PACT Guidelines

Guidelines for data access/transfer and publications for supplementary biomarker analyses involving collaboration between the CIMAC-CIDC Network and the Clinical Trial Team/Clinical Trial Network/Sponsors from PACT-supported clinical trials

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Purpose of this document: The purpose of this document ("PACT Guidelines") is to explain the requirements for PACT-funded clinical trials working with the CIMAC-CIDC Network. Specific requirements for sample transfer will be captured in the PACT Human Material Transfer Agreement (HMTA) and/or Research Collaboration Agreement (RCA), which will be negotiated with your institution after official PACT JSC approval. The PACT HMTA and/or RCA will be consistent with the terms contained in the NCI HMTA.

The Cancer Immune Monitoring and Analysis Centers and Cancer Immunologic Data Commons Network is a National Cancer Institute (NCI) Cancer Moonshot initiative. In the Cancer Immune Monitoring and Analysis Centers and Cancer Immunologic Data Commons (CIMAC-CIDC) Network, CIMACs will perform bioassays on biospecimens from PACT-funded clinical trials. This PACT Funded-CIMAC Data will be transferred from the CIMACs to the CIDC, and certain clinical data elements (described in this document) will be extracted and transferred from the PACT-supported Clinical Trial Network/Clinical Research Sites, herein after referred to as "**Provider**", to the CIDC to enable supplementary biomarker analyses. CIMACs and the clinical trial investigators will work together collaboratively to conduct supplementary biomarker analyses. The goal of the CIMAC-CIDC Network is to identify biomarkers with translational potential for optimizing immunotherapeutic strategies for cancer patients.

Note: All PACT-funded clinical trials utilizing the CIMAC-CIDC Network for bioassays, regardless of IND sponsor, or whether the agreement is with FNIH, NCI, or the Clinical Trial Network directly, will be subject to the CTEP IP Option. In the HMTA, CIMACs, CIDC, and Provider agree to comply with the terms of the CTEP IP Option as it relates to the provision of rights to PACT/NCI Collaborators to data and inventions generated from the use of the Human Material. The Provider will be responsible for ensuring that all agreements directly between/among PACT/NCI Collaborators and Provider acknowledge that the PACT Research Project is subject to the terms of these PACT Guidelines and the PACT Human Material Transfer Agreement (HMTA).

This document addresses the following topics:

- Clinical Data and PACT-Funded CIMAC Data transfer to/within the CIMAC-CIDC
- Biomarker data repository and access
- Review process with PACT JSC and PACT Collaborator(s)
- Guidance for authorship of publications involving data deposited into CIDC
- Intellectual property

Important note regarding biospecimen transfers:

Biospecimens should **not** be transferred to the CIMACs until the following occur:

- The PACT JSC has approved the Research Project.
- The PACT Human Material Transfer Agreement (HMTA) has been signed.
- Any required protocol amendments have been approved by the appropriate parties.
- Any Provider/PACT Collaborator agreements related to the Research Project have been reviewed and approved for compliance with the PACT Guidelines and the HMTA.

Definitions:

"Agent" means an investigational drug, biologic, or product proprietary to a PACT/NCI Collaborator, that has been made available under an agreement between PACT/NCI Collaborator and your Institution or your Clinical Trial Network and used in association with the described Protocol.

"Biospecimens" means blood, serum, urine, saliva, other bodily fluid, bone marrow, cells, stool, or tissue samples/specimens collected under a Protocol from Human Subjects. The term "Biospecimen" further includes, without limitation, any tangible material directly or indirectly derived from such Biospecimens collected under a 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. The CIDC serves 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.

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

"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 US Department of Health and Human Services (HHS).

"**CTEP IP Option**" means the CTEP Intellectual Property (IP) Option, which 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 collected from Provider 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 Investigator" means, in accordance with 21 C.F.R. § 312.3, an individual who directs the administration or dispensation of Agent to a Human Subject, and who assumes responsibility for studying the Human Subjects under the Protocol, for recording and ensuring the integrity of research data, and for protecting the welfare and safety of Human Subjects, at a Clinical Research Site.

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

"Clinical Trial Network" means the clinical research sites/networks participating in the Research Project(s). These clinical research sites/networks could include either government, publicly, or privately supported networks.

"Clinical Trial Team" means investigators from the clinical trial and Provider, such as the trial Principal Investigator (PI), statistician, and translational leaders.

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

"**Exclusivity Period**" for the purposes of the applicable HMTA means:

(a) for the Clinical Data: the period beginning on the Effective Data 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 PACT-Funded CIMAC Data and PACT Results: the period ending at the time of publication of such PACT-Funded CIMAC Data and/or PACT Results, or twelve (12) months from the completion of the Research Project, whichever occurs first.

During the Exclusivity Period, Clinical Data, PACT-Funded CIMAC Data and PACT Results will be held in confidence for use only by the Clinical Trial Team, Supplementary Biomarker Analysis Team, CIMAC-CIDC Principal Investigators, and the PACT

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 PACT Collaborator's written request to the PACT JSC and upon showing such an extension is necessary pursuant to a regulatory filing.

"**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 the CIMAC-CIDC. 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 a Clinical Investigator conducting research under the Protocol 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 be readily ascertained. Federal 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 Collaborator" means a company that made available its Agent(s) for use in association with the Protocol(s). This includes agreements with NCI and/or directly with a Clinical Trial Network/Clinical Research Site. When the NCI Clinical Trial Network Protocol is also a PACT-Funded Trial Protocol, the NCI Collaborator will also be a PACT Collaborator.

"**Non-CIMAC Data**" means assay data transferred to the CIDC from an outside (non-CIMAC) lab to be used in the analysis of the PACT-Funded CIMAC Data and/or Clinical Data.

"PACT" is a project developed by a design team of scientists from industry, government, and academics entitled the "Partnership for Accelerating Cancer Therapies (PACT)" for which a research plan has been developed and ratified by the PACT Joint Steering Committee ("PACT JSC"). The PACT Research Plan will leverage recent National Cancer Institute ("NCI") investments in its CIMAC-CIDC Network to provide a systematic approach to immune and related oncology biomarker investigation in clinical trials by supporting development of standardized biomarkers and assays.

"PACT Policies" are set forth in the PACT Research Plan. These PACT Policies will be used as minimum requirements that all participants in the PACT partnership must adhere to; however, the policies will be clarified and extend for specific participants through additional relevant

contractual agreements, this Guidelines document, and generation of future governance documents when the PACT leadership agrees further guidance is required.

“PACT Collaborator” means a company that made available its Agent(s) for use in association with the PACT-Funded Trial Protocol(s). When the PACT-Funded Trial Protocol is also a NCI Clinical Trial Network Protocol, the PACT Collaborator will also be an NCI Collaborator.

"**PACT Donor**" means an organization that has entered or will enter into a separate agreement with the FNIH for funding PACT.

"PACT Funds" means the funds from PACT Donors provided by the FNIH to Institution for the Research to be performed pursuant to the PACT Research Plan.

“**PACT-Funded CIMAC Data**” means CIMAC-generated data supported by PACT Funds that includes, but is not limited to, assay output and data on assay validation and performance using clinical trial samples. The PACT-Funded CIMAC Data will be jointly owned Supplemental Biomarker Analysis Team, including 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.

“PACT-Funded Trial” means a clinical trial that has been selected by the PACT Clinical Trial Selection Working Group and the PACT JSC to have supplementary biomarker analysis supported by PACT Funds.

“PACT JSC” is the PACT Joint Steering Committee, one of the primary governance bodies for PACT, made up of voting members, which include both the NCI and industry partners, whose responsibilities include, but are not limited to, determining allocation of PACT Funds and selecting clinical trials for supplementary biomarker analyses support by PACT.

“PACT JSC-approved” means that a Research Project or other effort requiring PACT Funds has been reviewed by the PACT JSC and received a majority vote of approval to receive a portion of the PACT Funds.

“PACT Proposal Intake Form” means the *PACT Clinical Trial Supplementary Biomarker Assay Proposal Intake Form.* For each clinical trial submitted for PACT Funds consideration, the proposal response submitted in this form is jointly developed by the Clinical Trial Team, PACT Clinical Trial Selection Working Group, and CIMAC-CIDC. This form serves as the basis for 1) internal review by the PACT Clinical Trial Selection Working Group, 2) review and tracking by the CIMAC-CIDC network and 3) review by PACT JSC.

“PACT Research Plan” The document describing the overall scientific aims and governance of PACT, as well as the initial execution guidelines.

"PACT Results" means all information generated by the integrative analysis of the PACT-Funded CIMAC Data and Clinical Data by the Supplemental Biomarker Analysis Team using the Human Material under the Research Project.

"Primary Completion Date" means the date that the last participant in a 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 Institutional Review Board ("IRB")-approved clinical trial under which the Human Material was collected, in which an Agent is administered or dispensed to, or is 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.

"**Provider"** means the Clinical Trial Network/Lead Academic Organization/Clinical Research Site, as applicable, providing, or authorizing the provision of, the Human Material to CIMAC-CIDC.

"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 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 supplemental biomarker studies related to the Protocol described in each PACT Proposal Intake Form submission, which are collaboratively developed by the Supplemental Biomarker Analysis Team. To become a Research Project, the proposal must first be approved by the PACT JSC. That proposal should then become part of the existing Protocol by amendment; or in the case of completed Protocols (i.e., trial is closed, all patients have completed therapy, and trial has met its primary objectives), a stand-alone IRB-approved Protocol.

"**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.

"Supplemental Biomarker Analysis Team" means the collaborative team comprised of the Clinical Trial Team, CIMAC-CIDC investigators, and PACT Collaborator (as applicable) involved in the design and execution of the Research Project.

Guidelines:

1. Collaboration

The work to be performed within the CIMAC-CIDC is a collaboration between the Clinical Trial Team and the CIMAC-CIDC investigators throughout the translational study process, from bioassay selection and supplemental biomarker analyses, to publications.

The senior statistician from the clinical trial will be included among the clinical trial representatives and will collaborate with the CIMAC-CIDC statistician on the supplemental biomarker analyses in which the CIMAC-CIDC is involved.

2. Data Access and Use:

a. Transfer of Clinical Data to the CIDC

Use of the CIMAC-CIDC resource will require the Provider to agree to transfer the Clinical Data to the CIDC. The CIDC is intended to be the Clinical Data repository for trials using the CIMAC-CIDC.

i. **Timing of sending RCDE to CIDC**: To enable correlation of supplemental biomarker analyses with Clinical Data, **all Required Clinical Data Elements (RCDE) must be transferred to the CIDC before the PACT-Funded CIMAC Data can be made available to the Supplemental Biomarker Analysis Team** (i.e. including the Clinical Trial Team). Once the clinical annotation required for CIMAC biomarker correlative analysis is provided to the CIDC, the Supplemental Biomarker Analysis Team (including the Clinical Trial Team) can access the assay data via the CIDC.

ii. **Timing of sending the remaining Clinical Data to CIDC:** Use of the CIMAC-CIDC requires agreement to transfer all Clinical Data to the CIDC as soon as possible following clinical trial database lock or trial completion, but no later than 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 results are posted to ClinicalTrials.gov.

iii. The timing of the transfer of Clinical Data to CIDC will not affect transfer of Clinical Data to the clinical trial's NCI and/or PACT Collaborators.

iv. As the CIDC matures, informatics tools will be developed to streamline data transfer. However, the lack of such tools at the outset should not interfere with the submission of the Clinical Data using existing, available, and agreed-upon transfer tools between Provider and the CIDC.

v. Clinical Data transferred to the CIDC must be kept confidential and are subject to data use restrictions (described in Section 2.c).

vi. The Clinical Data will only be used to perform correlative studies described in Research Projects, or for improvement of assay performance and/or selection of assays.

b. Access to PACT-Funded CIMAC Data, Clinical Data, and PACT Results in CIDC for supplementary biomarker analysis by the Supplementary Biomarker Analysis Team:

i. The CIMACs will ensure that PACT-Funded CIMAC Data are submitted to the CIDC promptly after PACT Funded-CIMAC Data are available, and, if requested, also shared with the PACT JSC or NCI.

ii. The CIDC will serve as the data repository for PACT-Funded CIMAC Data, for Clinical Data, including RCDE, and for the PACT Results, and will provide the informatics platform for the analysis by the Supplemental Biomarker Analysis Team to generate the PACT Results.

iii. The CIDC will be responsible for notifying the Clinical Trial Network/ Clinical Trial Team of the availability of the PACT-Funded CIMAC Data and PACT Results, as soon as they are available in the CIDC. Access to the PACT-Funded CIMAC Data by the Clinical Trial Team may be delayed if any RCDE has not been provided to the CIDC.

iv. The Supplemental Biomarker Analysis Team will use the platform provided by the CIDC to perform their supplementary analyses. The CIDC may also provide analytical tools for data analysis within the CIDC portal and CIDC cloud infrastructure.

v. The PACT-Funded CIMAC Data will be accessible through the CIDC for use in the Research Project by the Supplementary Biomarker Analysis Team.

vi. The CIMAC will have full use of 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).

vii. The Provider will retain ownership of the Clinical Data, including the RCDE.

c. Data Security, Exclusivity Period and Human Subject Protections

i. The Supplemental Biomarker Analysis Team will access the PACT-Funded CIMAC Data, any transferred Clinical Data, and PACT Results within a confidential, secure environment in the CIDC. These data must be kept secure and confidential and comply with data use restrictions as defined below:

- The PACT-Funded CIMAC Data, Clinical Data, and PACT Results should not be released to any entity or individual outside the Supplemental Biomarker Analysis Team or outside of permissible

intra-CIMAC-CIDC network sharing use among CIMAC-CIDC Principal Investigators. (Please see Section 2f, below, regarding the terms of permissible intra-CIMAC-CIDC network data use.)

- All data accessed through the CIDC will be accessed and used only on a device with security controls adequate to protect sensitive identifiable information. Only approved persons will have access to the data, and control over the data will be maintained at all times. Hard copies of any data must similarly be stored under conditions sufficiently secure to avoid inappropriate access and must be shredded prior to discarding.

ii. An Exclusivity Period that will be in effect during which Clinical Data, PACT-Funded CIMAC Data and PACT Results will be held in confidence for use only by the Clinical Trial Team, Supplementary Biomarker Analysis team, CIMAC-CIDC Principal Investigators, and PACT Collaborator(s).

- The Exclusivity Period for Clinical Data is 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.

- The Exclusivity Period for PACT-Funded CIMAC Data and PACT Results is the period ending at the time of publication of such PACT-Funded CIMAC Data and/or PACT Results in accordance with the terms of the applicable HMTA, or twelve (12) months from the completion of the Research Project, whichever occurs first.

The Exclusivity Period may be extended on request by the PACT Collaborator, with PACT JSC approval and upon showing such an extension is necessary pursuant to a regulatory filing.

iii. During the Exclusivity Period, Clinical Data, or PACT Results and PACT-Funded CIMAC Data pertaining to Clinical Data in the CIDC will not be published by CIMAC-CIDC investigators without the permission of the PACT JSC and the Provider.

iv. Prior to the end of the Exclusivity Period, FNIH will contact the PACT Collaborator to see if an extension of the Embargo Period for regulatory filing is required.

v. Following publication of the PACT Results in a manuscript, and while the Exclusivity Period is still in effect, the Supplemental Biomarker Analysis Team may perform additional analyses of the PACT-Funded CIMAC Data or PACT Results with approval from the Clinical Trial Team(s)/Clinical Trial Network and PACT Collaborator(s) (if applicable). These additional analyses will require approval of a submitted a proposal to NCI describing the proposed analyses.

vi. After the Exclusivity Period, the Supplemental Biomarker Analysis Team may use the available data for all other analyses by following the procedures described in section on Data-sharing post-Exclusivity Period, below.

vii. Any analyses of data, and any use of the Clinical Data or PACT Results, that are planned for publication, including via manuscripts and abstracts, will be submitted to the PACT JSC for review and comment by the PACT and/or NCI Collaborator, and, if a proposal is for Cross-Trial Analyses, approval by CTEP, the relevant PACT/NCI Collaborator(s), and the Provider.

viii. CIMAC-CIDC will abide by all applicable regulations regarding Human Subject Protections.

d. Use of data by PACT Collaborator

i. PACT Collaborators have the right to use all Clinical Data, PACT-Funded CIMAC Data, and PACT Results, for internal use and regulatory filings related to the development and commercialization of their Agent(s) (see Section 2h, below).

ii. As appropriate, Provider will share Clinical Data, PACT-Funded CIMAC Data, and PACT Results with PACT Collaborator with notification to PACT JSC/FNIH.

iii. Following publication of the supplementary biomarker data in a manuscript, the PACT Collaborator may perform additional analyses for internal use or that are planned for publication, including via manuscripts, abstracts, or corporate publications, of their PACT-Funded CIMAC Data in coordination with and approval from the Supplemental Biomarker Analysis Team, and notification to the PACT JSC.

e. Data Ownership

i. The Supplemental Biomarker Analysis Team will jointly own the PACT Results, as well as the PACT-Funded CIMAC Data generated 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).

ii. The Provider will retain ownership of the Clinical Data, including the RCDE.

f. Cross-Trial Analysis

Cross-trial Analysis as well as confidential, internal sharing of data stored within the CIDC is permitted among CIMAC-CIDC investigators **for purposes of improvement of assay performance or selection of assays**. They will not, however, publicly disclose nor permit others to disclose, the results of such data use or Cross-Trial Analysis without the review and approval of the PACT JSC to ensure compliance with

Human Subjects protections and privacy considerations, except for Publications, which will be reviewed in accordance with the "Publication guidelines" section below by the PACT JSC, the PACT Collaborator(s) and Provider.

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 data generated by the use of Human Material are used, reviewed by the PACT 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 guidelines" section below.

Following the Exclusivity Period, the PACT-Funded CIMAC Data, Clinical Data, and PACT Results will be submitted to the controlled-access CIDC for sharing with approved requestors from the general research community (see Section 4, below.)

g. Non-CIMAC Data:

For certain trials, Non-CIMAC Data of sufficient quality may be transferred to the CIMAC-CIDC and added to the PACT-Funded CIMAC Data to enhance the supplemental biomarker analyses, depending on the compatibility of the data format and the study objectives. In receiving Non-CIMAC Data, the CIMAC-CIDC would be required to treat the non-CIMAC-Data in the same manner as Clinical Data for the purposes of confidentiality, use, and publication. Non-CIMAC-generated assay data could include prospective or retrospective assay data.

h. Inventions using data generated by use of Human Material from a PACT-Funded Trial

All newly generated IP from the PACT Results or PACT-Funded CIMAC Data will be subject to the CTEP IP Option for Collaborators (described in 3i) due to the use of the NCI-funded CIMAC-CIDC infrastructure.

i. Inventions using data generated by use of Human Material from an NCI - sponsored clinical trial

A responsible approach to management of intellectual property derived from any downstream discoveries that is consistent with the recommendations of the NIH's *Best Practices for the Licensing of Genomic Inventions* and the NIH Research Tools Policy is encouraged.

The management of patent applications in a manner that might restrict use of the joint findings and that could substantially diminish the value and public benefit provided by these resources is discouraged. However, if the Biospecimens proposed for a Research Project are from a clinical trial that was conducted under a binding collaborative agreement with NCI Collaborator, or was otherwise supported by NCI, they are subject to the terms of the CTEP Intellectual Property (IP) Option (http://ctep.cancer.gov/industryCollaborations2/guidelines_for_collaboration.htm) as well as the terms of the CTEP or Clinical Trial Network Collaborative Agreement under

which the study is conducted. Any discoveries from research performed on Biospecimens collected in NCI-supported trials will be subject to the CTEP IP Option.

For avoidance of doubt, an NCI Collaborator who has rights to an invention under the scope of the CTEP IP Option also has the right (a commercial non-exclusive, royalty-free license) to use any data generated in such studies for regulatory filings related to the development and commercialization of Agent.

3. Publication guidelines:

a. <u>Authorship:</u>

Supplemental biomarker studies using the CIMAC-CIDC resources are collaborative efforts between the CIMAC-CIDC network and the Clinical Trial Teams. **All publications based on PACT-Funded CIMAC Data should recognize this collaboration, through authorship, consistent with general authorship guidelines for collaborative work and mutually agreed upon by all parties.** Criteria for authorship will be determined in accordance with the International Committee of Medical Journal Editors (ICMJE) standards, taking into consideration the relative contributions of the parties.

While a given project may have specific arrangements regarding authorship, some general guidelines can be considered, as follows:

i. **Manuscript/abstract on primary clinical outcome in which CIMAC-CIDC work involves PACT-Funded CIMAC Data or PACT Results:** Generally, if ancillary biomarker endpoints are included in the primary manuscript for the clinical outcome, the PIs leading the trial (and the statistician analyzing the trial) will have the lead authorship roles. CIMAC-CIDC investigators will be included as co-authors or co-lead-authors depending on their specific collaboration in accordance to the level of contribution to the research.

ii. **Non-primary-outcome manuscripts/abstracts of the trial in which CIMAC-CIDC work generates the main findings:** For secondary abstracts/manuscripts that report primarily PACT-Funded CIMAC Data or PACT Results, it may be appropriate that CIMAC-CIDC lead investigators/statisticians have the lead or co-lead authorship roles. However, each situation is unique and will have to be agreed upon by all of those collaborating in the study.

iii. **CIMAC-CIDC-initiated Cross-Trial Analysis (i.e., across multiple trials):** Depending on the primary purpose of the Cross-Trial Analysis, the Clinical Trial Network/Clinical Trial Team(s) and CIMAC-CIDC will have to come to agreement on authorship roles. Clinical and CIMAC-CIDC investigators will be included in accordance with their level of contribution to the research.

b. Publications:

All manuscripts, abstracts, presentations, or posters using data and/or materials from clinical trials using Agent(s) provided by PACT Collaborator(s), will be sent to FNIH, c/o Stacey Adam at sadam@fnih.org and Jenny Peterson-Klaus at jpeterson-klaus@fnih.org for advisory review and comment by the PACT JSC and the PACT Collaborator no later than thirty (30) days before submission for proposed manuscripts and seven (7) days before disclosure for proposed abstracts or presentations.

The PACT Collaborator shall have the right to request that publication be delayed for up to an additional thirty (30) days in order to ensure that the PACT Collaborator's confidential and proprietary data, in addition to the PACT Collaborator(s)'s intellectual property rights, are protected.

In all oral presentations or written publications arising from the use of the Human Material from PACT-Funded Trials, PACT-Funded CIMAC Data, or PACT Results, the PACT team (including NCI and industry sponsors), CIMAC-CIDC, PACT Collaborator, and Provider will be acknowledged unless requested otherwise. Acknowledgement language for the PACT team will be provided to each Supplemental Biomarker Analysis Team.

Press releases and other media presentations must also be forwarded to FNIH (at PACT@fnih.org) at least five (5) days prior to release for review and will be shared with NCI CTEP for review and approval by both the PACT and the NCI prior to release.

Note: While PACT Collaborator comments are not binding, authors must address all comments made by PACT Collaborator. However, information proprietary to the PACT Collaborator may be redacted at the PACT Collaborator's request.

4. Data-sharing post-Exclusivity Period

a. The data sharing plans for PACT-Funded Trials will be consistent with the guidelines in the NCI Cancer Moonshot℠ Public Access and Data Sharing Policy: https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/funding/public-access-policy. The Policy applies to all NCI-Supported Cancer Moonshot℠ Research Projects with resulting Publications and Underlying Primary Data, to the extent feasible. The requirements of this Policy are in addition to those requirements and expectations specified under other applicable NIH public access and data sharing policies including but not limited to the NIH Public Access Policy. the NIH Data Sharing Policy, and the Genomic Data Sharing Policy. For additional information, see NIH Sharing Policies and Related Guidance on NIH-Funded Research Resources.

b. At the end of the Exclusivity Period, the PACT-Funded CIMAC Data, Clinical Data, and PACT Results will be available in the controlled-access CIDC for sharing with approved requestors from the general research community. Each requestor will submit a proposal that will be shared with the relevant PACT/NCI Collaborator(s) for a review and comment period of four (4) weeks. Requestors will be required to execute a NCI Data Use Agreement (DUA) prior to receiving the requested data. All such DUAs will

contain terms providing to the PACT/NCI Collaborator: 1) manuscript review, 2) the CTEP IP Option, and 3) the data use rights as granted to the PACT/NCI Collaborator in any applicable agreements with the PACT/NCI Collaborator. A summary of the requests received for the PACT-Funded CIMAC Data, Clinical Data, and/or Results from the Protocol(s) can be provided to the Provider.

c. For cooperative group trials, these requirements are in addition to those for the NCTN/NCORP Data Archive.

d. Data sharing must also comply with the data-sharing requirements as described in the Requests for Applications (RFAs) for the CIMACs and CIDC, found at the links below:
https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-17-005.html
https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-17-006.html

The CIMAC-CIDC institutions and the Provider acknowledge that they have read and understood the PACT Guidelines. The CIMAC-CIDC institutions and Provider acknowledge that adherence to these agreed upon guidelines is a basic tenet and required for appropriate functions of the partnership. To the extent that there is a conflict between the PACT Guidelines and the terms of an applicable HMTA, the terms of the HMTA will control. If the PACT Guidelines are revised and a CIMAC-CIDC institution or Provider does not accept the revised PACT Guidelines, the CIMAC-CIDC institutions or Provider may terminate the applicable HMTA in accordance with the terms of the HMTA.

SIGNATURES

CIDC

By: _____

Name:
Title:
Date:

CIMAC

By: _____

Name:
Title:
Date:

Provider

By: _____

Name:
Title:
Date: