

National Cancer Institute PREVENT Program

Collaboration Agreement

The mission of the National Cancer Institute's Division of Cancer Prevention (DCP) PREVENT Cancer Preclinical Drug Development Program (PREVENT) is to enable and facilitate translation into the clinic of novel preventative interventions (small molecules, natural products, or biologicals). NCI will actively partner with successful applicants to help them move their novel cancer preventive chemical or biological agents (singly or in combination) and biomarkers from the lab bench towards IND filing, proof-of-principle clinical testing, and registration or validation. 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 <https://prevention.cancer.gov/major-programs/prevent-cancer-preclinical>.

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 of this Agreement shall govern the collaboration between the Institution and NCI. 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"):
 - a. Are any of the Research Materials of human origin?
 Yes
 No
 - b. If "Yes" in a. above, were those Research Materials collected in accordance with 45 CFR Part 46?
 Yes (please provide Assurance number: _____)
 No
 Not Applicable (please explain: _____)
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:

The Institution will collaborate with NCI to conduct preclinical work in support of an Investigational New Drug Application (IND) based on the Research Project. In conducting a portion of the Research Project, NCI may 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). The preclinical work for the Research Project may include:

- a) Evaluation of analogs for lead selection;
 - b) Evaluation of vaccines for lead selection;
 - c) Current Good Manufacturing Practice (cGMP) production of the agent as specified in the PREVENT application;
 - d) Modulation of a molecular target;
 - e) Whole-body imaging for tissue distribution and target binding affinity;
 - f) Pharmacokinetics (PK) and pharmacodynamic (PD) assay development and validation;
 - g) Animal PK and PD and efficacy; or
 - h) Other IND-directed toxicology studies of the agent as specified in the PREVENT application.
3. The NCI is authorized to conduct the activities described herein pursuant to Sections 301, 402 and 410 of the Public Health Services Act [42 U.S.C. §§ 241, 282 and 285];
 4. 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 are developed during the conduct of the Research Project. The Institution will be free to utilize Project Data and Project Materials for the Institution's own purposes, including commercial development, consistent with their obligations under this Agreement.

Upon consultation with the Institution, the NCI may provide the Institution with Project Data in IND format. The Parties agree that any of the Project Data designated as IND data by NCI will be kept confidential between the Institution and NCI until either the IND data is published, or both Parties provide written consent to a release.

5. The Institution agrees NCI has the following express rights to use the Project Data, and Project Materials:
 - a) the right to use Project Data, and Project Materials for NCI's internal research use; and
 - b) the right to supply Project Materials, subject to availability, or Project Data to other non-profit institutions upon their request, subject to the terms of an appropriate agreement, including for use in clinical trials.

Use of any Project Materials or Project Data will be in accordance with all Federal statutes and regulations, NIH policy, or other U.S. national law.

6. 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.
7. In all oral presentations or written publications concerning the Research Project, including about the Research Materials, Project Materials or Project Data, each Party will acknowledge the other Party's contribution, unless requested otherwise. The Institution will acknowledge NCI's contribution as follows:

"This project has been conducted in cooperation with the National Cancer Institute, Division of Cancer Prevention, PREVENT Cancer Preclinical Drug Development Program (PREVENT)."

8. 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 Material that is stamped "CONFIDENTIAL" or any of the disclosing Party's oral information about this Research Material that is identified in writing as "CONFIDENTIAL" within thirty (30) days of the oral disclosure ("Confidential Information").

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.

Confidential Information excludes Project Data and information about Project Materials. The Parties will use reasonable efforts to keep the Project Data and information about Project Materials confidential until published or until a corresponding patent application has been filed, whichever occurs first.

9. 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 or the Freedom of Information Act pertains.

10. 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. The 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 the Institution or by the NCI. THE PROJECT MATERIALS AND PROJECT DATA ARE BEING SUPPLIED TO THE INSTITUTION WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.
11. Each Party shall be liable for any loss, claim, damage, or liability that said Party incurs as a result of its activities 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). No indemnification for any loss, claim, damage, or liability is intended or provided by any Party under this Agreement.
12. NCI will inform the Institution of any inventions made by its employees and contractors that are directed to the Research Material, 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 the 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.
13. In exchange for NCI's contributions 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, to any inventions developed by the Institution during the conduct of the Research Project. The Institution is free to license these inventions, given that any license agreement with a third-party provides for the rights granted to the Government under this Article.
14. 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) Typically, 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 apply to NCI for a license to such inventions in accordance with 37 CFR Part 404.

15. 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. The Institution acknowledges that access to any future NCI resources or programs will only be after approval by appropriate committees or NCI units.

16. NCI may unilaterally terminate this Agreement at any time by providing written notice to the Institution. The terms of Articles 3-16 shall survive early termination or expiration of this Agreement.

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

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

19. This Agreement will expire five (5) 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

ACCEPTED AND AGREED

FOR THE NATIONAL CANCER INSTITUTE

Authorized Signatory for NCI and Title

Date

Read and Understood by the NCI Investigator:

NCI Investigator and Title

Date

NCI Address for Notices Related to this Agreement:

Technology Transfer Center, NCI
9609 Medical Center Drive, Room 1E-530, MSC97
Rockville, MD 20850

FOR THE INSTITUTION

Authorized Signatory for Institution and Title

Date

Institution Investigator and Title

Date

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).