

National Cancer Institute Prevent Program

Material Transfer Agreement

This transfer is from the National Cancer Institute Division of Cancer Prevention PREVENT Program. The mission of the PREVENT Program is to enable and facilitate translation into the clinic of novel preventative interventions (small molecules, natural products, or biologicals) by partnering with successful applicants to facilitate the milestone-driven progression towards clinical evaluation and registration. Approved PREVENT projects are provided access to the NCI's drug discovery and preclinical and clinical development resources. A specific description of the PREVENT program is available at <http://prevention.cancer.gov/programs-resources/programs/prevent>. 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":

Approximately:

2. The above Research Material is the property of the Institution and will be used in connection with the following approved PREVENT research project ("Research Project") described with specificity as follows (use an attachment page if necessary):

Cycle __proposal __ entitled "_____"

NCI will conduct preclinical work in support of an Investigational New Drug Application (IND) for the Research Material. This preclinical work may include:

- 1) Evaluation of analogs for lead selection;
- 2) Current Good Manufacturing Practice (cGMP) production of the Research Material;
- 3) Modulation of a molecular target;
- 4) Whole-body imaging for tissue distribution and target binding affinity;
- 5) Pharmacokinetics (PK) and pharmacodynamic (PD) assay development and validation;
- 6) Animal PK and PD and efficacy; and
- 7) Other 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 their own purposes, including commercial development, consistent with their obligations under this Agreement. The NCI has the express right to use the Research Material, Project Data, and Project Materials in NCI's clinical research development activities. NCI will also have the right to supply such Project Materials, subject to availability, to other non-profit institutions upon request, subject to the terms of an appropriate agreement, including for use in clinical trials. Use of any Project Materials will be in accordance with all Federal statutes and regulations, NIH policy, or other national law.

4. In the event the Parties wish to collaborate in the conduct of clinical studies with the Research Material, Project Materials or Project Data, a new agreement with provisions for clinical development will be executed. In the event that only the Institution wishes to conduct clinical trials, an appropriate new agreement or Amendment to this Agreement for the transfer of clinical materials may be executed.

5. In all oral presentations or written publications concerning the Research Project, each Party will acknowledge the other Party's contribution to this 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, Division of Cancer Prevention (PREVENT)."

6. 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 this Research Project that is stamped "CONFIDENTIAL" or any of the disclosing Party's oral information about this 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 designated as IND data 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.

7. 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.

8. 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).

9. Normally, NCI will not acquire intellectual property rights to inventions made by its employees under PREVENT 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.

10. In exchange for the support provided by the NCI under the PREVENT Program, the NCI 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, Institution inventions developed during the Research Project. Any licenses granted by Institution to a third party shall provide for the rights granted to the Government under this Article.

11. 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 a contractor not described in 10(a) or 10(b) is going to be used in connection with the Research Project, the Institution will be notified so that the Parties may negotiate an Amendment to this Agreement to permit the use of such contractor or subcontractor by the NCI.

12. 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.

13. NCI may unilaterally terminate this Agreement at any time by providing written notice to the Institution. The terms of Articles 4,5,6,7,8,9,10,11,12,13,15 shall survive early termination or expiration of this Agreement.

14. The undersigned expressly certify and affirm that the contents of any statements made herein are truthful and accurate.

15. This MTA shall be construed in accordance with Federal law as applied by the Federal courts in the District of Columbia

16. 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.

SIGNATURE PAGE FOLLOWS

For: National Cancer Institute

Date NCI Investigator and Title

Date Authorized Signatory for NCI and Title

NCI Official and Mailing Address:

For: Institution

Date Investigator and Title

Date Authorized Signatory for Institution and Title

Institution 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).