**NATIONAL CANCER INSTITUTE (NCI)**

 **FORMULARY MATERIAL TRANSFER AGREEMENT**

**Provider:** NCI as represented by the Division of Cancer Treatment and Diagnosis

**Institution:** University of

**Approved Investigator:** Dr. Doctor, M.D., as an employee of the University of

**NCI Collaborator(s):**

**Definitions:**

“**Approved Investigator”** is an Institution investigator who has current investigator registration documents on file with the Pharmaceutical Management Branch (PMB) of NCI. To be an Approved Investigator for this Agreement the Institution investigator must be from an NCI-Designated Cancer Center that has been audited by NCI in the past 3 years and specifically approved by NCI to participate in the NCI Formulary.

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

 **“Formulary Protocol”** for clinical studies under this Agreement is the FDA, and applicable institutional review board (IRB), approved protocol to be used for any clinical research that will be undertaken using the Formulary Agent(s) as listed in ~~Exhibit~~ Attachment A.

**“GCP”** means the Good Clinical Practice standards officially published by the European Medicines Agency (EMA), the FDA and the International Conference on Harmonization 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 any Formulary Agent.

**“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.

“**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 (Investigational Agent) is performed in human subjects in the United States or intended to support a United States licensing action. The sponsor for the IND under this Agreement is the Institution or Approved Investigator.

**“NCI Collaborator”** means the pharmaceutical or biotechnology company having a CRADA with NCI to provide Formulary Agent(s) to the NCI Formulary, as listed above.

**“NCI Formulary”** is the [***Cancer Moonshot***](https://www.whitehouse.gov/the-press-office/2016/02/01/fact-sheet-investing-national-cancer-moonshot) initiative, a public-private partnership with pharmaceutical and biotechnology companies to expedite cancer researchers’ access to investigational agents and approved drugs for their research projects from a preapproved list and test them for new indications or in new combinations.

**“Study”,** as listed in Attachment A, means the clinical research and/or the non-clinical research to be conducted under this Agreement.

The Institution and the NCI agree as follows:

1. **Transfer**. Following receipt of all required documentation, NCI agrees to transfer to Institution the following Formulary Agent(s) for use by Approved Investigator in Study described in Attachment A:

(a), for Protocol #, entitled “XXXXX”;

(b) \_\_\_\_\_ (mg or g), for non-clinical research.

1. **Use.**
	* 1. Formulary Agent(s) will be used by Approved Investigator solely in connection with the Study as described with specificity in Attachment A of this Agreement. The Formulary Agent(s) will not be used for commercial purposes. Institution and Approved Investigator agree to comply with all Federal rules and regulations including GCPs and GLPs applicable to clinical trials and the handling of the Formulary Agent(s). Approved Investigator(s) and Institution acknowledge that they are solely responsible for the conduct of the Study.
		2. Approved Investigator will retain control over the Formulary Agent(s) and not transfer Formulary Agent(s) to other parties not directly involved in the conduct of the Study without prior written approval from NCI Collaborator and NCI.
		3. No analysis or modification of the Formulary Agent will be performed without NCI Collaborator’s prior written consent.
		4. After completion of the Study or upon termination of this Agreement in accordance with Article 13, below, any unused quantity of a Formulary Agent will be disposed of as required by all applicable laws and regulations at Institution’s cost (and in accordance with NCI Collaborator’s instructions, if provided). No Formulary Agent is to be sent back to NCI or NCI Collaborator. Approved Investigator will provide NCI Collaborator with a report of destruction of such unused Formulary Agent.
2. **Confidentiality**. 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 NCI's or NCI Collaborator’s written information about the Formulary Agent(s) that is stamped "CONFIDENTIAL” (“Confidential Information”) except for information (i) that was previously known to Institution or (ii) that is or becomes publicly available without breach of this Agreement by Institution or (iii) which is disclosed to Institution without a confidentiality obligation by a third party having a lawful right to do so or (iv) is independently developed by Institution’s personnel who have not had access to Confidential Information as demonstrated by competent written proof, or (v) is required to be disclosed by law. Any oral disclosures to Institution will 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 will be deemed confidential.
3. **Publications.**
4. Approved Investigator may publish or otherwise publicly disclose the results of the Study, however, NCI Collaborator will have forty-five (45) days to review proposed clinicaltrials.gov results and reports submissions and proposed manuscripts for publication, and ten (10) days 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. NCI Collaborator will have seven (7) days to review and approve the initial clinicaltrials.gov submission. NCI Collaborator may request in writing that a proposed publication be delayed for up to sixty (60) additional days as necessary to file, or request Approved Investigator, and/or Institution to file a patent application or other action to protect NCI Collaborator’s intellectual property interests.
5. If Approved Investigator and/or Institution are unwilling to delay the publication or presentation, Approved Investigator/Institution will remove from the publication or presentation the information which NCI Collaborator has specified it reasonably believes would jeopardize its intellectual property interests. Manuscripts to be submitted for publication and proposed abstracts or presentations by Approved Investigators will be sent to NCI’s Regulatory Affairs Branch at ***NCI CTEP Publications*** for forwarding to NCI 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 Study, Institution agrees to acknowledge NCI, the NCI Formulary program and NCI Collaborator’s contribution of the Formulary Agent(s) unless requested otherwise.
6. **Data.** Institution and Approved Investigator agree that all results of the Study will be provided to the NCI for forwarding to or for access by NCI Collaborator including all public disclosures as described in Article 4. Further, Approved Investigator agrees to keep data and results generated under this Agreement confidential until published and agrees that NCI and NCI 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 and Approved Investigator will provide any such data and results upon request. Institution and Approved Investigator further agree to make sure the informed consent form includes language providing the NCI and the NCI Collaborator with access to all data, including raw data and case report forms for regulatory purposes.
7. **Intellectual Property.** Institution will retain title to any patent or other intellectual property rights in inventions made solely by its employees in the course of the Study. Title to any patent or other intellectual property rights in inventions made jointly by Institution employees and NCI Collaborator employees will be held jointly by Institution and NCI Collaborator. Institution agrees to notify NCI and Collaborator upon the filing of any patent applications related to research with the Formulary Agent(s) under this Agreement and to provide any applicable NCI Collaborator the rights described in the [***NCI Cancer Therapy Evaluation Program (CTEP) Intellectual Property Option to Collaborator***](http://ctep.cancer.gov/industryCollaborations2/guidelines_for_collaboration.htm)***.***
8. **Warranty.** NCI and NCI Collaborator make no representations that the use of the Formulary Agent(s) will not infringe any patent or proprietary rights of third parties.
9. **Endorsement.** Institution agrees not to claim, infer, or imply endorsement by the U.S. Federal government of the Study, the Institution or personnel conducting the Study or any resulting product.
10. **Liability.** Unless prohibited by law from doing so, Institution agrees to hold the Government and NCI 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).
11. **Law.** This Agreement will be construed in accordance with Federal law as applied by the Federal courts in the District of Columbia.
12. **Third Party Beneficiary.** NCI 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.
13. **Certification.** The undersigned Provider and Institution expressly certify and affirm that the contents of any statements made herein are truthful and accurate.
14. **Termination.**
	1. If only non-clinical studies are conducted, this Agreement will terminate at the earlier of (i) three (3) years from the date of the last signature below; or (ii)

 thirty (30) days after either Party receives written notice of the other Party’s desire to terminate this Agreement; or

immediately upon the mutual agreement of the Parties in writing.

* 1. If clinical studies are conducted, this Agreement will remain in effect until the completion of the Protocol(s), or will terminate immediately if the Parties mutually agree for safety concerns, or thirty (30) days after Institution receives written notice of NCI’s need to terminate this Agreement. For the purposes of this Agreement, completion of a protocol is defined as all patients having completed treatment with the Formulary Agent.

**FOR CLINICAL FORMULARY PROTOCOLS:**

1. For any Study that involve a Formulary Protocol, the Institution agrees as follows:
2. Approved Investigator will develop Formulary Protocol and obtain NCI Collaborator approval of a Formulary Protocol. A copy of the NCI Collaborator-approved protocol and NCI Collaborator’s approval notification must be submitted to NCI for NCI approval of Formulary Protocol.
3. An initial draft version of the Formulary Protocol must be submitted to the NCI at the same time it is provided to NCI Collaborator for Formulary Agent forecasting purposes.
4. 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 NCI Collaborator in providing the Formulary Agent(s) for the research by including NCI Formulary standard protocol language into the final Formulary Protocol. Approved Investigator will also include language in the informed consent stating that the NCI Collaborator will have access to all data, including raw data, from the Protocol for regulatory purposes. In addition to the Formulary Protocol, all associated documents, including informational documents and advertisements, must be reviewed and approved by the appropriate IRB(s) before starting the Formulary Protocol.
5. Approved Investigator will submit an IND Application to the FDA to conduct the Formulary Protocol in accordance with obligations of 21 CFR Part 312, and will be responsible for all regulatory submissions to the FDA concerning the Formulary Protocol. Approved Investigator will cross-file on NCI Collaborator’s IND and/or drug master file (DMF), to the extent applicable, and will be responsible for all applicable regulatory information. All Approved Investigators participating in Formulary Protocol must have current investigator registration documents, including FDA Form 1572, Financial Disclosure, Curriculum Vitae, and Supplemental Investigator Data Form, on file with the NCI. The Form 1572s and Financial Disclosures are available for request by the FDA only and would be provided directly from the NCI to the FDA upon receipt of a written request from the FDA. The IND must be in effect prior to beginning the Formulary Protocol.
6. Approved Investigator will provide NCI and NCI Collaborator with a copy of, the IND Safe-to-Proceed letter, the version of the Formulary Protocol on which the letter is based, and all applicable IRB approvals, all prior to NCI approval of the Formulary Protocol and shipment of the Formulary Agent(s) by the NCI’s Pharmaceutical Management Branch (PMB). 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.
7. Approved Investigator will be responsible for submitting the Formulary Protocol to clinicaltrials.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 after the Formulary Protocol is approved by NCI Collaborator.
8. The 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 will be copied to NCI Collaborator.
9. As the IND Sponsor, the Approved Investigator will 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 NCI Collaborator within 24 hours of FDA notification.
10. The Approved Investigator will notify NCI Collaborator of all significant meetings and communications with the FDA concerning the Formulary Protocol and the Formulary Agent(s). Further, the Approved Investigator will provide NCI Collaborator 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 the IND under this Agreement or to the Approved Investigators on the Formulary Protocol, except to the extent that those documents contain the proprietary information of a third party or dissemination is prohibited by law.
11. In accordance with the Formulary Protocol, the Approved Investigator will submit the required data elements, at the specified intervals, to the specified NCI clinical data reporting system, which will be made available to NCI and the NCI Collaborator.
12. Institution will notify NCI Collaborator within twenty-four (24) hours of Approved Investigator and/or 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 Formulary Agent or drug delivery system related to: (1) identity, (2) performance, (3) reliability, (4) safety, (5) quality, (6) durability, (7) purity, or (8) effectiveness.
13. The following items should be submitted throughout the course of study, to the NCI at addresses provided with copies to the NCI Collaborator:
14. Notification of any changes in protocol status, IND status and notification of any amendments to the Formulary Protocol that may affect Formulary Agent(s) supply needs to ***CTEP Protocol and Information Office***
15. Copies of continuing IRB review approvals to ***CTEP Protocol and Information Office***
16. Copies of any abstracts, manuscripts, proposed clinicaltrials.gov submissions and publications to ***NCI CTEP Publications***
17. Data submission through the specified NCI Clinical Data Reporting system
18. Expedited serious Adverse Events through CTEP-AERS
19. If requested by NCI, Approved Investigator will forward copies of all safety reports submitted to the FDA per 21 CFR 312.32 to NCI at ***CTEP AE Support*** for any Formulary Agent that is also subject to a CTEP-sponsored IND.

**SIGNATURES**

**INSTITUTION**

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<Name of Authorized Signatory for Institution> Date

<Title>

 Read and Understood by:

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<Dr. Doctor, M.D.> Date

Recipient’s Address:

Phone:

Email:

**NATIONAL CANCER INSTITUTE**

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Sherry Ansher, Ph.D. Date

Associate Chief, Agreement Coordination Group

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

CTEP Alternate Technology Development Coordinator

For a clinical Study where the Formulary Agent(s) are supplied to support a Formulary Protocol:

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James Doroshow, M.D. Date

Director, Division of Cancer Treatment and Diagnosis

Please address all correspondence related to this agreement to Lora Spencer at the following address by express mail:

Lora Spencer, J.D., M.B.A.

Research and Development Agreements Advisor, Regulatory Affairs Branch

Cancer Therapy Evaluation Program

9609 Medical Center Dr., Room 5W530

Bethesda MD 20892-9740 (if US Postal Service), Rockville MD 20850 (if private carrier)

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).

**Attachment A**

**Summary of Study**

The Formulary Agent(s) to be provided:

**If for clinical use:**

Formulary Agent(s) will be used in the following approved clinical trial:

Formulary Protocol#:

Entitled:

Quantity Requested:

Summary of Clinical Research:

**Or**

**If for non-clinical use**

Formulary Agent(s) will be used in the following approved research proposal:

**Attachment B**

**Approved Investigator Checklist for**

**Clinical Research using Formulary Agent(s)**

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

 Submit to ***CTEP Protocol and Information Office***

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 your IND submission, accompanied by the version of the Formulary Protocol on which this decision was based;
3. Documentation of IRB approval of the above Formulary Protocol;
4. A Copy of the final protocol and NCI Collaborator’s written approval of the Formulary Protocol;
5. Documentation of Institutional Biosafety Committee (IBC) approval, if pertinent to the Formulary Agent(s); and
6. Written documentation of Active Approved Investigator Registration Status for all Approved Investigators participating on the Formulary Protocol:

By Express Courier (FEDEX, UPS, etc.):

Pharmaceutical Management Branch

CTEP, DCTD, NCI
Room 5W228, MSC 9725
9609 Medical Center Drive

Rockville, MD 20850
(240) 276-6575