

MATERIAL TRANSFER AGREEMENT

The NCI-supported Pediatric Preclinical Testing Program (PPTP) is a comprehensive program to systematically evaluate new agents against childhood solid tumor and leukemia models. The PPTP is supported through a National Cancer Institute (NCI) research contract. The primary goal of the PPTP 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 contractual agreements.

NCI: National Cancer Institute, Division of Cancer Treatment and Diagnosis

Institution:

Institution's PPTP Investigator:

1. NCI agrees to transfer to the Pediatric Preclinical Testing Program (PPTP) Investigator the following material provided by _____ ("Collaborator"): _____ ("Research Material"), which is proprietary and confidential to Collaborator. The Research Material is provided to DCTD, NCI for the PPTP under a Material Transfer Agreement between NCI Collaborator 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 MAY NOT BE USED IN HUMANS. The Research Material will only be used for research purposes by Institution's PPTP Investigator and staff members in his/her laboratory, for the research project described below, under suitable containment conditions. 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 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. Further, Institution and PPTP 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 will be used by Institution's PPTP Investigator solely in connection with the following research project ("Research Project") described with specificity as follows:

This Research Material will be used for preclinical studies to evaluate the Research Material against panels of pediatric tumors comprised of neuroblastoma, brain tumors, osteosarcoma, soft tissue sarcomas, Ewing family tumors, Wilms tumor, Rhabdoid tumor and models of acute lymphoblastic leukemia, in SCID or athymic nude mice. The *in vivo* primary screen comprises various tumor models and represents many of the cancer types that occur in children. Additional studies will determine the sensitivity *in vitro* of cell lines representing many of these same tumor types.

4. Institution, Institution's PPTP Investigator and other Institution staff members in PPTP Investigator's laboratory shall not (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 structures or properties are not already publicly known or expressly provided for in the Research Project; and if Institution, Institution's PPTP 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 Collaborator Inventions as defined in Section 12 hereof and shall be treated in accordance with the provisions of that section.

5. The Research Material is 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 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. Institution's PPTP Investigator agrees to retain control over the Research Material and further agrees not to transfer the Research Material to other people not under her or 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 PPTP Investigator will lawfully dispose of the Research Material as directed by NCI (with certification of such destruction provided to NCI).

6. The Research Material is provided as a service to the research community. IT IS BEING SUPPLIED TO INSTITUTION 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 make no representations that the use of the Research Material will not infringe any patent or proprietary rights of third parties. Collaborator has agreed to hold Institution and participating PPTP institutions harmless and to indemnify Institution and participating PPTP 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. Institution makes no representations that the use of the results will not infringe any patent or proprietary rights of third parties. Institution assumes 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, 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 harmless and to indemnify the Government and Collaborator for all liabilities, demands, damages, expenses and losses arising out of Institution's use for any purpose of the Research Material, 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 inform NCI at least quarterly or more frequently as specified by contractual arrangements of the results of the Research Project using the Research Material in accordance with this section and will confidentially inform NCI promptly of any significant results that arise from such Research Project so that NCI may promptly forward such results and notification to Collaborator in confidence. Results of the Research Project shall be provided exclusively and in confidence to the NCI and the PPTP Steering Committee (NCI staff and selected childhood cancer

experts who advise NCI staff concerning the Research Material evaluated by the PPTP). 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, PPTP 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 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. For the avoidance of any doubt, the identity or identification of the Research Material, any non-public code number or designation associated with the Research Material and any link between the Research Material as identified in the Research Project and the Research Material as they may otherwise be known or identified shall all constitute Confidential Information of the Collaborator. 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 PPTP 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 PPTP Investigator will acknowledge NCI's and Collaborator's contribution of the Research Material 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. Institution agrees to notify NCI and Collaborator upon the filing of any patent applications related to research with this Research Material under this Agreement and abide by the following terms of the Intellectual Property Option to Collaborator (the current NCI Intellectual Property Option to Collaborator or any updates can also be found at <http://ctep.cancer.gov/industryCollaborations2/>):

Institution agrees to promptly notify the NCI and Collaborator in writing of any inventions, discoveries or innovations made by the Institution's Investigator or any other employees or agents of Institution, whether patentable or not, which are conceived or first actually reduced to practice pursuant to the Research Project.

For inventions described in patent disclosures that claim the use and/or the composition of the Research Material(s) (Section A Inventions), Institution agrees to grant to Collaborator(s): (i) a royalty-free, worldwide, non-exclusive license for commercial purposes with the right to sub license to affiliates or collaborators working on behalf of Collaborator for Collaborator's development purposes; and (ii) a time limited first option to negotiate an exclusive, or co-exclusive, if applicable, world-wide, royalty bearing license for commercial purposes, including the right to grant sub licenses, subject to any rights of the Government of the United States of America, on terms to be negotiated in good faith by the Collaborator(s) and Institution. If Collaborator accepts the non-exclusive commercial license, the Collaborator agrees to pay all out of pocket patent prosecution and maintenance costs which will be pro-rated and divided equally among all licensees. If Collaborator obtains an exclusive commercial license, in addition to any other agreed upon licensing arrangements such as royalties and due diligence requirements, the Collaborator agrees to pay all out of pocket patent prosecution and maintenance costs. Collaborator(s) will notify Institution, in writing, if it is interested in obtaining a commercial license to any Section A Invention within three (3) months of Collaborator's receipt of a patent application or six (6) months of receipt of an invention report notification of such a Section A Invention. In the event that Collaborator fails to so notify Institution, or elects not to obtain an exclusive license, then Collaborator's option expires with respect to that Section A Invention, and Institution will be free to dispose of its interests in accordance with its policies. If Institution and Collaborator fail to reach agreement within ninety (90) days, (or such additional period as Collaborator and Institution may agree) on the terms for an exclusive license for a particular Section A Invention, then for a period of three (3) months thereafter Institution agrees not to offer to license the Section A Invention to any third party on materially better terms than those last offered to Collaborator without first offering such terms to Collaborator, in which case Collaborator will have a period of thirty (30) days in which to accept or reject the offer. If Collaborator elects to negotiate an exclusive commercial license to a Section A Invention, then Institution agrees to file and prosecute patent application(s) diligently and in a timely manner and to give Collaborator an opportunity to comment on the preparation and filing of any such patent application(s). Notwithstanding the above, Institution is under no obligation to file or maintain patent prosecution for any Section A Invention.

For those inventions not covered by Section A, but are nevertheless conceived or first actually reduced to practice pursuant to the Research Project and to those inventions that are conceived or first actually reduced to practice pursuant to the Research Project that use non-publicly available clinical data or specimens from patients treated with the NCI-provided Research Material (including specimens obtained from NCI DCTD-funded tissue banks) (Section B Inventions), Institution agrees to grant the following to the collaborator: (i) a paid-up nonexclusive nontransferable, royalty-free, world-wide license to all Section B Inventions for research purposes only; and (ii) a nonexclusive, royalty-free, world-wild license to (a) disclose Section B Inventions to a regulatory authority when seeking marketing authorization of the Research Material and (b) disclose Section B Inventions on a product insert or other promotional material regarding the Research

Material after having obtained marketing authorization from a regulatory authority. Notwithstanding the above, Institution is under no obligation to file or maintain patent prosecution for any Section B Invention.

For all Section A and Section B Inventions, regardless of Collaborator's decision to seek a commercial license, Institution agrees to grant Collaborator a paid-up, nonexclusive, royalty-free, world-wide license for research purposes only. Institution retains the right to make and use any Section A Invention for all non-profit research, including for educational purposes and to permit other educational and non-profit institutions to do so.

Institution agrees, at Collaborator's request and expense, to grant to Collaborator a royalty-free exclusive or co-exclusive license to inventions made by Institution's Investigator(s) or any other employees or agents of Institution, which are or may be patentable or otherwise protectable, as a result of research utilizing the Research Material(s) outside the scope of the Research Project (Unauthorized Inventions). Institution will retain a non-exclusive, non-sub-licensable royalty free license to practice the invention for research use purposes.

Institution agrees to promptly notify NCI DCTD (NCICTEPpubs@mail.nih.gov) and Collaborator(s) in writing of any Section A Inventions, Section B Inventions, and Unauthorized Inventions upon the earlier of: (i) any submission of any invention disclosure to Institution of a Section A, Section B, or Unauthorized Invention, or (ii) the filing of any patent applications of a Section A, Section B, or Unauthorized Invention. Institution agrees to provide a copy of either the invention disclosure or the patent application to the Collaborator and to NCI DCTD which will treat it in accordance with 37 CFR Part 401. These requirements do not replace any applicable reporting requirements under the Bayh-Dole Act, 35 USC 200-212, and implementing regulations at 37 CFR Part 401.

13. The failure of Institution or Institution's PPTP 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 PPTP Investigator to return immediately any Research Material 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 three (3) 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 Page

SIGNATURES

INSTITUTION

Date

XXXXXX

Date

XXXXXX

Institution's Official and Mailing Address:

XXXXXX

NATIONAL CANCER INSTITUTE

Date

Thomas P. Clouse, J.D., M.F.S., CLP
Technology Transfer Specialist
Technology Transfer Center, NCI

Date

Sherry Ansher, Ph.D.
Associate Chief, Research and Development Agreements

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).