**NATIONAL CANCER INSTITUTE (NCI)**

 **FORMULARY MATERIAL TRANSFER AGREEMENT**

**FOR CLINICAL OR NON-CLINICAL RESEARCH**

**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:** All capitalized terms defined herein shall have the meaning consistent with those set forth in the Cooperative Research and Development Agreement (CRADA) between NCI and the NCI Collaborator.

“**Approved Investigator”** is an investigator responsible for serving as the lead researcher of a clinical or non-clinical study and who (i) is not an NCI employee; (ii) is approved to participate in the NCI Formulary; (iii) has (or will have) executed an NCI Formulary Material Transfer Agreement; (iv) in the case of a clinical study, (A) is a Clinical Investigator and (B) is the Sponsor for the applicable Study/Protocol; and (v) submits a Protocol/Proposal which is approved by Collaborator.

 **“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 Attachment A.

“**Formulary Proposal**” for Non-Clinical studies under this Agreement is the non-clinical investigation in which a drug is used in vivo or in vitro. It proposes and describes the objective(s), design, methodology, statistical considerations, and organization of a research study, which requires Collaborator’s written approval. For the purposes of this MTA, the term, Proposal, for a Non-Clinical Study involving any animals, includes any and all associated documents required by the applicable IACUC.

**“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.

“**Identifiable Private Information” or “IPI” about a Human Subject** means private information from which the identity of the subject is or may readily be ascertained. Regulations defining and governing this information include 45 C.F.R. Part 46 and 21 C.F.R. Part 50.

“**Institutional Animal Care and Use Committee”** or “**IACUC**” means, in accordance with the Animal Welfare Act codified in Title 9 C.F.R., Chapter 1, Subchapter A - Animal Welfare, Parts 1, 2, and 3, an institutional committee established to protect the welfare of animals used in research and education.

“**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.

“**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 directly from NCI drug repository or indirectly through the Collaborator the following Formulary Agent(s) for use by Approved Investigator in Study described in Attachment A:

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

(b) \_\_\_\_\_ (mg or g), as necessary for completing the approved Formulary Protocol in a clinical research or the approved Formulary Proposal in a 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 on behalf of Approved Investigator agrees to comply with all Federal rules and regulations including GCPs and GLPs applicable to clinical trials and/or non-clinical research 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.

No analysis or modification of the Formulary Agent will be performed without NCI Collaborator’s prior written consent except for what’s deemed necessary to complete the clinical or non-clinical Study as described in Attachment A.

* + 1. In the event that any animal research is included in the approved Formulary Proposal, such animal research shall be done in strict accordance with the Formulary Proposal(s), as approved by the IACUC, and no substantive changes in a finalized Formulary Proposal will be made unless mutually agreed upon, in writing, by the Parties and Collaborator.
		2. 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 returned to Collaborator at Collaborator’s expense or disposed as directed by Collaborator properly in compliance with all applicable laws and regulations at Institution’s cost (and in accordance with NCI Collaborator’s instructions, if provided) with a written proof of destruction.
1. **Confidentiality**. To the extent permitted by law and except for IPI if any for which the obligation to maintain confidentiality will extend indefinitely, 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 confidential information about the Formulary Agent(s) that is provided by or on behalf of NCI or NCI Collaborator and that is stamped "CONFIDENTIAL” or would otherwise be recognizable to a reasonable person skilled in the industry as being confidential or proprietary (“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, (v) information that relates to potential hazards or cautionary warnings associated with the production, handling, or use of the Formulary Agent, or (vi) is required to be disclosed by law or court order. 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 automatically 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 and treated as Confidential Information accordingly.
2. **Publications.**
3. Approved Investigator may publish or otherwise publicly disclose the results of the Study, which public disclosures may be in the form of abstract, manuscript, reports, or presentation. However, in the case of an approved clinical study under this Agreement, NCI Collaborator will have forty-five (45) days to review proposed clinicaltrials.gov results and reports submissions and proposed manuscripts for publication, and seven (7) business days to review proposed abstracts or presentations to assure that NCI Collaborator’s Confidential Information is protected, except when a shortened time period under a court order or the Freedom of Information Act pertains.
4. NCI Collaborator may request in writing that a proposed manuscript, resulted from an approved clinical or non-clinical Study outlined in Attachment A 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. Any proposed press release by Institution that references or relies upon the Study under this Agreement shall be submitted to NCI and NCI Collaborator for review and comment at least five (5) business days before publication.
6. 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.
7. **Data.** Institution agrees and Approved Investigator knowledges that all data and results of the Study generated under this Agreement (“**Study Data**”) 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, Institution on behalf of Approved Investigator agrees to keep Study Data confidential until published and agrees that NCI and NCI Collaborator will have the right to use any and all such Study Data for any lawful purposes including regulatory filing and patent applications. In the case of an approved clinical Study under this Agreement, Institution further agrees to make sure the informed consent form includes language providing the NCI and the NCI Collaborator with access to all Study Data, including raw data and case report forms for regulatory purposes.
8. **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 timely notify NCI and Collaborator upon the filing of any patent applications related to the Study 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)***.***
9. **Study Reports**.
	1. **Interim Study Reports**. The Approved Investigator of Formulary Proposal shall provide Collaborator with bi-annual Study reports that outline the progress of the approved Proposals and shall copy NCI Formulary via NCIFormulary@mail.nih.gov, and may provide more information or updates at Collaborator’s reasonable requests. The Approved Investigator of Formulary Protocol shall provide Collaborator with quarterly reports that outline the progress of the Protocol(s) and shall copy NCI Formulary via NCIFormulary@mail.nih.gov.
	2. **Final Study Report**. Approved Investigators will provide to Collaborator exchange final reports of their clinical or Non-clinical Study results within six (6) months after the expiration completion or termination of each Study under this Agreement. These reports shall set forth the technical progress made and any publications arising from the research. Abstracts and publications provided to CTEP by Approved Investigators and further provided by CTEP to Collaborator will fulfill this final report obligation. With respect to clinical studies, a copy of the IND(s) Annual Report will also fulfill this reporting obligation.
	3. **Safety Reporting and IND Annual Reports**. Safety reports and IND Annual Reports in any Formulary Protocol under this Agreement is set forth in Article 15.
10. **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.
11. **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.
12. **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).
13. **Law.** This Agreement will be construed in accordance with Federal law as applied by the Federal courts in the District of Columbia.
14. **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.
15. **Certification.** The undersigned Provider and Institution expressly certify and affirm that the contents of any statements made herein are truthful and accurate.
16. **Expiration and Termination.**
	1. In the event of termination or expiration of the CRADA to which this Agreement correlates, this Agreement non-clinical Studies hereunder will terminate automatically in accordance with the termination provisions in the applicable CRADA.
	2. If only non-clinical Studies are conducted, this Agreement shall terminate at the earlier of (i) three (3) years (“Term”) from the date of the last signature below (“Effective Date”); or (ii) thirty (30) days after either Party receives a written notice of the other Party’s desire to terminate this Agreement; or immediately upon the mutual agreement of the Parties in writing.
	3. If clinical Studies are conducted, this Agreement will remain in effect until the completion of the Protocol(s), or shall terminate immediately if the Parties mutually agree for safety concerns, or thirty (30) days after Institution and/or Approved Investigator receives written notice of NCI’s need to terminate this Agreement (“Term”). For the purposes of this Agreement, completion of a protocol is defined as all patients having completed treatment with the Formulary Agent.
	4. The Term of this Agreement may be extended, and the provisions of this Agreement may be modified only by amendment signed by the duly authorized signatory for each Party.
	5. The provisions of Paragraphs 3, 4, 5, 6, 8, 9, 10, 11, 12, and 14(e) will survive the expiration or early termination of this Agreement.

**FOR CLINICAL FORMULARY PROTOCOLS:**

1. For any Study that involve a Formulary Protocol, the Institution agrees, and the Approved Clinical Investigator acknowledges 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, and NIH Biosketch 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). Institution agrees and Approved Investigator further acknowledges 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. Approved Investigator will copy the NCI Collaborator on all such CTEP-AERs reports.
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 the 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 shall submit the required data elements, at the specified intervals, to the specified NCI clinical data reporting system. In addition, according to Paragraph 7(a), the Approved Investigator shall send quarterly reports to the Collaborator (and copy NCI Formulary via NCIFormulary@mail.nih.gov), which will be made available to NCI.
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.

**SINGATURES APPEAR ON NEXT PAGE**

**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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Jianqiao Zhang, 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 Svetlana Nazarenko at the following address by express mail:

Svetlana Nazarenko, MS

Clinical Program Manager, Division of Cancer Treatment and Diagnosis/Office of the Director

National Cancer Institute/National Institutes of Health

9609 Medical Center Drive, Room 5W416, Rockville, MD 20850

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

And/or at NCIFormulary@mail.nih.gov

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 a Clinical Study:**

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

Formulary Protocol#:

Entitled:

Summary of the Clinical Study:

**And/Or**

**If for a Non-Clinical Study:**

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

Formulary Proposal #:

Entitled:

Summary of the Non-Clinical Study:

**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. Documentation of Active Approved Investigator Registration Status for all Approved Investigators participating on the Formulary Protocol via submission through the CTEP Registration and Credential Repository.