# **MATERIAL TRANSFER AGREEMENT**

Provider: Division of Cancer Treatment and Diagnosis, National Cancer Institute

Recipient: University School of Medicine

Recipient’s Investigator: Dr. John Doe, Ph.D., as an employee of the University School of Medicine

1**.** Provider agrees to transfer to Recipient's Investigator the following Research Material:

1.0 mg of Agent X (NSC 00000), an agent proprietary to Collaborator A, Inc. (Collaborator)

2. THIS RESEARCH MATERIAL MAY NOT BE USED IN HUMANS. The Research Material will only be used for research purposes by Recipient's Investigator in his/her laboratory, for the Research Project described below, under suitable containment conditions. This Research Material will not be used by for-profit recipients for screening, production or sale, for which a commercialization license may be required. Recipient agrees to comply with all Federal rules and regulations applicable to the Research Project and the handling of the Research Material.

2(a). Is Research Material of human origin?

 Yes

 No

2(b). If yes in 2(a), was Research Material collected according to 45 CFR Part 46, "Protection of Human Subjects"?

 Yes (Please provide Assurance Number)

 No

 Not Applicable

3. This Research Material will be used by Recipient's Investigator solely in connection with the following research project ("Research Project") described with specificity as follows (use an attachment page if necessary):

This Research Material will be used for preclinical studies investigating the effects of the Research Material in a cancer cell line.

3(a). Are any materials used in the Research Project of human origin?

 Yes

 No

3(b). If yes in 3(a), were human-origin materials collected according to 45 CFR Part 46, "Protection of Human Subjects"?

 Yes (Please provide Assurance Number)

 No

 Not Applicable

4. (a). To the extent permitted by law, Recipient agrees to treat in confidence, for a period of three (3) years from the date of its disclosure, any of Provider's or Collaborator’s written information about this Research Material that is stamped "CONFIDENTIAL," except for

information that was previously known to Recipient or that is or becomes publicly available or which is disclosed to Recipient without a confidentiality obligation. Any oral disclosures to Recipient shall be identified as being CONFIDENTIAL by written notice delivered to Recipient within thirty (30) days after the date of the oral disclosure.

4. (b). Recipient may publish or otherwise publicly disclose the results of the Research Project, however Collaborator will have thirty (30) days to review proposed manuscripts and three (3) days to review proposed abstracts to assure that CONFIDENTIAL Information is protected, except when a shortened time period under court order or the Freedom of Information Act pertains. Collaborator may request in writing that a proposed publication be delayed for up to thirty (30) additional days as necessary to file a Patent Application. Manuscripts to be submitted for publication by Recipient’s Investigators will be sent to NCI’s Regulatory Affairs Branch [NCICTEPpubs@mail.nih.gov] for forwarding to Collaborator for review as soon as they are received and in compliance with the timelines outlined above. Abstracts to be presented by Recipient’s Investigators will be sent to NCI’s Regulatory Affairs Branch [NCICTEPpubs@mail.nih.gov] for forwarding to Collaborator as soon as they are received, preferably no less than three days prior to submission, but prior to presentation or publication, to allow for preservation of U.S. or foreign patent rights. In all oral presentations or written publications concerning the Research Project, Recipient will acknowledge Provider's or Collaborator’s contribution of this Research Material unless requested otherwise.

5. This Research Material is proprietary to Collaborator. Collaborator has agreed to allow NCI to make their proprietary compound available for this Research Project. Recipient's Investigator agrees to retain control over this Research Material and further agrees not to transfer the Research Material to other people not under her or his direct supervision without advance written approval of Provider. When the Research Project is completed, the Research Material will be disposed of, if directed by Provider.

6. This Research Material is provided as a service to the research community. IT IS BEING SUPPLIED TO RECIPIENT WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. Provider makes no representations that the use of the Research Material will not infringe any patent or proprietary rights of third parties.

7. Recipient shall retain title to any patent or other intellectual property rights in inventions made by its employees in the course of the Research Project. Recipient agrees not to claim, infer, or imply endorsement by the Government of the United States of America (hereinafter referred to as "Government") of the Research Project, the institution or personnel conducting the Research Project or any resulting product(s). Unless prohibited by law from doing so, Recipient agrees to hold the Government harmless and to indemnify the Government for all liabilities, demands, damages, expenses and losses arising out of Recipient's use for any purpose of the Research Material.

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

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

10. Results of the Research Project shall be provided to the Provider. Publications shall be provided to Provider and Collaborator as described in Article 4.

11. Recipient (“Institution”) agrees to notify Provider and Collaborator upon the filing of any patent applications related to research with this Research Material under this Agreement and abide by the following terms of the Intellectual Property Option to Collaborator:

 Institution agrees to promptly notify the Provider (NCI) and Collaborator in writing of any inventions, discoveries or innovations made by the Recipient’s Investigator or any other employees or agents of Institution, whether patentable or not, which are conceived or first actually reduced to practice pursuant to the Research Project.

For inventions described in patent disclosures that claim the use and/or the composition of the Research Material(s) (Section A Inventions), Institution agrees to grant to Collaborator(s): (i) a royalty-free, world-wide, non-exclusive license for commercial purposes with the right to sub license to affiliates or collaborators working on behalf of Collaborator for Collaborator’s development purposes; and (ii) a time limited first option to negotiate an exclusive, or co-exclusive, if applicable, world-wide, royalty bearing license for commercial purposes, including the right to grant sub licenses, subject to any rights of the Government of the United States of America, on terms to be negotiated in good faith by the Collaborator(s) and Institution. If Collaborator accepts the non-exclusive commercial license, the Collaborator agrees to pay all out of pocket patent prosecution and maintenance costs which will be pro-rated and divided equally among all licensees. If Collaborator obtains an exclusive commercial license, in addition to any other agreed upon licensing arrangements such as royalties and due diligence requirements, the Collaborator agrees to pay all out of pocket patent prosecution and maintenance costs. Collaborator(s) will notify Institution, in writing, if it is interested in obtaining a commercial license to any Section A Invention within three (3) months of Collaborator’s receipt of a patent application or six (6) months of receipt of an invention report notification of such a Section A Invention. In the event that Collaborator fails to so notify Institution, or elects not to obtain an exclusive license, then Collaborator’s option expires with respect to that Section A Invention, and Institution will be free to dispose of its interests in accordance with its policies. If Institution and Collaborator fail to reach agreement within ninety (90) days, (or such additional period as Collaborator and Institution may agree) on the terms for an exclusive license for a particular Section A Invention, then for a period of three (3) months thereafter Institution agrees not to offer to license the Section A Invention to any third party on materially better terms than those last offered to Collaborator without first offering such terms to Collaborator, in which case Collaborator will have a period of thirty (30) days in which to accept or reject the offer. If Collaborator elects to negotiate an exclusive commercial license to a Section A Invention, then Institution agrees to file and prosecute patent application(s) diligently and in a timely manner and to give Collaborator an opportunity to comment on the preparation and filing of any such patent application(s). Notwithstanding the above, Institution is under no obligation to file or maintain patent prosecution for any Section A Invention.

 For those inventions not covered by Section A, but are nevertheless conceived or first actually reduced to practice pursuant to the Research Project and to those inventions that are conceived or first actually reduced to practice pursuant to the Research Project that use non-publicly available clinical data or specimens from patients treated with the NCI-provided Research Material (including specimens obtained from NCI DCTD-funded tissue banks) (Section B Inventions), Institution agrees to grant the following to the collaborator: (i) a paid-up nonexclusive nontransferable, royalty-free, world-wide license to all Section B Inventions for research purposes only; and (ii) a nonexclusive, royalty-free, world-wide license to (a) disclose Section B Inventions to a regulatory authority when seeking marketing authorization of the Research Material and (b) disclose Section B Inventions on a product insert or other promotional material regarding the Research Material after having obtained marketing authorization from a regulatory authority. Notwithstanding the above, Institution is under no obligation to file or maintain patent prosecution for any Section B Invention.

For all Section A and Section B Inventions, regardless of Collaborator’s decision to seek a commercial license, Institution agrees to grant Collaborator a paid-up, nonexclusive, royalty-free, world-wide license for research purposes only. Institution retains the right to make and use any Section A Invention for all non-profit research, including for educational purposes and to permit other educational and non-profit institutions to do so.

Institution agrees, at Collaborator's request and expense, to grant to Collaborator a royalty-free exclusive or co-exclusive license to inventions made by Institution’s Investigator(s) or any other employees or agents of Institution, which are or may be patentable or otherwise protectable, as a result of research utilizing the Research Material(s) outside the scope of the NCI DCTD Research Project (Unauthorized Inventions). Institution will retain a non-exclusive, non-sub-licensable royalty free license to practice the invention for research use purposes.

Institution agrees to promptly notify NCI DCTD (NCICTEPpubs@mail.nih.gov) and Collaborator(s) in writing of any Section A Inventions, Section B Inventions, and Unauthorized Inventions upon the earlier of: (i) any submission of any invention disclosure to Institution of a Section A, Section B, or Unauthorized Invention, or (ii) the filing of any patent applications of a Section A, Section B, or Unauthorized Invention. Institution agrees to provide a copy of either the invention disclosure or the patent application to the Collaborator and to NCI DCTD which will treat it in accordance with 37 CFR Part 401. These requirements do not replace any applicable reporting requirements under the Bayh-Dole Act, 35 USC 200-212, and implementing regulations at 37 CFR Part 401.

12. This Agreement shall terminate two (2) years from the date of the last signature below.

# **Signatures Begin on Next Page**

**SIGNATURES**

**RECIPIENT**

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Date John Doe, Ph.D.

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Date Authorized Signature for Recipient and Title

Recipient's Official and Mailing Address:

John Doe, Ph.D.

Associate Professor

Department of Biochemistry

University School of Medicine

City, State, Zip

Phone:

**NATIONAL CANCER INSTITUTE**

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Date Sherry Ansher, Ph.D.

 Associate Chief, Agreement Coordination Group

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Date Jason Cristofaro, J.D., Ph.D.

CTEP Alternate Technology Development Coordinator

Please address all correspondence related to this agreement to Sally Hausman at the following address by express mail:

Sally Hausman

Senior Specialist, Research and Development Agreements

Regulatory Affairs Branch

Cancer Therapy Evaluation Program

9609 Medical Center Dr., Rm. 5W-530

Rockville, MD 20850

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).