EXHIBIT C

JHU 2131
Merck Sharp v. Johns Hopkins
IPR2024-00650

INVESTIGATOR INITIATED
CLINICAL TRIAL RESEARCH AGREEMENT
(US Single Site - Study Drug)

This Agreement is entered into as of the last date on the signature page hereof, by and between THE JOHNS HOPKINS UNIVERSITY having a School of Medicine with an Office of Research Administration located at 733 North Broadway, Suite 117, Baltimore, MD 21205, hereinafter called "Institution," and MERCK SHARP & DOHME CORP. with its address at One Merck Drive, Whitehouse Station, New Jersey 08889 USA, hereinafter called "Merck."

Principal Investigator (named in Article 2 below) and Institution desire to sponsor and conduct a study of the safety and/or efficacy of MK-3475 which may be or include a pharmaceutical product, biological product, device or diagnostic agent provided to Institution hereunder (the "Study Drug") through certain clinical research in accordance with the Protocol identified below (the "Study"). Merck, consistent with its commitment to clinical research, wishes to provide certain support to Institution on the terms and conditions described in this Agreement. The parties hereto agree as follows:

1. **Scope of Work**

The Institution and Principal Investigator (named in Article 2 below) shall perform the Study in accordance with the terms of this Agreement and the final protocol including as it may be amended in accordance with the terms of this Agreement, for the Study entitled "Phase 2 Study of MK-3475 in Patients with Microsatellite Unstable (MSI) Tumors" Protocol Number MK-3475-016 (the "Protocol") MISP Database number 50642, which has been accepted by Merck in writing and incorporated into this Agreement by reference. Institution represents and warrants that, to its best knowledge, its facilities and patient population are adequate to perform the Study contemplated by this Agreement and the Protocol. Institution and Principal Investigator agree that all aspects of the Study will be conducted in conformity with all applicable federal, state, local laws and regulations. Institution and Principal Investigator further agree not to conduct any research activities with the Study Drug which are contrary to the provisions of the Protocol or outside the scope of the Protocol. Principal Investigator (or Institution) will undertake the Study as the legal sponsor of the Protocol and will fulfill the requisite sponsor duties and obligations in conducting the Study.

2. **Principal Investigator**

Institution's principal investigator is Dung Thi Le, MD ("Principal Investigator"). Principal Investigator will be responsible for the direction and supervision of all Study efforts, in accordance with the Protocol and this Agreement. Principal Investigator and Institution shall provide all of the services contemplated herein through fully trained and competent Study Staff (as defined below) having a skill level appropriate for the tasks assigned to them and shall ensure that all Study Staff (as defined below) comply with the terms of this Agreement and the Protocol. "Study Staff" means any persons providing services on behalf of Institution in connection with the Study, and may include: (i) employees, agents, officers, and directors of Institution, including without limitation the Principal Investigator, and (ii) any contractors or other third parties approved by Merck in writing in

accordance with Article 14. Principal Investigator and Institution will ensure that any investigators and any Study Staff comply with the terms of this Agreement and the Protocol. In the event that Principal Investigator leaves or is removed from the Institution, then Institution shall, within ten (10) days of becoming aware of such departure by Principal Investigator, provide written notice of such event to Merck. Any successor to Principal Investigator must be approved, in writing, by Merck and such successor shall be required to agree to abide by all the terms and conditions of the Protocol and this Agreement and to sign each such document as evidence of such agreement (although failure to so sign will not relieve such successor from abiding with all the terms and conditions of the Protocol and this Agreement).

Institution represents and certifies that it will not use in any capacity, in connection with any services to be performed under this Agreement, any individual who has been debarred pursuant to the Federal Food, Drug and Cosmetic Act, disqualified as a testing facility, disqualified as a clinical investigator or excluded from a federal healthcare program.

Institution agrees to inform Merck, in writing, as soon as reasonably possible under the circumstances, if any person who is performing services hereunder is debarred, disqualified or excluded or if any action, suit, claim, investigation or legal or administrative proceeding is pending, or, to the best of Institution's knowledge, is threatened, relating to the debarment, disqualification or exclusion of Institution or any person performing services hereunder. Institution represents and certifies that no action, suit, claim investigation or legal or administrative proceeding is pending or threatened relating to Principal Investigator's debarment, disqualification or exclusion and Institution agrees to inform Merck in writing, as soon as reasonably possible under the circumstances, if any such action, suit, claim, investigation or legal or administrative proceeding is threatened or commenced for Principal Investigator's debarment, disqualification or exclusion.

3. **Clinical Trial Approvals**

A. Institution shall be responsible for obtaining the following:

(i) obtaining an Investigational New Drug Application unless the Protocol is exempt;

(ii) approval of the Protocol, any informed consent relating to the Study and advertisement, if any, pertaining to the enrollment of subjects in the Study by the appropriate Institutional Review Board ("IRB") prior to beginning any Study on human subjects;

(iii) an informed consent which complies with all applicable federal, state, and local laws and regulations signed by or on behalf of each human subject prior to the subject's participating in the Study that does not reference Merck as the sponsor or make any representations on behalf of Merck but may list the type of support provided by Merck under this Agreement; and

(iv) an IRB approved Health Insurance Portability and Accountability Act authorization to use and disclose personal health information (either incorporated into the informed consent form or in a separate document) which complies with all applicable federal, state, and local laws and regulations signed by or on behalf of each human subject prior to the subject's participating in the Study.

B. In the event the IRB requires changes in the Protocol, Merck shall be advised in advance and all modifications to the Protocol must be approved in advance by Merck. Institution and Principal Investigator shall not modify the Study described in the Protocol once finalized and after approval by the IRB without the prior written approval of Merck.

C. Principal Investigator and Institution shall ensure that IRB approval shall be maintained current at all times and in the event that the Study continues beyond the period of the initial IRB approval, shall ensure that appropriate periodic IRB re-approval is obtained without lapse in approval status and provide Merck with IRB re-approval date. In the event that IRB approval lapses, becomes suspended, or withdrawn, Principal Investigator or Institution shall notify Merck within twenty-four (24) hours of that event and IRB's reasons for approval lapse, suspension or withdrawal.

4. **Term of Agreement**

The term of this Agreement shall commence on the last date of the signature page hereof and shall continue in effect, unless earlier terminated in accordance with Article 5, until the Study is completed and all final Study documentation, including but not limited to Study manuscripts, required to be provided under the Protocol and this Agreement is received and accepted by Merck. If at any time Institution or Principal Investigator have reason to believe that the Study will not be initiated or completed as per the schedule initially anticipated and agreed upon by the parties, Merck will be advised, in writing, of the reason(s) and length of additional time required to commence or complete work, and this Agreement may be terminated by Merck as provided in Article 5.

5. **Termination and Enrollment Cap**

A. Merck or Institution may terminate this Agreement by giving thirty (30) days written notice to the other party. In the event a thirty (30) day notice period is determined by Institution or Merck to be insufficient notice based upon evaluation of risks to enrolled research subject(s) then receiving the Study Drug, the parties will cooperate to safely withdraw subjects from treatment over a mutually agreeable period of time but in no event shall Merck's obligation to supply Study Drug hereunder extend beyond a reasonable period. Notwithstanding the foregoing, in the event Merck or Institution believes that immediate termination is necessary due to its evaluation of risks to enrolled research subject(s), Merck or Institution may terminate this Agreement immediately.

B. Either party may terminate this Agreement upon written notice to the other party if the other party breaches any of its material obligations under this Agreement and such breach, if capable of being cured, is not cured within thirty (30) days of written notice of such breach.

C. In the event of any termination or expiration of this Agreement (including but not limited to completion of the Study):

(i) upon providing or receiving a notice of termination of this Agreement, Institution shall stop enrolling patients in the Study and shall cease conducting the Study; and

(ii) comply with the applicable provisions of Article 10 concerning the return or destruction of the Study Drug and Merck provided materials.

D. The termination or expiration of this Agreement shall not relieve either party of its obligation to the other in respect of:

(i) This section is intentionally left blank;

(ii) complying with record keeping and reporting obligations (under Article 6 hereof);

(iii) complying with any publication obligations (under Article 9 hereof) and obtaining any written approval and consents for any publicity and promotional purposes (under Article 16 hereof);

(iv) complying with obligations relating to the Study Drug and any other Merck provided material (under Article 10 hereof);

(v) indemnification and insurance obligations (under Article 11 hereof);

(vi) inspection rights (under Article 6.D hereof);

(vii) obligation to assign inventions and assist in obtaining patent protections as required under Article 12 hereof; and

(viii) Merck's obligations under Article 6H;

all of which obligations are binding on the appropriate party and shall remain in full force and effect as set forth in this Agreement.

6. **Records and Reports**

A. Principal Investigator and Institution shall have the following record keeping and reporting obligations:

(i) preparation and maintenance of written records in accordance with laws, regulations and good clinical practice;

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(ii) a Study manuscript for a peer reviewed journal within one-year from the final subject being examined or receiving an intervention for the purposes of final collection of data of the Study regardless of the Study results;

(iii) monthly teleconferences at which the Principal Investigator shall provide Study progress updates including, but not limited to, enrollment log requests and any other Study update information as reasonably requested by Merck; and

(iv) final clinical study report containing raw data ("CSR") within a reasonable time after completion of the Study but in no event longer than three (3) months after completion of the Study. The final CSR shall be made of descriptive data, tables, and data listings, and contain all non-serious adverse experiences as a line listing or table, but may not include an analysis of the data. Any Study subject level data submitted to Merck will only be coded with a number and no other personal identifiers such as birth date or Study subject initials.

Upon MSD's request, with reasonable advance notice during the course of the Study, Principal Investigator shall also provide the Study data or Study database, if applicable, free of charge to MSD. Data that should be available to Merck includes: documentation of eligibility in terms of prior lines of therapy and Microsatellite Instability "MSI" results; provide availability for review of MSI testing results; and access to imaging scans. The final Study database shall be transferred to MSD as an electronic copy in the existing SAS format or other format that is mutually acceptable to the parties.

B. Reporting Procedures for Exchange of Adverse Event Information.

(i) **Serious Adverse Event**" or "**SAE**" shall mean any untoward medical occurrence in a Study subject who is administered the Study Drug that results in death, a life-threatening drug experience, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect, cancer, or is a new cancer if the cancer is the condition of the Study, or overdose. Other important medical events that may jeopardize the patient or may require intervention to prevent one of the outcomes listed previously should also be considered "serious".

(ii) Serious Adverse Events shall be reported in accordance with the Protocol. All adverse events (both expected and unexpected) will be captured on the appropriate Study-specific case report forms (CRFs).

(iii) All Serious Adverse Events, regardless of causality to Study drug and/or administration will be forwarded to Merck's Global Safety ("Merck GS")

group (facsimile number: 215-993-1220) within two (2) business days of learning of the event. Notification shall be in the form of a completed CIOMS I/MedWatch (or other mutually agreed upon format). All SAE shall be transmitted in the English language and contain the reporter's name and the Study subject identifier code. Randomization codes for all other SAEs will be provided to Merck GS at end of Study if the Study drug has been blinded in the Study.

(iv) Non-serious Events of Interest will be forwarded to Merck GS and will be handled in the same manner as SAEs.

(v) Although pregnancy and lactation are not considered adverse events, it is the responsibility of investigators or their designees to report any pregnancy or lactation in a subject (spontaneously reported to them), including the pregnancy of a male subject's female partner who has provided written consent to provide information regarding pregnancy, that occurs during the trial or within 120 days of completing the trial. All subjects who become pregnant must be followed to the completion/termination of the pregnancy. Pregnancy outcomes of spontaneous abortion, missed abortion, benign hydatidiform mole, blighted ovum, fetal death, intrauterine death, miscarriage and stillbirth must be reported as serious events (Important Medical Events). If the pregnancy continues to term, the outcome (health of infant) must also be reported to Merck GS.

(vi) Institution and Principal Investigator shall fully comply with all of their respective reporting obligations to the applicable regulatory authorities with respect to any Adverse Event ("AE"), SAE or Suspected Unexpected Serious Adverse Reaction ("SUSAR") that arises from the Study.

C. In the event Principal Investigator or Institution becomes aware of a defect or possible defect in the Study Drug provided under this Agreement (or placebo provided by Merck being tested or used as a reference in the Study), Institution and/or Principal Investigator agree to notify Merck within one business day of first becoming aware of the defect or possible defect. Such defect or possible defect can include but not be limited to any inadequacy of a Study Drug device related to its identity, quality, durability, reliability, safety or performance, such as malfunction, misuse or use error and inadequate labeling

D. Principal Investigator and Institution shall conduct the Study and maintain records and data during and after the term or early termination of this Agreement in compliance with all applicable legal and regulatory requirements, including without limitation, any applicable requirements of the FDA. If required by law, regulation, regulatory authority or to confirm compliance with this Agreement and the Protocol, Merck or Merck's representatives shall have the right to examine and inspect all records and reports related to the Study Drug or directly relating to the Study, at mutually agreeable times with reasonable advance notice and during normal business hours (subject to applicable patient confidentiality considerations and Institution's standard access

procedures), at Merck's expense. Principal Investigator and Institution shall take any action necessary, as reasonably requested by Merck, to properly correct or address any deficiencies noted during any inspection and agree to cooperate with Merck with respect to any action taken to address any such deficiencies.

E. Principal Investigator shall notify Merck within twenty-four (24) hours in the event that the FDA or any other regulatory authority notifies the Study site of a pending inspection that concerns the Study or Institution's ability to perform clinical research. In addition, Principal Investigator will forward to Merck any written communication received as a result of such inspection within twenty-four (24) hours of receipt of such communication. Such responses shall be made as soon as possible under the circumstances or within any earlier deadline set by the issuing regulatory authority. Principal Investigator shall also provide to Merck a complete description of documents and any correspondence provided to any inspector, to the extent permitted by law. In the event the FDA or other regulatory authority requests or requires any action to be taken to address any citations, Principal Investigator and Institution agree, after consultation with Merck, to take such action as necessary to address such citations.

F. A copy of all 15 Day Reports and Annual Progress Reports are to be submitted as required by the applicable regulatory authority by the Principal Investigator. Principal Investigator agrees to cross reference this submission according to local regulations, to the Study Drug number (IND, CSA, etc) at the time of submission. Additionally Principal Investigator agrees to submit a copy of these reports to Merck (Attn: Global Safety; FAX 215 993-1220) at the time of submission to the appropriate regulatory agency.

G. Merck may provide the Principal Investigator and Institution, at Study initiation and on an ongoing basis, with information regarding the Study Drug, including but not limited to safety information.

H. Merck shall comply with all laws and regulations regarding subject data privacy that apply to Merck, including the use and disclosure of individually identifiable health information ("Health Information") of subjects enrolled in the Study. Merck agrees, and Merck will require that any party to whom Merck discloses Health Information ("Recipient") agrees, to use and disclose the Health Information only in accordance with laws and regulations that apply to Merck. Merck represents that Merck and any Recipient hereunder will not use Health Information to recruit research subjects to additional studies, to advertise additional studies or products or to perform marketing or marketing research.

7. **Funding**

No Funding shall be provided by Merck under this Agreement. Merck acknowledges that the Study is being funded by Swim Across America, who may have access to the results of the Study.

8. **Confidential Information**

This section intentionally left blank.

9. **Data, Publications and Other Rights**

In recognition of the importance of disseminating information relating to any novel or important observations or results arising from the Study and understanding that such need must be balanced with Merck's obligations to comply with appropriate rules and regulations of the FDA, the parties hereby agree to the following:

A. All Study data and results will be owned by Institution. To the extent permitted by law, Institution agrees that all Study data and results generated during the course of the Study may be used fully by Merck for any legitimate business purpose without any additional payments being made to Institution or Principal Investigator.

B. Subject to the terms and conditions of this Agreement, Institution and Principal Investigator have the right to publish or publicly present the results of the Study. Merck shall have the right to review and comment on any Public Presentation. Principal Investigator and Institution further agree to provide twenty (20) days written notice to Merck prior to submission for publication or presentation to permit Merck to review drafts of abstracts and manuscripts for publication (including, without limitation, slides and texts of oral or other public presentations and texts of any transmission through any electronic media, e.g. any computer access system such as the Internet, World Wide Web etc., collectively or individually a "Public Presentation") which report any results arising out of the Study.

C. Principal Investigator will consider in good faith any comments received from Merck regarding the accuracy of a publication. This paragraph shall not be interpreted to give Merck any editorial control for any public presentation. Merck may provide additional comments concerning the presentation/manuscript provided however that Institution shall not have to address such comments. Principal Investigator agrees to acknowledge Merck in any Public Presentation using the following or similar language: "Supported in part by a research grant from Investigator-Initiated Studies Program of Merck Sharp & Dohme Corp.. The opinions expressed in this paper are those of the authors and do not necessarily represent those of Merck Sharp & Dohme Corp."

D. If Merck believes there is a patentable subject matter contained in any Public Presentation submitted for review, Merck shall promptly identify such subject matter to Institution. If Merck requests and at Merck's expense, Institution and Principal Investigator shall use their reasonable efforts to assist Merck to file a patent application covering such subject matter with the United States Patent and Trademark Office or through the Patent Cooperation Treaty prior to any publication. Merck shall have the right to delay publication or presentation of any Public Presentation for a period not to exceed sixty (60) days after the initial review period if publication or presentation of such Public Presentation would affect Merck's ability to obtain patent protection for any Institution Invention. For the avoidance of doubt, notwithstanding anything to the contrary

herein, the maximum allowable delay for any publication is eighty (80) days from the date of submission to Merck for review.

E. In making a Public Presentation, Institution and/or Principal Investigator shall comply with all laws, regulations and accepted guidelines of peer reviewed medical journals and any specific guidelines established by congresses and/or the journals to which the Public Presentation will be submitted. Institution and/or Principal Investigator shall ensure that designated authors and contributors on all such Public Presentations shall meet the minimum requirements of International Committee of Medical Journal Editors.

F. Principal Investigator and/or Institution shall be the responsible party as defined in Section 801 of the Food and Drug Administration Amendments Act of 2007 ("Responsible Party") and agrees to register the Study at www.clinicaltrials.gov, the U.S. National Library of Medicine website prior to initiation of the Study (i.e. prior to shipment of Drug supply). Responsible Party shall submit the required clinical trial results and information from the Study to Director of NIH for inclusion in the results registry data bank at www.clinicaltrials.gov no later than one (1) year after either the estimated completion date of the Study as defined by the Food and Drug Administration Amendments Act of 2007, or the actual date of completion of the Study, whichever occurs first. For avoidance of doubt and without limitation, such submission is not considered a Public Presentation under this Agreement.

10. **Clinical Supplies**

A. As applicable for the Protocol, Merck shall make available sufficient quantities of Study Drug free of charge to carry out the Study in a quantity and delivery schedule acceptable to both parties. Institution and Principal Investigator shall take responsibility for and reasonable steps to maintain appropriate records and assure appropriate supply, handling, storage, distribution and usage of the Study Drug and any other Merck provided materials, including but not limited to equipment, in accordance with the Protocol and any applicable laws and regulations relating thereto. The Study Drug and any other Merck provided materials, including but not limited to equipment, may not be used for any other purpose than that stated in the Protocol and may not be transferred to any third party except as contemplated herein without Merck's written approval except for the provision of the Study Drug to Study subjects in accordance with the Protocol and at no cost to the Study Subjects. Study Drug will not be used in research that is subject to consulting or licensing obligations to a third party unless written permission is obtained from Merck. Institution and Principal Investigator will be responsible for any additional packaging if required, and appropriate additional labeling, e.g. for dispensing, of the Study Drug for the Protocol. Institution and Principal Investigator will obtain prior written agreement form Merck concerning any special requirements for shipment and customs clearance of the Study Drug. Merck will provide Institution and Principal Investigator with the proper packaging, storage and disposal requirements for the Study Drug as applicable. As appropriate, Institution and Principal Investigator are responsible for ensuring any necessary Quality Agreements are in place between Institution and Merck, and/or Institution and contract packager.

1. **Clinical Image:** If active Study Drug and matching placebo is required, Merck

will supply clinical image Study Drug. If supplied in bulk for repackaging into individual patient packs, then it is Institution's responsibility to ensure repackaging is performed and final packs are released for use according to U.S. regulations. If individual packs are supplied, Merck will ensure all appropriate approvals are given before the Study Drug is sent to Institution. This will include Good Manufacturing Practice (GMP) certification of the Study Drug if being supplied for the U.S. Merck will provide its Chemistry, Manufacturing, Control (CMC) information to the Food and Drug Administration (FDA) to support Institution's regulatory submission when needed and address any questions the FDA on the CMC information. Merck will not ship Study Drug (active and placebo) until Merck has been advised of FDA approval.

2. **Non-Marketed:** When the Study Drug does not have marketing authorizations in the country where the Study is being conducted, Institution and Principal Investigator agree that any and all references to the Study Drug in a public forum, including registries, must be limited to the Merck "MK-3475" nomenclature. Chemical name or structure, generic name, molecular formula, or other such information about the compound is not to be disclosed publicly. Additionally, detailed references or information concerning any comparator drug in the Study should not be made or disclosed in any public forum.

B. At the conclusion of the Study, or upon earlier termination of this Agreement, Institution shall either return to Merck or Merck's agent all unused Study Drug, (unless written authorization to retain or destroy them is given by Merck) or Institution shall destroy all remaining Study Drug pursuant to the International Conference on Harmonisation/Good Clinical Practice (ICH/GCP) Guidelines and upon Merck's request provide Merck with copies of documentation of such destruction and documentation of Study Drug accountability.

C. In addition to the other requirements under this Agreement and the Protocol, in the event a re-supply of Study Drug is required in order to continue the conduct of the Study in accordance with this Agreement and the Protocol, it will be done conditional on Merck's receipt of the following: (i) Current IRB Approval documentation, (ii) Correspondence confirming Principal Investigator notification of the IRB of any applicable IND Safety Alert Reports and any Investigator Brochure Updates, if applicable, (iii) Progress Reports for enrollment, safety and drug accountability and, (iv) if drug re-supply is required, you notify Merck six months prior to drug expiry.

11. **Indemnification**

A. Merck shall indemnify, defend and hold harmless Institution, Principal Investigator, The Johns Hopkins Hospital, The Johns Hopkins Bayview Medical Center, and/or other affiliated and cooperating hospitals and institutions, as well as the trustees, directors, officers, agents, employees, students, the members of their Institutional Review Boards, and others holding academic appointments within those institutions and their respective heirs, successors, and assigns ("Institution Indemnitees") from and against any third-party liabilities, losses, damages, demands, claims, actions, proceedings and attorney's fees associated with Merck's defense or costs of judgments (collectively "Losses") which may be made or instituted against any of them as a result of (i) manufacturing defect in the Study Drug provided by Merck under this Agreement or the

failure of such Study Drug to meet applicable manufacturing specifications; (ii) any use by Merck of the results, data and inventions resulting from the Study; (iii) any willful misconduct or acts of negligence by Merck. Notwithstanding the foregoing, Merck's indemnification obligation shall not apply to the extent the liability is caused by an Institution Indemnitees' (i) failure to adhere to the terms and provisions of this Agreement, of the Protocol, or agreed amendments thereto (ii) failure to comply with applicable laws and regulations, including but not limited to FDA or other governmental or state requirements, law, rules or regulations applicable to the performance of its obligations under this Agreement, or (iii) breach of this Agreement, negligence or willful misconduct in the performance of Study activities.

B. Other than for the express liability assumed by Merck as provided in paragraph A above, Institution, shall indemnify, defend and hold harmless Merck, its officers, directors, agents, employees, its parent corporation, subsidiaries and affiliates, ("Merck Indemnitees"), from and against any Losses arising out of any willful misconduct or negligence in Institution's performance of its obligations under this Agreement, provided however, Institution's foregoing obligations will not apply to the extent Losses are attributable to a Merck Indemnitee's (i) failure to adhere to the terms and provisions of this Agreement, of the Protocol, or agreed amendments thereto (ii) failure to comply with applicable laws and regulations, including but not limited to FDA or other governmental or state requirements, law, rules or regulations applicable to the performance of its obligations under this Agreement, or (iii) breach of this Agreement, negligence or willful misconduct in the performance of Study activities.

C. Either party's indemnity obligation is subject to the following conditions:

(i) prompt notification to indemnifying party whenever indemnified party has information from which it may reasonably conclude an incident of bodily injury or death or damage to property has occurred and the prompt reporting to indemnifying party of all pertinent data surrounding such incident (provided that any failure to promptly notify or report only relieves the indemnifying party of its obligations to indemnify to the extent of actual prejudice, if any);

(ii) compliance by indemnitees with all of their obligations with regard to adverse event reporting procedures as set forth in this Agreement (provided that any failure to promptly report only relieves the indemnifying party of its obligations to indemnify to the extent of actual prejudice, if any);

(iii) reasonable cooperation and assistance by indemnified party in the investigation and defense of the claim or action along with authorization to indemnifying party to carry out the sole management and defense of the claim or action, provided that Indemnitee will have the right to retain separate counsel at its own expense; and

(iv) Indemnified party shall not compromise or settle the claim or action without the prior written approval of indemnifying party.

However, notwithstanding the foregoing, a party can take over the defense of a claim or action on its own behalf provided it releases the party who is providing the indemnification of the claim from any obligations under this Article concerning the claim.

12. **Inventions and Patent**

A. Institution understands and acknowledges that the Study Drug which is being provided to Institution for the purpose of conducting the Study is the property of Merck and/or that it may be subject to certain intellectual property rights owned by or licensed to Merck. This Agreement shall not be deemed or construed to convey, transfer, or license any of such intellectual property rights to Institution, other than the limited rights necessary to permit Institution to conduct the Study during the term of this Agreement. Nothing contained in this Agreement shall be deemed to grant either directly or by implication, estoppel or otherwise any license under any patents, patent applications or other proprietary interests to any other inventions or discoveries of either party.

B. Ownership and rights to any new and patentable or unpatentable discovery, technology, or other intellectual property arising from the performance of the Protocol and Study shall be governed by the following provisions: Inventions made solely by the Principal Investigator or employees of Institution shall be the property of Institution (hereinafter "Institution Inventions"); and inventions made jointly by employees or agents of Merck and either the Principal Investigator or employees of Institution shall be the joint property of Merck and Institution (hereinafter "Joint Inventions"). Institution will promptly notify Merck in writing of any such inventions. Institution and Merck shall consult and agree upon the patent filing and prosecution strategy for all Joint Inventions.

C. The foregoing notwithstanding, any inventions or discoveries arising out of any unauthorized use or modifications to the Study Drug, whether patentable or not, made by the Principal Investigator or other employees of Institution shall be the sole property of Merck (hereinafter "Merck Inventions"). Institution will promptly notify Merck in writing of all Merck Inventions. Upon Merck's request and at Merck's sole expense, Institution will provide Merck with reasonable assistance in obtaining patents to any such Merck Inventions, including causing the execution of any necessary assignments or other documents.

D. Institution hereby grants Merck a paid-up non-exclusive royalty free, sub-licensable, worldwide license to all Institution Inventions for its internal, non-commercial and development purposes, and an exclusive option to obtain an exclusive, worldwide license for commercial purposes, including the right to grant sub-licenses, to all Institution Inventions and to Institution's entire right, title and interest in and to all Joint Inventions. The parties agree to use good faith efforts to negotiate commercially reasonable terms for the exclusive license. Merck shall execute its option within six (6) months of Merck's receipt of written notice of said invention. In the event that Merck fails to so notify Institution or fails to obtain an exclusive license, then Merck's option shall expire with respect to said invention.

13. **Notice**

Whenever any notice is to be given hereunder, it shall be in writing and mailed postage prepaid by certified or registered mail (return receipt requested), commercial overnight carrier (return receipt requested) or personally delivered to the appropriate party at the address indicated below, or at such other place or places as either party may designate in a written notice to the other. Notice shall be deemed to have been received upon receipt.

To Institution:

Michael B. Amey
Associate Dean, Research Administration
Office of Research Administration
The Johns Hopkins University School of Medicine
733 North Broadway, Suite 117
Baltimore, Maryland 21205

With a copy to Principal Investigator at:

Dung Thi Le, M.D.
CRB 407 – Oncology
1650 Orleans St.
Baltimore, MD 21287

To Merck:

Merck Sharp & Dohme Corp.
MAILSTOP: UG4D-72
351 North Sumneytown Pike
North Wales, PA 19454-2505
Attn.: Robert Iannone, MD
MK-3475 OCSP-RC Chair

14. **Assignment**

The rights and obligations of Institution and Principal Investigator under this Agreement may not be assigned or subcontracted to others without Merck's prior written consent and any attempted assignment or delegation in violation hereof shall be void. Institution and Principal Investigator shall ensure that all third parties who provide services on behalf of Institution or Principal Investigator comply with the terms and conditions of this Agreement. Merck may assign this Agreement to an affiliated company without the prior consent of Institution or Principal Investigator. Notwithstanding any such assignment by Merck, Merck shall remain liable for all of its obligations under this Agreement.

15. **Applicable Law**

This Agreement shall be construed in accordance with Maryland law.

16. **Publicity**

No party shall use the name of another party (or the name of any employee, agent, faculty, division or affiliated companies of a party) for promotional purposes without the prior written consent of the party whose name is proposed to be used.

17. **Independent Contractor**

It is agreed by the parties that Institution and Principal Investigator are acting in the capacity of independent contractors hereunder and not as employees, agents or joint venturers of or with Merck. Neither Institution nor Principal Investigator shall have any authority to represent, bind or act on behalf of Merck.

18. **Agreement Modifications**

Neither this Agreement nor the Protocol may be altered, amended or modified except by written document signed by the parties.

19. **Severability**

If any term or condition of this Agreement, the deletion of which would not adversely affect the receipt of any material benefit by a party hereunder, shall be held illegal, invalid or unenforceable, the remaining terms and conditions of this Agreement shall not be affected thereby and such terms and conditions shall be valid and enforceable to the fullest extent permitted by law.

20. **No Waiver**

Failure on the part of a party to exercise or enforce any right conferred upon it hereunder shall not be deemed to be a waiver of any such right nor operate to bar the exercise or enforcement thereof at any time or times thereafter.

21. **Force Majeure**

Noncompliance by a party with the obligations of this Agreement due to force majeure, (laws or regulations of any government, war, civil commotion, destruction of production facilities and materials, fire, flood, earthquake or storm, labor disturbances, shortage of materials, failure of public utilities or common carriers), or any other causes beyond the reasonable control of the applicable party, shall not constitute breach of this Agreement and such party shall be excused from performance hereunder to the extent and for the duration of such prevention, provided it first notifies the other party(ies) in writing of such prevention and that it uses its best efforts to cause the event of the force majeure to terminate, be cured or otherwise ended.

22. **Entire Understanding**

This Agreement, including any exhibits and schedules hereto, constitutes the entire agreement between the parties with respect to the subject matter hereof. This Agreement supersedes and cancels all previous agreements among the parties, written and oral in respect of the subject matter hereof. In the event of any inconsistency between this Agreement and the Protocol, the terms of this Agreement shall govern. The parties to this Agreement agree that a copy of the original fully executed Agreement (including an electronic copy (e.g. PDF) may be used for any and all purposes for which the original signature may have been used. The parties agree they will have no rights to challenge the use or authenticity of this document based solely on the absence of an original signature.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed, by duly authorized representatives, as of the last date written below.

[redacted]

THE JOHNS HOPKINS UNIVERSITY	MERCK SHARP & DOHME CORP.
BY Patricia Travis RN, PhD CCRP for	BY
NAME Michael B. Amey	NAME Eric H. Rubin, MD
TITLE Associate Dean, Research Admin.	TITLE Vice President & Therapeutic Area Head Oncology Clinical Development
DATE 8/2/13	DATE 14 AUG 2013

8/2/13

Although not a party hereto, I hereby acknowledge that I have read and agree to abide with the terms of this Agreement, including the Protocol, and that I will act and perform my duties in the Study in accordance therewith.

Dung Thi Le, MD
Principal Investigator

DATE 8/2/13

IIS CTRA US Single Site (Drug Funding) 2012-08-20