Cancer Immune Monitoring and Analysis Centers - Cancer Immunologic Data Commons (CIMAC-CIDC)
Human Material Transfer Agreement
(HMTA)

Template Version: December 20, 2021

The purpose of this Human Material Transfer Agreement ("**Agreement**") is to transfer National Cancer Institute (NCI)-sponsored clinical trial biospecimens and associated data from **<Provider Name>** ("**Provider**"), to collaborate under the CIMAC-CIDC on correlative studies as described in the Research Project (defined below) for Protocol # <**Protocol Number**>, which used the agent <**Agent Name**> from <**Collaborator Name**>.

Certain CIMACs (collectively "**Recipient CIMACs**") will be receiving the biospecimens as specified in Appendix A of this Agreement; and the data related to the biospecimens will be provided to Dana-Farber Cancer Institute, Inc. (the "**CIDC**"), and may be accessed, as described below, by Leland Stanford Junior University, the University of Texas MD Anderson Cancer Center, Dana-Farber Cancer Institute, Inc., and the Icahn School of Medicine at Mount Sinai ("the **CIMACs**"). The CIMACs and CIDC are jointly the "**Recipients**". Each Recipient and the Provider is hereafter individually referred to as a "**Party**" and jointly as the "**Parties**". This Agreement is effective as of the date of last signature of an authorized representative of a Party below ("**Effective Date**").

The Parties mutually agree as follows:

I. Definitions:

"**Agent**" means an investigational drug, a biologic, or a product proprietary to an NCI/Pharma Collaborator, that has been made available under an agreement between the NCI/Pharma Collaborator and the National Cancer Institute (NCI) or a Provider and is used in association with an NCI-supported clinical trial.

"**Biospecimens**" means blood, serum, urine, saliva, other bodily fluid, bone marrow, cells, stool, or tissue samples/specimens collected from Human Subjects under the Protocol. The term "Biospecimen" further includes, without limitation, any tangible material derived from such Biospecimens collected under the Protocol from Human Subjects, such as genes, gene fragments, gene sequences, proteins, protein fragments, protein sequences, DNA, RNA, and any subcellular structure, and their unmodified derivatives.

"**CIDC**" means the Cancer Immunologic Data Commons, hosted at Dana-Farber Cancer Institute, Inc. The CIDC will serve the bioinformatics needs of the CIMACs, including the provision of a centralized data repository, optimization of data collection methodologies suitable for immune-related biomarkers, data integration, and provision of a shared infrastructure for integrative and correlative analysis.

"**CIMAC Data**" means CIMAC-generated data in the performance of the Research Project, including, but not limited to, assay output and data on assay validation and performance using Biospecimens.

"**CIMACs**" means the four Cancer Immune Monitoring and Analysis Centers, (1) Dana-Farber Cancer Institute, Inc., (2) Leland Stanford Junior University (Stanford University), (3) the University of Texas MD Anderson Cancer Center, and (4) the Icahn School of Medicine at Mount Sinai, which are responsible for providing a wide range of bioassays on Biospecimens from Human Subjects enrolled in NCI-supported clinical trials associated with one or more Agents.

"**CIMAC-CIDC**" means the network composed of the four CIMACs and the CIDC supported by NCI U24 Cooperative Agreements to provide an infrastructure to support correlative studies in clinical trials involving immunotherapies, including Cross-Trial Analysis. The goal of this research is to identify biomarkers with translational potential for optimizing therapeutic strategies for the treatment of cancer.

"**CIMAC-CIDC Guidelines**" refers to the most recent version of the document *"Guidelines for data access/transfer and publications for correlative studies involving collaboration between the CIMAC-CIDC Network and the Clinical investigators/Clinical Trial Networks on NCI-supported clinical trials"*, as found at https://cimac-network.org/documents. Any changes to the CIMAC-CIDC Guidelines are reviewed and approved by the CIMAC-CIDC Network and Provider before implementation and each version of the CIMAC-CIDC Guidelines must be distributed to CIMAC-CIDC and Provider authorized representatives for approval prior to implementation.

"**CIMAC-CIDC Principal Investigators**" means those individuals listed as Principal Investigators or Co-Principal Investigators for the CIMAC or CIDC on the NCI Grant.

"**CLIA**" means Clinical Laboratory Improvement Amendments, which regulate laboratory testing and require clinical laboratories to be certified by their state as well as the Centers for Medicare and Medicaid Services before they can accept Human Subjects Biospecimens for diagnostic testing.

"**CTEP**" means the Cancer Therapy Evaluation Program, of the Division of Cancer Treatment and Diagnosis (DCTD), which is a program within NCI that plans, assesses, and coordinates all aspects of clinical trials, including extramural clinical research programs, internal resources, treatment methods and effectiveness, and compilation and exchange of data. NCI is part of the National Institutes of Health (NIH), a component of the U.S. Department of Health and Human Services (HHS).

"**CTEP IP Option**": The CTEP Intellectual Property (IP) Option is a term of award of the NCI Grants and applies to all NCI-supported clinical trials, regardless of the IND sponsor, and to all CIMAC-CIDC Research Projects. Inventions conceived, as defined under United States patent law, or actually reduced to practice in performance of the Research Project under the Agreement shall be managed in accordance with the terms of the CTEP IP Option, which can be found at:

(a) http://ctep.cancer.gov/industryCollaborations2/guidelines_for_collaboration.htm, or
(b) The Federal Register, Vol. 76, No. 48, pages 13404-13410 (2011) (https://www.gpo.gov/fdsys/pkg/FR-2011-03-11/pdf/FR-2011-03-11.pdf)

"**Clinical Data**" means data from Provider collected on the Protocol: demographics; pathology and staging; pathology reports; outcome data; toxicity; study treatments; prior molecular data (if captured); prior therapies (if captured); digital images (if relevant);

Required Clinical Data Elements (defined below); and information on the Specimen Tracking Manifest.

"**Clinical Research Site(s)**" means the site(s) at which the Protocol will be performed.

"**Clinical Trial**" means the clinical trial associated with the Protocol specified in Appendix A.

"**Clinical Trial Network**" means the NCI-supported clinical research network participating in the Research Project. This could be the Experimental Therapeutics Clinical Trials Network (ETCTN), a Network Group of the National Clinical Trials Network (NCTN), the Cancer Immunotherapy Trials Network (CITN), and/or another network/consortium supported by NCI.

"**Clinical Trial Team**" means investigators from the Clinical Trial and the Provider, such as the Clinical Trial principal investigator (PI), statistician, and translational leaders.

"**Confidential Information**" means confidential scientific or business information, provided by one Party to another as described below in the Section on Confidential Information.

"**Correlative Study Analysis Team**" means the collaborative team comprised of Clinical Trial Team and CIMAC-CIDC investigators involved in the design and execution of the Research Project.

"**Cross-Trial Analysis**" means analysis with data obtained from more than one clinical trial.

"**Effective Date**" means the date of the last authorized representative's signature below.

"**Exclusivity Period**" for the purposes of this Agreement means:

(a) for the Clinical Data: the period beginning on the Effective Date and ending six (6) months after the primary outcome of the Clinical Trial is either published in manuscript form or, if there is no such publication made within twelve (12) months after the Primary Completion Date of the Clinical Trial, six (6) months after the Clinical Trial results are posted to ClinicalTrials.gov.

(b) for the CIMAC Data and Results: the period ending at the time of publication of such CIMAC Data and/or Results in accordance with the terms of this Agreement, or twelve (12) months from the completion of the Research Project, whichever occurs first.

During the Exclusivity Period, Clinical Data, CIMAC Data, and Results will be held in confidence for use only by the Clinical Trial Team, Correlative Study Analysis Team, CIMAC-CIDC Principal Investigators, and the NCI/Pharma Collaborator(s) providing the Agent(s) for the Clinical Trial. The Exclusivity Period may be extended by not more than eighteen (18) months, granted in six (6) month increments upon NCI/Pharma Collaborator's written request to NCI and upon showing such an extension is necessary pursuant to a regulatory filing.

"**Human Material**" means the Biospecimens, and/or any Clinical Data (including information on the Specimen Tracking Manifest and the Required Clinical Data Elements) collected under the Protocol, that are transferred by the Provider to a Recipient under this Agreement, as listed in Appendix A. For the sake of clarity, CIDC will not receive any Biospecimens. The only Human Material received by CIDC will be Clinical Data.

"**Human Subject**" means, in accordance with the definition in 45 C.F.R. § 46.102(f), a living individual about whom an investigator conducting research obtains:

(a) data through intervention or interaction with the individual; or

(b) Identifiable Private Information.

"**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.

"**Identifiable, Sensitive Information**" or "**ISI**" means, in accordance with the Public Health Service Act at 42 U.S.C. 241(d)(4), information that is about an individual and that is gathered or used during the course of research described in 42 U.S.C. 241(d)(1)(A) through which an individual is identified, or for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual (see https://humansubjects.nih.gov/coc/faqs).

"**NCI Grants**" are the NCI U24 Cooperative Agreements for the CIMACs and CIDC as set forth in RFA-CA-17-005 and RFA-CA-17-006 (https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-17-005.html and https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-17-006.html) and Notices of Award CA224331, CA224285, CA224309, CA224316, and CA224319 as amended.

"**NCI/Pharma Collaborator**" means a company that made available its Agent(s) for use in association with the Protocol, regardless of whether such Agent(s) were made available through agreements with NCI and/or through agreements directly with the Provider.

"**Primary Completion Date**" means the date that the last participant in the Clinical Trial was examined or received an intervention and that data for the primary outcome measure were collected. Whether the Clinical Trial ended according to the Protocol or was terminated does not affect this date.

"**Protocol**" means the clinical trial protocol that is listed in Appendix A by title and number.

"**Publication**" means all manuscripts, abstracts, presentations, or posters under this Agreement using the Human Material, Results, or CIMAC Data.

"**Required Clinical Data Elements**" **or** "**RCDE**" are a subset of the Clinical Data. RCDE are comprised of 1) the Clinical Data required to perform the Research Project, including all variables and endpoints as specified in the NCI-approved Research Project, as well as 2) demographics; prior therapies (if captured); pathology; pathology reports; and information on the Specimen Tracking Manifest.

"**Research Project**" means the specific, NCI-approved correlative studies related to the Protocol and described in each NCI-approved biomarker plan collaboratively developed by the Correlative Study Analysis Team, as described in Appendix A of this Agreement.

"**Research Proposal**" means the proposal developed by the Correlative Study Analysis Team which serves as the basis for internal review and tracking by the CIMAC-CIDC Network and NCI. Once approved by NCI, the Recipient CIMAC(s), and the CIDC, the Research Proposal becomes the Research Project.

"**Results**" means all information generated by the integrative analysis of the CIMAC Data and Clinical Data by the Correlative Study Analysis Team using the Human Material in the performance of the Research Project.

"**Specimen Tracking Manifest**" refers to a secure web-based method for sending Human Subject demographics, clinical reports, specimen tracking, sample processing, transmittal data, and specimen quality assurance information.

II. Terms and Conditions

1. CIMAC-CIDC Guidelines.

   The Parties acknowledge that they have read and understood the CIMAC-CIDC Guidelines as of the Effective Date. The Parties acknowledge that adherence to these agreed upon guidelines is a basic tenet and required for appropriate functions of the partnership. All Research Projects must adhere to the CIMAC-CIDC Guidelines. To the extent that there is a conflict between the terms of this Agreement, including Appendix A, and the CIMAC-CIDC Guidelines, the terms of this Agreement will control. If the CIMAC-CIDC Guidelines are revised after the Effective Date and a Party does not accept the revised CIMAC-CIDC Guidelines, the Party may terminate this Agreement, in accordance with the provisions below.

2. Collection of Human Material.

   Provider represents to Recipients that it has obtained Institutional Review Board (IRB) approval and authorization to collect and transfer to Recipients the Human Material pursuant to all applicable laws and regulations related to the protection of Human Subjects.

3. Transfer of Human Material.

   (a) The Parties will ensure that each Research Project is approved by NCI, the Recipient CIMAC(s), and the CIDC before the transfer of any Human Material from the Provider to the Recipient CIMAC(s). NCI approval includes the requirement of review of any agreements between or among Provider and NCI/Pharma Collaborator(s) related to the Human Material, to ensure the terms comply with the CIMAC-CIDC Guidelines and with this Agreement.

   (b) Biospecimens that are transferred from the Provider to a Recipient CIMAC will not be redistributed from such Recipient CIMAC to another CIMAC (regardless of whether such CIMAC is a Recipient CIMAC or otherwise) unless approved in writing by NCI. The Provider shall retain title to Biospecimens.

   (c) Transfer of the Human Material outside of the CIMAC-CIDC will require the prior written permission of the Provider and, for NCI-supported Protocols, NCI, as well as an appropriate transfer agreement between the CIMAC-CIDC and the non-CIMAC-CIDC recipient that contains restrictions and obligations that are consistent with this Agreement.

   (d) Provider is responsible for transferring the CLIA form concurrently with the Biospecimens if a CLIA assay is going to be performed on the Biospecimens.

(e) Provider will transfer the Specimen Tracking Manifest to Recipient CIMACs and CIDC as directed by NCI concurrently with the transfer of the Biospecimens.

4. Use of Human Material.

(a) Recipients will ensure that the Human Material will only be used in accordance with the NCI-approved Research Project as specified in Appendix A. For clarity, other than the Clinical Data that is contained in the Specimen Tracking Manifest, the CIMACs will access the Clinical Data only through the CIDC.

(b) Recipients will ensure that Human Material will only be used in compliance with all applicable laws and regulations concerning the use of Biospecimens and Clinical Data, including, as applicable, IRB approval and institutional certification.

(c) Recipients agree to comply with the terms of the CTEP IP Option as it relates to the provision of rights to NCI/Pharma Collaborators to data and inventions generated from the use of the Human Material. Notwithstanding anything to the contrary in this Agreement, Recipients disclaim any liability for NCI/Pharma Collaborator's commercial use of such data or invention.

(d) Recipients agree to:

i. Use appropriate administrative, technical, and physical safeguards to prevent use or disclosure of the Human Material other than as provided for in this Agreement; and

ii. Promptly notify Provider of its discovery of any use or disclosure of the Human Material, of which a Recipient becomes aware, that is not permitted by this Agreement.

(e) Recipient CIMACs will store, for a period as mutually agreed, or destroy or return residual Biospecimens, as requested by Provider, at the conclusion of the Research Project, or on termination of this Agreement.

5. CIMAC Data and Results.

(a) The CIMAC Data will be accessible through the CIDC and available for use by the Provider and the CIMACs that generated the data from the Human Material for the performance of the Research Project or by a CIMAC/CIDC approved by NCI to perform Cross-Trial Analysis.

(b) Each Recipient CIMAC will transfer the CIMAC Data it generates from the Human Material as well as all Results to CIDC promptly after such CIMAC Data or Results are available.

(c) CIDC will be responsible for notifying Provider of the availability of the CIMAC Data and Results from the Recipient CIMACs in the CIDC.

(d) After all RCDE have been provided to CIDC, Provider will, through the CIDC, have access to the available CIMAC Data generated by the Recipient CIMAC(s) from the Human Material, and to the Results generated.

(e) The Recipient CIMACs will have full access to and use of the CIMAC Data and Results, in accordance with this Agreement. Provider will have use of the Results and the CIMAC Data generated from the Human Material without accounting to the other Party(ies) after the expiration of the Exclusivity Period and in compliance with the Sections on Publication and Authorship of this Agreement. Recipients will at all times retain rights to use Results and the CIMAC Data for all purposes in accordance with this Agreement.

(f) The Recipient CIMAC will solely own all CIMAC Data that it generates that is not specifically related to a Research Project (for example, improvements to assays that are not directly related to specific Human Material). Each Recipient CIMAC will have full rights to use the CIMAC Data that it generates that is not specifically related to the Research Project or use of the Human Material (for example, improvements to assays that are not directly related to specific Human Material).

(g) CIDC will transfer Clinical Data, Results, and CIMAC Data to NCI promptly after each data set is complete, but no later than at the time of publication, or, if no publication, then twelve (12) months from the completion of the relevant data set.

(h) The Parties understand that, after the Exclusivity Period and consistent with all NCI and NIH data sharing and public access policies, the CIMAC Data, Clinical Data, and Results provided to the NCI from the CIDC will be made available in controlled-access data archives or data commons for sharing with approved requestors from the general research community.

6. Cross-Trial Analysis.

(a) Cross-Trial Analysis as well as confidential, internal use of data stored within the CIDC is permitted among CIMAC-CIDC Principal Investigators **for purposes of improvement of assay performance or selection of assays**. Each of the Recipients, however, agrees they will not publicly disclose nor permit others to disclose, the results of such data use or Cross-Trial Analysis without the review and approval of NCI to ensure compliance with Human Subjects protections and privacy considerations, except for Publications, which will be reviewed in accordance with the Publication Section below by NCI, the NCI/Pharma Collaborator(s), and Provider.

(b) Cross-Trial Analysis **for research questions**, i.e., beyond purposes of assay improvement/assay selection, will require a written proposal to be approved by NCI, and, if Clinical Data or data generated by the use of Human Material are used, reviewed by the NCI/Pharma Collaborator(s) and approved by the Provider(s). All Publications resulting from any Cross-Trial Analysis will be submitted to NCI for review in accordance with the Publication Section below.

For purposes of Cross-Trial Analysis, all Protocol investigators (and other appropriate members of the Clinical Trial Team) will be considered CIMAC-CIDC investigators and have all the rights and responsibilities described in this agreement related solely to approved Cross-Trial Analysis. Please note that

Protocol investigators will only have access to the Clinical Data, CIMAC Data, and Results specific to the approved Cross-Trial Analysis in which they are participating.

7. Human Subject Protections.

If Recipients receive Identifiable Sensitive Information (ISI) from Provider, or ISI or IPI is ascertained through Recipients' use of the Human Material, or receive the coded Human Material with the key to such ISI or IPI, then Recipients agree to:

(a) Abide by all applicable Human Subjects and other regulations and guidance, which may include:

(i) The Privacy Act of 1974, as amended, at 5 U.S.C. §552a ("Privacy Act"), the Health Information Portability and Accountability Act of 1996 (HIPAA) or other equivalent privacy regulations,

(ii) 45 C.F.R. Part 46, 21 C.F.R. Parts 50 and 56, and FDA Good Clinical Practice Guidelines (ICH E6 Good Clinical Practice: Consolidated Guidance, 62 FR 25692 (1997)), and

(iii) A certificate of confidentiality issued to NIH in accordance with 42 U.S.C 241(d) of the Public Health Service Act,

(b) Maintain any transferred ISI or IPI in a secure manner that restricts access by any individual not involved in the Research Project (e.g., for paper records – locked file cabinets or continual physical presence in a room that locks, or, for electronic records – encryption and password protection); and

(c) Remove or destroy any ISI or IPI at the earliest time at which removal or destruction can be accomplished consistent with the Research Project; and

(d) Make no further use or disclosure of the ISI or IPI unless approved by Provider or required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or State laws requiring the reporting of communicable diseases to State and local health departments), excluding ISI, to the extent that such ISI is immune from the legal process, and is not, without the consent of the Human Subject, admissible as evidence or used for any purpose in any action, suit, or other judicial, legislative, or administrative proceeding; and

(e) Not contact or make any effort to identify Human Subjects, without specific written approval from Provider.

8. Confidential Information.

(a) All Confidential Information disclosed by a disclosing Party that is transferred to a receiving Party under this Agreement will be clearly marked "CONFIDENTIAL" by the disclosing Party, will be used by each receiving Party only to fulfill its obligations under this Agreement, and will be maintained in confidence by each receiving Party for a period of five (5) years from the expiration or termination of this Agreement.

(b) Any Confidential Information that is orally disclosed must be summarized in writing and marked "CONFIDENTIAL" by the disclosing Party and such notice must be provided to the receiving Parties within thirty (30) days of the oral disclosure.

(c) Notwithstanding the foregoing, any failure by a Party to mark documents "CONFIDENTIAL" or to reduce oral disclosures to writing will not relieve the receiving Parties of any obligations herein if by the nature of the information, to a reasonable person under the circumstances it would constitute Confidential Information.

(d) For the avoidance of doubt, Confidential Information includes any unpublished confidential scientific or business information incorporating an Agent provided by the NCI or NCI/Pharma Collaborator.

(e) Consistent with this Article, Confidential Information includes any unpublished confidential scientific or business information involving Human Material.

(f) Confidential Information will not include information provided by a disclosing Party to a receiving Party that:

(i) Has been published or is otherwise publicly available on or before the time of disclosure by the disclosing Party to the receiving Party under this Agreement or was in the possession of or readily available to the receiving Party without, to the best of the receiving Party's knowledge, being subject to a confidentiality obligation from another source prior to the disclosure by the disclosing Party;

(ii) Has become publicly known, by publication or otherwise, not due to any unauthorized act of the receiving Party;

(iii) The receiving Party can demonstrate it developed independently, or acquired without reference to, or reliance upon, such Confidential Information of the disclosing Party; or

(iv) The disclosing Party expressly authorizes, by prior written agreement, the receiving Party to disclose.

(g) IPI and ISI are not considered to be Confidential Information and, notwithstanding any other provision of this Agreement, the obligation to not disclose IPI or ISI to any other entity will be covered by the Article entitled "Human Subject Protections" in this Agreement and, to the extent permissible, will extend indefinitely.

9. Publication.

(a) The Parties agree that all proposed Publications related to the Protocol will be sent to NCI, at NCICTEPpubs@mail.nih.gov, for advisory review and comment by NCI and NCI/Pharma Collaborator at least thirty (30) days before submission for publication for proposed manuscripts and seven (7) days before submission for publication for proposed abstracts or disclosure for presentations or posters. The Recipients will ensure that all disclosures related to the Human Material will

also be forwarded to nciCIMACpubs@mail.nih.gov. NCI will send the submission or disclosure for advisory review and comment by NCI staff, by NCI/Pharma Collaborator, and, during the Exclusivity Period, by the Correlative Study Analysis Team and the Provider. NCI/Pharma Collaborator will have the right to request in writing that a Publication be delayed for up to an additional thirty (30) days from the end of the original 30-day review period in order to ensure that any NCI/Pharma Collaborator's Confidential Information and intellectual property rights are protected.

(b) In all Publications arising from the use of Human Material, each of NCI, NCI/Pharma Collaborator, CIMAC-CIDC, and Provider will be acknowledged unless such entity requests otherwise.

(c) The Parties will ensure that all press releases and other media presentations related to the use of Human Material or to the Research Project will be forwarded to NCI (at NCICTEPpubs@mail.nih.gov, copying nciCIMACpubs@mail.nih.gov) at least five (5) days prior to release for review by NCI, the Provider, the NCI/Pharma Collaborator, and other Parties as needed. No Party may use the name of any other Party or any adaptation thereof in any form of advertising or promotion without the prior written approval of another Party.

10. Authorship.

Correlative studies using CIMAC-CIDC resources are collaborative efforts between the CIMAC-CIDC and the Clinical Trial Team. Criteria for authorship of any publication arising under this Agreement will be determined in accordance with the International Committee of Medical Journal Editors (ICMJE) standards, taking into consideration the relative contributions of the Parties and the applicable Clinical Trial Team(s). The application of the ICMJE standards will be applied through discussion with and agreement of the entire Correlative Study Analysis Team. Additionally, recognition of individual authorship of each contributor will be determined in accordance with the ICMJE standards and agreement of the members of the Correlative Study Analysis Team for each Research Project. The Provider's standard operating procedure (SOP) shall be used for any Publication reporting the primary results of the Clinical Trial when the Provider is leading the Clinical Trial.

11. Warranty.

The Human Material is understood to be experimental in nature and may have hazardous properties. **No Party makes any warranties, express or implied, as to any matter whatsoever, including without limitation, as to the quality, fitness for any particular purpose, merchantability, or noninfringement with regard to any Human Material, Cross-Trial Analysis, CIMAC Data, or Results.** Each Party agrees that a Party providing Human Material, CIMAC Data, or Results will not be held liable for any loss, harm, illness, or other damage or injury (each a "**Liability**") arising from another Party's receipt, handling, use, or disposal of the Human Material, CIMAC Data, or Results except to the extent such Liability arises from or is due to the gross negligence or willful misconduct of the providing Party.

12. Entire Agreement.

This Agreement together with all Appendices constitutes the entire agreement between the Parties with respect to the Human Material to be transferred under this Agreement, and supersedes and replaces all prior agreements, understandings, commitments, communications, and representations made among the Parties, whether written or oral, with respect to the same. This Agreement may not be amended, supplemented, or otherwise modified except by a written agreement executed by authorized representatives of each of the Parties. Headings included herein are for convenience only and will not be used to construe this Agreement. No Party may assign its rights under this Agreement without the prior written consent of the other Parties. Any purported assignment that does not comply with this Section is null and void, *ab initio*.

13. Severability; Waiver.

If any provision of this Agreement is held to be illegal, invalid, or unenforceable, then such illegality, invalidity, or unenforceability will attach only to such provision and will not in any manner affect or render illegal, invalid, or unenforceable any other provision of this Agreement. This Agreement will be carried out as if any such illegal, invalid, or unenforceable provision were not contained herein. No waiver by a Party of any term or condition of this Agreement, no matter how long continuing or how often repeated, will be deemed a waiver of any subsequent act or omission, nor will any delay or omission on the part of any Party to exercise any right, power, or privilege or to insist upon compliance with any term or condition of this Agreement be deemed a waiver of such right, power, or privilege or to excuse any similar subsequent failure to perform any such term or condition. All waivers must be in writing and signed by the Party granting such waiver.

14. Force Majeure.

Nonperformance under this Agreement by any Party shall be excused to the extent that performance is rendered impossible by strike, fire, earthquake, flood, hurricane or other natural disaster, war, insurrection, invasion, hostilities, terrorist threats or acts, riot or other civil unrest, governmental acts or orders or restrictions, national or regional emergencies, failure of suppliers, or any other reason where failure to perform is beyond the reasonable control of the non-performing Party. In such event the affected Party, as the case may be, will promptly notify the other Parties of such inability and of the period for which such inability is anticipated to continue. Without limiting the foregoing, the Party subject to such inability will use reasonable and diligent efforts to minimize the duration of any force majeure event.

15. Term.

This Agreement will remain in force for the term of the NCI Grant or until the Research Project has been completed, whichever occurs first, at which time this Agreement will automatically expire. The term may be extended, and the provisions of this Agreement may be modified only by amendment signed by a duly authorized representative for each Party. This Agreement may be terminated prior to its expiration by any Party for any

reason upon thirty (30) days' written notice to each of the other Parties.

16. Survival.

    All rights and obligations or liabilities that are expressly identified as surviving, or by their nature or context logically survive any expiration or early termination of this Agreement (e.g., Human Subject Protections, Confidential Information, Publication, Authorship, CTEP IP Option), will survive in accordance with their terms to the degree necessary to permit their complete fulfilment or discharge.

17. Independent Contractors.

    No Party has or will have the right to direct or control the activities of any other Party in performing any obligation under this Agreement. The Parties' relationship is that of independent contractors, and nothing in this Agreement establishes or will be deemed to establish a relationship of principal and agent between or among any of the Parties, or between or among any agents or employees of any of the Parties for any purpose whatsoever. This Agreement does not and will not be construed as creating a joint venture, partnership, or any other form of legal association or arrangement which would impose liability upon one Party for the act or failure to act of any other Party. Under no circumstances will any Party be considered an employee or agent of any other Party.

18. Notices.

    All notices required or permitted under this Agreement will be sent by email and will be deemed to have been received when email notification of delivery is received at the email address listed below.

The Parties hereby agree to the terms of this Agreement by having an authorized representative or officer sign or electronically sign below. Each Party is responsible only for their own obligations under the Agreement. This Agreement may be executed in one or more counterparts, each of which together will be deemed original but all of which together will constitute one and the same document. Transmission of an executed counterpart by Portable Document Format (PDF) or other common format electronic file to each of the other Parties will constitute valid execution and delivery of this Agreement. This Agreement will become binding when each Party has executed at least one counterpart.

SIGNATURES

Agreed to by:

RECIPIENTS

Dana-Farber Cancer Institute CIDC

By: _____

Name:
Title:
Email: MTA@dfci.harvard.edu; grantsandcontracts@dfci.harvard.edu; innovation@dfci.harvard.edu;
Phone:
Date:

Dana-Farber Cancer Institute CIMAC

By: _____

Name:
Title:
Email:

Phone:
Date:

Leland Stanford Junior University CIMAC

By: _____

Name:
Title:
Email:
Phone:
Date:

Icahn School of Medicine at Mount Sinai CIMAC

By: _____

Name:
Title:
Email:
Phone:
Date:

The University of Texas MD Anderson Cancer Center CIMAC

By: _____

Name:
Title:
Email:
Phone:
Date:

PROVIDER

<Provider Name>

By: _____

Name:
Title:
Institution:
Email:
Phone:
Date:

Read and Acknowledged by:

Dana-Farber Cancer Institute CIDC
Principal Investigator

By: _____

Name:
Title:
Email:
Phone:
Date:

Dana-Farber Cancer Institute CIDC
Principal Investigator

By: _____

Name:
Title:
Email:
Phone:
Date:

Dana-Farber Cancer Institute CIMAC
Principal Investigator

By: _____

Name:
Title:
Email:
Phone:
Date:

Dana-Farber Cancer Institute CIMAC
Principal Investigator

By: _____

Name:
Title:
Email:
Phone:
Date:

Leland Stanford Junior University CIMAC
Principal Investigator

By: _____

Name:
Title:
Email:
Phone:
Date:

Icahn School of Medicine at Mount Sinai CIMAC
Principal Investigator

By: _____

Name:
Title:
Email:
Phone:
Date:

The University of Texas MD Anderson Cancer Center CIMAC
Principal Investigators

By: _____

Name:
Title:
Email:
Phone:
Date:

By: _____

Name:
Title:
Email:
Phone:
Date:

By: _____

Name:
Title:
Email:
Phone:
Date:

If ETCTN trial:

Protocol <Protocol Number>	**<Name of LAO> LAO**
Principal Investigator	UM1 Grant Principal Investigator
By: _____	By: _____
Name:	Name:
Title:	Title:
Institution:	Institution:
Email:	Email:
Phone:	Phone:
Date:	Date:

Acknowledged by NCI:

_____
Jason Cristofaro, JD, PhD, or Designee
Alternate Technology Development Coordinator
Office of the Director
Division of Cancer Treatment and Diagnosis
National Cancer Institute
Date: _____

Appendix A

Human Material to be Transferred

The following information relates to Biospecimens and Clinical Data (collectively "**Human Material**") that will be transferred from Provider to the CIMAC-CIDC Network under this Agreement, in quantities as mutually agreed by the Parties, for use in the Research Project:

1. **Protocol <Protocol Number> - <** *"Protocol Title"* **>**
2. **Research Project:** CIMAC studies for Protocol <Protocol Number>
3. **Agent used under Protocol:** <Name of Agent>
4. **Collaborator providing Agent:** <Name of NCI/Pharma Collaborator>
5. **Principal Investigator on Protocol:** <Name of Protocol Principal Investigator>
6. **Biospecimens to be transferred:** Biospecimens described in the NCI-approved CIMAC studies for Protocol <Protocol Number>
7. **Clinical Data to be transferred:** Clinical Data collected under the Protocol, as specified in the Definitions of this HMTA, including the Required Clinical Data Elements to carry out the NCI-approved CIMAC studies for Protocol <Protocol Number>

The Parties agree that Human Material transferred pursuant to this HMTA will not be transferred to Recipients, until:

1. All IRB or other approvals and Protocol amendments required for the transfer and use of the Human Material are in place, and
2. NCI written approval for the Research Project has been received by Provider.