CHILDREN'S ONCOLOGY GROUP
MATERIALS TRANSFER AGREEMENT (MTA)

This agreement ("Agreement") concerns the distribution and use of certain biological materials and is made among _____("INSTITUTION") and Public Health Institute ("PHI"), on behalf of Children's Oncology Group ("COG"). INSTITUTION, PHI and COG are individually known as Party, and collectively, as the "Parties".

WHEREAS, PHI is an established federal grantee organization, under a grant provided by the National Cancer Institute ("NCI"), and under such grant, is responsible for certain COG-wide activities, including administrative oversight and support of COG conducted clinical trials;

COG is a NCI established cooperative group that includes over 8,000 pediatric cancer specialists located at approximately 200 medical centers (the "COG Member Institutions") in the United States, Canada, Australia, New Zealand. COG conducts clinical trials to establish improved treatments for children with cancer, and to translate new laboratory and clinical research findings into new therapies.

COG cooperative research consists of collaboration among the NCI, the COG Member Institutions, other academic institutions, and industry partners. COG is committed to distributing biological material, specimens, and/or tissue as part of the general implementation of its research agenda and the specific implementation of its protocols. To that end, COG has agreed to provide INSTITUTION certain biological material, specimens, and/or tissue and for this reason, INSTITUTION shall be considered a "RECIPIENT" under this Agreement of such material. To assure that the material provided continues to be managed according to the COG and NCI guidelines, COG asks that the RECIPIENT agree to the following prior to receiving the biological material, specimens, and/or tissue.

NOW, THEREFORE, in consideration of the terms, conditions, and mutual covenants hereinafter contained or incorporated by reference herein, and other good and valuable consideration, which may include certain sums for services performed by INSTITUTION, the receipt and sufficiency of which is hereby acknowledged, the Parties do hereby agree to the following:

1. INSTITUTION (RECIPIENT) is one of certain designated reference laboratories, COG Member Institutions, academic institutions and/or industry partners that receives and/or has requested certain biological material, specimens, and/or biological tissue (with the foregoing known as "MATERIAL") based on (a) participation of RECIPIENT (or a Principal Investigator employed by and/or staff of RECIPIENT) in the COG cooperative group and/or (b) because of a consulting relationship or other vendor relationship with one or more of the following: COG or a committee or subcommittee thereof, the operational divisions of the COG (including the COG Operations Center, COG Biopathology Center, the COG Statistics and Data Center).
2. For this Agreement, the MATERIAL and its permitted uses are limited as stated on **Attachment A**. Furthermore, the Parties agree that:
    a. The Material and the associated data are the property of the Children's Oncology Group and are made available solely for the study designated on **Attachment A** and that the Material and data will be used solely for the purpose described.
    b. The Material and the associated data shall <u>not</u> be further distributed by RECIPIENT without the COG's prior written consent, and the RECIPIENT shall refer any request for them to the COG Operations Center operating under the exclusive direction of the COG Group Chair.
    c. Any Material and associated data delivered pursuant to this Agreement are understood to be experimental and collected as a result of human subjects research for which informed consent was obtained and for which a privacy authorization might apply. RECIPIENT agrees to limit the use of the Material and data uses that are within the scope of the informed consent and any relevant privacy authorization.

d. The RECIPIENT acknowledges that the Material and associated data will be provided as coded specimens without the names of the human subjects and that the COG will not release any identifiable information about the specimens to the RECIPIENT.

e. The RECIPIENT agrees to use the Material (tissue, biological specimen, etc.) and associated data in compliance with all applicable statutes and regulations (and requirements for IRB/Privacy Board/Ethics Board review and approval), and specifically agrees to adhere to all requirements necessary for maintaining human subject confidentiality associated with the Material and data.

f. For research projects which require access to treatment and/or outcome data maintained by the COG Operations Center, the RECIPIENT agrees to complete a Data Use Agreement with the COG.

g. For the Material and data referenced herein and during any collaboration between an "Institutional Author" (defined below) and certain "COG Collaborator(s)"(defined below), where the Institutional Author works with COG Collaborators on a protocol or study involving a correlation of data obtained from his or her use of the Material and COG clinical trial data, the Institutional Author agrees to publish or present the data that he or she generates from the Material in accordance with the terms specified in subsection 2(g)(i). For the purpose of this subsection 2(g), "Institutional Author" refers to the Principal Investigator/Laboratory Director who is the signatory to this Agreement or any investigator so designated by Recipient. For the purpose of this section "COG Collaborators" refers to the relevant COG study committee, COG Disease Committee, COG scientific/medical committee or key COG researcher(s) who collaborate with the Institutional Author as noted above.

   i. All abstracts, journal articles, texts, and presentations (including those submitted to electronic media) which include access to and inclusion of COG clinical trial data for correlative analysis must be reviewed prior to submission by the COG Collaborator(s).

   ii. Authorship in these abstracts, publications and presentations will be appropriate to the relative contributions of the authors, including providing of these unique and unpublished specimens. In particular, if your study involves intellectual input from COG members in preparing the manuscript or input from the COG Statistical and Data Center (SDC), appropriate members of the COG will be included as co-authors in any manuscripts or abstracts submitted for publication or presentation. When research and intellectual contributions of COG members is of little consequence in your work, co-authorship is not required but citations of the COG, the COG Biopathology Center (BPC), and other appropriate grants and acknowledgement of the collaboration with the COG is required.

   iii. Acknowledgement in publications must state that the Material and data were provided by the Children's Oncology Group and must also reference the specific grant and/or funding support provided.

   iv. In the event that the Material constitutes cell lines or xenografts, acknowledgement in publications must state that the cell lines or xenografts and data were provided by the Children's Oncology Group Cell Culture/Xenograft Repository. When published, a copy of the paper (electronic preferred) should be sent to the COG Cell Culture Xenograft Repository.

3. The permitted uses of MATERIAL are stated in **Attachment A.** The MATERIAL will **not** be further distributed to others ("Secondary Recipient(s)") unless RECIPIENT obtains COG's express prior written consent from a COG operating division acting to implement a study and/or protocol

of the relevant COG study committee unless such permission is expressly stated in **Attachment A**. Such consent shall state the field of use for MATERIAL and any use not specifically stated therein shall not be deemed to be included within the scope of permissible uses for the MATERIAL. RECIPIENT agrees to ensure that Secondary Recipient(s) agree to use and dispose of MATERIAL (and if applicable, publish, present, use, or dispose of data and results) in accordance with the terms of this Agreement.

4. The data and results generated solely by Recipient (or the Principal Investigator who is the signatory to this Agreement) from the use of the MATERIAL shall be exclusively the property of the Recipient.
5. The MATERIAL and any corresponding COG clinical trial data or data associated with the MATERIAL when it is provided to Recipient shall be exclusively the property of COG.
6. Any data and results generated from the Material provided to the RECIPIENT and correlated and analyzed in conjunction with a COG protocol or COG study shall be the property jointly of the Recipient and COG.
7. Sections 2(g), 4, and 6 do not apply to designated COG Reference Laboratories or commercial laboratories retained by COG to provide scientific laboratory services. In this case, all data, including the data and results generated from the Material shall be the property of COG.
8. If RECIPIENT is a COG Member Institution, RECIPIENT acknowledges that this MATERIAL is provided as part of the resources and infrastructure provided by participation in the COG cooperative group, and that the foregoing is in addition to any funding reimbursement, payment, and/or other support from COG.
9. Any MATERIAL delivered pursuant to this Agreement are understood to be experimental and collected as a result of human subjects research for which informed consent, privacy authorization, and other ethical review and approval (from an IRB or similarly constituted research ethics board) was obtained. Notwithstanding any other term or provision, no use of MATERIAL is permitted if it has not been the subject of the required IRB review and approval or if it is not within the scope of the relevant informed consent, privacy authorization, and/or IRB policy or rule.
10. The RECIPIENT agrees that the MATERIAL will be provided as coded specimens without names of the COG research subjects. RECIPIENT will not release any identifiable information about the MATERIAL or COG research subjects to any third party unless required by law, and then only if RECIPIENT provides COG reasonable notice so that COG may file an objection or other motion in the relevant tribunal or proceeding.
11. RECIPIENT agrees to use the MATERIAL in compliance with all applicable statutes and regulations, and governmental policy and specifically agrees to adhere to all requirements necessary for maintaining research subject confidentiality associated with the MATERIAL.
12. The RECIPIENT understands that while the Biopathology Center or other repository or Member Institution of the COG attempts to avoid supplying MATERIAL contaminated with infectious agents such as hepatitis and HIV, all human cells and biological material should be handled as if potentially infectious. RECIPIENT and PRINCIPAL INVESTIGATOR acknowledge that they are aware of and follows OSHA regulations for handling human specimens and PRINCIPAL INVESTIGATOR will instruct his/her staff to abide by those rules. RECIPIENT further agrees to assume all responsibility for informing and training its employees, agents, representatives or other staff handling MATERIAL of the dangers and procedures for safe handling of human tissues. The MATERIAL is provided by COG as a service to the research community without warranty of merchantability or fitness for a particular purpose and without any other warranty or representation, express or implied.

13. Neither PHI nor COG, nor any of their respective affiliates, trustees, directors, employees, agents, representatives, or divisions (hereinafter, individually, an Indemnified Party; collectively, the "Indemnified Parties") assumes any responsibility or liability for the use (or further distribution of, if any) of MATERIAL by RECIPIENT or PRINCIPAL INVESTIGATOR. RECIPIENT agrees to assume all risks and responsibility in connection with the receipt, handling, storage and use of MATERIAL. RECIPIENT further agrees to indemnify, defend and hold harmless the Indemnified Party and/or Indemnified Parties from any claims, costs, damages or expenses resulting from use or further distribution of the MATERIAL by RECIPIENT; except to the extent such claims, costs, damages or expenses arises from COG's or PHI's gross negligence or reckless or willful misconduct. For INSTITUTIONS that are entities created by a federal or State Government, based on a public charter, or an agency or subdivision of a governmental authority and that are subject to limited liability based on applicable law (including limitations in statutes or State Constitutional provisions relating to Torts and Contracts or grants of sovereign immunity), INSTITUTION (RECIPIENT) agrees to indemnify or provide equivalent permitted reimbursement as stated above in this Section 13 to the maximum amount permissible under applicable law.
14. WHILE COG (IN ITS OPERATIONAL ASPECTS AND THROUGH ITS MEMBER INSTITUTIONS) STRIVES FOR COMPLIANCE WITH GCP PRINCIPLES, THE PARTIES ACKNOWLEDGE THAT COG OBLIGATIONS TO THE NATIONAL CANCER INSTITUTE (NCI) AND THE PROCEDURES IT FOLLOWS AS A COOPERATIVE GROUP MAY LEAD TO POTENTIAL OR ACTUAL DEVIATIONS FROM GCP (INCLUDING GCP ICH). PURSUANT TO THE TERMS OF THIS AGREEMENT, COG (AND, AS APPLICABLE, THE PHI, EACH,) HAS PROVIDED AND NOW PROVIDES ANY MATERIAL, DATA AND RELATED FACILITIES, DATABASES, RECORDS, AND OTHER INFORMATION (AND ACCESS THERETO), IN CONNECTION WITH ANY ANTICIPATED GOVERNMENTAL OR REGULATORY AUDIT OR FOR ANY OTHER REASON, ON AN "AS IS" BASIS, WITH NO OTHER WARRANTIES OR REPRESENTATIONS, IMPLIED OR EXPRESS, AND IS NOT PROVIDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF NONINFRINGEMENT, DATA ACCURACY, FITNESS FOR A PARTICULAR PURPOSE OR MERCHANTABILITY. INSTITUTION (RECIPIENT) USES OR RELIES UPON DATA AND MATERIAL AT ITS OWN RISK.
15. If INSTITUTION or PRINCIPAL INVESTIGATOR would like to use, disseminate, or conduct research on the data and/or MATERIAL for purposes that are not described in **Attachment A**, such entity or person agrees to submit a research plan or protocol to COG and obtain prior written approval from COG before engaging in such tasks.
16. INSTITUTION and PRINCIPAL INVESTIGATOR each acknowledges that because of COG's status as a network group established and funded by NIH, federal law and governmental policy may apply and govern the development, ownership, and commercialization of intellectual property arising out of the performance of this Agreement. Any use or exploitation of intellectual property arising out of the performance of this agreement shall be governed by each Party's regulatory and legal obligations to NCI, other governmental agencies or subdivisions thereof, applicable law, regulation, and policy including NIH policy relating to inventions and patents. All inventions arising from use of the data and/or material provided are subject to the provisions of the CTEP Intellectual Property Option To Collaborator at **http://ctep.cancer.gov/industryCollaborations2/guidelines_for_collaboration.htm**
17. INSTITUTION and PRINCIPAL INVESTIGATOR agree to cooperate fully with COG and PHI and to execute any additional documents, waivers, agreements and/or consents required to establish the rights to COG stated in this Agreement. Failure to comply with this paragraph shall constitute a material breach of this Agreement entitling PHI and COG to all remedies, including without

limitation to immediately terminate all payments otherwise due under this Agreement and to seek preliminary and permanent injunctive relief and damages.

18. If disclosure, transmission, or use of data and/or MATERIAL takes place outside of the United States and United States law is found not to apply, then the applicable law, regulation, policies and ethical requirements of that country equivalent to those in the foregoing sentence shall apply. To the extent possible, the legal, regulatory, policy, and ethical requirements of the United States shall apply. For any transmission or disclosure outside the United States, INSTITUTION and/or PRINCIPAL INVESTIGATOR (and each one's employees, agents, or representatives), remain exclusively responsible to the extent legally permissible in that jurisdiction for knowledge of and compliance with relevant import and export law and regulations and knowledge of the relevant laws, regulation, policies and ethical requirements as stated in this section.
19. The RECIPIENT and PRINCIPAL INVESTIGATOR agree that they are exclusively responsible for maintaining communication with and ensuring oversight, review and approval by the local and/or relevant Institutional Review Board (IRB) (or similarly constituted research ethics board outside the United States) with respect to the MATERIAL, data, other tissue and material provided by COG or other activity covered by or referenced in this agreement. Further, the RECIPIENT and PRINCIPAL INVESTIGATOR agree to provide COG copies of documents submitted to the IRB or similarly constituted ethical board upon request of COG or in accordance with a COG policy or procedure.
20. Should any part or provision of this agreement be held unenforceable or in conflict with the applicable laws or regulations of any jurisdiction, the invalid or unenforceable part or provision shall be replaced with a provision which accomplishes, to the extent possible, the original business purpose of such part or provision in a valid and enforceable manner, and the remainder of this agreement shall remain binding upon the parties hereto.
21. No waiver or modification of this Agreement will be binding upon either Party unless made in writing and signed by the Party or Party's duly authorized representative.
22. Any failure of a Party to enforce any of the terms or provisions of this Agreement shall not be construed as a waiver of such terms or provisions or the right of the Party thereafter to enforce each and every such term or provision of this Agreement.
23. Each Party warrants and represents that it has the right to enter into this agreement, that the terms of this agreement are valid and binding obligations, and are not inconsistent with any other contractual and/or legal obligations that the party may have. The persons executing this agreement represent and warrant that they have the full power and authority to enter into this agreement on behalf of their respective entities.
24. RECIPIENT agrees that its employees, staff, agents, or representatives, which include its research personnel and PRINCIPAL INVESTIGATOR, are bound to terms which conform to the terms of this Agreement.
25. In the event of a conflict between the terms of this Agreement and any attachment or exhibit, the terms of this Agreement shall supersede and govern.

Agreed:
Signed:

_____

INSTITUTION authorized representative Date

Name:_____

Title: _____

PRINCIPAL INVESTIGATOR/Laboratory Director: I have read and understood the conditions outlined in this Agreement and I agree to abide by them in the receipt and use of the COG study MATERIAL and data.

Signed:

_____

PRINCIPAL INVESTIGATOR/Laboratory Director Date

Name:_____

Title: _____

Signed:

_____

Public Health Institute Authorized representative Date

Name: Emily A. Meier

Title: Director, Clinical Research Administration and Agreements

Acknowledged:

_____

Children's Oncology Group Date

Name: Deborah Crabtree

Title: Senior Director of Administration

Attachment A

Date: _____

Study/Protocol Number: _____

Study/Protocol Title: _____

_____

Study/Protocol Version and Date: _____

Description of Material [Description of Material should conform to description found in study document and/or protocol]:

Permitted Uses of Material: