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 and compliance with Part 2 of this Agreement, below.

1.7. **Sharing Prohibition:** You will not share the Data or any derivatives which constitute Data with anyone, whether within or outside your Institution, without the prior written permission of an authorized representative of St. Jude (subject to the applicable data access committee). You agree not to transfer or disclose the Data, in whole or part, 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 by signing the additional applicant signature page below. If you would like to add additional applicants to your data access agreement, please contact us at support@stjude.cloud. Examples of prohibited Data sharing include, but are not limited to (i) making available any Data received from St. Jude Cloud to anyone not identified in or covered by this Agreement, (ii) making derivatives which still constitute Data (as defined in the definition of *Data* above) by containing the same fundamental elements and/or adding no intellectual contribution and sharing it with anyone not identified in or covered by this Agreement, (iii) generating results data or files (e.g., called somatic or germline variants)

to make derivatives which still constitute Data and allowing access or use by anyone not identified in or covered by this Agreement, including but not limited to allowing placement in public or private databases accessible by individuals not identified in or covered by this Agreement, and (iv) bundling any Data as part of necessary information for an algorithm or tool to be run (e.g., including reduced dimensionality data in a machine learning model available to others not on the agreement). Algorithms which are developed or refined using Data but do not include the Data in any way within or as a part of the algorithm and do not require Data to be present at runtime are allowed. If You are interested in including St. Jude data (such as germline or somatic variants) into a public or private database as defined in (iii), please contact us at support@stjude.cloud.

1.8. **Limited License:** After this Agreement is signed and the Data are made available to you, You have a limited, revocable license to use the Data for the term of this Agreement as stated in Paragraph 1.13 for the research described in this Agreement consistent with and only for so long as You comply with the terms of this Agreement and the St. Jude Cloud Platform Terms of Use. Your license is limited by the terms of this Agreement. Subject to the applicable Schedule 1, 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 part of the Data in any product for sale or for any commercial purpose unless you receive separate, written permission of an authorized representative of St. Jude.

1.9. **Duty to Preserve Privacy of Data Subjects:** Data are considered de-identified under the HIPAA regulations. You agree to preserve at all times the confidentiality of information and the privacy of the 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.

1.10. **Data Security:** You will access the Data consistent with all applicable and all appropriate data security and management requirements and measures to protect the Data from disclosure. You agree to use applicable U.S. and EU best practices for administrative, technical, and physical security requirements to protect the confidentiality, integrity, and resilience of the Data. All devices used to access or, if allowed pursuant to Part 2 of this Agreement, download the Data must meet commercially reasonable and industry standard security requirements at the time of download or access, including without limitation secure coding training, unique passphrase, separation of accounts (especially in the case of elevated privileges), controlled access limited to those with permission to access, encryption in transit, incident response training, secure configuration, privacy and security training, account monitoring and management, encryption on mobile devices and removable media, and secure deletion upon decommission. You will notify St. Jude immediately in the event of unauthorized breach or access by others to the Data.

1.11. **No Agreement to Provide Services:** St. Jude has no duty to assist in Your use of the Data. You will not rely on St. Jude to provide any further technical, biological, or any other expertise.

1.12. **Application and Use of Data:** You agree to submit an application providing a purpose and project (research use) for Your use of the Data. You agree to complete the application fully and accurately and you agree to update this information whenever your project changes. You agree that Your use of 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.

1.13. **Term:** The Term of this Agreement is no longer than one year (beginning on the date you access the Data). 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 or the applicable Data Access Committee. If requested, 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.

1.14. **Data Reissue:** You recognize that we may make corrections to the data over time. If we contact you about data that we correct, you agree to use the corrected version. If the reissue is at the request of sample donors and/or other ethical scrutiny, You will destroy earlier downloaded versions of the Data.

1.15. **Publication Policy/Schedule 1:** You agree to abide by the terms of the applicable Publication Policy corresponding to the Data Set you seek to access, referred to as Schedule 1 and located at <https://www.stjude.cloud/docs/citing-stjude-cloud/>. 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 (“Embargo Date”), or until the Data is published by the Principal Investigator of St. Jude or other institution providing the Data Set, whichever occurs first. Each Data Set has its own Embargo Date (see <https://www.stjude.cloud/docs/guides/data/metadata/> for more information). If you use more than one Data Set, the latest Embargo Date will apply to any publication using the Data Sets, and all Data Sets must be past their Embargo Date before research can be published.

1.16. **No Warranty:** 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.

1.17. **Acknowledgment:** You agree to acknowledge St. Jude Children’s Research Hospital, Inc., and/or other institution(s) providing samples or Data, as outlined in the applicable Schedule 1(s). 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 for each Data Set, entitled Schedule 1, and located at <https://www.stjude.cloud/docs/citing-stjude-cloud/>.

1.18. **Limitation on Liability:** You agree that St. Jude Children’s Research Hospital and any other institution providing samples or Data indicated in an applicable Schedule, and any Data Subjects, original data creators, depositors, or copyright holders, anyone identified in any applicable Schedule 1, and the funders of the research generating 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) bear no liability for direct, 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.

1.19. **License Restrictions regarding Data:** 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.

1.20. **License Restrictions regarding Data Storage and Use:** 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.

1.21. **License Limitation:** You agree that nothing in this agreement shall operate to transfer to You, including User Institution, any intellectual property rights relating to the Data except as expressly stated in this Agreement.

1.22. **Termination:** This Agreement, and the limited license it provides will terminate immediately upon any breach of this Agreement by You or 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. St. Jude may terminate access to Data at any time based on Your breach of this Agreement.

1.23. **Updates of Agreement:** St. Jude or its appointed agent may 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 may contact You. You agree that, if You are contacted by St. Jude and told 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, You will promptly enter into the new agreement or discontinue use of the Data.

1.24. **Report to the Data Access Committee:** 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.

1.25. **Governing Law:** This Agreement shall be interpreted and construed in accordance with the laws of the United States of America and the State of Tennessee except and only to the extent User Institution is a United States state instrumentality that is legally required to rely on its state law for sovereign immunity. 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.

1.26. **Indemnity:** You agree to indemnify, defend, and hold harmless St. Jude Children's Research Hospital, Inc., and any other institutions identified in the applicable Schedule 1 providing and/or having rights in the Data for any damages or liability (i) arising from your access, download, use, storage, maintenance, of the Data, (ii) any publications derived from your access to the Data, and (iii) Your or Your institution's breach of this Agreement, unless such indemnification is expressly prohibited by the laws of Your State or Country. Nothing herein waives a Party's right to claim to sovereign immunity or to seek to rely on any mandatory state law imposing a maximum cap on liability of a state.

1.27. **Downloading and Copying of Data:** 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 stated in Your application that you plan to do so and You comply with Part 2 of this Agreement, Specific Terms for Downloading from or Copying of Data Outside the St. Jude Cloud Platform. To the extent that you are granted express permission to download Data or otherwise copy Data 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 1.6), 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 Parts 1 and 2 of this Agreement.

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

This section applies only if You download or copy Data to a location outside the St. Jude Cloud Platform. If You download or copy Data outside the St. Jude Cloud Platform, You must comply with Parts 1 and 2 of Agreement except Part 1, Paragraph 1.6.

2.1. **Sharing Prohibition:** You will not share any Data that You download or copy with any other person or entity in or outside your Institution except for Users in Your Institution who also sign this Agreement.

2.2. **Compliance with Laws:** 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. St. Jude makes no representations about foreign law.

2.3. **Inspection:** 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.

2.4. **Data Security:** Although Data are considered de-identified under HIPAA regulations, 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 will 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>.

2.5. **Data Storage:** 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. If Data is being downloaded to a high performance computing (HPC) environment where file storage system encryption is not technically feasible, then the encryption requirement can be deferred if appropriate physical safeguards protecting the file storage system from unauthorized access and/or potential loss of Data and storage media are in place. Appropriate physical safeguards include, but are not limited to, a dedicated, locked data center space, multifactor access control, detailed records of data center access, and monitored video cameras.

2.6. **Expertise:** You agree that You have the computation infrastructure and expertise to analyze the Data that you download.

2.7. **Termination:** You agree that this Agreement will terminate immediately upon any breach of this Agreement by You or Your 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.

2.8. **Applicability of Terms:** 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 this Part 2, Download Terms.

2.9. **Information Security Official:** 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 4.2, Effective October 13, 2020

THE SIGNATORIES BELOW AGREE WITH AND ACCEPT THIS AGREEMENT FOR ACCESS AND/OR DOWNLOAD OF CONTROLLED ACCESS GENOMIC SEQUENCING DATA (VERSION 4.2, October 13, 2020) SUBJECT TO THIS AGREEMENT AND THE APPLICABLE PUBLICATION POLICY FOR THE RELEVANT DATASET, KNOWN AS SCHEDULE 1, AND LOCATED AT <https://www.stjude.cloud/docs/citing-stjude-cloud/>:

Dataset Title:

- Pediatric Cancer Genome Project and Childhood Solid Tumor Network (PCGP)**
- Clinical Genomics and Genomes for Kids (G4K)**
- St. Jude Lifetime Cohort Study (SJLIFE)**
- Sickle Cell Genome Project (SGP)**
- Childhood Cancer Survivor Study (CCSS)**
- Pan-Acute Lymphoblastic Leukemia (PanALL)**

Check the Datasets above that You request.

Initial here _____ if you wish to download or copy data from the St. Jude Cloud Platform.

CONTEMPLATED USE

Please use the following space to provide a project description of the research including contemplated use of the St. Jude Data, that constitutes biomedical research. Include information about what research question you will be investigating and how the requested data will aid in your research. Add blank pages as needed (150 words or more):

For and on behalf of User*:

*** 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. The Principal Investigator is signing on behalf of himself or herself, and those in his/her laboratory or on his/her project but does not sign on behalf of the User Institution unless so authorized by the User Institution.

Read and Understood:

Principal Investigator

Signature:

Print name:

Job title:

Institution:

Email address:

**Telephone
Number:**

Address:

Date:

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

Signature: _____

Print name: _____

Job title: _____

Institution: _____

Email address: _____

Date: _____

Signature: _____

Print name: _____

Job title: _____

Institution: _____

Email address: _____

Date: _____

Signature: _____

Print name: _____

Job title: _____

Institution: _____

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Print name: _____

Job title: _____

Institution: _____

Email address: _____

Date: _____

Signature: _____

Print name: _____

Job title: _____

Institution: _____

Email address: _____

Date: _____

Signature: _____

Print name: _____

Job title: _____

Institution: _____

Email address: _____

Date: _____

For and on behalf of User* and User Institution:

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 to this AGREEMENT FOR ACCESS AND/OR DOWNLOAD OF CONTROLLED-ACCESS GENOMIC SEQUENCING DATA.**

Signature: _____

Print name: _____

Job title: _____

Institution: _____

Email address: _____

**Telephone
Number:** _____

Address: _____

Date: _____

For and on behalf of User* and User Institution:

Information Technology Director or Chief Information Security Officer of the Institution (or person in a similar role authorized to make representations about information protection and security)***

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

Signature: _____

Print name: _____

Job title: _____

Institution: _____

Email address: _____

**Telephone
Number:** _____

Address: _____

Date: _____

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