**Clinical Trial Participation Agreement**

This Clinical Trial Participation Agreement (the “Agreement”) is entered into by the National Cancer Institute, having its principal place of business at 9609 Medical Center Drive, Rockville, MD 20850 (“NCI”) and [Company Name], having its principal place of business at [Company Address] (“Pharmaceutical Collaborator”), on the other hand. NCI and Pharmaceutical Collaborator may be referred to herein individually as a “Party” and collectively as the “Parties.”

**RECITALS**

Whereas, NCI is sponsoring a clinical protocol entitled “Molecular Analysis for Therapy Choice” (“NCI-MATCH”) and

Whereas, Pharmaceutical Collaborator intends to support the clinical trial (the “Study”) in accordance with a clinical research protocol entitled NCI MATCH (the “Protocol”), as such Protocol may be amended from time to time by providing; and

**Whereas**, Pharmaceutical Collaboratorshall supply pharmaceutical agent(s) for the Study (an “Agent”) as listed in Exhibit A and that may be updated during the term of this Agreement in return for access to certain Agent-related data arising from the Study as described in more detail in this Agreement.

Now, Therefore, in consideration of the foregoing and the mutual covenants and promises set forth herein and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties agree as follows:

**INTRODUCTION**

NCI will provide substantial funding and will be the IND sponsor for this collaborative Study. The Division of Cancer Treatment and Diagnosis (DCTD), National Cancer Institute (NCI), recognizes the importance of the pharmaceutical industry in the clinical development of new anti-cancer agents. DCTD wishes to foster collaboration with industry whenever possible. As part of its mission to improve cancer care, DCTD shares with industry the important goal of defining the contribution of a new drug or biologic in the treatment of cancer.

NCI-MATCH is a clinical trial that will enroll patients with solid tumors or lymphomas who have progressed on standard therapy. This study aims to establish whether patients with tumor mutations/amplifications in one of the genetic pathways of interest (defined in the protocol), are more likely to derive clinical benefit as defined by objective response or progression-free survival if treated with agents targeting that specific pathway in a single-arm. Biopsies will be performed, and targeted next generation sequencing as well as a defined panel of immunohistochemistry and fluorescence in situ hybridization assays will be performed. All sequencing will be performed in a CLIA-certified Laboratory. Each treatment in NCI-MATCH will be a separate protocol “arm” and results will be interpreted independently of other “arms.”

**AGREEMENT**

The terms and conditions of this Agreement are set forth below.

**Article 1. Definitions**

"*Adverse Event*" means an adverse clinical event as defined under 21 CFR 312.32 IND Safety Reports and other applicable Federal Regulations. DCTD shall establish and maintain records and make reports to the FDA for the following Adverse Events: (1) all serious, unexpected adverse events, (2) any significant increase in the frequency of serious expected adverse events, and (3) any significant increase in the frequency of therapeutic failures. Specific NIH and NCI guidelines and policies for reporting Adverse Drug Experience, as well as common toxicity criteria, have been developed. These guidelines and policies appear in the "Investigator's Handbook: A Manual for Participants in Clinical Trials of Investigational Agents Sponsored by the Division of Cancer Treatment, and Diagnosis, National Cancer Institute", <http://ctep.cancer.gov/investigatorResources/docs/InvestigatorHandbook.pdf>.

"*Affiliates*" means any corporation or other business entity controlled by, controlling, or under common control with Pharmaceutical Collaborator. For this purpose, "control" means direct or indirect beneficial ownership of at least fifty (50) percent of the voting stock, or at least fifty (50) percent interest in the income of such corporation or other business.

"*Agent*" means the pharmaceutical agent(s) to be provided by Pharmaceutical Collaborator for use in the Study, as such pharmaceutical agent(s) are listed on Exhibit A.

"*Amendment*" means any formal change to this Agreement that is made after its effectiveness in accordance with Article 23 of this Agreement.

"*Annual Report*" means a brief report of the progress of an IND-associated investigation, which the IND sponsor is required to submit to the FDA within sixty (60) days of the anniversary date that the IND went into effect (pursuant to 21 CFR 312.33). DCTD shall provide Pharmaceutical Collaborator a copy of the portion of the Annual Report related to the Agents under this Agreement simultaneously with the submission of the Annual Report to the FDA.

“*Clinical Data and Results*” means all the clinical information, data, and results developed or obtained in connection with the Study.

“CLIA refers to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 under which the Centers for Medicare and Medicaid Services regulates all laboratory testing (except research) performed on humans in the United States (<http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/clia/>)

"*Clinical Site*" means a site or institution that will participate in performance of the Study.

"*Confidential Information*" means confidential scientific, business or financial information and data, provided that such information and data:

are not publicly known or available from other sources who are not under a confidentiality obligation to the source of the information;

have not been made available by its owners to others without a confidentiality obligation;

are not already known by or available to the receiving Party without a confidentiality obligation;

do not relate to potential hazards or warnings associated with the production, handling or use of the subject matter of this Agreement.

If any one or more of the above provisions of this definition are not met, the relevant information shall no longer be considered proprietary.

"*CTEP*" means the Cancer Therapy Evaluation Program, DCTD, NCI.

"*DCTD*" means the Division of Cancer Treatment and Diagnosis, NCI.

"*DHHS*" means the Department of Health and Human Services.

"*Drug Master Files*" or "*DMFs*" means reference files submitted to FDA that are used in the review of investigational and marketing applications for human agents. Drug Master Files allow another party to reference this material without disclosing to that party the contents of the file.

“*ECOG-ACRIN*” means the NCI National Clinical Trials Network (NCTN) Cooperative Group that is leading the Protocol within the NCTN.

"*FDA*" means the Food and Drug Administration, DHHS.

*“FNLCR”* means the Frederick National Laboratory for Cancer Research in Frederick, MD, operated under contract by Ledios Biomedical Research (formerly SAIC-Frederick).

"*Funding Agreement*" means a contract, grant, or cooperative agreement entered into between a Federal agency and another party for the performance of experimental, developmental, or research work funded in whole or in part by the Federal Government.

"*Government*" means the U.S. Government and any of its agencies.

"*Human Subjects*" means individuals whose physiologic or behavioral characteristics and responses are the objects of study in a research project. Under the Federal regulations for the protection of human subjects, human subjects are defined as living individuals about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information (45 CFR 46.102(f)).

"*IDE*" means Investigational Device Exemption as defined in Title 21 Code of Federal Regulations (CFR) Part 812 and required before a clinical trial that uses a significant risk device can begin.

"Identifiable Private Information" means patient-identifying data from medical records or attached to patient specimens, to be obtained prospectively or from stored medical records or specimens, that can be linked to individual human subjects, either directly or indirectly through codes.

"*IND*" means an Investigational New Drug Application. The IND is the legal mechanism under which experimental drug research is performed in the United States. An IND is submitted to the Food and Drug Administration in order to conduct experimental clinical trials. The FDA regulations require continual updates to the IND including, but not limited to, Annual Reports, adverse drug experience reports, new protocols, protocol amendments and pharmaceutical data.

"*Investigator*" means any physician who assumes full responsibility for the treatment and evaluation of Study subjects according to the Protocol, as well as the integrity of the Study-related data.

"*Investigator Brochure (IB)*" means a document containing all the relevant information about the Agent, including preclinical pharmacology, preclinical toxicology, and detailed pharmaceutical data. Also included, if available, is a summary of current knowledge about pharmacology and mechanism of action and a full description of the clinical toxicities.

“*Molecular Profiling Data*” means the data derived from the genetic sequencing and other molecular assays performed on Study subjects’ tumors for the purpose of determining the Study Arm in which the Study subject will be enrolled.

"*NCTN*" means the National Clinical Trials Network (effective March 1, 2014), a consolidated and integrated program funded by NCI with the overall goal of conducting a spectrum of definitive clinical trials across a broad range of diseases and diverse patient populations, as well as development efforts preliminary to those trials, as part of NCI’s overall clinical research program for adults and children with cancer. The NCTN Program is comprised of four U.S. adult Network Cooperative Groups, one Canadian adult Network Cooperative Group, and one pediatric Network Cooperative Group.

"*Network Cooperative Group*" means one of the six (6) participants in the NCTN. Each Network Cooperative Group is comprised of investigators who join together to develop and implement protocols. The lead Network Cooperative Group of the Protocol, through its central operations and statistical center, supports the administrative and regulatory requirements of the clinical research, performs central data collection and analysis, verifies compliance with the Protocol via a quality assurance program and site visit auditing, and publishes the study results.

"*NDA*" means a New Drug Application. The NDA is the formal process by which the FDA approves a drug for commercial distribution.

"*NIH*" means the National Institutes of Health, PHS, DHHS.

"*PHS*" means the Public Health Service, DHHS.

"*PMB*" means the Pharmaceutical Management Branch of CTEP, NCI.

"*PRC*" means the CTEP Protocol Review Committee which reviews all studies involving NCI investigational agents and/or activities supported by NCI.

“*Protocol*” means the Master Screening Protocol and Study Arms. Protocol is also referred to as Study in the CTA.

"*Protocol Amendment*" means an amendment to the Protocol or Study, including the addition of a Study Arm.

"*Raw Data*" means the data collected on the case report forms which contain identifiable private information.

"*Regulatory Affairs Branch*" means the Regulatory Affairs Branch, CTEP, DCTD, NCI.

"*Sponsor*" means an organization or individual who assumes legal responsibility for overseeing clinical trials with investigational drugs.

“*Study* *Arm(s)*” means the sub-studies of the Protocol. The arms are studies of an agent or treatment in a group of patients whose tumors manifest particular molecular features.

"*Study Arm Data*" means Study Data specifically pertaining to a Study Arm.

"*Study Data*" means the Clinical Data and Results and Molecular Profiling Data generated or obtained by ECOG-ACRIN, Clinical Sites, Investigators and their personnel, or by NCI supported clinical laboratories in the course of, and as a result of, performance of the Study.

"*Summary Data*" means a summary of the Clinical Data and Results used by DCTD to prepare an Annual Report to the FDA.

**Article 2. Protocol**

The Protocol will be determined by ECOG-ACRIN and DCTD in consultation with the FDA. The Protocol will consist of a 1) Master Screening Protocol, containing procedures common to all arms of the Study, and 2) Study Arms, comprising phase 2 sub-studies of Agents in molecularly defined cohorts of patients. DCTD will be the IND sponsor for the Study and will be responsible for all regulatory submissions to the FDA concerning the Study. The scope and nature of, as well as the instructions and timeline for, the finalized Study will be set forth in the Protocol. Pharmaceutical Collaborator shall have the opportunity to review and comment on the Master Screening Protocol and any Study Arms that use Pharmaceutical Collaborator's Agent(s) within two (2) weeks after receipt of the Master Screening Protocol and Study Arms, and shall be informed of any Master Screening Protocol (or relevant Study Arms) Amendments that are relevant to the Agent(s), and shall have the opportunity to review and comment on such Protocol Amendments within one (1) week after receipt of each Protocol Amendment. A copy of the final approved Master Screening Protocol and relevant Study Arm(s) will be forwarded to Pharmaceutical Collaborator by DCTD at the same time it is submitted to the FDA. DCTD shall consider Pharmaceutical Collaborator’s comments in good faith. If Pharmaceutical Collaborator objects to any material change to the Study Arm(s) with respect to the Agent(s), Pharmaceutical Collaborator and DCTD shall discuss such proposed material changes before finalization of the Protocol Amendment. Notwithstanding anything to the contrary herein, as between the Parties, all final decisions regarding the Master Screening Protocol, Study Arms, Protocol Amendments and the conduct of the Study shall be made by DCTD. DCTD reserves the right to remove any Agent from the Study at any time; Pharmaceutical Collaborator will have final authority over the provision of Agent to DCTD. There should be frequent and full interchange between Pharmaceutical Collaborator and DCTD.

**Article 3. Performance**

Subject to Pharmaceutical Collaborator’s compliance with its obligations regarding the Study, ECOG-ACRIN and NCI/DCTD shall use their reasonable efforts to perform the Study substantially in accordance with the Protocol. ECOG-ACRIN/NCI DCTD agree to comply with all applicable laws and regulations, including but not limited to, the Federal Food, Drug and Cosmetics Act, 21 USC § 301 *et. seq*. and the provisions of 45 CFR Part 46, “Protection of Human Subjects” during the performance of the Study.

DCTD will cross-file on Pharmaceutical Collaborator’s IND and/or DMF, to the extent applicable, and will be responsible for all applicable regulatory information. Pharmaceutical Collaborator will provide a letter of cross-reference to Pharmaceutical Collaborator’s IND and/or DMF to FDA and provide a copy to DCTD to include in the DCTD IND.

DCTD will submit required information to FDA regarding the investigational use of the assays in the NCI-MATCH according to the provisions of 21 CFR 812 (Investigational Device Exemptions).

**Article 4. Adverse Events, Annual Reports and Other IND Data**

DCTD shall report all serious and unexpected adverse events involving the Agent(s) to FDA in accordance with the reporting obligations of 21 CFR 312.32 and will, concurrently, forward all such relevant Adverse Event reports to Pharmaceutical Collaborator. All serious and unexpected adverse events will be reported to DCTD using CTEP AERS. All other Adverse Event reports involving the Agent(s) received by DCTD shall be reported to the FDA consistent with 21 CFR § 312.32 and 312.33. It is Pharmaceutical Collaborator’s responsibility to ensure that DCTD has the most current contact information for reporting Adverse Events to Pharmaceutical Collaborator.

In the event that Pharmaceutical Collaborator informs the FDA of any Adverse Events involving the Agent(s) that arise outside of the Study, Pharmaceutical Collaborator must notify the DCTD at the same time at [CTEPsupportAE@tech-res.com](mailto:CTEPsupportAE@tech-res.com). DCTD will then notify the investigator(s) at the Sites, if appropriate.

**Article 5. Drug Information and Supply**

Pursuant to the Protocol and DCTD’s written instructions, Pharmaceutical Collaborator will provide to DCTD, without charge, formulated and acceptably labeled clinical-grade or commercially labeled (as applicable) Agent(s) on a schedule that will ensure adequate and timely performance of the Study and in the quantities necessary to complete the Study Arm(s) in accordance with the Protocol. Agent(s) will be provided to the PMB, DCTD, NCI’s Clinical Repository for distribution to US Sites only participating on the Protocol. The PMB shall take responsibility for and reasonable steps to maintain appropriate records and assure appropriate supply, handling, storage, distribution and usage of the Agent(s) in accordance with the terms of this Agreement, the Protocol and any applicable laws and regulations relating thereto. The contact person for the PMB, NCI Clinical Repository will be Mr. Charles Hall, Chief, Pharmaceutical Management Branch (Telephone Number 240-276-6575) and the Pharmaceutical Collaborator contact will be (Telephone Number ). Pharmaceutical Collaborator will provide Certificates of Analysis to the PMB for each lot of each Agent provided. Pharmaceutical Collaborator will provide the PMB written notification of ongoing stability testing protocols and results for each lot of each Agent provided. Pharmaceutical Collaborator also will provide draft Agent labels to the PMB for review and approval and agrees to reasonable labeling revisions to comply with DCTD label guidelines. NCI NSC (National Service Center) numbers will be required to be on the label of Agent. PMB and Pharmaceutical Collaborator will negotiate the inventory requirements and Agent shipments sufficient to meet DCTD’s requirements for the Study Arm(s) of the Protocol. Pharmaceutical Collaborator will have final authority over the provision of its Agent to DCTD. The Parties understand and agree that delivery of the Agent(s) to DCTD shall not convey any ownership interest therein to DCTD, notwithstanding the use of such Agent(s) by DCTD in conducting the Study. Pharmaceutical Collaborator shall provide to DCTD any material information known to it regarding the safety, efficacy, recommended dosage or usage, recommended storage conditions, and known risks or contraindications, if any, with respect to the Agent(s). ECOG-ACRIN and all participating NCTN sites will use each Agent only as specified in the Protocol. Upon any termination of this Agreement, the PMB, shall return to Pharmaceutical Collaborator or, at Pharmaceutical Collaborator’s request destroy, any remaining quantities of the Agent, in either case at Pharmaceutical Collaborator’s expense. Pharmaceutical Collaborator shall provide DCTD with a copy of the Investigator Brochure for the Agent and all Agent-related materials and items (particularly information that may impact patient safety including, but not limited to, adverse drug experiences and formulation and preclinical data, including toxicology findings) in order to enable NCI and ECOG-ACRIN to perform the Study Arm involving the Agent(s). Any IB received by the PMB should be formatted according to the current FDA Portable Document Format Specifications. IB updates and summaries of changes also must be provided to DCTD. IBs should be sent to IBCoordinator@ mail.nih.gov. DCTD will be responsible for providing the IBs to all participating Investigators in the Study.

**Article 6. Data Collection and Data Rights**

Patient enrollment will be open to all U.S. adult NCTN Network Group U.S. sites. Patients will be registered through the NCI Cancer Trials Support Unit, and NCI and ECOG-ACRIN will assign Study subjects to an appropriate Study Arm, maintain a database pertinent for the Study, and conduct the interim and final analyses in accordance to the terms of the Study.

Routine reports, data, analyses and forms generated from the Study database that are specific to the Study Arm Data and the Agent(s) will be made available to the Pharmaceutical Collaborator on a quarterly basis coinciding with submission of the Clinical Data and Results to the CDUS. Should Pharmaceutical Collaborator request “non-routine” reports, data, statistical analyses, case report forms, or non-standard ECOG-ACRIN forms, which are over and above the standard statistical or data management measures normally carried out in the conduct of a major clinical trial by ECOG-ACRIN, additional funding negotiations and execution of a separate contract will be required.

All other requests by Collaborator or other third parties for access to data generated under this Agreement, including sale of such data for any purpose, must be reviewed and approved by NCI prior to any release.

ECOG-ACRIN policy does not permit anyone with a financial conflict of interest to participate in any analyses of Study Data; Pharmaceutical Collaborator representation during analyses of Study Data is thus excluded. The Study Data from other Study Arms in which Pharmaceutical Collaborator’s Agent(s) is not used will not be made available to Pharmaceutical Collaborator. Pharmaceutical Collaborator understands that case report forms, if provided, will be supplied with patient identifiers redacted. Pharmaceutical Collaborator further understands that all patient information must be and will remain confidential. In the event that Pharmaceutical Collaborator shall come into contact with a Study subject’s Identifiable Private Information, including medical records and/or Study subject specimens, Pharmaceutical Collaborator shall hold in confidence the identity of the Study subject and shall comply with all applicable law(s) regarding the confidentiality of such records as if these records were subject medical records. Pharmaceutical Collaborator shall maintain the confidentiality of all Identifiable Private Information that has been disclosed to Pharmaceutical Collaborator in connection with this Study or pursuant to this Agreement in accordance with applicable state and federal privacy and security laws.

All Clinical Data and Results (including all Study Arm Data) are the sole property of ECOG-ACRIN. All Molecular Profiling Data done in the Clinical Assay Development Network and the Molecular Characterization Laboratory at FNLCR are the property of NCI. DCTD will make somatic Molecular Profiling Data from patients treated on relevant Study Arms available to the Pharmaceutical Collaborator at least twice a year. Pharmaceutical Collaborator may use the Molecular Profiling Data for research and development and regulatory purposes related to the commercialization of its Agent(s).

Molecular Profiling Data on all patients screened or enrolled on the Study will be deposited into a controlled access database. All collaborators contributing agents to the trial will receive Molecular Profiling Data and Study Arm Data for all patients enrolled onto a Study Arm with their agent. Following publication of the primary endpoint of the Study, investigators will be able to request access to the Molecular Profiling Data from the Study. A registration process for all investigators requesting access will be developed. Collaborators will also be able to register and request access. No protected health information will be deposited into the database.

**Article 7. FDA Meetings; FDA Testimony; Forms and Financial Disclosures**

All meetings with FDA concerning the Agent(s) will be discussed by Pharmaceutical Collaborator and DCTD in advance and will be held on mutually agreed upon dates.

On occasion, data from an ECOG-ACRIN trial is used to support an NDA to the FDA. It is recognized that certain individuals, such as the Study’s chair and/or principal investigator and/or statistician, or principal investigators of individual arms of the Study, may be requested by the Pharmaceutical Collaborator to appear before the FDA or its advisory committees to present the Study Data. However, this Agreement does not obligate any member of ECOG-ACRIN or NCTN to present Study Data to the FDA or its advisory committees in support of an NDA by Pharmaceutical Collaborator.

ECOG-ACRIN does not maintain financial disclosures, 1572s or IRB approvals. ECOG-ACRIN uses a central file kept and maintained by PMB and the Cancer Trials Support Unit (“CTSU”). ECOG-ACRIN’s database uses a date field with data provided by the NCI to ensure that the information is on file and current before registration to any study may occur. The 1572s and CVs 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 NCI will not provide financial disclosure forms to the Pharmaceutical Collaborator. If Pharmaceutical Collaborator requires financial disclosure information for an NDA by Pharmaceutical Collaborator, Pharmaceutical Collaborator will make arrangements with the NCI PMB contractor to obtain the requested information at Pharmaceutical Collaborator’s expense. If requested by the FDA, the PMB will provide a copy of the FDA Form 1572 and CV for Investigators participating in the Study. The PMB is not able to provide copies of the FDA Form 1572 and CVs for all participating investigators unless specifically requested to do so in writing by the FDA. In such a case, Pharmaceutical Collaborator’s financial support for time and expenses to produce these documents will require further negotiation and execution of a separate contract.

**Article 8. Confidential Information**

Any preclinical or formulation data considered confidential and marked as such by Pharmaceutical Collaborator will be treated as such by DCTD, ECOG-ACRIN and NCTN investigators. DCTD shall treat in confidence any of Pharmaceutical Collaborator’s written Confidential Information about the Agent(s), if stamped "CONFIDENTIAL," for a period of three (3) years from the date of disclosure, unless Pharmaceutical Collaborator informs DCTD that the Confidential Information is still secret and confidential, in which case the obligations hereof shall extend for a further period of two (2) years. Any Confidential Information which is orally disclosed must be summarized in writing and marked "CONFIDENTIAL" within thirty (30) days of such disclosure. Such Confidential Information shall not include information or data exempted from the definition of “Confidential Information" under Article 1.

**Article 9. Monitoring**

In accordance with the DSM guidelines (see <http://www.cancer.gov/clinicaltrials/conducting/dsm-guidelines/>), ECOG-ACRIN will formulate a plan for data and safety monitoring for the Study, which may or may not be included in the Protocol. In accordance with CTEP program monitoring guidelines, and (ii) the NCI audit guidelines at <http://ctep.cancer.gov/branches/ctmb/clinicalTrials/monitoring_coop_ccop_ctsu.htm>), each NCTN site is audited at least once every three (3) years, but remains at annual risk of an audit. For this Study, additional auditing will be considered as directed by the FDA. Additional routine monitoring of institutional performance review reports and timeliness of reporting of serious adverse events is conducted to identify Network Cooperative Group institutions that may require more frequent audits.

**Article 10. Publications**

Pharmaceutical Collaborator recognizes that the results of studies undertaken by NCI Investigators must be published and agrees that Investigators reserve the right to present and publish the Study Data at symposia, national or regional professional meetings, in professional journals, or through other means of their own choosing, the data, methods and results of the Study undertaken under this Agreement.

ECOG-ACRIN undertakes to advise and obligate its Investigators working on this Study that manuscripts shall be submitted to NCI for review by NCI and Pharmaceutical Collaborator no less than thirty (30) days prior to submission for publication to allow Pharmaceutical Collaborator, and NCI time to review for accuracy of background information and any patent opportunities. Abstracts proposed to be presented by Investigators will be sent to NCI promptly after they are received by ECOG-ACRIN, preferably at least three (3) days prior to submission but in all cases prior to presentation or publication. In all events, Investigators shall have final authority to determine the scope and content of any presentation or publication. In accordance with NCI policy, ECOG-ACRIN maintains the full right to present and publish the Study Data at such time and place as it sees fit. Manuscripts from all Clinical Sites disclosing Study Arm Data or otherwise involving the Agent(s) should have Pharmaceutical Collaborator, NCI-DCTD and ECOG-ACRIN advisory review and comment to assure that Confidential Information is protected prior to submission for publication. A publication or other public disclosure containing Agent-related data or results shall be delayed for up to an additional thirty (30) days upon written request by either Party to this Agreement as necessary to preserve U.S. or foreign patent or other intellectual property rights.

All abstracts, manuscripts and presentations should be sent to NCI at [NCICTEPpubs@mail.nih.gov](mailto:NCICTEPpubs@mail.nih.gov) for forwarding to Pharmaceutical Collaborator and NCI staff.

**Article 11. Use of Name**

Pharmaceutical Collaborator may use, refer to and disseminate reprints of scientific, medical and other published articles which disclose the name of DCTD or NCI consistent with U.S. copyright laws, provided such use does not constitute an endorsement of any commercial product or service by DCTD or NCI. Pharmaceutical Collaborator shall take every step possible to ensure that references in such articles are accurate, and shall explicitly state that any such reference does not claim, infer or imply an endorsement or recommendation of the product by the NCI, NIH, PHS or DHHS. Pharmaceutical Collaborator shall not use the name of NCTN, ECOG-ACRIN, DCTD or NCI or any of the foregoing in any advertising, packaging, or promotional material in connection with the Agent(s) except with the written permission of ECOG-ACRIN, DCTD or NCI (as applicable) or as may be required by law. Pharmaceutical Collaborator-issued press releases that reference or rely upon the work of ECOG-ACRIN and DCTD in connection with the Study shall be made available to ECOG-ACRIN and DCTD at least seven (7) days prior to publication for review and comment. They should be sent to Dr. Sherry Ansher, Regulatory Affairs Branch (email [anshers@ctep.nci.nih.gov](mailto:anshers@ctep.nci.nih.gov)).

**Article 12. Patents; Infringement**

All Clinical Sites and Investigators participating in the Study, as well as the Clinical Assay Development Network and the Molecular Characterization Laboratory at FNLCR (providers of services related to the Study), are bound by the intellectual property obligations described at the following sites: <https://federalregister.gov/a/2011-5609> and <http://ctep.cancer.gov/industryCollaborations2/guidelines_for_collaboration.htm>. These intellectual property obligations (which may be referred to as the CTEP IP Option to Collaborator) include those that cooperative group “Institutions” (and for this purpose, the Clinical Assay Development Network and the Molecular Characterization Laboratory at FNLCR is an “Institution”) owe to the Pharmaceutical Collaborator as the “Collaborator” in the Study.

Pharmaceutical Collaborator warrants, to the best of its knowledge, that DCTD’s use of the Agent(s) in this Agreement does not infringe any U.S. Letters Patent (except U.S. Letters Patent issued upon an application which is now or may hereafter be kept secret or otherwise withheld from issue).

Pharmaceutical Collaborator shall promptly report to DCTD each notice or claim of patent or copyright infringement based on use or exploitation of the Agent(s) of which Pharmaceutical Collaborator has knowledge.

**Article 13. Termination**

A. This Agreement expires on the earlier to occur of the completion of the Study and release of the final Study Data to the public. Termination or expiration of this Agreement shall not affect any rights or obligations which accrued prior thereto or in connection therewith.

B. This Agreement may be terminated at any time by the mutual written consent of the Parties.

C. DCTD may unilaterally terminate the Agreement at any time by giving written notice to the other Party at least sixty (60) days prior to the desired termination date.

D. DCTD shall have the right to terminate the Study Arm, or to terminate the entire Study (with or without termination of this Agreement, in DCTD’s discretion), upon reasonable advance written notice to the Pharmaceutical Collaborator if there is a discontinuation, reduction, or denial of Study funding from NCI.

E. Either Party may terminate the Study Arm upon written notice to the other Party:

1. if such Party reasonably believes in good faith that (a) the safety of Study Arm subjects is jeopardized by administration of the Agent(s), (b) the accrual of Study Arm subjects will not meet projections for accrual, or (c) there exists a regulatory action or safety-related issue that makes continued use of the Agent in the Study Arm impossible, illegal, or unethical; or
2. (a) the authorization and approval to perform the Study or the Study Arm is withdrawn by the FDA, the IRB, or other regulatory agency, (b) in the event of the other Party’s breach of any of the material terms and conditions of this Agreement, where such breach is not remedied within thirty (30) days after receipt of written notice from the non-breaching Party specifying such breach and demanding its cure.

F. On expiration or earlier termination of this Agreement (other than for safety or regulatory reasons), Pharmaceutical Collaborator will supply enough of the Agent(s) to complete the Study Arm as then ongoing or approved, pursuant to the provisions of Article 5. If the Study or the Study Arm is terminated early, DCTD will provide then-available Study Arm Data to Pharmaceutical Collaborator when available for release.

**Article 14. Liability; Liability Disclaimer**

No indemnification for any loss, claim, damage, or liability is intended or provided by DCTD or ECOG-ACRIN under this Agreement. Pharmaceutical Collaborator shall indemnify, defend, and hold harmless DCTD and ECOG-ACRIN and each Study site, and their respective trustees, directors, officers, faculty, employees, students, contractors and agents from and against any and all costs, expenses, liabilities, damages, losses and harm (including reasonable legal expenses and attorneys’ fees) (collectively “Losses”) arising out of or resulting from any third party suits, claims, actions or demands (collectively, “Claims”) to the extent resulting from or caused by: (a) the negligence, recklessness or willful misconduct of Pharmaceutical Collaborator or its officers, directors, employees, contractors or agents, (b) Pharmaceutical Collaborator’s breach of its obligations, covenants, representations, or warranties under this Agreement, or (c) bodily injury to a Study subject that is sustained as a result of the Agent that is administered in the course of the Study in accordance with the Protocol, except in each case to the extent that a Claim or Loss arises out of or results from the negligence, recklessness or willful misconduct of any of the Study investigators in DCTD or ECOG-ACRIN. Except as otherwise expressly set forth in this Agreement, each Party shall be liable for any loss, claim, damage, or liability that said Party incurs as a result of said Party's activities under this Agreement, except that DCTD, as an agency of the United States, assumes liability only to the extent as provided under the Federal Tort Claims Act (28 U.S.C. Chapter 171 Sections 2671-2680).

IT IS UNDERSTOOD THAT DCTD and ECOG-ACRIN ARE NOT RESPONSIBLE FOR THE ACTS OR OMISSIONS OF THE Pharmaceutical Collaborator. DCTD and ECOG-ACRIN SHALL NOT BE LIABLE BEFORE OR AFTER TERMINATION OF THIS AGREEMENT UNDER ANY CONTRACT, STRICT LIABILITY, NEGLIGENCE OR OTHER LEGAL OR EQUITABLE THEORY (A) FOR ANY DIRECT, SPECIAL, INCIDENTAL, CONSEQUENTIAL OR OTHER DAMAGES RELATED TO ANY AGENT(S), PRODUCT, MATERIAL, EQUIPMENT, SERVICE OR OTHER ITEM PROVIDED HEREUNDER BY Pharmaceutical Collaborator, OR ANY PRODUCT, MATERIAL, EQUIPMENT, SERVICE OR ITEM SUPPLIED TO THIRD-PARTIES BY Pharmaceutical Collaborator AS A RESULT OF A PROTOCOL OR STUDY CONDUCTED HEREUNDER OR (B) FOR COST OF PROCUREMENT OF SUBSTITUTE SERVICES OR ANY SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RELATED TO ANY SUBJECT MATTER OF AN OBLIGATION UNDER THIS AGREEMENT. DCTD’s and ECOG-ACRIN’s SOLE RESPONSIBILITY HEREUNDER ARE TO USE REASONABLE EFFORTS IN PERFORMING THE PROTOCOL OR STUDY ACCORDING TO ITS TERMS.

**Article 15. Governing Law**

This Agreement shall be governed by and construed in accordance with Federal law as construed by the Federal Courts of the District of Columbia.

**Article 16. Severability**

The terms of this Agreement are severable. If any item or provision of this Agreement shall to any extent be invalid or unenforceable, the remainder of this Agreement shall not be affected, and each remaining item and provision of this Agreement shall be valid and shall be enforceable to the fullest extent permitted by law.

**Article 17. Survivability**

The provisions of this Agreement as they relate to confidentiality and drug supply shall survive the expiration or earlier termination of this Agreement.

**Article 18. Compliance with DHHS Regulations**

DCTD, ECOG-ACRIN and Pharmaceutical Collaborator will comply with all DHHS regulations relating to Human Subject use, and all PHS policies relating to the use and care of laboratory animals.

**Article 19. Amendments**

Upon mutual agreement of the Parties, this Agreement may be amended as necessary to ensure the Agreement accurately reflects the terms and scope of the collaborative Study. Each such Amendment shall be in writing signed by authorized representatives of each of the Parties.

**Signatures Begin on Next Page**

**SIGNATURES**

This Agreement, and any amendments hereto, sets forth all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties with respect to the subject matter of this Agreement, and supersedes and terminates all prior agreements, negotiation and understandings between the Parties, whether oral or written, with respect to such subject matter, and there are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties hereto with respect to such subject matter other than as set forth herein. In the event of any conflict between the terms and conditions of this Agreement and those in the Exhibits hereto, the terms and conditions of this Agreement shall control.

By executing this Agreement, each of the undersigned represents and confirms that he or she is fully authorized to bind the identified Party to its terms. Each of the undersigned expressly certifies or affirms that the contents of any statement made or reflected in this document are truthful and accurate.

**Agreed to and Accepted by:**

***For the National Cancer Institute:***

Jeffrey Abrams, M.D. Date

Associate Director,

Cancer Therapy Evaluation Program

*Address correspondence related to this Agreement to:*

Sherry S. Ansher, Ph.D.

Associate Chief

Regulatory Affairs Branch, NCI

9609 Medical Center Drive 5W-526

Rockville MD 20850

anshers@mail.nih.gov

***For [Pharmaceutical Collaborator]:***

(Signature) Date

(Printed Name and Title)

Address:

Exhibit A

Agent(s)