**NATIONAL CANCER INSTITUTE PEDIATRIC PRECLINICAL IN VIVO TESTING PROGRAM**

**MATERIAL TRANSFER AGREEMENT**

The NCI-supported Pediatric **P**reclinical **i**n **V**ivo **T**esting Program (PIVOT or NCI Pediatric PIVOT) is a comprehensive program to systematically evaluate new agents against childhood solid tumor and leukemia models. The PIVOT is funded through a National Cancer Institute (NCI) cooperative agreement with each of the participating institutions and the Coordinating Center. Testing occurs at one or more of the following institutions (“Institutions”) with PIVOT investigators (“Institution’s PIVOT Investigator” or “Investigator”): Ann & Robert H. Lurie Children’s Hospital of Chicago (Xiaonan Li), Children’s Cancer Institute Australia (Richard Lock), The Children’s Hospital of Philadelphia (Yael Mosse), University of Texas, MD Anderson Cancer Center (Rickard Gorlick), Sloan Kettering Institute for Cancer Research (Filemon Dela Cruz), St. Jude Children’s Research Hospital (Michael Dyer), and The University of Texas Health Science Center, San Antonio (Peter Houghton). General PIVOT operation and data analysis occur at the PIVOT Coordinating Center at Jackson Laboratory (Carol Bult). The Coordinating Center is also referred to as The Jackson Laboratory. The primary goal of the PIVOT is to identify new agents that have the potential for significant activity when clinically evaluated against selected childhood cancers. The terms of this Material Transfer Agreement are consistent with the above mentioned funding agreements.

NCI: National Cancer Institute, Division of Cancer Treatment and Diagnosis (DCTD)

Collaborator:

1. Collaborator agrees to transfer to NCI the following Research Material, which is proprietary and confidential to Collaborator for use in the PIVOT:

Research Material: , an initial supply of \_\_\_\_\_\_mg (g).

1. THE RESEARCH MATERIAL MAY NOT BE USED IN HUMANS. The Research Material will not be used (i) for commercial purposes, including for screening, production or sale, for which a commercialization license may be required or (ii) in any research in which a for-profit company (other than Collaborator) has rights or an option to obtain rights, including the right to obtain access to data or results. Coordinating Center and the PIVOT Institutions that receive Research Material from NCI under this Agreement agree to comply with all Federal rules and regulations applicable to the Research Project and the handling of the Research Material.
2. The Research Material will be provided for use by PIVOT Investigators solely in connection with the following research project ("Research Project") described with specificity as follows (use an attachment page if necessary). No testing will be conducted by Coordinating Center.

This Research Material will be used for preclinical studies to evaluate the Research Material against *in vivo* panels of pediatric tumors including neuroblastoma, brain tumors, osteosarcoma, soft tissue sarcomas, Ewing family tumors, Wilms tumor, rhabdoid tumor, models of acute lymphoblastic leukemia, and other cancers as appropriate using SCID or other immunodeficient mice strains. Additional studies may be conducted to determine the sensitivity *in vitro* of cell lines representing many of these same tumor types, and pharmacokinetic and pharmacodynamic testing may be used to further explore mechanism of action and mechanism of resistance. Research project is detailed in the attached hereto as Appendix A. All activities carried out by the Parties under the Collaboration will be governed by this Agreement and the terms specified in a Research Project Plan.

1. Neither NCI, Coordinating Center, Institution, Institutions’ PIVOT Investigators, nor other Institution employees or agents who have access to Research Material from NCI under this Agreement shall (a) make any complements, analogs, conjugates, derivatives or modifications of the Research Material or (b) sequence, analyze, or otherwise determine the chemical structure or physical properties of the Research Material, to the extent such structure or properties are not already publicly known or expressly provided for in the Research Project description; and if Institution, Institution’s PIVOT Investigator, or Institution employee or agent does so in violation of the foregoing, then Coordinating Center and Institution hereby agree that all such complements, analogs, conjugates, derivatives, modifications, and sequences are Unauthorized Inventions as defined in Section 12 and shall be treated in accordance with the provisions of that section.
2. The Research Material is proprietary and confidential to Collaborator. Collaborator has agreed to allow NCI to make its proprietary compound available to Institutions’ PIVOT Investigators solely for use in furtherance of this Research Project. No license grant to or assignment of interest in the Research Material, express or implied, by estoppel or otherwise is intended or shall be construed by Collaborator’s agreement to provide Research Material for the Research Project. NCI and Coordinating Center may distribute the Research Material only to PIVOT Investigators at Institutions who have signed MTAs with the NCI consistent with the terms of this Agreement and solely for use in furtherance of the Research Project. When the Research Project is completed, NCI and Coordinating Center will oversee the lawful disposal of the Research Material by the Institution’s PIVOT Investigator (with certification of such destruction provided to Collaborator), unless directed otherwise by Collaborator.
3. The Research Material IS BEING SUPPLIED TO NCI BY THE COLLABORATOR AND THEREAFTER BY NCI TO INSTITUTIONS WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. Collaborator makes no representations that the use of the Research Material will not infringe any patent or proprietary rights of third parties. Collaborator agrees to hold NCI, Coordinating Center and Institutions harmless and to indemnify NCI, Coordinating Center and Institutions for all liabilities, demands, damages, expenses and losses arising out of Collaborator’s use for any purpose of the data resulting from the Research Project. NCI, as an agency of the United States, assumes responsibility for any liabilities, damages, losses and costs incurred in connection with NCI’s use, handling, storage, transfer, or disposal of the Research Material only to the extent provided under the Federal Tort Claims Act, 28 U.S.C. Ch. 171.
4. Updates and results of the Research Project will be provided exclusively and in confidence to the NCI and the PIVOT Steering Committee (NCI staff and Institution’s PIVOT Investigators and Coordinating Center staff involved in PIVOT). NCI agrees to provide Collaborator with updates and results of the Research Project using the Research Material following Steering Committee’s receipt of such updates and results and will inform Collaborator promptly of any significant results that arise from such Research Project. NCI and Collaborator agree that, subject to the publication rights under Section 11 of this Agreement, each Party shall keep the research results confidential until the results are published by the NCI, Coordinating Center and PIVOT Institutions in accordance with Section 11 of this Agreement, and that Collaborator and its affiliates and agents are hereby granted the right to use, without further consideration, all data and results generated under this Research Project for any lawful purpose, including for Collaborator’s own analyses and for use in regulatory or intellectual property filings. Collaborator agrees that from time to time, NCI will disclose the results to selected childhood cancer clinicians in order to assist their planning of clinical trials of anti-cancer agents. All selected childhood cancer experts and clinicians who need to have access to the Research Project results are under an obligation of confidentiality no less restrictive than in this Agreement.
5. The undersigned Collaborator and NCI expressly certify and affirm that the contents of any statements made herein are truthful and accurate.
6. This Agreement shall be construed in accordance with Federal law as applied by the Federal courts in the District of Columbia.
7. To the extent permitted by law, NCI agrees to treat in confidence, for a period of five (5) years from the date of its disclosure, any of Collaborator’s written information about the Research Material that is/are stamped "CONFIDENTIAL" (“Confidential Information”), except for information that NCI can clearly demonstrate by competent written proof was previously known to NCI or that is or becomes publicly available without breach of this Agreement by NCI or which is disclosed to NCI without a confidentiality obligation by a third party having a lawful right to do so or is independently developed by Institution’s personnel who have not had access to Confidential Information as demonstrated by competent written proof, or is required to be disclosed by law. Any oral disclosures from Collaborator to NCI of Confidential Information shall be summarized in writing within thirty (30) days after the date of the oral disclosure. All Confidential Information shall be used solely in furtherance of the Research Project and not for any other purpose.
8. Collaborator agrees that NCI, Coordinating Center and PIVOT Institutions may publish the data and results generated under the Research Project in peer-reviewed scientific journals or present those data and results at academic symposia or similar professional meetings in accordance with the following provisions. Such public disclosure may be made only after Collaborator has had forty-five (45) days to review the proposed disclosure to determine if it includes any Confidential Information or patentable invention, except when a shortened time period under court order or the Freedom of Information Act pertains. To ensure Collaborator’s review of proposed disclosure, NCI will provide a copy of the proposed disclosure to Collaborator not less than forty-five (45) days prior to submission of a paper for publication and not less than seven (7) days prior to submission of an abstract for publication. In all oral presentations or written publications concerning the Research Project, NCI, Coordinating Center and PIVOT Investigators will acknowledge Collaborator’s contribution of the Research Material unless requested otherwise.
9. All Institutions participating in the PIVOT have signed Material Transfer Agreements (MTAs) (web site: <https://ctep.cancer.gov/industryCollaborations2/default.htm>) with the NCI for the transmittal of Collaborator’s Research Material to Institutions. The Coordinating Center has signed a Collaboration Agreement with NCI for carrying out its PIVOT activities including data analysis. Said MTAs with Institutions and Collaboration Agreement with Coordinating Center include the Intellectual Property Option (“IP Option”) to Collaborator offering Collaborator first rights of negotiation to Institutions’ and Coordinating Center’s inventions, and publication provisions consistent with the terms and obligations of this Agreement. The terms of the Intellectual Property Option (“IP Option”) to Collaborator as described at: <https://ctep.cancer.gov/branches/rab/intellectual_property_option_to_collaborators.htm>. See also: The Federal Register, Vol. 76, No. 48, pages 13404-13410 (2011) (<https://www.gpo.gov/fdsys/pkg/FR-2011-03-11/pdf/FR-2011-03-11.pdf>).
10. This Agreement constitutes the entire agreement and understanding of the parties and supersedes any prior agreements, promises or understandings, written or verbal, relating to the subject matter hereof. This Agreement may not be changed or supplemented, nor may any provision or the benefit thereof be waived, except by a writing duly signed by all parties.
11. Each party represents to the other that (a) it has the full power and authority, and has taken all necessary actions and has obtained all necessary authorizations, licenses, consents and approvals required, to execute and perform this Agreement, (b) is not bound by or subject to any law that would conflict with, prohibit or interfere with the performance of its obligations hereunder, and (c) neither party is nor shall become party during the term of this Agreement to any agreement, arrangement, joint venture, collaboration, competitive project, or other dealing whatsoever with any other person or body that would or might affect, conflict with or prejudice this Agreement or the rights of either party under it.
12. This Agreement shall terminate XXX (X) years from the date of the final signature. Section 4, 5, 6, 7, 9, 10, 11, 12, 15 shall survive the termination for the period provided therein.

**Signatures Begin on the Next PageSIGNATURES**

**COLLABORATOR**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | |  |  | |
| **Signature** | |  | **Date** | |
| Printed Name: |  | | |  |
| Title: |  | | |  |

Collaborator’s Mailing Address

(please provide information)

**NATIONAL CANCER INSTITUTE:**

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| --- | --- | --- |
|  |  |  |
| Jason V. Cristofaro, J.D., Ph.D.  Intellectual Property Program Manager |  | **Date** |

Please address all correspondence related to this agreement to Dr. Zhang at the following address:

Jianqiao Zhang, Ph.D.

Regulatory Affairs Branch

Cancer Therapy Evaluation Program

DCTD, NCI, NIH

9609 Medical Center Dr., Rm. 5-W534

Rockville, MD 20850 (Fed Ex only)

(240) 276-6580 tel.

Any false or misleading statements made, presented, or submitted to the Government, including any relevant omissions, under this Agreement and during the course of negotiation of this Agreement are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§ 3801‑3812 (civil liability) and 18 U.S.C. § 1001 (criminal liability including fine(s) and/or imprisonment).

Appendix A

Research Plan