**NCI CANCER THERAPY EVALUATION PROGRAM**

**NON-CLINICAL**

**MATERIAL TRANSFER AGREEMENT**

**Provider:** Division of Cancer Treatment and Diagnosis (DCTD), of the National Cancer Institute (NCI), part of the National Institutes of Health (NIH) an agency of the Department of Health and Human Services (HHS)

**Recipient (Or Institution):**

**Investigator(s):**  **,** employee(s) of the Recipient

**Collaborator:**

**Agent:** No less than **X mg** of [insert **Agent Name**]([insert any alternate names], NSC# XXXXX) an agent proprietary to Collaborator.

**Research Project**: [Insert no more than one paragraph. e.g. “The Agent will be used for preclinical studies investigating the effects of the Agent in a cancer cell line”]

Provider and Collaborator have entered into a Cooperative Research and Development Agreement (**CRADA**) under which the Collaborator has agreed to allow Provider to make the Agent available to the Recipient for the Collaborator-approved Research Project.

Therefore, the Provider and Recipient (each a “**Party**” and Collectively the “**Parties**”) agree to the following terms, effective as of the date of the last authorized signature below (“**Effective Date**”), and Recipient will ensure that the Investigator(s) will comply with these terms:

1. **Transfer.** The Agent will be Transferred to the Recipient either directly from the Collaborator or from the Provider.
2. **Use.**
	1. The Agent will only be used for the Collaborator-approved Research Project, under suitable containment conditions. The Agent will not be used in humans or for commercial purposes, including screening, production or sale.
	2. Recipient agrees to retain control over the Agent and further agrees not to transfer the Agent to entities not under the Investigator(s) direct supervision without advance written approval of Provider.
	3. Recipient agrees to comply with all Federal rules and regulations applicable to the use and the handling of the Agent. Recipient will ensure that any individuals involved in the Research Project are aware of, and will abide by, the terms of this Agreement.
	4. If any materials used in the Research Project are of human-origin, Recipient will abide by all applicable human subjects and other regulations and guidance including the collection of human materials in accordance with 45 CFR Part 46 and Institutional Review Board approval for use.
	5. The Agent will not be modified in any way without the prior written approval of Collaborator unless it is inherently required for Recipient Investigator(s) to conduct the Research Project . The Recipient will not attempt to determine the structure of the Agent (e.g. the chemical structure, the amino acid sequence or the nucleotide sequence) or otherwise characterize the Agent without the prior approval of the Collaborator.
	6. If any Collaborator-approved Research Project includes activities involving live animals, Recipient agrees to comply with all applicable law and regulations with regard to the uses and handling of live animals in research, including but not limited to U.S. Animal Welfare Act.
3. **Confidential Information.**
	1. To the extent permitted by law, Recipient agrees to treat in confidence, for a period of five (5) years from the date of its disclosure, any of Provider's or Collaborator’s written information about this Agent that is stamped "CONFIDENTIAL" (“**Confidential Information**”) except for information that:
		* 1. Is within the public domain prior to the time of the disclosure or thereafter becomes within the public domain other than as a result of disclosure by the Recipient or any of its representatives in violation of this Agreement;
			2. Was, on or before the date of disclosure in the possession of the Recipient;
			3. Is acquired by the Recipient from a third party not under an obligation of confidentiality;
			4. Is hereafter independently developed by the Recipient, without reference to the information received from the disclosing Party; or
			5. The disclosing Party expressly authorized the Recipient to disclose.
	2. Any oral disclosures to Recipient will be identified as being Confidential Information by written notice delivered to Recipient within thirty (30) days after the date of the oral disclosure.
	3. The Parties acknowledge that failure to mark an item “CONFIDENTIAL” or failure to reduce an orally disclosed item to writing and mark that item “CONFIDENTIAL” does not constitute a designation of non-confidentiality when the confidential nature would be reasonably recognized by the Recipient from the subject matter or subject type of the information disclosed.
	4. If Confidential Information is required to be disclosed by law, regulation or court order, Recipient is permitted to make such disclosure provided that the Recipient gives the Provider or Collaborator reasonable written notice of the requirement prior to making such disclosure unless prohibited by law, court order or regulation, and provided that the Recipient uses all reasonable effort to secure confidential protection for such Confidential Information.
4. **Publications.**
	1. Recipient may publish or otherwise publicly disclose the results of the Research Project (“**Results**”); however, Collaborator will have thirty (30) days to review proposed manuscripts and three (3) working days to review proposed abstracts or presentations to assure that Confidential Information is protected. Collaborator may request that a proposed publication be delayed for up to thirty (30) additional days as necessary to file a patent application.

* 1. All manuscripts and abstracts, to be presented or submitted for publication by Recipient, will be sent to NCI’s Regulatory Affairs Branch, at **NCICTEPpubs@mail.nih.gov**, for forwarding to Collaborator for review. In all oral presentations or written publications concerning the Research Project, Recipient will acknowledge Provider's and Collaborator’s contribution of this Agent unless requested otherwise.
1. **Reports.** Recipient will provide a summary of Results in confidence to Provider through NCICTEPACG@mail.nih.gov upon completion of the Research Project. Or, on a written request by Collaborator and at no more than six (6) monthly intervals, Recipient will provide status updates without raw data regarding Research Project progress and projected milestone changes directly to CTEP through NCICTEPACG@mail.nih.gov, who will then forward to the Collaborator.

1. **Warranty.**
	* + 1. The Agent is provided as a service to the research community. **Recipient acknowledges that, to the maximum extent permitted by applicable law, Collaborator has disclaimed and excluded any and all representations, warranties, conditions or other terms, whether written or oral, expressed or implied, with respect to the Agent, including any representation or warranty of quality, performance, merchantability or fitness for a particular use or purpose.**
			2. The Recipient acknowledges that not all of the characteristics of the Agent may be known and agrees that the Research Project will, therefore, be conducted with prudence and appropriate caution.
			3. Provider and Collaborator make no representations that the use of the Agent will not infringe any patent or proprietary rights of third parties.
			4. The Results are provided to Collaborator with no warranties, express or implied, including any warranty of merchantability or fitness for a particular purpose. Recipient makes no representations that the use of the Results will not infringe any patent or proprietary rights of third parties.
2. **Liability.** Provider and Collaborator will not be liable for any loss, harm, illness or other damage or injury arising from Recipient’s receipt, handling, use or disposal of the Agent.
3. **Third-Party Beneficiary**. The Collaborator whose Agent is used in the Research Project is hereby designated as an intended third-party beneficiary of this Agreement and is entitled to independently enforce all rights and obligations under this Agreement.
4. **Endorsement.** Recipient agrees not to claim, infer, or imply endorsement by the Government of the United States of America or the Collaborator of the Research Project, the Recipient or personnel conducting the Research Project or any resulting product.
5. **Intellectual Property**.
	1. “Invention” means any invention or discovery that is or may be patentable or otherwise protected under Title 35 of the United States Code, or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act, 7 U.S.C. §§ 2321 et seq.
	2. Recipient will retain title to any patent or other intellectual property rights in Inventions made by its employees in the course of the Research Project.
	3. Recipient agrees to notify Provider and Collaborator upon the filing of any patent applications related to research with the Agent and abide by the terms of the Intellectual Property Option (“**IP Option**”) to Collaborator as described at: <https://ctep.cancer.gov/branches/rab/intellectual_property_option_to_collaborators.htm>. See also: The Federal Register, Vol. 76, No. 48, pages 13404-13410 (2011) (<https://www.gpo.gov/fdsys/pkg/FR-2011-03-11/pdf/FR-2011-03-11.pdf>).

* 1. The Parties agree that the term “Institution” in the IP Option refers to the Recipient. Any reference to an exclusive option regarding an Invention directed to more than one Agent is understood by Recipient to be co-exclusive with respect to the applicable Collaborators whose Agent(s) are claimed by such Inventions. In the event of a conflict in the IP Option language between the foregoing Federal Register notice and ctep.cancer.gov web site, the Federal Register notice will govern.
1. **Termination and Expiration.**
	1. This Agreement will expire **two (2) years** from the Effective Date.
	2. The term of this Agreement may be extended, and the provisions of this Agreement may be modified only by written amendment signed by a duly authorized signatory of each Party.
	3. Either Party may terminate this Agreement before expiration by providing thirty (30) days written notice to the other Party.
	4. When the Research Project is completed, or upon the expiration or earlier termination of this Agreement, whichever comes first, any unused Agent and the Confidential Information will be disposed of, unless otherwise directed by Provider or Collaborator. Disposal will be in accordance with all applicable laws, regulations and safety policies.
	5. The relevant provisions of this Agreement that by their nature would continue beyond termination or expiration of this Agreement (including, without limitation, the sections covering Intellectual Property and Confidentiality) will survive the expiration or earlier termination of this Agreement, which includes Paragraphs 3, 4, 6-9, 10, and 11.
2. **Law.**  If Recipient is an agency of a U.S. state, and under the constitution and the laws of that state possesses certain rights and privileges that subject Recipient to certain limitations and restrictions, then notwithstanding any provision hereof, nothing in this Agreement is intended to be, nor will it be construed to be, a waiver of the sovereign immunity of the state or a prospective waiver or restriction of any of the rights, remedies, claims, and privileges of the state.

**Signatures Begin on Next Page**

**SIGNATURES**

**RECIPIENT**

Accepted and Agreed:

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

<Authorized Official’s Name> Date

<Title>

Recipient's Contact Information:

Address:

Email:

Phone:

**INVESTIGATOR(S)**

Read and Understood:

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

<Name> Date

<Title>

Investigator’s Contact Information:

Address:

Ph:

Email:

**NATIONAL CANCER INSTITUTE**

Accepted and Agreed:

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

CTEP Alternate Technology Development Coordinator

Please email all correspondence related to this agreement to NCIctepRequests@mail.nih.gov