

**NATIONAL CANCER INSTITUTE
EXPERIMENTAL THERAPEUTICS PROGRAM (NExT)
MATERIAL TRANSFER AGREEMENT**

This transfer is from the National Cancer Institute Experimental Therapeutics Program (NExT). The mission of NExT is to advance clinical practice and bring improved therapies to patients with cancer by partnering with selected applicants to facilitate the milestone-driven progression of new anticancer drugs and imaging agents towards clinical evaluation and registration. NCI-approved NExT projects are provided access to the NCI's drug discovery, preclinical, and clinical development resources.

Once an applicant's project is selected, a project management team will be formed. The project management team will include individuals from the institution submitting the drug or agent, the relevant National Cancer Institute staff, and the appropriate National Cancer Institute contractor staff. The project management team will set milestones, timelines, and conditions for continuation or termination of the project. A project management officer from the National Cancer Institute will ensure that the timelines and milestones are being met and recommend to the NExT Senior Advisory Committee (SAC) continuation, modification, or termination of the Research Project. A detailed description of NExT is available at <http://next.cancer.gov/>.

This Agreement is made by and between the National Cancer Institute, an agency of the United States Government (herein after referred to as "NCI") and _____ (herein after referred to as "Institution"). Collectively or individually, the NCI and the Institution shall also be referred to as "Parties" or "Party." The terms and conditions of this Agreement are as follows:

1. Institution agrees to transfer to NCI the following materials and/or data "Research Material":
2. The above Research Material is the property of the Institution and will be used in connection with the following NExT-approved research project ("Research Project"). The details of the Research Project are set forth in Proposal #:

Cycle ____ Proposal# ____ entitled _____

The Research Material will be used in support of the Research Project. Preclinical and clinical drug development resources available through NExT on a milestone basis may include, but are not limited to, the following:

- Evaluation of analogs for lead selection;
 - Current Good Manufacturing Practice (cGMP) production of the Research Material;
 - Modulation of a molecular target;
 - Whole-body animal imaging for tissue distribution and target binding affinity;
 - Pharmacokinetics (PK) and pharmacodynamic (PD) assay development and validation;
 - Animal PK and PD and efficacy; and
 - IND-directed toxicology studies on the Research Material.
3. The NCI agrees to transfer to the Institution research data ("Project Data") and reasonable quantities of any materials ("Project Materials") generated by the NCI or its contractors that is developed during the conduct of the Research Project. Institution will be free to utilize Project Data and Project Materials for its own purposes, including commercial development, consistent with its obligations under this Agreement. If Institution designates a third party to receive all or part of the Project Materials and Project Data, then the Institution will ensure that such third party complies with the

terms of this Agreement. The NCI has the express right to use the Research Material, Project Data, and Project Materials in NCI's clinical or non-clinical research development activities. NCI will also have the right to provide such Project Data and Project Materials, subject to availability, to other non-profit institutions upon request, subject to the terms of an appropriate agreement, including for use in research in human subjects. Use of any Project Materials will be in accordance with all Federal statutes and regulations, NIH policy, or other national law. Any transfer of Project Data and Project Materials to Institution for use in support of research in human subjects, within the meaning of 45 C.F.R. Part 46 and 21 C.F.R. Part 50, is subject to the terms of the Clinical Addendum, as referenced herein. In the event the Parties wish to collaborate in a joint research project for the conduct of clinical studies with the Research Material, Project Materials or Project Data, a new agreement with provisions for joint clinical development will be executed.

4. In all oral presentations or written publications concerning the Research Project, each Party will acknowledge the other Party's contribution to the Research Project of Research Material, Project Materials, or Project Data unless requested otherwise. The Institution will acknowledge NCI's contribution as follows:

"This project has been supported through the National Cancer Institute Experimental Therapeutics Program (NEXT)."

5. To the extent permitted by law, each Party agrees to treat in confidence, for a period of three (3) years from the date of the disclosure, any of the disclosing Party's written information about the Research Project that is stamped "CONFIDENTIAL" or any of the disclosing Party's oral information about the Research Project that is identified in writing as "CONFIDENTIAL" within thirty (30) days of the oral disclosure ("Confidential Information"). However, any of the Project Data, including pre-clinical data, which has been identified by the NCI or its contractor or sub-contractor as data that is required to be submitted to the FDA in an IND will be kept confidential indefinitely or until published.

The obligations of a Party shall not extend to any part of the Confidential Information of the other Party:

- (a) that can be demonstrated to have been in the public domain or publicly known at the time of disclosure; or
 - (b) that can be demonstrated to have been in the possession of or that can be demonstrated to have been readily available to such Party from another source prior to the disclosure; or
 - (c) that becomes part of the public domain or publicly known by publication or otherwise, not due to any unauthorized act by such Party; or
 - (d) that can be demonstrated as independently developed or acquired by such Party without reference to or reliance upon such Confidential Information; or
 - (e) that is required to be disclosed by law or a court or administrative body of competent jurisdiction.
6. The Parties may publish or otherwise publicly disclose the results of the Research Project, however, before either Party submits a paper or abstract for publication or otherwise intends to publicly disclose information resulting from the Research Project, the other Party shall be provided thirty (30) days to review the proposed publication or disclosure or ten (10) days for any abstract to determine if it includes any Confidential Information, except when a shortened time period under court order of Freedom of Information Act pertains.

7. THIS RESEARCH MATERIAL IS BEING SUPPLIED TO THE NCI WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. Institution warrants that it has the right to supply Research Material to NCI for the Research Project, and to the Institution's knowledge, there are no encumbrances on the further clinical or commercial development of Research Material by Institution or by the NCI. THE PROJECT MATERIALS ARE BEING SUPPLIED TO THE INSTITUTION WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. No indemnification for any loss, claim, damage, or liability is intended or provided by any Party under this Agreement, except that the NCI, as an agency of the United States, assumes liability only to the extent as provided under the Federal Tort Claims Act (28 U.S.C. Chapter 171).
8. Normally, NCI will not acquire intellectual property rights to inventions made by its employees under NExT which are directed to the use of the Research Material. NCI will inform the Institution of any such inventions, and after consultation with the Institution, NCI will decide whether or not to file a patent application on any such invention. If NCI does file a patent application, the Institution will be given an opportunity to negotiate for a license in accordance with the procedures set forth in 37 CFR Part 404. NCI does not have the authority to grant research licenses in advance, but it is consistent with NIH's policies for Institution to use any patentable inventions that might result from this Research Project for non-profit research and teaching purposes at no cost to the Institution. Inventorship will be determined in accordance with U.S. patent law.
9. In exchange for the support provided by the NCI under the NExT Research Project, the U.S. Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced, throughout the world by or on behalf of the Government for research or other Government purposes, any inventions that may be developed by Institution under the Research Project. Any licenses granted by Institution to a third party shall provide for the rights granted to the Government under this Article.
10. In conducting a portion of the Research Project, it may be necessary for NCI to utilize the services of one or more of the NCI's contractors or subcontractors under a funding agreement as defined by 35 U.S.C. § 201(b):
 - a. Normally the contractor may elect and retain title to inventions developed under the contract under the provisions of the Bayh-Dole Act (35 U.S.C. § 200, et. seq.). Such NCI contractors have, as a term and condition of their contract, agreed to offer to the Institution a first option to negotiate a license to use inventions made using the Research Material.
 - b. Certain other NCI contractors or subcontractors may be subject to a Determination of Exceptional Circumstances (35 U.S.C. § 202(a)(ii)), through which their rights in inventions made using the Research Material may be assigned to the Government. Institution may then apply to NIH for a license to such inventions in accordance with 37 CFR Part 404.
 - c. In the event that it is necessary for NCI to transfer Research Material to a contractor not described in 11(a) or 11(b) to conduct a portion of the Research Project, the Institution will be notified so that the Parties may document the transfer of Research Material to

such contractor or subcontractor by the NCI, if applicable.

11. The Institution agrees not to claim, infer, or imply endorsement by the Government of the United States of America of the activities under this Agreement. Institution acknowledges that the access to any future NCI resources or programs will only be after approval by appropriate committees or NCI units.
12. NCI may unilaterally terminate this Agreement and the Clinical Addendum at any time by providing written notice to the Institution. The terms of Articles 3-12 and 15 shall survive early termination or expiration of this Agreement.
13. The undersigned expressly certify and affirm that the contents of any statements made herein are truthful and accurate.
14. This Agreement will expire three (3) years after the date of final signature. Said expiration date may be changed by mutual agreement and written Amendment of this Agreement.
15. If termination or expiration should occur under Article 12 or 14 above, Research Materials may be held by NCI for any use.

SIGNATURE PAGE FOLLOWS

For: National Cancer Institute

Date NCI Investigator and Title

Date Authorized Signatory for NCI and Title

NCIs Official and Mailing Address:

NCI Technology Transfer Center
6120 Executive Blvd. Suite 450
Rockville, MD 20852

For: Institution

Date Investigator and Title

Date Authorized Signatory for Institution and Title

Institution's Official and Mailing Address:

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).

Clinical Addendum to NExT Material Transfer Agreement

NCI is providing Project Materials and Project Data to Institution for Institution's use in support of research in human subjects. Institution agrees to the following clinical terms.

1. Project Data may include data, including pre-clinical data, which has been identified by the NCI or its contractor or sub-contractor as data that is required to be submitted to the FDA in an IND (collectively "**IND Data**"). Clinical Material shall mean Project Materials provided by NCI for use in support of research in human subjects.
2. The NCI must be assured that the Clinical Material and IND Data it develops are used, communicated and reproduced appropriately and completely. The Institution agrees to retain control over this Clinical Material and IND Data and further agrees not to transfer the Clinical Material or IND Data to a third party not under Institution's direct supervision, other than investigators participating in clinical trials under an active IND supporting the use of the Clinical Material, without prompt written notice to NCI. If Institution designates a third party to receive all or part of Clinical Material or IND Data then the Institution will ensure that such third party complies with the terms of this Agreement and has a written agreement consistent with the terms of this Agreement and Clinical Addendum.
 - a. Use of Clinical Material. The NCI is providing this Clinical Material for use in research in human subjects where an active IND is on file with the FDA or under an active foreign equivalent application on file with the appropriate foreign health authority. Upon completion of all research in human subjects using the Clinical Material, Institution may use any remaining Clinical Material for non-clinical research purposes only.
 - b. Use of IND Data in support of an IND. In order to ensure that the FDA or equivalent foreign health authority receives a complete data set for its review, Institution agrees to ensure that all IND Data, in its entirety, are included in a submitted IND or foreign health equivalent prior to the use of Clinical Material. Institution agrees to ensure that any third party to which Institution transfers IND Data provides written assurance that all such IND Data will be included in an IND and submitted to the FDA or foreign health equivalent. Upon request of NCI, Institution will provide the NCI with a copy of such written assurance before Institution shares or transfers the IND Data.
3. Appropriate Approvals for Use of Clinical Material. Institution agrees to ensure that all appropriate approvals are obtained, including from the FDA, the Office for Human Research Protections (OHRP), and an appropriate Institutional Review Board (IRB) and other applicable approvals as required by applicable Federal law, statutes, and regulation, including but not limited to, 45 C.F.R. Part 46 and 21 C.F.R. Part 50, or other national law of the respective study site, that govern the use of investigational agents in clinical trials. Institution will provide the NCI with copies of the FDA Acknowledgement Letter that the IND has been filed, any correspondence from the FDA relating to a possible Clinical Hold status on the IND or otherwise, and the signed IRB approval letter before the Clinical Material is shipped.
 - a. Use of Clinical Material and IND Data in Accordance with Applicable Regulations and

Institution Policies. Institution agrees that the use of the Clinical Material and IND Data will be in accordance with clinical protocols approved by the appropriate IRB under a filed IND at the FDA or corresponding foreign health authority. Institution agrees to submit all amendments to clinical protocols to the IRB and the FDA or corresponding foreign health authority.

- b. Use in accordance with Federal law. Institution agrees to ensure that the Clinical Material and IND Data are used in accordance with all Federal law, statutes, and regulations, including but not limited to, 45 C.F.R. Part 46 and 21 C.F.R. Part 50, or other national law of the respective study site, that govern the use of investigational agents in clinical trials.
4. Upon request of NCI, Institution agrees to provide all results of the research using the supplied Clinical Material and IND Data to NCI, including all publications and to provide NCI with copies of Annual Reports to the FDA or corresponding foreign health authority.
5. THIS CLINICAL MATERIAL, PROJECT MATERIALS, OR PROJECT DATA IS BEING SUPPLIED TO INSTITUTION BY THE NCI WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. NCI makes no representations that the use of the Clinical Material, Project Materials or Project Data will not infringe any patent or proprietary rights of third parties. Unless prohibited by law from doing so, Institution agrees to hold the Government of the United States of America (hereinafter referred to as "Government") harmless and to indemnify the Government for all liabilities, demands, damages, expenses and losses arising out of Institution's use for any purpose of the Clinical Material, Project Materials or Project Data.
6. The Clinical Material that is provided by NCI to the Institution will be used in accordance with this Agreement and Clinical Addendum or disposed of in accordance with Institution's policies, unless otherwise directed by NCI.