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

DRAFT Version: April 24, 2019

The purpose of this Human Material Transfer Agreement ("**Agreement**") is to transfer NCI-sponsored clinical trial biospecimens and associated data from the "**Provider**" (identified on the Signature Page), to one or more of: Dana-Farber Cancer Institute, Inc., Leland Stanford Junior University, the University of Texas MD Anderson Cancer Center, and the Icahn School of Medicine at Mount Sinai (each a "**CIMAC**"); and data related to the biospecimens to Dana-Farber Cancer Institute, Inc. (the "**CIDC**"), (all 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 Provider's authorized signature below ("**Effective Date**").

The Recipients will use the biospecimens and associated data to collaborate with the Provider on correlative studies as described in the Research Project for the Protocol, which used agent(s) from the NCI/Pharma Collaborator(s).

The Parties mutually agree as follows:

I. Definitions:

"**Agent**" means an investigational drug, a biologic, or a product proprietary to a NCI/Pharma Collaborator, that has been made available under an agreement between NCI/Pharma Collaborator and National Cancer Institute (NCI) or a Clinical Trial Network and is used in association with a 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 including, but not limited to, assay output and data on assay validation and performance using clinical trial samples. The CIMAC Data will be jointly owned by the Provider and the CIMAC that generated the data from the Human Material. The CIMAC will own the data they generate that do not relate to a Research Project (for example, improvements to assays that are not directly related to specific Human Material).

"**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 clinical trials.

"**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.

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

"**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 applies to all NCI-supported clinical trials, regardless of the IND sponsor, and to all CIMAC-CIDC Research Projects. All inventions resulting from the Research Projects are subject to 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); 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 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 trial principal investigator (PI), statistician, and translational leaders.

"**Confidential Information**" includes 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.

"**Embargo Period**" means the period during which data generated from a clinical trial supported in whole or in part by NCI will be held in confidence for use only by the Clinical Trial Team, Correlative Study Analysis Team, CIMAC-CIDC Principal Investigators, and any relevant NCI/Pharma Collaborators. The Embargo Period will be in effect until six (6) months after the primary outcome of the trial is either published in manuscript form or, if there is no publication, six (6) months after the results are posted to ClinicalTrials.gov. The Embargo Period may be extended on NCI/Pharma Collaborator request to NCI.

"**Human Material**" means the Biospecimens, and/or any Clinical Data or other information (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 each Letter of Transfer (an example is provided in Appendix A).

"**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/Pharma Collaborator**" means a company that made available its Agent(s) for use in association with the Protocol. This includes agreements with NCI and/or directly with a Clinical Trial Network/Clinical Research Site.

"**Protocol**" means the Institutional Review Board ("IRB")-approved clinical trial under which the Human Material was collected, in which an Agent was administered or dispensed to, or used involving, one or more Human Subjects. It describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The term "Protocol" includes any and all associated documents, including informed consent forms. The Protocol name and number are listed in Appendix A.

"**Provider**" means the Clinical Trial Network/Lead Academic Organization/Clinical Research Site, as applicable, providing, or authorizing the provision of, the Human Material to Recipient. The Provider is identified on the Signature Page.

"**Recipient**" means the CIDC and each CIMAC, as specified above, receiving the Human Material from the Provider.

"**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.

"**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 proposed study 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 under the Research Project.

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

II. Terms and Conditions

1. CIMAC-CIDC Guidelines.

   The Parties agree to use the Human Material, the CIMAC Data, and the Results in accordance with the CIMAC-CIDC Guidelines.

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 before the transfer of any Human Material from the Provider. NCI approval includes the

requirement of review of any agreements between Provider and Pharma Collaborator related to the Human Material, to ensure the terms comply with the CIMAC-CIDC Guidelines.

(b) Biospecimens that are transferred from the Provider to a Recipient will not be redistributed from that Recipient CIMAC to another non-recipient CIMAC unless approved in writing by NCI.

(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 Recipients 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. For clarity, other than in the Specimen Tracking Manifest, the CIMACs will only access the Clinical Data 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 and provide rights to NCI/Pharma Collaborators to data and inventions generated from the use of the Human Material.

(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 CIMAC(s) will store, for a period as mutually agreed; or destroy; or return residual Biospecimens at the conclusion of the Research Project as requested by Provider.

5. CIMAC Data and Results.

(a) Each Recipient CIMAC will transfer the CIMAC Data they generate from the Human Material as well as all Results to CIDC as soon as the data are available.

(b) CIDC will be responsible for notifying Provider of the availability of the CIMAC Data and Results in the CIDC.

(c) After all RCDE have been provided to CIDC, Provider will have access to and use of the CIMAC Data as well as the Results generated from the Human Material through the CIDC. Provider and Recipient will jointly own all rights, title, and interest in and to all such CIMAC Data and Results. Each Party may use such CIMAC Data and Results without accounting to the other Party.

(d) Each Recipient will own the data they generate that is not related to the Research Project.

6. Cross-Trial Analysis.

(a) Cross-Trial Analysis as well as confidential, internal sharing of data between the CIDC and the CIMACs is permitted among CIMAC-CIDC Principal Investigators **for purposes of improvement of assay performance or selection of assays**. The Recipients, however, agree they will not publicly disclose (through Publication or otherwise), nor permit others to disclose, the results of such data sharing or Cross-Trial Analysis without the express, written approval of NCI, and review by the relevant NCI/Pharma Collaborator(s) and Provider(s).

(b) Cross-Trial Analysis **for research questions**, i.e., beyond purposes of assay improvement/assay selection, will require a written proposal to be reviewed and approved by NCI, and, if Clinical Data or Results are used, the relevant NCI/Pharma Collaborator(s), and, during the individual data Embargo Period for each of the Protocols in the Cross-Trial Analysis, 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.

7. Human Subject Protections.

If Recipients receive Identifiable Sensitive Information from Provider, or identifying information ascertained through Recipients' use of the Human Material, or the coded Human Material with the key to such information, 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 information 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 information that may be used to identify a Human Subject 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 information 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 information to be deemed confidential that is transferred between the Parties under this Agreement ("Confidential Information") 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 the 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 providing Party and such notice must be provided to any receiving Party 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 Party(ies) of any obligations herein if by the nature of the information, it would reasonably constitute proprietary or Confidential Information.

(d) Notwithstanding the above, Confidential Information also includes any proprietary or unpublished information incorporating an Agent or a Protocol provided by any of the Parties, the NCI, or NCI/Pharma Collaborator.

(e) Consistent with this Article, Confidential Information includes any information involving Human Material that a Party asserts are confidential and proprietary.

(f) Confidential Information will not include information provided 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.

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

(g) ISI is not considered to be Confidential Information and, notwithstanding any other provision of this Agreement, the obligation to not disclose ISI to any other entity will extend indefinitely.

9. Publication.

(a) The Parties agree that all manuscripts, abstracts, presentations, or posters using data and/or materials derived from NCI-supported clinical trials ("**Publications**") 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. NCI will send the submission or disclosure for advisory review and comment by NCI staff, by NCI/Pharma Collaborator, and, during the Embargo Period, by the Correlative Study Analysis Team and the Clinical Trial Network/ Provider. NCI/Pharma Collaborator will have the right to request that publication be delayed for up to an additional thirty (30) days in order to ensure that NCI/Pharma Collaborator(s)'s Confidential Information and intellectual property rights are protected.

(b) In all oral presentations or written 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) at least five (5) days prior to release for review by NCI 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. All Publications based on CIMAC-CIDC-generated data will recognize this collaboration, through authorship, consistent with the CIMAC-CIDC Guidelines and mutually agreed upon by the Parties.

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 the Human Material, any Cross-Trial Analysis, CIMAC Data, or any Results. Each Party agrees that Provider and NCI will not be held liable for any loss, harm, illness, or other damage or injury (each a "Liability") arising from such Party's receipt, handling, use, or disposal of the Human Material, except to the extent such Liability arises from or is due to the negligence or willful misconduct of Provider and/or NCI.

12. Entire Agreement.

    This Agreement, the NCI-approved Research Project, and the CIMAC-CIDC Guidelines constitute 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 between 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. Term.

    This Agreement will remain in force for the term of the CIMAC-CIDC funding from NCI, 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.

15. 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 will survive in accordance with their terms to the degree necessary to permit their complete fulfilment or discharge.

16. 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.

17. 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

RECIPIENTS

Dana-Farber Cancer Institute CIDC

By: _____
Name:
Title:
Email:
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:

Acknowledged by NCI:

_____
Jason Cristofaro, JD, PhD, or Designee
Intellectual Property Advisor
Office of the Director
Division of Cancer Treatment and Diagnosis
National Cancer Institute

SIGNATURES (continued)

PROVIDER

[Provider Name]

By: _____

Name:

Title:

Institution:

Email:

Phone:

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. **Agent(s) used under Protocol:** [name(s) of investigational agent(s) used in Protocol]
3. **Collaborator(s) providing Agent(s):** [name(s) of Collaborator(s) providing investigational agent(s) to Protocol if any]
4. **Principal Investigator on Protocol:** [name of Principal Investigator listed on Protocol]
5. **Biospecimens to be transferred:** Biospecimens described in the NCI-approved CIMAC studies for Protocol [Protocol number] (see [relevant section] of Protocol [Protocol Number])
6. **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] (see [relevant section] of Protocol [Protocol Number])

Before Human Material is transferred, the Provider agrees that the following will be in place:

1. This executed HMTA between the Provider and Recipients
2. All IRB or other approvals and Protocol amendments required for the transfer and use of the Human Material
3. NCI approval for the Research Project