

The Children's Brain Tumor Tissue Consortium  
**DATA ACCESS AGREEMENT**

**Introduction and Statement of Policy**

The Children's Brain Tumor Tissue Consortium (CBTTC) is a multi-institutional cooperative research program dedicated to the study of childhood brain tumors. The ultimate goal of the CBTTC is to improve outcomes for children with brain tumors by supporting research leading to new biomarkers and therapies. The mission of the CBTTC is to collect high-quality brain tumor, adjacent normal (where possible), parental/sibling DNA (when available) and associated biofluid specimens with correlative highly dimensional clinical data, facilitate the generation and integration of data from biospecimens, develop cell lines and transplantable tumor models from submitted specimens, and share the data, research results, and resources from these efforts among CBTTC member institutions and with the world-wide scientific and medical research communities. The long-term goal of the CBTTC is to actively stimulate tissue-based research and increase worldwide access to the genomic and molecular analysis of large numbers of brain tumor specimens in support of our community's shared mandate to develop new therapies, identify new therapeutic targets, and employ new biologically-based biomarkers.

Implicit in the CBTTC mission is the establishment of data management and collaborative analyses systems to further scientific progress in brain tumor research recognizing that such data-driven research and discovery will be greatly enhanced by making data rapidly and readily available to scientific investigators under the human subjects protocols used to collect and donate participant's data and samples to the CBTTC. To support this vision, the CBTTC supports data sharing and collaborative discovery through CBTTC-supported portals/platforms, NIH-supported portals/platforms, or other public platforms with approved security and patient privacy protection. The CBTTC adheres to [NIH guidelines for genomic data sharing](#) and follows the longstanding principles of rapid data release as articulated in the [Bermuda](#) and [Ft. Lauderdale](#) agreements with no pre-established data embargo periods on quality controlled data. Because the volume of human genomic and phenotypic data contained in the CBTTC is substantial and, in some instances, potentially sensitive (e.g., data related to the presence or risk of developing particular diseases or conditions and information regarding family relationships or ancestry), data must be shared in a manner consistent with the research participants' informed consent, and the confidentiality of the data and the privacy of participants must be protected. As such, access to human genomic data will be provided fully to research investigators who, along with their institutions, have certified their agreement with the expectations and terms of access detailed below.

**This agreement governs the terms on which access will be granted to the data generated within the Children's Brain Tumor Tissue Consortium (CBTTC).**

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.

**In signing this agreement, you are agreeing to be bound by the terms and conditions of access set out in this agreement. Moreover, You agree that You are a researcher dedicated to the advancement of research and that You take responsibility for the distribution and use restrictions defined in this Agreement, and for the protection of the Data by You or Your collaborators.**

Definitions of terminology used in this document are found in the Appendix.

The effective date of this agreement shall be the Project Approval Date, as specified on the Data Access Committee (DAC) approval notification.

## **Terms of Access**

### **Research Use**

You agree that if access is approved, (1) the PI named in the Data Access Request (DAR) and (2), any other investigators working on the proposed research project under the oversight of the PI, shall become approved Users of the requested dataset(s). You are the responsible party for both the DAA and the DAR. Research use will occur solely in connection with the research project described in the DAR. New Uses of these data outside those described in the DAR will require submission of an amendment of the existing DAR and/or submission of a new DAR.

Any new use of these data outside those described in the DAR will require submission of an amendment of the existing DAR and/or submission of a new DAR.

CBTTC Investigators, or their direct institutional collaborators, who provide the data or samples used to generate controlled-access datasets subject to the Data Sharing Policy are exempt from the limitation on the scope of the research use as defined in this DAR. However, any scientific collaborators, including contractors, who are not at the same institution as the PI must submit their own DAR.

The CBTTC anticipates that the CBTTC datasets will be regularly updated with additional information on existing Data Subjects and addition of new Data Subjects and datasets. Unless otherwise indicated, all statements herein are presumed to be true and applicable to the access and use of all versions of CBTTC datasets.

### **1. Approved User Responsibilities**

You agree through the submission of the DAR that You have reviewed and understand the principles for responsible research use and data handling of the genomic datasets. You and Your Approved Users further acknowledge You are responsible for ensuring that all uses of the data are consistent with US specific national, tribal, and state laws and regulations, as appropriate, as well as relevant institutional policies and procedures for managing sensitive genomic and phenotypic data. Through submission of the DAR, upon request by the DAC you agree to submit either a project renewal or close-out request prior to the expiration date of a one-year data access period or other DAC-approved access period. You also agree to submit an annual progress update providing a brief summary or a final progress report upon request by the DAC upon request on or prior to the one-year anniversary of the DAR or DAC-approved access period, as described under Research Use Reporting below. Failure to submit a renewal or complete the close-out process, including confirmation of data destruction of any downloaded data if specified by DAC, may result in termination of all current data access.

### **2. Public Posting of Approved User's Research Use Statement**

You agree that You and Your Approved Users will allow for information about yourselves and your approved use to be posted publicly on the CBTTC website and/or associated CBTTC portals/platforms. This information includes Your name, institution, project title, research use statement, and a non-technical summary of the research use statement.

### **3. Non-Identification**

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. You accept that genomic sequence data may be provided “as is” without associated phenotype/clinical data or data verifying and/or validating the presence of putative genetic alterations.

### **5. Non-Transferability**

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 or external collaborators, except as necessary to advance research. Should You wish to share the Data with a collaborator within the same Institution, you must inform the CBTTC as an addendum to Your DAR. A third party or a Collaborator outside Your institution must make a separate application for access to the Data informing the CBTTC of the collaboration on the identified project.

You agree to use the data for the approved purpose and projects described in your application; use of the data for a new purpose or project will require a new application and/or amendment to existing DAA and approval. You and Your Approved Users acknowledge responsibility for ensuring the review and agreement to the terms within this DAA and the appropriate research use of CBTTC data by research staff associated with any approved project, subject to applicable laws and regulations. CBTTC genomic datasets obtained through this DAR, in whole or in part, may not be sold to any individual at any point in time for any purpose.

### **6. Data Security and Data Release Reporting**

You and Your Approved Users, including if applicable the institutional Information Technology Director or a designee, acknowledge the CBTTC’s expectation that they have reviewed and agree to handle the requested dataset (s) according to current [NIH-defined Security Best Practices](#) and if applicable, Your Institutional Review Board, including the detailed descriptions of requirements for security and encryption. These include, but are not limited to:

- You agree to keep data secure and confidential at all times and to adhere to information technology practices in all aspects of data management to assure that only authorized individuals can gain access to CBTTC datasets. This agreement includes the maintenance of appropriate controls over any copies or derivatives of the data obtained through this Data Access Request.
- 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.
- Requesters and PIs agree to notify the CBTTC DAC of any unauthorized data sharing, breaches of data security, or inadvertent data releases that may compromise data confidentiality within 24 hours of when the incident is identified. As permitted by law, notifications should include any known information regarding the incident and a general description of the activities or process in place to define and remediate the situation fully. Within 3 business days of the CBTTC DAC notification, the Requester, through the PI and the Institutional Signing Official, agree to submit

to the CBTTTC Data Access Committee a detailed written report including the date and nature of the event, actions taken or to be taken to remediate the issue(s), and plans or processes developed to prevent further problems, including specific information on timelines anticipated for action.

All notifications and written reports of data security incidents should be sent to:

**CBTTTC CONTACT:**

Email: [CBTTTCAdmin@email.chop.edu](mailto:CBTTTCAdmin@email.chop.edu)

Marked: Urgent- Data Security Issue

## **7. Intellectual Property**

By requesting access to CBTTTC dataset (s), You acknowledge the CBTTTC intellectual property principles as outlined below and align with NIH guidelines:

- Achieving maximum public benefit is the ultimate goal of data distribution through the CBTTTC approved/ designated data repositories. The CBTTTC encourages broad use of CBTTTC-supported genotype phenotype data that is consistent with a responsible approach to management of intellectual property derived from downstream discoveries, as outlined in the [NIH Best Practices for the Licensing of Genomic Inventions](#) and the NIH's [Research Tools Policy](#).
- CBTTTC institutions maintain an intellectual property consensus policy defined within the consortium's Constitution, which outlines the specific policy and procedures related to CBTTTC-associated discoveries following the NIH's Best Practices for the Licensing of Genomic Inventions and its Research Tools policy (see [www.ott.nih.gov/](http://www.ott.nih.gov/)).
- CBTTTC considers CBTTTC datasets as pre-competitive and urges You and Your Approved Users to avoid making IP claims derived directly from the CBTTTC dataset (s). It is expected that these CBTTTC-provided data, and conclusions derived therefrom, will remain freely available, without requirement for licensing. However, the CBTTTC also recognizes the importance of the subsequent development of IP on downstream discoveries, especially in therapeutics, which will be necessary to support full investment in products to benefit the pediatric cancer patient population.
- The Children's Hospital of Philadelphia (CHOP) serves as the steward for all specimens and data in the CBTTTC.

## **8. Research Dissemination and Acknowledgement of CBTTTC datasets**

The intent of the CBTTTC is to promote dissemination of research findings from CBTTTC dataset (s) as widely as possible through web-based portals, data repositories, scientific publication or other appropriate public dissemination mechanisms. You are strongly encouraged to publish and disseminate Your CBTTTC dataset (s) results in accessible formats, journals, and/or to present research findings at scientific meetings. As such, the only mandate will be that within an associated acknowledgement section that it be stated "was made possible in part due to The Children's Brain Tumor Tissue Consortium (CBTTTC)."

Furthermore, it is strongly encouraged that CBTTTC members utilizing CBTTTC biospecimens and/or data also include in “On behalf of The Children’s Brain Tumor Tissue Consortium (CBTTTC)” as part of their affiliation.

## **9. Research Use Reporting**

To assure adherence to CBTTTC policies and procedures for CBTTTC dataset (s), You agree to provide annual (or as other-wise approved by the DAC) progress updates on how these data have been used, including data-deposition, presentations, publications, and the generation of intellectual property. Progress updates are provided as part of the project renewal or project close-out processes, prior to the expiration of the data access period. Approved Users who are seeking renewal or close-out of a project agree to complete the appropriate online forms and provide specific information such as data-deposition, publications or presentations that resulted from the use of the requested dataset(s), a summary of any plans for future research use, any violations of the terms of access described within this DAR and the implemented remediation, and information on any downstream intellectual property generated from the data. You are also encouraged to include general comments regarding topics such as the effectiveness of the data access process (e.g., ease of access and use), appropriateness of data format, challenges in following the policies, and suggestions for improving data access or the program in general. Lastly, the CBTTTC maintains several data repositories and collaborative research environments and as such we also strongly encourage return and deposition of the project's results and associated data within CBTTTC-hosted portals. As such, You and Your collaborators also agree that any publicly hosted data derived from, integrated with, or including CBTTTC data may be requested for integration and use within CBTTTC approved data platforms.

## **10. Non-Endorsement, Indemnification**

The Requester and Approved Users acknowledge that although all reasonable efforts have been taken by the CBTTTC to ensure the accuracy and reliability of controlled-access data obtained through the attached DAR, the CBTTTC, its members, and contributing Investigators do not and cannot warrant the results that may be obtained by using any data included therein. The CBTTTC, its members, and all contributors to these datasets disclaim all warranties as to performance or fitness of the data for any particular purpose. No indemnification for any loss, claim, damage, or liability is intended or provided by any party under this agreement. Each party shall be liable for any loss, claim, damage, or liability that said party incurs as a result of its activities under this agreement

## **11. Termination and Violations**

This Data Access Agreement will be in effect for a period of one year from the date of the dataset (s) are made accessible to the You and Your Approved Users unless otherwise specified by the DAC. At the end of the access period, You agree to report progress, and renew access or close-out the project. Upon project closure-out, You agree to release any new data generated from this Data Access Agreement to CBTTTC or an approved data repository, and if requested to destroy all Your local copies of the requested dataset(s), except as required by publication practices or law to retain them. New data generated from CBTTTC dataset (s) may not be destroyed prior to releasing to CBTTTC. With advance notice and approval by CBTTTC Scientific Committee and/or DAC, the project and this DAA may be transferred to another Approved User at the same institution. In this case, documentation/confirmation must be provided that You and Your Approved User are using the dataset (s) under a CBTTTC-approved DAR.

You and Your Approved Users acknowledge that the CBTTC may terminate this agreement and immediately revoke access to all CBTTC datasets at any time if You are found to no longer be in agreement with the policies, principles, and procedures set forth in this DAA and CBTTC Data Use Policy Guidelines.

**By submission of the attached Data Access Request or as available on-line:**

You attest to Your and Your Approved Users' qualifications for access to and use of CBTTC dataset(s) and agree to the CBTTC principles, policies, and procedures for the use of the requested datasets as articulated in this document, including the potential termination of access should any of these terms be violated.

You and Your Approved Users further acknowledge that You have shared this document, and the CBTTC Data Use Policy Statement datasets with any Approved Users, appropriate research staff, and all other Key Personnel and collaborators identified in the DAR.

You acknowledge that You have shared this document and relevant documents with Your appropriate institutional departments if applicable, and that You have assured compliance with local institutional policies related to technology transfer, information technology, privacy, and human subjects research.

You and Your Approved Users acknowledge that You have reviewed and understand the CBTTC specific research use, reporting, and dissemination policies as outlined in this DAA.

## DEFINITIONS

*CBTTC* means the Children's Brain Tumor Tissue Consortium.

*Data* means all and any clinical, genomic, molecular, and phenotypic data obtained from the CBTTC.

*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.

*Approved User* is a user approved by the relevant Data Access Committee(s) to access one or more datasets for a specified period of time and only for the purposes outlined in the investigator's approved research use statement. Staff members and trainees under the direct supervision of the Approved User are also Approved Users and must abide by the terms laid out in the Data Access agreement.

*Collaborator* is an individual who is not under the direct supervision of the principal investigator (PI) (e.g., not a member of the PI's laboratory) who assists with the PI's research project. Internal collaborators are employees of the Requester or work at the same location/campus as the PI. External collaborators are not employees of the Requester and/or do not work at the same location as the PI, and consequently must be independently approved to access CBTTC data.

*Contributing Investigator* is an investigator who submitted a genomic dataset to a CBTTC-approved data repository or an associated NIH-designated data repository.

*Data Access Request (DAR)* is a request submitted to a Data Access Committee for a specific project specifying the data to which access is sought, the planned research use, and the names of collaborators and the Information Technology Director. Collaborators and project team members on a request must be from the same institution or organization. Alternatively, collaborators from a separate institution must apply separately for access referencing the collaborative project for approved use/access.

*Data Derivative* is any data including individual-level data or aggregate genomic data that stems from the original dataset deposited (e.g. imputed or annotated data) in CBTTC-designated or approved data repositories. Summary information that is expected to be shared through community publication practices is not included in this term.

*Data Access Agreement (DAA)* is an agreement between the Approved User, the Requestor, and CBTCC regarding the terms associated with data access and the expectations for use of CBTTC datasets. The DAA is signed by the investigator requesting the data and her/his Institutional Signing Official.

*CBTTC Approved User Code of Conduct:* The CBTTC adheres to key principles and practices agreed to by all research investigators requesting access to CBTTC controlled-access genomic data. The elements

within the Code of Conduct reflect the adherence to the terms of access in the Data Access Certification agreement. Failure to abide by the Code of Conduct may result in revocation of an investigator's access to any and all approved datasets.

*Information Technology (IT) Director* is an individual with the necessary expertise and authority to vouch for the IT capacities at an academic institution, company, or other research entity and the ability of that institution to comply with NIH data security expectations. The IT Director is to be included as key personnel in the Data Access Request.

*Institutional Signing Official* is generally, an official at an institution with the authority to sign on behalf of the submitting investigator or an investigator who has submitted a Data Access Request or Project Request to the CBTTTC, authorized to enter their institution into a legally binding contract.

*Progress Update* is information included with the Data Access Request (DAR) renewal or close-out summarizing the analysis of CBTTTC datasets obtained through the DAR and any publications and presentations derived from the work.

*Project Renewal* is renewal of a principal investigator's access to controlled-access datasets for a prior-approved project before the expiration date of a Data Access Request or Project Request.