**NCI FORMULARY MATERIAL TRANSFER AGREEMENT**

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

Institution: **University of**

Institution’s Investigator: **Dr. Doctor, M.D**., an employee of the Instution

Collaborator: **Company**

**Definitions:**

**“Formulary Agent**” or “Investigational New Drug” or “Investigational Agent” means, in accordance with the definition in 21 C.F.R. § 312.3, a new drug or biological drug that is used in a clinical investigation. For this Agreement, Formulary Agent means agent(s), provided by or on behalf of the Provider Collaborator under a Cooperative Research and Development Agreement (“CRADA”) between Provider and the Collaborator. The Formulary Agent(s) may also be used in non-clinical, preclinical lab studies as part of a Proposal under this Agreement.

 “**GCP**” means the Good Clinical Practice standards officially published by the EMA, the FDA and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) that may be in effect from time to time and are applicable to the testing of the Formulary Agent(s).

“**GLP**” means the Good Laboratory Practice standards for laboratory activities for pharmaceuticals or biologicals, as applicable, as set forth in the United States Federal Food, Drug and Cosmetic Act and or the United States Public Health Service Act and any regulations or guidance documents promulgated thereunder (as such may be amended from time to time), together with any similar standards of good laboratory practice that are required by any regulatory authority, as applicable.

**“Institution’s Investigator”** means an investigator who is not an employee of Provider and is participating in the NCI Formulary. For clinical studies under this agreement the Institution’s Investigator must have current investigator registration documents on file with the Pharmaceutical Management Branch (PMB), NCI (“**Approved Investigator”**). For the purposes of this Agreement, to qualify as an Approved Investigator, Institution must that have been audited by NCI in the past 3 years and the Institution’s Investigator must be approved by NCI to participate in the NCI Formulary.

“**Investigational New Drug Application**” or “**IND**” means a filing in accordance with 21 C.F.R. Part 312 under which clinical investigation of an experimental drug or biologic (under this Agreement, a Formulary Agent) is performed in Human Subjects in the United States or intended to support a United States licensing action.

**“NCI Formulary”** is a Cancer Moonshot initiative that will expedite cancer researchers’ access to investigational agents and approved drugs for their research projects.

“**Study**” means the clinical research study described by the Formulary Protocol identified in Section 1 and Section 3.

Provider and Institution agree to the following terms:

1. Provider agrees to transfer to Institution’s Investigator the following Formulary Agent(s): **AAAA**

 each in sufficient quantities for the conduct of the protocol **XXXX** [IND Sponsor **xxxx**; IND# **yyyy** (“Formulary Protocol”) and/or non-clinical study (together “Proposal”) as approved by the Collaborator.

1. The Formulary Agent(s) will only be used for the Proposal. The Formulary Agent(s) will not be used for commercial purposes. Institution and Institution’s Investigator agree to comply with all Federal rules and regulations, GCPs and GLPs applicable to clinical trials and the handling of the Formulary Agent(s), when applicable. Institution acknowledges that it is solely be responsible for the conduct of the Proposal.
2. The Formulary Agent(s) will be used by Institution's Investigator solely in connection with the following Proposal summarized as follows: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. (a) To the extent permitted by law, Institution 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 the Formulary Agent(s) that is marked “CONFIDENTIAL” (“Confidential Information”) except for information that was previously known to Institution or that is or becomes publicly available without breach of this Agreement by Institution or which is disclosed to Institution without a confidentiality obligation by a third party having a lawful right to do so or is independently developed by Institution’s personnel who have not had access to Confidential Information as demonstrated by competent written proof, or is required to be disclosed by law. Any oral disclosures to Institution shall be identified as being Confidential Information by written notice delivered to Institution within thirty (30) days after the date of the oral disclosure. Notwithstanding the foregoing, failure to mark the information as "CONFIDENTIAL" does not constitute a designation of non-confidentiality when the confidential nature would be reasonably recognized by the receiving Party from the subject matter or subject type of the information disclosed and such information shall be deemed confidential.

* 1. Institution’s Investigator may publish or otherwise publicly disclose the results of the Formulary Protocol and/or non-clinical Proposal, however Collaborator will have forty-five (45) days from receipt to review proposed clinicaltrials.gov results reports submissions and similar regulatory submissions outside of the U.S., proposed manuscripts, and ten (10) days from receipt to review proposed abstracts or presentations to assure that Confidential Information is protected, except when a shortened time period under court order or the Freedom of Information Act pertains. Collaborator will have seven (7) days from receipt to review and approve the initial clinicaltrials.gov submission. Collaborator may request in writing that a proposed publication be delayed for up to sixty (60) additional days from receipt as necessary to file, or request Investigator and/or Institution file, a Patent Application or other action to protect its intellectual property interests. If Approved Investigator and/or Sponsor are unwilling to delay the publication or presentation, Approved Investigator and Sponsor will remove from the publication or presentation the information which Collaborator has specified it reasonably believes would jeopardize its intellectual property interests. Manuscripts to be submitted for publication and proposed abstracts or presentations by Institution’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. In all oral presentations or written publications concerning the Formulary Protocol and/or Proposal, Institution will acknowledge Provider's or Collaborator’s contribution of the Formulary Agent(s) unless requested otherwise.
1. Institution's Investigator agrees to retain control over the Formulary Agent(s) and further agrees not to transfer any Formulary Agent to other parties not directly involved in the conduct of the Proposal without prior approval from Collaborator and Provider.
2. Provider and Collaborator make no representations that the use of the Formulary Agent(s) will not infringe any patent or proprietary rights of third parties.
3. Institution agrees not to claim, infer, or imply endorsement by the Government of the United States of America (hereinafter referred to as "Government") of the Proposal, the institution or personnel conducting the Proposal or any resulting product. Unless prohibited by law from doing so, Institution agrees to hold the Government and Collaborator harmless and to indemnify the Government and Collaborator for all liabilities, demands, damages, expenses and losses arising out of Institution's use for any purpose of the Formulary Agent(s).
4. The undersigned Provider and Institution expressly certify and affirm that the contents of any statements made herein are truthful and accurate.
5. This Agreement will be construed in accordance with Federal law as applied by the Federal courts in the District of Columbia.
6. Institution agrees that results of the Proposal shall be provided to the Provider for forwarding to Collaborator including all public disclosures as described in Article 4(b). Further, Institution will keep data and results generated under this Agreement confidential until published and agrees that Provider and Collaborator will have the right to use any and all such data and results for any lawful purposes including regulatory filing and patent applications. Institution will provide any such data and results upon request.
7. Institution shall retain title to any patent or other intellectual property rights in inventions made solely by its employees in the course of the Proposal. Title to any patent or other intellectual property rights in inventions made jointly by Institution employees and Collaborator employees shall be held jointly by Institution and Collaborator. Institution agrees to notify Provider and Collaborator upon the filing of any patent applications related to research with the Formulary Agent(s) under this Agreement and to provide the Collaborator the rights described in the CTEP Intellectual Property Option to Collaborator, which may be found at: <http://ctep.cancer.gov/industryCollaborations2/guidelines_for_collaboration.htm>
8. Third Party Beneficiary: For Formulary Agent(s) and/or data and results originating under this Agreement, the Collaborator 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.
9. **For Studies related to a Formulary Protocol**, Institution and Approved Investigator agree to the following:
	1. Approved Investigator will develop the Formlary Protocol and obtain Collaborator approval of a Formulary Protocol version prior to submission to Provider for Provider’s approval.
	2. Approved Investigator will submit, or arrange for submission of, the Formulary Protocol to all appropriate IRBs, and ensure that the IRBs are notified of the role of Collaborator in providing the Formulary Agent(s) for the research by including the NCI Standard Protocol Language into the final Formulary Protocol. In addition to the Formulary Protocol, all associated documents, including informational documents and advertisements, must be reviewed and approved by all appropriate IRBs before starting the clinical investigation.
	3. Approved Investigator will submit an IND Application to the FDA to conduct the Formulary Protocol in accordance with obligations of 21 CFR 312, be the IND Sponsor for the Study and will be responsible for all regulatory submissions to the FDA concerning the Study. Approved Investigator will cross-file on Collaborator’s IND and/or DMF, to the extent applicable, and will be responsible for all applicable regulatory information. All Approved Investigators participating in clinical trials must have current investigator registration documents (Form 1572, Financial Disclosure, Curriculum Vitae, and Supplemental Investigator Form) on file with the Provider. The Form 1572s and CVs are available for request by the FDA only and would be provided directly from the Provider to the FDA upon receipt of a written request from the FDA. The IND must be in effect prior to beginning the clinical investigation.
	4. Approved Investigator will send Provider and Collaborator: a copy of the IND Safe-to-Proceed letter, the version of the Formulary Protocol on which is the letter is based, and the IRB approval, all prior to shipment of the Formulary Agent(s) by the NCI’s Pharmaceutical Management Branch. Approved Investigator further agrees that the Formulary Agent(s) will be used only in accordance with the FDA approved Formulary Protocol and in accordance with FDA IND regulations and all Federal laws and regulations that govern the use of investigational agents in clinical trials.
	5. Approved Investigator will be responsible for submitting the Formulary Protocol to clintrials.gov within twenty-one (21) days of initiating patient enrollment, and providing the results reporting as required, it being understood that no such submission will be made until the Formulary Protocol is approved by Collaborator.
	6. Approved Investigator will submit all serious adverse events to the CTEP-Adverse Event Reporting System (CTEP-AERS), according to the expedited adverse event reporting requirements stipulated in the Formulary Protocol. All such CTEP-AERs reports shall be copied to Collaborator.
	7. As IND Sponsor, the Approved Investigator shall report Adverse Events to the FDA in compliance with both 21 CFR § 312.32 and 312.33, and will forward copies of all such reports to Collaborator within 24 hours of FDA notification.
	8. Approved Investigator will notify Collaborator of all significant meetings and communications with the FDA concerning the Formulary Protocol and the Formulary Agent(s). Further, the the Institution will provide Collaborator and Provider with copies of FDA meeting minutes, all transmittal letters for IND submissions, formal questions and responses that have been submitted to the FDA, Annual Reports, and official FDA correspondence, pertaining either to an IND under this Agreement or to the investigators on the Formulary Protocol, except to the extent that those documents contain the proprietary information of a third party or where dissemination is prohibited by law.
	9. Approved Investigator will submit the required data elements, at least quarterly, to the specified NCI Clinical Data Reporting system, which will be made available to Provider and Collaborator.
	10. Approved Investigator agrees to provide Collaborator with (i) an electronic draft of the final study report for Collaborator review thirty (30) days before report finalization, and (ii) the final version of the final study report promptly following Study completion. Publications or clinical results required by **clinicaltrials.gov** resulting from the Study will also fulfill this reporting obligation if they contain (i) summary results for each of the primary, secondary and exploratory objectives in the Formulary Protocol, and (ii) a summary of all Study-related adverse events. Approved Investigator shall consider in good faith any comments provided by Collaborator on the draft of the final study report and shall not include any statements relating to the Formulary Agent(s) which have not been approved by Collaborator.
	11. Institution agrees that the following items will be submitted throughout the course of the Study, to the addresses provided:
	12. Notification of any changes in Formulary Protocol status: CTEP via pio@ctep.nci.nih.gov for forwarding to the Collaborator.
	13. Copies of continuing IRB review approvals: pio@ctep.nci.nih.gov
	14. Copies of any abstracts, manuscripts, proposed **clintrials.gov** submissions and similar regulatory submissions outside of the U.S. and publications: NCICTEPpubs@mail.nih.gov
	15. Data submission, through the specified NCI Clinical Data Reporting system
	16. Expedited serious Adverse Events, through CTEP AERS
	17. If a Formulary Agent is subject to a CTEP-sponsored IND as well, then copies of all safety reports submitted to the FDA per 312.32 by the Institution, will be forwarded to Provider at CTEPsupportAE@tech-res.com.
	18. Institution agrees that the Formulary Agent(s) supplied are for investigational use only under the Institution’s IND and the Formulary Protocol, and may not be sold commercially or transferred to a third party not involved in the conduct of the Formulary Protocol without prior written approval from the Provider and Collaborator.
	19. Approved Investigator will:
10. Keep appropriate records and take reasonable steps to ensure that any Formulary Agent is used only in accordance with the Formulary Protocol and applicable laws and FDA regulations;
11. Ensure the Formulary Agent(s), and all Confidential Information supplied by Collaborator relating to the Formulary Agent(s), will be used solely for the conduct of the Study;
12. Not perform an analysis of, or make a modification to, a Formulary Agent without Collaborator’s prior written consent;
13. Ensure any unused quantity of a Formulary Agent will be disposed as required by all applicable laws and regulations at Institution’s cost (and Collaborator’s instructions, if provided). No Formulary Agent supply is to be sent back to Collaborator, and Collaborator will be provided a certificate of destruction of such unused Formulary Agent.
14. Notify Collaborator within twenty-four (24) hours of Institution receiving notification or becoming aware of any product complaint related to a Formulary Agent. For purposes of this requirement, a product complaint is any written, electronic, or oral communication that alleges deficiencies of a drug or drug delivery systems related to: (1) identity, (2) performance, (3) reliability, (4) safety, (5) quality, (6) durability, (7) purity, or (8) effectiveness.
	1. Institution understands that Collaborator may sponsor its own clinical trials and hold its own IND for studies performed outside the scope of this Agreement. All data from those clinical trials are proprietary to Collaborator.

**Signatures Begin On Next Page**

**SIGNATURES**

**RECIPIENT**

Accepted and Agreed:

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<Authorized Official’s Name> Date

<Title>

Recipient's Contact Information:

Address:

Email:

Phone:

**RECIPIENT’S INVESTIGATOR**

Read and Understood:

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<Name> Date

<Title>

Recipient's Investigator’s Contact Information:

Address:

Email:

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

(The Agreement will require Dr. Doroshow’s signature if a Formulary Agent is supplied to support the Formulary Protocol.)

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Date James Doroshow, M.D.

 Director, Division of Cancer Treatment and Diagnosis, NCI

Please email all correspondence related to this agreement to Anna Amar at **anna.amar@nih.gov**.

**APPENDIX A**

**Approved Investigator Checklist for**

**Clinical Material Transfer Agreement**

The documents listed below must be on file at CTEP prior to Formulary Protocol approval and shipment of a PMB-supplied Formulary Agent:

 Submit to pio@ctep.nci.nih.gov:

1. A copy of the FDA acknowledgement letter of IND submission, which states the IND number, sponsor, title, date of submission and date of receipt;
2. A copy of the FDA’s Safe-to-Proceed letter regarding the IND submission, accompanied by the version of the Formulary Protocol on which this decision was based; and
3. Documentation of IRB approval of the above Formulary Protocol.
4. Documentation of Institutional Biosafety Committee (IBC) approval, if pertinent any Formulary Agent.
5. Written documentation of Active NCI Investigator Registration Status for any Approved Investigators participating on the Formulary Protocol.