

Agreement for the Acquisition of Test Compounds for Distribution to the Comparative Oncology Trial Consortium

The parties to this Agreement are the National Cancer Institute, Center for Cancer Research, and [Company].

Definitions:

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

“Test Compound” means any investigational agent or compound, including any progeny or unmodified derivatives thereof, that the Provider wishes to contribute to the COTC.

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

“COTC Member” means a non-NCI third party qualified COTC investigator and his/her associated institution which shall have access to the Test Compound through the NCI.

“COTC” means the Comparative Oncology Trial Consortium, a newly created 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.

“Confidential Information” means any existing data about the Test Compound or Study Data, as further described in Article 5 of this Agreement, arising from use of Test Compound 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.

“Research Project” means a research plan for the study of Provider’s Test Compound and which has been previously approved by the COTC for study.

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

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Recitals:

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

COTC Members agree that the NCI will act on behalf of the COTC to negotiate and execute COTC Material Transfer Agreements for the introduction of Test Compounds for COTC-approved Research Projects.

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

In furtherance of COTC-approved Research Projects, NCI may further distribute Test Compound to COTC Members in accordance with the terms of this Agreement.

Provider and their associated investigators wish to make available Provider's Test Compound for study by the COTC, that Test Compound being defined below as:

The parties to this instrument agree to the terms as follows:

1. The above Test Compound 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 between Provider and COTC, COTC Members and NCI shall not (a) make any complements, analogs, conjugates, derivatives, or modifications of the Test Compound, or (b) sequence, analyze, or otherwise determine the chemical structure or physical properties of the Test Compound to the extent such structures or properties are not already publicly known or expressly provided in confidence in furtherance of the Research Project.
2. **TEST COMPOUND WILL NOT BE MADE AVAILABLE TO THE NCI, THE COTC AND/OR ANY COTC MEMBER FOR USE IN HUMAN SUBJECTS, INCLUDING FOR PURPOSES OF DIAGNOSTIC TESTING.**
3. Absent a separate agreement between the Provider and COTC Member or between Provider and the NCI, the Test Compound will be used only for the Research Project. The Test Compound will not be used for commercial purposes such as production, sale, or screening. Along with the Test Compound, Provider may also supply data about the Test Compound (Provider Confidential Information).
4. Provider understands that the Test Compound may be forwarded to COTC Members for use in COTC-approved Research Projects in strict accordance with the terms of this Agreement. NCI and COTC Members may retain title to patent rights in inventions made by its employees in the course of the Research Project.
5. It is anticipated that COTC Members using the Test Compound may wish to disclose or publish Study Data in oral scientific presentations or through peer-reviewed or non-peer reviewed publications. COTC Member (or NCI, as a

COTC participating site), as a condition of receiving the Test Compound, shall provide Study Data to the NCI and the COTC forty-five (45) days prior to disclosure. During this forty-five (45) day period, this same Study Data will also likewise be provided to the Provider and are to be considered COTC Confidential Information. Should any party indicate in writing the need to delay the disclosure to secure rights to a patentable discovery, the disclosing party or parties shall delay the disclosure for an additional forty-five (45) day period. Notwithstanding the foregoing, COTC Member, Provider and COTC will together determine 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. The purpose of this coordination is to ensure the proper pooling of data and to reflect the comprehensive nature of COTC-sponsored research studies. This requirement shall not be construed as preventing a COTC Member from publishing Study Data that it has specifically generated provided that COTC Member first meet the aforementioned obligations for the coordination of COTC-sponsored publications. Furthermore, Provider is hereby granted the right to use, without further consideration, all Study Data involving Provider's Test Compound 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.

6. a) Provider, NCI, COTC Members and COTC each agree to treat in confidence any Confidential Information and agree to employ all reasonable efforts to maintain Confidential Information as confidential. This degree of care shall be no less than the degree of care a party uses to preserve and safeguard its own confidential information. Confidential Information does not extend to any part of information of any party (a) that can be demonstrated to have been in the public domain or publicly known at the time of disclosure; (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; (c) that becomes part of the public domain or publicly known by publication or otherwise, not due to any unauthorized act by such party; (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 court order.

b) Provider, NCI, COTC Members and COTC hereby acknowledge that each 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.
7. Any Confidential Information provided by any party shall be kept in confidence for a period of four (4) years from date of disclosure or until the data is published, whichever occurs sooner. Prior to any publication of any Study Data from use of the Test Compound in an approved Research Project, Provider shall have forty-

five (45) days prior to publication to request in writing redaction of any information in said publication that can be identified as Provider Confidential Information. Should Provider indicate in writing the need to delay the disclosure to secure rights to a patentable discovery, the disclosing party or parties shall delay the disclosure for an additional forty-five (45) day period.

8. Any Test Compound 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 COMPOUND WILL NOT INFRINGE ANY PATENT, COPYRIGHT OR TRADEMARK. COTC Member agrees to either return any unused Test Compound to the NCI following the completion of the Research Project, or to destroy the Test Compound upon the request of Provider. The NCI shall destroy or return to the Provider any remaining Test Compound upon request of the Provider.
9. Provider represents to the best of its knowledge the use of the Test Compound will not infringe any patent or proprietary rights of third parties. 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 Compound 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. Provider 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).
10. In all instances in which Provider is a company or for-profit entity, and only in such instances, the Provider shall defend, indemnify and hold harmless the COTC Member and its employees from any and all liabilities, claims, actions or suites arising out of or in connection with 1) COTC Member's use of the Test Compound during the course of the Research Project, and 2) Provider's use of Study Data. Provider warrants that it maintains a policy or program of insurance or self-insurance at levels sufficient to support the indemnification obligations assumed herein. Unless the Provider is self-insured, upon request the Provider will provide evidence of its insurance and will provide to the COTC Member and NCI, thirty (30) days prior, written notice of cancellation of its coverage.

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.

11. 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.
12. NCI asserts that any use of the Test Compound by a COTC Member 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.
13. The Test Compound is provided for deposit with the NCI at no cost.
14. COTC Member shall notify the NCI and Provider in writing of any inventions, discoveries or innovations made by COTC Member using the Test Compound, whether patentable or not, which are conceived or first actually reduced to practice in the performance of the Research Project. In instances where 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 Compound that necessarily uses the Test Compound) 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 Compound. Should NCI invent a patentable discovery using the Test Compound in such instances in which NCI is not the Provider, NCI will notify the Provider and NCI will seriously consider Provider's request for a nonexclusive, partially exclusive, or exclusive royalty bearing license to practice said invention subject to the terms of 35 U.S.C. §§207-209, and the implementing regulations.
15. If Test Compound is of animal origin, Provider will insert hereto the Institutional Animal Care and Use Committee (IACUC) approval number _____, and the institutional animal welfare assurance number _____, or equivalent.
16. Term: This Agreement shall be effective on the date it is fully executed by NCI and Provider and shall terminate in four (4) years unless sooner terminated as provided herein or extended by mutual written agreement of the Parties.

17. 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.

Exhibit B

MATERIAL TRANSFER FORM FOR THE COTC/ PROVIDER AGREEMENT

This Material Transfer Form is to memorialize the transfer of “_____” (Test Compound) to the COTC Member noted below. Use of the Test Compound by the COTC Member shall only be for use in the noted Research Project 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