CHILDREN'S ONCOLOGY GROUP

CHILDREN'S ONCOLOGY GROUP CELL CULTURE/XENOGRAFT REPOSITORY

MATERIALS TRANSFER AGREEMENT (MTA) FOR CELL LINES OR XENOGRAFTS PLACED IN THE OPEN DISTIRBUTION LIST ("OPEN DISTRIBUTION – INDUSTRY)

This agreement ("Agreement") concerns the distribution and use of certain biological materials and is made among _____ ("RECIPIENT") and The Children's Hospital of Philadelphia® ("CHOP"), on behalf of Children's Oncology Group ("COG"). RECIPIENT, CHOP and COG are individually known as Party, and collectively, as the "Parties".

WHEREAS, CHOP 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;

The Children's Oncology Group (COG) is a National Cancer Institute (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, Mexico, Australia, New Zealand and selected countries in Europe. 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. The 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 RECIPIENT certain biological material, specimens, and/or tissue under this Agreement. 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 RECIPIENT, the receipt and sufficiency of which is hereby acknowledged, the Parties do hereby agree to the following:

1. RECIPIENT is one of certain 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 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 associated data will be used by RECIPIENT solely for the purpose described in **Attachment A**.

    b. The MATERIAL and the associated data shall **not** 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 associated 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. The RECIPIENT Author (defined below) agrees to publish or present the data that he or she generates from the MATERIAL and associated data in accordance with the terms specified in subsection 2(g)(i). For the purpose of this subsection 2(g), "RECIPIENT Author" refers to the Principal Investigator/Laboratory Director or any investigator so designated by Recipient.

    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 RECIPIENT.

    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 associated 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 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 by COG 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 jointly owned by RECIPIENT and COG.

7. RECIPIENT shall share any the data generated under this Agreement with COG, for COG's internal research purposes only. No other use or distribution to any third party by COG of such data is permitted, without the prior written consent of RECIPIENT.

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. RECIPIENT shall not have access to identifiable information. All MATERIAL provided by COG to RECIPIENT via a Unique Sample ID.

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 acknowledges that it is aware of and follows OSHA regulations for handling human specimens and will instruct its 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 CHOP 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 of any data generated by RECIPIENT under this Agreement by RECIPIENT. 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 the use of any data generated by RECIPIENT under this Agreement by RECIPIENT.

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 CHOP, 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 NON-INFRINGEMENT, DATA ACCURACY, FITNESS FOR A PARTICULAR PURPOSE OR MERCHANTABILITY. RECIPIENT USES OR RELIES UPON DATA AND MATERIAL AT ITS OWN RISK.

15. If RECIPIENT 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. RECIPIENT acknowledges that because of COG's status as a cooperative 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 and applicable parts of the Intellectual Property Option To Collaborator" at: http://ctep.cancer.gov/industryCollaborations2/guidelines_for_collaboration.htm

17. RECIPIENT agrees to cooperate fully with COG and CHOP 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 CHOP 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, RECIPIENT (and its 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. 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.

20. 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.

21. 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.

22. 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.

23. RECIPIENT agrees that its employees, staff, agents, or representatives, which include its research personnel, are bound to terms which conform to the terms of this Agreement.

24. 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.

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[**The rest of this page left intentionally blank**]

IN WITNESS WHEREOF, the parties have caused this valid and binding Agreement to be duly executed by authorized signatories as indicated below.

Agreed:

Signed:

_____

RECIPIENT authorized representative Date

Name: _____

Title: _____

Signed:

_____

CHILDREN'S HOSPITAL OF PHILADELPHIA Authorized representative Date

Name: _____

Title: _____

Acknowledged:

_____

Children's Oncology Group Date

Name:_____

Title: _____

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: