

**Memorandum of Understanding (MOU) for participation in the National
Cancer Institute - Center for Cancer Research (NCI-CCR)
Comparative Oncology Trial Consortium (COTC)**

The National Cancer Institute and _____ (hereinafter “COTC Member”) are the parties to this MOU.

A. Introduction and Background:

A central mission of the Center for Cancer Research (CCR), National Cancer Institute (NCI) is the development and delivery of novel cancer treatment strategies for cancer patients. A significant hurdle in the translation of information from the laboratory to the clinic is the availability of appropriate preclinical cancer models. Through a number of new initiatives created by the CCR, an essential infrastructure now exists to facilitate the translational research process. These efforts include the creation of the CCR– Comparative Oncology Program. The goal of this Program is to include naturally occurring cancers seen in pet animals into studies of cancer biology and drug development.

The NCI-CCR Comparative Oncology Program has established a **multi-center Comparative Oncology Trial Consortium (COTC)** to facilitate translational cancer research in pet animals through the development of shared reagents and infrastructure useful in the study of comparative cancer models. We are pleased that you and your institution have elected to participate in the NCI-CCR COTC.

The COTC will initiate pet animal trials in collaboration with NCI investigators, academic institutions and/or the pharmaceutical industry. These trials will be implemented through the collective caseloads of the consortium membership with trial oversight and data management provided by the CCR – Comparative Oncology Program. The results of these pet animal trials will be rapidly translated into the development plans for novel therapeutics, diagnostics, and prognostics for human cancer patients. The data generated through these studies will be available to COTC members to facilitate larger investigator-initiated pet animal trials that may further complement this translational process.

B. Definitions:

“*COTC*” means the Comparative Oncology Trial Consortium, a research consortium, led by the NCI-Comparative Oncology Program, consisting of NCI-CCR and all COTC Members assembled to conduct collaborative translational cancer research in pet animals. COTC may be dissolved at any time by and at the discretion of NCI-CCR.

“*COTC Member*” means a non-NCI third party qualified COTC institution which shall have access to the Test Article through the NCI.

“Confidential Information” means any existing data about the Test Article or Study Data, as further described in Article 7 of this Agreement, arising from use of Test Article in any Research Project. Any Confidential Information shall be appropriately noted in writing as “Confidential.” Any Confidential Information which is orally disclosed must be reduced to writing and marked “Confidential” by the disclosing party within thirty (30) days of such disclosure.

“NCI-CCR” means the National Cancer Institute, Center for Cancer Research.

“Protocol” means the formal, detailed description of the clinical evaluation of the Test Article to be conducted by the COTC Member, solely or in collaboration with other COTC members, and the NCI, under the Research Project. The Protocol defines both the Research Project PIs who are chiefly responsible for the Study Data and the rules for authorship. The Protocol is the property of the Provider and the NCI.

“Provider” means any entity which is contributing Test Articles to the COTC for use in a COTC-approved Research Project.

“Research Project” means a research project, including the Protocol and supporting investigations, for the study of Provider’s Test Article and which has been previously approved by the COTC, NCI-CCR, and Provider. The Research Project is to be described in the transfer agreement shown as Appendix B.

“Study Data” means any research results which arise from the Research Project and which are conducted by a COTC Member or the NCI-CCR.

“Test Article” means any material, device, methodology, or computer software, including any progeny, unmodified derivatives, or unmodified functional subunits thereof, that the Provider wishes to contribute to the COTC.

C. The COTC Membership Agreement

Recitals

The NCI and the COTC are working together to facilitate translational cancer research through the development of shared technologies and infrastructure useful in the study of comparative pet animal cancer models.

COTC Member agrees that the NCI will act on behalf of the COTC to negotiate a COTC Material Transfer Agreement for the introduction of Test Articles for COTC-approved Research Projects.

The NCI will act as a central repository of Test Articles to be distributed to COTC Members (exceptions to be determined on a case by case basis, as necessary). Likewise the NCI and

COTC Members shall conduct research on Test Articles as defined by a specific COTC protocol.

The parties to this MOU agree to adhere to the following terms:

1. The Test Article is the property of the Provider, and is being made available to the COTC as a service to the research community. Unless expressly agreed upon, COTC Member shall not do any of the following:
 - (a) make any complements, analogs, conjugates, derivatives, or modifications of the Test Article;
 - (b) sequence, analyze, or otherwise determine the chemical or physical structure, or physical properties, of the Test Article to the extent such structures or properties are not already publicly known or expressly provided in confidence in furtherance of the Research Project;
 - (c) reverse engineer the Test Article;
 - (d) disassemble the Test Article except as necessary in furtherance of the Research Project.
2. **TEST ARTICLE WILL NOT BE MADE AVAILABLE TO THE COTC MEMBER FOR USE IN HUMAN SUBJECTS, INCLUDING FOR PURPOSES OF DIAGNOSTIC TESTING.**
3. Absent a separate agreement between the Provider and COTC Member, the Test Article will be used only for the Research Project as described in the transfer agreement shown as Appendix B. The Test Article will not be used for commercial purposes such as production, sale, or screening. Along with the Test Article, Provider may also supply data about the Test Article (Provider Confidential Information).
4. Each Test Article will be obtained under a Material Transfer Agreement (MTA) between the NCI and each Provider.
5. COTC Member shall access Test Articles for COTC-approved Research Projects from NCI and receipt of Test Articles shall be in strict accordance with this Memorandum of Understanding. Each transfer of a Test Article to COTC Member shall be memorialized by way of a signed Material Transfer Form attached as Exhibit 1.
6. Test Articles distributed to COTC Members will be used in accordance only with COTC-approved Research Projects. COTC-proposed Research Projects will be established in the following manner:
 - i) Proposals: a proposal to initiate a Research Project may be initiated by the NCI or any active member of the COTC.

- ii) Review of Proposals: COTC Member must submit proposals, including a draft Protocol, to the NCI in written form. Proposals will be reviewed and evaluated for scientific merit and translational potential by the NCI-CCR, with input from the COTC and the Provider on an as needed basis. The selection of proposals for provision of Test Article shall be at the discretion of the NCI-CCR.
- iii) Proposal Development: Meritorious proposals may be revised during their review through a collaborative effort of the NCI-CCR, interested COTC members, the Provider, and the COTC Data Safety and Monitoring Board (COTC DSMB).

7. Any Confidential Information shall be held in confidence in accordance with the following terms:
- a. Each party agrees to accept the Confidential Information and employ all reasonable efforts to maintain the Confidential Information of the other party secret and confidential for a period of four (4) years from the date of disclosure or until data is published, whichever occurs sooner. In maintaining Confidential Information in confidence, recipient of Confidential Information agrees to employ no less than the degree of care it employs to preserve and safeguard its own confidential information. The Confidential Information of the disclosing party shall not be disclosed, revealed, or given to anyone by the receiving party except employees, agents, or collaborators of the receiving party who have a need for the Confidential Information in connection with the receiving party's evaluation, and such employees, agents, and collaborators shall be advised by the receiving party of the confidential nature of the Confidential Information and that the Confidential Information shall be treated accordingly.
 - b. Each party hereby acknowledges that the other party shall not incur any liability merely for examining and considering the Confidential Information; however, each party agrees that it will not use the Confidential Information of the other party for any purpose except as set forth herein.
 - c. The obligations of a party shall not extend to any part of the Confidential Information of the other party:
 - i) that can be demonstrated to have been in the public domain or publicly known at the time of disclosure; or
 - ii) 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

- iii) that becomes part of the public domain or publicly known by publication or otherwise, not due to any unauthorized act by such party; or
 - iv) that can be demonstrated as independently developed or acquired by such party without reference to or reliance upon such Confidential Information; or
 - (v) that is required to be disclosed by law or court order. A party that receives such a requirement will promptly notify the other party of the disclosure requirement, and will limit its disclosure to only that portion of the Confidential Information that is necessary to satisfy the disclosure requirement.
- 8. The COTC member agrees to provide its Study Data to the NCI and COTC in accordance with the Protocol. COTC Member agrees that the NCI has the right to share Study Data with the Provider and the COTC. NCI represents that the Provider and COTC will treat the Study Data as COTC Confidential Information. COTC Member hereby grants Provider the right to use, without further consideration, all Study Data involving Provider's Test Article for Provider's own internal analyses, for use in regulatory filings, or to support patent filings on inventions owned in whole or in part by Provider.
- 9. It is anticipated that COTC Member may wish to disclose or publically present Study Data that it has generated or that has been generated by other COTC Members. COTC Member, as a condition of receiving the Test Article, acknowledges the value of review and commentary on such disclosures by the NCI-CCR, the COTC, and the Provider, and agrees to:
 - (a) Obtain NCI-CCR review of planned disclosures before making any disclosure of Study Data; and,
 - (b) Provide the NCI with copies of anticipated disclosures no less than 45 days prior to the date of disclosure; and,
 - (c) Allow NCI to share such planned disclosures with the COTC and the Provider; and,
 - (d) Coordinate its disclosure activities with the COTC, NCI and the Provider so as to enable the NCI-CCR to assist in determining the most appropriate mechanism for public dissemination of the Study Data. All parties agree to coordinate their activities regarding publication with one another prior to submission of a paper or abstract for publication or presentation.

COTC Members will abide by rules for authorship in accordance with the Protocol.

In the event that the COTC Member's disclosure would include the Confidential Information of another party, the COTC Member agrees to notify that party and the NCI-CCR, and to remove such Confidential Information if so requested by that party.

10. Any Test Article delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. THE PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESSED OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE TEST ARTICLE WILL NOT INFRINGE ANY PATENT, COPYRIGHT OR TRADEMARK. COTC Member agrees either to return any unused Test Article to the NCI following the completion of the Research Project, or to destroy the Test Article upon the request of Provider.
11. Each party hereby assumes any and all risks of personal injury and property damage attributable to the negligent acts of that party and the officer, employees, and agents thereof. Study Data from use of the Test Article being supplied to Provider are disclosed with no warranties, express or implied, including any warranty of merchantability or fitness for a particular purpose. COTC Member and NCI make no representation that the use of the Study Data will not infringe any patent or proprietary rights of third parties. COTC Member understands 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. §171)
12. If the Provider is a company or for-profit entity, NCI will ensure that such Provider agrees to indemnify the COTC against liabilities resulting from the willful misconduct or gross negligence of the Provider.

In all instances in which NCI or similar academic group is the Provider, Provider extends no indemnity in any form to any COTC Member or to the COTC.
13. It is anticipated that in the course of the Research Project, COTC Member may require specific funding for certain aspects of the Research Project. In instances in which Provider is a company or for-profit entity, and only in such instances, COTC Member agrees to work with Provider in good faith as deemed necessary by COTC Member and Provider for Provider to allocate resources in furtherance of any required aspects of the Research Project. Any agreement for the purposes of funding and allocation of such resources will be in strict accordance with the terms of this Agreement.
14. COTC Member's use of the Test Article will be in compliance with all standards of COTC Member's Animal Care and Use Committee. Furthermore, informed consent will be obtained from pet owners of all animals included in the Research Project.
15. The parties do not anticipate that COTC Member will create new inventions under the Research Plan; however, COTC Member agrees it will notify the NCI and Provider in writing of any inventions, discoveries, or innovations made by COTC Member using the Test Article, whether patentable or not, which are conceived or

- first actually reduced to practice in the performance of the Research Project. In instances in which Provider is either 1) a company or for-profit entity, or 2) an academic group, COTC Member shall grant Provider (subject to obligations to the United States Government under the Bayh-Dole Act of 1980 and to the extent permissible under the Tax Reform Act of 1986 and any implementing IRS Revenue Procedures) a royalty-free non-exclusive license to practice any invention (that was invented as a direct result of the COTC Member's use of the Test Article that necessarily uses the Test Article) and is conceived or first actually reduced to practice in the performance of the Research Project, for any purpose, including commercial purposes. Furthermore, Provider is free to negotiate with COTC Member for an exclusive, royalty-bearing commercialization license to practice any such invention involving the Test Article. Provider is likewise free to negotiate with the NCI for a non-exclusive, partially exclusive, or exclusive license to practice any invention developed by the NCI involving the Test Article.
16. If Test Article is of animal origin, Provider shall provide to the NCI their Institutional Animal Care and Use Committee (IACUC) approval number, and their institutional animal welfare assurance number (or equivalent).
 17. COTC Member agrees to make tissue samples developed during the Research Project available to the NCI, and other COTC members including the COTC pharmacodynamics core labs, and the Provider, for the Research Project and other research purposes, under terms substantially similar to the NIH Simple Letter Agreement for the Transfer of Materials (see <http://www.ott.nih.gov/pdfs/slaform.pdf>).
 18. COTC Oversight. COTC implementation of this MOU will be through NCI-CCR oversight.
 19. Work done outside of the Research Project is not permitted. Any violation of the provisions of this Memorandum of Understanding or of the corresponding COTC Material Transfer Form (Exhibit 1) may result in suspension and subsequent revocation of membership in the COTC as determined solely by the NCI-CCR-Comparative Oncology Program.
 20. Term: This Agreement shall be effective on the date it is fully executed by the parties and shall terminate in four (4) years unless sooner terminated as provided herein or extended by mutual written agreement of the parties.
 21. Termination: Each party shall have the right to terminate this Agreement, without cause, upon not less than sixty (60) days prior written notice to the other party.

As recognized by the parties below, the purpose of this Memorandum of Understanding is to acknowledge the agreement of each party to the COTC membership.

ACCEPTED AND AGREED TO:

National Cancer Institute

COTC Member Authorized Signatory

Robert Wilttrout, Ph.D.
Director, Center for Cancer Research
National Cancer Institute

Date

Name: _____ Date
Title: _____
Employer Name: _____

Address:

Address:

c/o NCI Technology Transfer Center
6120 Executive Blvd., EPS 450
Rockville, MD 20852
Tel.: 301-496-0477

Acknowledged and Understood:

COTC Member lead scientific investigator
Date: _____

Exhibit 1

MATERIAL TRANSFER FORM FOR THE COTC/ PROVIDER AGREEMENT

This Material Transfer Form is to memorialize the transfer of “_____” (Test Article) to the COTC Member noted below. Use of the Test Article by the COTC Member shall be for only the Research Project described below and in strict accordance with the Memorandum of Understanding between the National Cancer Institute and the COTC Member.

COTC Member:

Address:

Acknowledged and understood:

COTC Member Investigator:

Title:

Signature/Date:

Authorized Signatory for COTC Member:

Signature/Date of Recipient:

Authorized Signatory for NCI:

Title:

Signature/Date:

Research Project