



**St. Jude Global Alliance  
SJCARES Registry Data Transfer Agreement**

**Rider to the**

**St. Jude Global Alliance Medical Institution Membership Agreement**

**By and Between**

**Insert MoH or Governing Agency, if applicable**  
On Behalf of

**Insert Member Institution Name**  
**(“Member Institution”)**

**And**

**St. Jude Children’s Research Hospital, Inc.**

Individually each is a “Party” and together are the “Parties”

This Data Transfer Agreement (“Agreement”) is entered into by and between **St. Jude Children’s Research Hospital, Inc.**, a Tennessee not-for-profit corporation located at 262 Danny Thomas Place, Memphis, Tennessee 38105, U.S.A. (hereinafter referred to as “St. Jude”), and [If applicable, Enter MoH or Gov. Agency] on behalf of [**Insert Member Institution Name**] (“Member Institution”), a Member of the St. Jude Global Alliance with its principal place of business at [Member Institution Address], pursuant to the existing Medical Institution Membership Agreement (the “MIMA”) previously entered by the above Parties and with this Rider being effective as of the date provided on the signature page(s) hereof. St. Jude and Member Institution are hereinafter collectively referred to as “Parties” or individually, as a “Party.”

**Definitions:** Each capitalized term used in this Agreement and not otherwise defined shall have the meaning set forth below:

1. **Confidential Information:** All intellectual property and proprietary information that relates to or is used in connection with the business and affairs of a Party, including written material, information, and programs stored or otherwise available on a computer, and information in any other format or medium. Confidential Information of St. Jude includes: (i) all budgets, strategic plans, marketing plans, financial information, data, documents, records, and other materials, which contain information relating to the operation of the Alliance; (ii) all methods, techniques, and procedures utilized in providing services to patients not readily available through sources in the public domain; (iii) all proprietary computer software, programs, data files, and documentation; and (iv) all Alliance Standard Operating Procedures (SOPs) and the methods and manner by which St. Jude conducts the Alliance and related activities. Except as otherwise required under this Agreement, a Party shall have no obligation to identify specifically its Confidential Information. Confidential Information shall exclude any information that (a) is already lawfully known to the person to whom it is disclosed, (b) is a matter of public knowledge through legitimate means, (c) has been published in any publication for public distribution, or (d) was filed as public information with any governmental authority, except in each case to the extent such information was made public as a result of the act or omission of the non-originating Party, including any breach of an obligation of confidentiality.
2. **DATA:** Hospital-based cancer registry data with Protected Health Information (PHI) included. DATA is only visible to Member Institution, and Member Institution can view only the PHI that it submitted.
3. **Data Registry:** The information that an individual institution enters into a registry to have a record for its



own use.

4. **Institution:** A research institution or hospital that is a member of the St. Jude Global Alliance and submits DATA to the Data Registry.
5. **Institutional Review Board (IRB) or Ethics Committee:** An administrative body established to protect the rights and welfare of human research subjects recruited to participate in clinical research activities conducted under the auspices of the institution with which it is affiliated.
6. **Protected Health Information (PHI):** Information relating to the past, present, or future health status of an individual such as diagnoses, treatment information, medical test results, and prescription information, and national identification numbers and demographic information such as birth dates, gender, ethnicity, and contact information.
7. **De-identified DATA:** All DATA with individual identifiers removed. Individual identifiers are: name; geographical subdivisions and geocodes; dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; age; phone numbers; fax numbers; electronic mail addresses; Social Security numbers (or equivalent); medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; web Universal Resource Locators (URLs); internet Protocol (IP) address numbers; biometric identifiers, including finger and voice prints; full face photographic images and any comparable images; any other unique identifying number, characteristic, or code.
8. **SJCARES Data Warehouse:** St. Jude Global Childhood Cancer Analytics Resource and Epidemiologic Surveillance System. A secure data warehouse where Member Institutions that use the Data Registry will store and share de-identified DATA to form a global registry where any authorized representative of a St. Jude Global Alliance Institution Member may access the de-identified DATA and use for reporting and research, subject to the policies and procedures of the St. Jude Global Alliance and further terms defined in this Agreement.

#### Terms of Agreement:

By entering into this Agreement, Member Institution requests that St. Jude accept Member Institution's DATA and information into the Data Registry. St. Jude agrees to provide each contributing institution access to its own database, accept DATA derived from Member Institution and retain limited access to date identifiers for its quality monitoring purposes only. St. Jude will de-identify the DATA prior to its inclusion in the SJCARES Data Warehouse.

#### 1. Registry and Study Data

##### A. Data Registry

- 1) St. Jude developed and provides a Data Registry with the primary objective for institutions to store and access their DATA.
- 2) The Data Registry conforms to and complies with regulations and industry standards for data security, including but not limited to, administrative safeguards, physical safeguards, and technical safeguards that protect the confidentiality, integrity, and availability of DATA.
- 3) Member Institution DATA are stored in a secure Data Registry segregated from other institutions' data.
- 4) St. Jude staff will only have direct access to dates in the DATA for central quality control monitoring and to assist the Institution with quality assurance activities. St. Jude staff will not have access to any other identifiers.



- 5) Each Member Institution owns its DATA, will be able to view only its DATA, and will not publish or share its DATA externally without appropriate local ethics or equivalent administrative review.
- 6) Member Institution may run reports and download its DATA in the Data Registry according to Member Institution's ethics procedures; no separate St. Jude Institutional Review Board review is required.
- 7) Member Institution is not restricted from disclosing and sharing its DATA in accordance with local ethics and privacy requirements.
- 8) In addition to registering its pediatric cancer patients and tracking patient outcomes in the Data Registry, Member Institution will be a member of the SJCARES Data Warehouse. Prior to migrating Member Institution's DATA from the Data Registry to the SJCARES Data Warehouse, St. Jude staff will electronically de-identify the Member Institution's DATA, with only originating institution and unique patient ID remaining.
- 9) As a participant in the SJCARES Data Warehouse, a minimum of one (1) Investigator from Member Institution will be eligible for co-authorship on publications that include Member Institution's de-identified DATA, contingent on the eligible Investigator completing all journal-specific forms and requirements prior to submission deadlines.
- 10) Investigators from any institution may propose and conduct research on de-identified and/or anonymized DATA from the SJCARES Data Warehouse in accordance with the policies and procedures of the St. Jude Global Alliance.
- 11) Member Institutions with studies approved according to the St. Jude Global Alliance policies will receive de-identified DATA from the SJCARES Data Warehouse that pertain to the proposed research question/study. Specific terms for the transfer of de-identified DATA will be stipulated under a separate data access agreement.
- 12) Investigator will not allow the use of the DATA in making patient-specific decisions regarding or guiding the direct clinical or medical management of a patient.

## B. Study Data

- 1) Within thirty (30) days of the Parties' execution of this Agreement and upon the successful completion of pre-access training requirements by all named members of the Member Institution Data Registry team, Member Institution will be provided access to the Data Registry to begin collection of DATA.
  - 2) Member Institution will enter DATA directly into a secure, cloud-based, electronic data capture tool with strict account management and end to end encryption.
  - 3) As part of monitoring the quality of DATA, St. Jude staff may request or be asked by Member Institution to review Member Institution records on-site.
2. **Proprietary Rights.** DATA are the property of Member Institution, and Member Institution makes the Data available to the Registry. For avoidance of doubt, notwithstanding any other term herein, DATA are proprietary to Member Institution and Member Institution owns and shall continue to own all right, title, and interest in its DATA.
- 1) St. Jude shall have an exclusive, unrestricted, royalty-free right to use and distribute the de-identified DATA from the SJCARES Data Warehouse for the common good and according to the St. Jude Global Alliance policies and procedures.
  - 2) Member Institution will conduct its own ethics reviews and comply with local ethics requirements before publishing on DATA self-downloaded from the Data Registry or Data Warehouse.



- 3) Member Institution must provide acknowledgement of St. Jude in all presentations and publications that contain DATA downloaded from the Data Registry and Data Warehouse, using the following language : *This study makes use of data from the St. Jude Children’s Research Hospital Global Childhood Cancer Analytics Resource and Epidemiological Surveillance System-Cancer Registry.*
  - 4) Member Institution shall refer third-party requests for access to de-identified data to the authorized representative of the St. Jude Global Alliance, which serves as broker for data requests. “Third-party” does not include Member Institution’s affiliates.
  - 5) Investigator will not use the SJCARES DATA to create a commercial or open source product that includes the SJCARES DATA in the product.
  - 6) Investigator will not transfer or disclose the SJCARES DATA in whole or part, or any identifiable material derived from the DATA, to others outside of Investigator’s Project Team including other Investigators and laboratories in Investigator’s Institution.
3. **Indemnification.** Member Institution agrees to hold harmless and indemnify St. Jude and its directors, agents, officers, and employees and professional staff who accept DATA under this Agreement (“Indemnified Party” or collectively “Indemnified Parties”) from and against any and all third party claims or suits that directly result from Member Institution’s collection, storage, and use of DATA unless the claims or suits result from negligence or willful misconduct on the part of an Indemnified Party or a breach of an applicable law or regulation by an Indemnified Party.
4. **Use of Name.** Without limiting and as further detailed in the MIMA, the Parties agree to the following paragraph: Neither Party may originate any publicity, news release, or other written or oral public announcement to the public press, stockholders, or otherwise, relating to the execution of this Agreement, any amendment to this Agreement, or to performance under or the existence of an arrangement between the Parties without the other Party’s prior written approval, which shall not be unreasonably withheld. Neither Party shall use the other Party’s name (or any variant of the other Party’s name) or the name of the other Party’s affiliated entities in any advertising or other promotional material in connection with the use and/or disclosure of DATA pursuant to this Agreement.
5. **Compliance with Applicable Laws, Regulations, and Standards.** Member Institution represents and warrants that, to the best of its knowledge, DATA are collected and transferred in accordance with all applicable local laws, rules, and regulations, including Good Clinical Practices guidelines, informed consent, data privacy laws, and Institutional Review Board or Ethics Committee (“IRB/EC”) review requirements (St. Jude IRB letter designating the Data Registry as non-research is provided as Annex 2).
- 1) Member Institution and St. Jude will use DATA in compliance with all applicable laws, rules, and regulations, and specifically, to adhere to their respective applicable requirements for maintaining patient confidentiality associated with DATA.
  - 2) Member Institution, its affiliates, agents, and subcontractors will comply with U.S. export control laws, rules, and regulations with respect to DATA use and any distribution of DATA.
  - 3) If Member Institution wishes to conduct research on DATA directly downloaded from the Data Registry and outside the SJCARES Data Warehouse, the Member Institution shall collect, use, store, access, and disclose Protected Health Information only as permitted by the Member Institution’s IRB/EC, or equivalent, and by the law of the country in which DATA originated.
  - 4) This Agreement shall be interpreted and construed in accordance with the laws of the United States of America and the State of Tennessee. If there is a conflict between the English version of this document and a version in another language, the English version will prevail.



**IN WITNESS WHEREOF**, the Parties have caused this SJCARES Rider to be executed by their authorized officials below and effective as of the date signed by the last such official (or effective as of the effective date of the MIMA if it is later). This SJCARES Registry Data Transfer Agreement Rider may be executed in exact counterparts.

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

Name of Authorized Official: Carlos Rodriguez-Galindo, MD

Title: EVP and Chair, St. Jude Global

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

Date: \_\_\_\_\_

Recommended By:

Title:

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

Date: \_\_\_\_\_

**[INSERT MEMBER INSTITUTION NAME]**

Name of Authorized Official:

Title of Authorized Official:

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

Date: \_\_\_\_\_

St. Jude Global Alliance Primary Delegate:

Title:

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

Date: \_\_\_\_\_

Read and Understood (if different from above):

Registry Director:



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

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

Date: \_\_\_\_\_

SAMPLE



## ANNEX ONE

### **Data Access for SJCARES Data Warehouse DATA and Terms of Use**

for

### **Downloading from or Copying of DATA Outside the SJCARES Data Warehouse**

**SAMPLE  
DO NOT SIGN**

Indicate by putting Principal Investigator (Investigator) initials here [\_\_\_\_], if Investigator requests permission to download or copy SJCARES Data Warehouse De-identified DATA. Investigator initials noted here mean that Investigator agrees to comply with all terms of this Application, including these Download Terms except those prohibiting download of Data or copying it outside the Data Registry Platform. (These Download Terms do not apply to those accessing DATA from the Platform.) By signing this Application, Investigator agrees:

1. The DATA from SJCARES Data Warehouse is provided “as is.” St. Jude Global Alliance makes no warranty or representation about the accuracy or reliability of the DATA in the SJCARES Data Warehouse. Investigator acknowledges that St. Jude Children’s Research Hospital, the institution that submitted the SJCARES DATA, and data subjects, original data creators, depositors, and copyright holders, and the funders of the SJCARES Data Warehouse or any part of the SJCARES DATA supplied to User bear no legal responsibility for the accuracy or comprehensiveness of the DATA and accept no liability for indirect, consequential, or incidental damages or losses arising from use of the DATA, or from the unavailability of, interruption in, or loss of access to the DATA for any reason.
2. Investigator will not share any SJCARES Data Warehouse DATA that Investigator downloads or copies with any other person or entity in or outside Investigator Institution outside of the Project Team without the prior written permission of an authorized representative of St. Jude Global Alliance Steering Committee. Should Investigator wish to share SJCARES DATA with a collaborator within or outside Investigator’s Institution, collaborator must notify the authorized representative of the St. Jude Global Alliance Steering Committee for access to SJCARES DATA.
3. To gain access to the SJCARES DATA, Investigator must submit a scientific concept proposal with objectives and methodology and composition of the Project Team that will be using the DATA to the authorized representative of the St. Jude Global Alliance Steering Committee. If approved by the Steering Committee, Investigator will obtain and use the SJCARES DATA for the purpose and project described in Investigator’s proposal as the Committee approves. Investigator use of the SJCARES DATA for a different, other, or new purpose or project will require a new application to and approval by the Committee.
4. Investigator accepts that DATA that User downloads or copies is subject to US laws and may be subject to laws of foreign jurisdictions with which Investigator might be responsible for complying.
5. The St. Jude Global Alliance Steering 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. Member Institution’s Chief Information Security Officer or equivalent will verify Investigator institution’s ability and commitment to complying with the data protection and security measures stated herein.
6. Although DATA are de-identified and Investigator may not upload or use any identifiable data on the Data Registry Platform, Investigator will employ appropriate best practice security measures, all devices used to access or download the SJCARES Data Warehouse DATA will meet commercially reasonable



and industry standard security requirements for protected health information at the time of download or access, and Investigator will notify the St. Jude Global Alliance Steering Committee and St. Jude Global Registry team immediately in the event of unauthorized breach or access to data by others. Investigator agrees not to make any attempt to identify any individual based on the DATA provided.

7. SJCARES Data Warehouse DATA downloaded and copied must be stored in a secure manner that blocks access from outside the institution and restricts external access to cloud storage.
8. St. Jude Global Alliance does not guarantee that it can provide computational infrastructure or expertise. Investigator represents that Investigator has the computation infrastructure and expertise to analyze the data that Investigator downloads.
9. Investigator must request in writing to an authorized representative of the St. Jude Global Alliance Steering Committee to access the DATA after this period. Investigator will destroy DATA downloaded or copied after one (1) year from obtaining the DATA, unless Investigator receives permission in writing to extend time by the authorized representative of the St. Jude Global Alliance Steering Committee.
10. The SJCARES DATA are made available for one (1) year from the date that the Investigator obtains the SJCARES DATA. Investigator will destroy all SJCARES DATA and all copies that Investigator makes of the SJCARES DATA after one (1) year from obtaining the data, unless permission to extend time is given in writing by the authorized representative of the St. Jude Global Alliance. Investigator must re-apply to access the SJCARES DATA after this period.
11. Investigator will acknowledge St. Jude Children’s Research Hospital, Inc, and the version of the SJCARES DATA included in any work or invention based in whole or part on the SJCARES DATA and in any published paper related to the SJCARES DATA using the following language : *This study makes use of data from the St. Jude Children’s Research Hospital Global Childhood Cancer Analytics Resource and Epidemiological Surveillance System-Cancer Registry.*
12. Investigator agrees that this Annex will terminate immediately upon any breach of its terms by Investigator or Investigator Institution, and Investigator will be required to discontinue access and to destroy any DATA that Investigator has accessed or copied or downloaded.

**SIGNATORIES BELOW AGREE WITH AND ACCEPT THIS AGREEMENT FOR ACCESS TO CONTROLLED ACCESS DATA.**

**ST. JUDE GLOBAL ALLIANCE MEMBER INSTITUTION**

Name of Authorized Official: \_\_\_\_\_

Title of Authorized Official: \_\_\_\_\_

Signature of Authorized Official: \_\_\_\_\_

Date: \_\_\_\_\_

Principal Investigator: \_\_\_\_\_

Title of Principal Investigator: \_\_\_\_\_

Signature of Principal Investigator: \_\_\_\_\_

Date: \_\_\_\_\_

**SAMPLE  
DO NOT SIGN**  
**SAMPLE  
DO NOT SIGN**



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## ANNEX TWO

### St Jude IRB Review



Institutional Review Board #00000029 FWA00004775

Nickhill Bhakta, MD  
GLOBAL PEDIATRIC MEDICINE

RE: **NR18-040 CAREREG** - CAREREG: THE ST. JUDE GLOBAL CHILDHOOD CANCER ANALYTICS RESOURCE AND EPIDEMIOLOGICAL SURVEILLANCE SYSTEM—CANCER REGISTRY

Dear Dr. Bhakta,

This is to certify that, on 5/10/2018, the New Project Submission, which includes **CAREREG project document initial version dated 5/8/2018 and the Data Model** submitted to the Institutional Review Board for consideration was evaluated by an OHSP staff member for a non human subject research determination.

IRB Review Status:

**The activity has been determined to not meet the definition of research, as defined in 45CFR46.102 (d):**

***Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.***

**Please keep this letter in your files.**

For further assistance, please contact the Office of Human Subjects' Protection at 901-595-4357 or email [hsp-1@stjude.org](mailto:hsp-1@stjude.org).

(Submission Link: [Pro00008700](#))

#### **Reminder of Principal Investigator's Responsibilities:**

As previously signed and certified, approval of this research involving human subjects is contingent upon your agreement:

1. To report to the Institutional Review Board for Human Research (IRB) any adverse effect or research related injuries which might occur in relation to the human experimentation. To read and comply with IRB reporting guidelines.



2. To submit in writing for prior IRB approval any alterations to the plan of human research.
3. To submit timely continuing review reports of this research as requested by the IRB.
4. To maintain copies of all pertinent information related to the research activities in this project, including copies of informed consent agreements obtained from all participants.
5. To notify the IRB immediately upon the termination of this project, and/or the departure of the Principal Investigator from this institution and the project.

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St Jude Children's Research Hospital Memphis, Tenn.

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