**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”): St. Jude Children’s Research Hospital (Michael Dyer), University of Texas, MD Anderson Cancer Center (Rickard Gorlick), University of Texas Health Science Center, San Antonio (Peter Houghton), Sloan Kettering Institute for Cancer Research (Filemon Dela Cruz), Ann & Robert H. Lurie Children’s Hospital of Chicago (Xiaonan Li), University of South Wales (Richard Lock), and Children’s Hospital of Philadelphia (Yael Mosse). 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 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)

Institution:

Institution’s PIVOT Investigator:

 1. NCI agrees to transfer to the PIVOT Investigator and the Institution Research Material(s) provided by NCI collaborators (“Collaborator(s)”). The Research Material(s) are provided to DCTD, NCI for the PIVOT under Material Transfer Agreements between NCI Collaborators and NCI. For purpose of Section 9 and Section 12 of this Agreement, if applicable, Collaborator shall also mean its affiliates, its agents, its licensee(s) of the Research Material and its business partner(s) co-developing the Research Material.

2. THE RESEARCH MATERIAL(S) MAY NOT BE USED IN HUMANS. The Research Material(s) will only be used for research purposes by Institution's PIVOT Investigator and staff members in his laboratory, for the research project described below, under suitable containment conditions. The Research Material(s) 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 the data or results. Institution agrees to comply with all Federal rules and regulations applicable to the research project described below and the handling of the Research Material(s). Further, Institution and PIVOT Investigator agree to comply with all applicable federal regulations and National Institutes of Health policies relating to the use and care of the laboratory animals.

3. The Research Material(s) will be used by Institution's PIVOT Investigator solely in connection with the following research project ("Research Project") described with specificity as follows:

This Research Material(s) 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. Institutions will use genetically characterized pediatric cancer models to develop a rigorous preclinical testing program to generate reliable data that can be used to inform development of new and more effective treatments for children with cancer. 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.

 4. Institution, Institution’s PIVOT Investigator and other Institution staff members in PIVOT Investigator’s laboratory shall not (a) make any complements, analogs, conjugates, derivatives or modifications of the Research Material(s) or (b) sequence, analyze, or otherwise determine the chemical structure or physical properties of the Research Material(s), to the extent such structures or properties are not already publicly known or expressly provided for in the Research Project; and if Institution, Institution’s PIVOT Investigator or staff members in his/her laboratory does so in violation of the foregoing, then Institution hereby agrees that all such complements, analogs, conjugates, derivatives modifications, and sequences are Unauthorized Inventions as defined in Section 12 hereof and shall be treated in accordance with the provisions of that section.

 5. The Research Material(s) are proprietary and confidential to Collaborator. Collaborator has agreed to allow NCI to make its proprietary compound(s) available to Investigator and Institution solely for use in furtherance of this Research Project. No license grant to or assignment of interest in Research Materials, express or implied, by estoppel or otherwise is intended or shall be construed by Collaborator’s agreement to provide Research Material(s) for the Research Project. Institution's PIVOT Investigator agrees to retain control over the Research Material(s) and further agrees not to transfer the Research Material(s) to other people not under his direct supervision without advance written approval of NCI after consultation with Collaborator. NCI shall obtain Collaborator’s consent for any such request. Collaborator reserves the right to distribute the Research Material to others and to use it for its own purposes. When the Research Project is completed, Institution’s PIVOT Investigator will lawfully dispose of the Research Material(s) as directed by NCI (with certification of such destruction provided to NCI).

6. The Research Material(s) are being supplied to Institutions by the Collaborator through NCI with no warranties, express or implied, including any warranty of merchantability or fitness for a particular purpose. NCI and Collaborator(s) make no representations that the use of the Research Material(s) will not infringe any patent or proprietary rights of third parties. Collaborator has agreed to hold Coordinating Center and participating PIVOT Institutions harmless and to indemnify Coordinating Center and participating PIVOT 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. Results of the Research Project disclosed by NCI to Collaborator are disclosed with no warranties, express or implied, including any warranty of merchantability or fitness for a particular purpose. Coordinating Center and Institutions make no representations that the use of the results will not infringe any patent or proprietary rights of third parties. Institutions assume sole responsibility for any liabilities, damages, losses and costs incurred in connection with Institution’s use, handling, storage, transfer, or disposal of the Research Material(s), except when such liabilities, damages, losses and costs arise from the gross negligence or willful misconduct of the Collaborator.

7. Subject to the rights set out in Section 12, Institution has the right to retain title to Institution Inventions as defined in Section 12. Institution agrees not to claim, infer, or imply endorsement by the Government of the United States of America (hereinafter referred to as "Government") of the Research Project, the institution or personnel conducting the Research Project or any resulting product(s). Unless prohibited by law from doing so, Institution agrees to hold the Government and Collaborator(s) harmless and to indemnify the Government and Collaborator(s) for all liabilities, demands, damages, expenses and losses arising out of Institution's use for any purpose of the Research Material(s), except when such liabilities, demands, damages, expenses or losses arise from the gross negligence and/or willful misconduct of the Collaborator.

8. NCI and Institution expressly certify and affirm that the contents of any statements made herein are truthful and accurate.

 9. Institution agrees to confidentially inform NCI, the Coordinating Center and the PIVOT Steering Committee (NCI staff, Institution’s PIVOT Investigators and Jackson Laboratory staff involved in PIVOT) promptly of any significant results and regularly of testing results that arise from such Research Project so that NCI may promptly forward such results and notification to Collaborator in confidence.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. The Institution, PIVOT Investigator, and NCI agree that, subject to publication rights under Section 11, they shall keep the research results confidential and that Collaborator is hereby granted the right to use, without further consideration, all data and results generated under this Research Project for any legitimate business purpose, including for Collaborator’s own analyses and for use in regulatory or intellectual property filings.

 10. To the extent permitted by law, Institution agrees to treat in confidence, for a period of five (5) years from the date of its disclosure, any of NCI's or Collaborator’s written information about the Research Material(s) that is/are stamped "CONFIDENTIAL" (“Confidential Information”) except for information that Institution can clearly demonstrate by competent written proof was previously known to Institution or that is or becomes publicly available without breach of this Agreement by Institution or which is disclosed to Institution 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 NCI to Institution of Confidential Information shall be summarized in writing within thirty (30) days after the date of the oral disclosure and marked “Confidential”. All Confidential Information shall be used solely in furtherance of the Research Project and not for any other purpose.

 11. Collaborator agrees that Institution or PIVOT Investigator may publish 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. In all oral presentations or written publications concerning the Research Project, Institution’s PIVOT Investigator will acknowledge Collaborator’s contribution of the Research Material(s) and NCI’s funding as well as other source of funding, if any, unless requested otherwise. 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 information, except when a shortened time period under court order or the Freedom of Information Act pertains. To ensure Collaborator’s review of the proposed disclosure, Institution will provide a confidential copy of the proposed disclosure to NCI not less than sixty (60) days prior to submission of such proposed disclosure for publication. Abstracts and other presentations must be provided to NCI in sufficient time to allow Collaborator at least ten (10) days to review any planned submission. Institution agrees not to submit proposed disclosures for publication until written notification from NCI of approval to do so; Institution must check with NCI to confirm that the review period has elapsed before submitting proposed disclosures for publication. If NCI or Collaborator has provided comments, Institution must address comments prior to submission. If requested in writing by the NCI, pursuant to a request by the Collaborator, Institution shall delete, or cause to be deleted, any Confidential Information; or withhold, or shall cause to be withheld, the proposed disclosure for an additional forty-five (45) days to allow the Collaborator to protect its confidential information or to cooperate with Institution in protecting the parties proprietary interests in the Institution Inventions. Failure by Institution to comply with the provisions of this Section 11 will constitute a violation of this Agreement and, at Collaborator’s request to NCI, may result in termination of all rights under this Agreement. Institution agrees not to submit proposed disclosures for publication without written notification from NCI of approval to do so.

12. Intellectual Property

* + - 1. Institution will retain title to any patent or other intellectual property rights in inventions made by its employees in the course of the Research Project.
			2. Institution agrees to notify Collaborator and Collaborator upon the filing of any patent applications related to research with the Research Material and abide by 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>).
			3. The Parties agree that the term “Institution” in the IP Option refers to the Institution under this Agreement. Any reference to an exclusive option regarding an invention directed to more than one Research Material is understood by Institution to be co-exclusive with respect to the applicable Collaborators whose Research Material(s) are claimed by such inventions.  In the event of a conflict in the IP Option language between the foregoing Federal Register notice and ctep.cancer.gov web site, the Federal Register notice will govern.

13. The failure of Institution or Institution’s PIVOT Investigator to comply with Sections 2, 3, 4, 5, 9, 10, 11 or 12 shall authorize NCI to terminate Institution’s rights under this Agreement and shall require Institution’s PIVOT Investigator to return immediately any Research Material(s) provided under this Agreement to NCI.

14. 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.

15. 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.

16. This Agreement shall terminate six (6) years from the date of the last signature. Sections 4, 5, 6, 7, 11 and 12 shall survive the termination. Section 10 shall survive the termination for the period provided therein.

**Signatures Begin on the Next PageSIGNATURES**

**INSTITUTION**

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

**INVESTIGATOR**

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|  |  |  |
| **Signature** |  | **Date** |
| Name: |  |  |
| Title: |  |  |

**Institution’s Mailing Address**

**FOR 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).