

...FOR CELL LINES OR XENOGRAFTS PLACED IN THE OPEN DISTRIBUTION LIST (“OPEN DISTRIBUTION LIST MTA”)

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 DISTRIBUTION LIST (“OPEN DISTRIBUTION LIST MTA”)

This agreement (“Agreement”) concerns the distribution and use of certain biological materials and is made among _____ (“INSTITUTION”) and the Children’s Oncology Group (“COG”). INSTITUTION and COG are individually known as Party, and collectively, as the “Parties”.

The Children’s Oncology Group (COG) is a National Cancer Institute (NCI) established cooperative group that includes over 5000 pediatric cancer specialists located at approximately 200 medical centers (the COG Member Institutions) in the United States, Canada, and Australia, New Zealand. COG conducts clinical trials to establish improved treatments for children with cancer, and to transition new laboratory and clinical research findings into new therapies.

COG cooperative research consists of collaboration among the NCI, the COG Member 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 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 the following:
 - a. An entity conducting scientific/medical research that receives certain biological material, specimens, and/or biological tissue (with the foregoing known as “MATERIAL”); in such a case, the scientist/laboratory director employed by or on the staff of the foregoing named entity is the “PRINCIPAL INVESTIGATOR” under this Agreement; and/or
 - b. Certain designated reference laboratories and/or COG Member Institutions that receives certain biological material, specimens, and/or biological tissue (with the foregoing known as “MATERIAL”) based on participation of RECIPIENT in the COG cooperative group and/or 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), or the affiliated organization (an affiliate) of COG, the National Childhood Cancer Foundation (“NCCF” or “Foundation”).
2. For this Agreement, the **MATERIAL consists of: cell lines, xenografts, progeny and/or products derived therefrom.**
 - a. The cell lines or xenografts, or products derived from them (DNA/RNA, etc) will 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.
 - b. Any cell lines or xenografts 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.

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- c. The RECIPIENT acknowledges that the cell lines/xenografts 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.
- d. The RECIPIENT agrees to use the SPECIMENS 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 cell lines or xenografts.
- e. Cell lines or xenografts provided pursuant to this Agreement are subject to the following:
 - i. 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(e). For the purpose of this subsection 2(e), “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.
 - ii. 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). If the COG Collaborator(s) interpret these data differently and/or have different conclusions about these data, the Institutional Author agrees to facilitate the submission of these differing COG views to the journal or organization that is reviewing the Institutional Author’s manuscript or draft. Alternatively, the Institutional Author agrees to submit a disclaimer prepared by the COG Collaborator(s) to the journal or organization that is reviewing the Institutional Author’s manuscript or draft.
 - iii. 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.
 - iv. 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.
 - v. 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.

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3. For research projects involving more than 10 cell lines or xenografts from the Open Distribution List or which, in addition to cell lines or xenografts, 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.
4. Any limitation on the permitted uses of MATERIAL may be stated in **Attachment A**. The MATERIAL will **not** be further distributed to others unless RECIPIENT obtains COG’s express prior written consent from a COG operating division acting to implement a COG study and/or COG protocol. 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.
5. [intentionally omitted]
6. 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, or NCCF on COG’s behalf.
7. 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.
8. 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 (or NCCF) reasonable notice so that COG (or NCCF) may file an objection or other motion in the relevant tribunal or proceeding.
9. 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.
10. 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. PRINCIPAL INVESTIGATOR acknowledges that he/she is aware of and follows OSHA regulations for handling human specimens and 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. MATERIAL, cell lines and xenografts are 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.
11. Neither COG nor its affiliates, 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 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. For INSTITUTIONS that are entities created by a federal or State Government, based on a public charter, or an agency or subdivision of a

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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 11 to the maximum amount permissible under applicable law.

12. 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 FOUNDATION, 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. INSTITUTION (RECIPIENT) USES OR RELIES UPON DATA AND MATERIAL AT ITS OWN RISK. THE FOREGOING MAY APPLY TO NCCF TO THE EXTENT THAT NCCF USES, OR PROVIDES COG (OR COG DERIVED) DATA, MATERIALS, OR INFORMATION PURSUANT TO NCCF PERFORMANCE UNDER THIS AGREEMENT.
13. 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.
14. INSTITUTION and PRINCIPAL INVESTIGATOR each 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 COG policies and procedures regarding the same and shall be consistent with 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/default.htm#guidelines_for_collaborations.
15. In the absence of an express policy or procedure stated herein, COG policy and procedure shall apply.
16. INSTITUTION and PRINCIPAL INVESTIGATOR agree to cooperate fully with COG and NCCF and to execute any additional documents, waivers, agreements and/or consents required to establish the rights to COG and NCCF stated in this Agreement. Failure to comply with this paragraph shall constitute a material breach of this Agreement entitling COG (or NCCF on COG’s behalf) 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.
17. 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

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the extent possible, the legal, regulatory, policy, and ethical requirements of the United States shall apply.

18. 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 NCCF on COG’s behalf), or other activity covered by or referenced in this agreement. Further, the RECIPIENT and PRINCIPAL INVESTIGATOR agree to provide COG (and/or NCCF) 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.
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. THIS AGREEMENT IS PROVIDED FOR CELL LINES AND XENOGRAFTS THAT ARE TO BE PLACED OR ARE ON THE OPEN DISTRIBUTION LIST. FOR OTHER CELL LINES OR XENOGRAFTS, PLEASE USE THE MATERIALS TRANSFER AGREEMENT (MTA) FOR CELL LINES OR XENOGRAFTS NOT PLACED ON THE OPEN DISTRIBUTION LIST.**
24. RECIPIENT agrees that its employees, agents, staff, or representatives, which include its research personnel and PRINCIPAL INVESTIGATOR, are bound to terms which conform to the terms of this Agreement.

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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:

Children’s Oncology Group Date
Name: _____
Title: _____

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Attachment A