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

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 Human Material Transfer Agreement (HMTA), to which your institution will be asked to formally agree.

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 below) 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 patients.

Note: Data and inventions generated by the CIMAC-CIDC Network are subject to the CTEP IP Option. Therefore, all NCI-supported clinical trials utilizing the CIMAC-CIDC Network for bioassays, regardless of IND sponsor, or whether the agreement is with NCI or the Clinical Trial Network directly, will be subject to the CTEP IP Option as well. The Clinical Trial Network will be responsible for ensuring that all agreements acknowledge that the CIMAC research project is subject to the terms of these CIMAC-CIDC Guidelines and the CIMAC-CIDC Human Material Transfer Agreement (HMTA). Additionally, these agreements must be shared with the NCI CTEP Regulatory Affairs Branch (NCICTEPACG@mail.nih.gov) prior to signature for review and confirmation.

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

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.

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 your described clinical investigation.

"Biospecimens" means blood, serum, urine, saliva, other bodily fluid, bone marrow, cells, stool, or tissue samples/specimens collected from Human Subjects under a Protocol. 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 providing a centralized data repository, optimization of data collection methodologies suitable for immune-related biomarkers, data integration, and a shared infrastructure for integrative and correlative analysis.

"CIMACs" means the four Cancer Immune Monitoring and Analysis Centers, at Dana-Farber Cancer Institute, Stanford University, The University of Texas MD Anderson Cancer Center, and the Icahn School of Medicine at Mount Sinai, who 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.

"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, a component of the US Department of Health and Human Services.

"**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 data and 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 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 that oversee the conduct and coordination of a particular clinical trial. 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.

"**Embargo Period**" means the period during which PACT-Funded CIMAC Data and PACT Results generated from a clinical trial supported by PACT Funds will be held in confidence for use only by the Clinical Trial Team, all CIMAC-CIDC investigators, and PACT Collaborator(s). All PACT-Funded CIMAC Data and PACT Results must be made available in the controlled-access CIDC for sharing with requestors from the general research community simultaneously with publication in manuscript form of the primary Supplementary Biomarker Analysis for the trial or within 6 months after the primary outcome of the trial is published in manuscript form or the results are posted on ClinicalTrials.gov, whichever occurs first. If the primary Supplementary Biomarker Analysis for the trial is included in the primary outcome manuscript, then the data must be made available for broad use within the CIDC simultaneously with that publication. The Embargo Period may be extended on PACT Collaborator request to PACT JSC.

"**Human Material**" means the Biospecimens, and/or any accompanying 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.

"**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 having a collaborative agreement with the NCI or a Network Group to provide 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 assay data supported by PACT Funds that includes, but is not limited to, assay output, data on assay validation and performance using clinical trial samples, and data from Cross-Trial Analysis.

"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 from 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. The supplemental biomarker studies will be described in each PACT JSC-approved PACT Proposal Intake Form. Such biomarkers studies will become part of an existing Protocol (by amendment if trial is ongoing); or, in the case of completed Protocols (trial is closed to accrual and treatment, all patients have completed therapy, and trial has met its primary objectives), a stand-alone Protocol approved by the Provider and PACT Collaborator, when necessary.

"**Protocol**" means the Institutional Review Board ("IRB")-approved clinical investigation 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 Clinical Trial Selection Working Group members (as needed) involved in the design and execution of the Research Project.

Guidelines:

1. 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, Use, and Sharing:**

   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 6 months after the primary outcome of the trial is either published in manuscript form or the results are posted to ClinicalTrials.gov.

iii. 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.

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

v. The Clinical Data will only be used to perform correlative studies described in Research Projects.

b. Access to PACT-Funded CIMAC Data and Clinical data in CIDC for supplementary biomarker analysis with the Clinical Trial Team:

i. CIMAC-CIDC will ensure that PACT-Funded CIMAC Data are submitted to the CIDC.

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 CIMAC-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.

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 Clinical Trial Team may download and use the data from the CIDC, within the restrictions defined below (Section 2.d).

NOTE: CIMACs will not provide bioassay data directly back to the Clinical Trial Team; rather, bioassay data will be accessible through the CIDC.

c. Data Security, Data Sharing, Embargo Period and Human Subject Protections

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

ii. 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. (Please see Section 3f, below, regarding the terms of permissible intra-CIMAC-CIDC network data sharing.)

- All data should be used only on computers and in locations with adequate security controls at all times.

ii. Since most PACT-Funded Trials will use Human Material from existing approved clinical trials from other Clinical Trial Networks/Clinical Research Sites, the CIMAC-CIDC data sharing plans must also comply with the existing data release timelines within these existing Protocol agreements between the Clinical Trial Team and the PACT Collaborator.

Honoring these existing agreements will result in an Embargo Period will be in effect during which PACT-Funded CIMAC Data and PACT Results generated from a clinical trial will be held in confidence for use only by the Clinical Trial Team, all CIMAC-CIDC investigators, and PACT Collaborator(s). The Embargo Period will be in effect until the primary supplementary biomarker analysis for the trial has been published in manuscript form or within 6 months after the primary outcome of the trial is published in manuscript form or the results are posted on ClinicalTrials.gov, whichever occurs first. After which the data must be made available in the controlled-access CIDC for sharing with requestors from the general research community simultaneously with that publication. If the primary supplementary biomarker analysis for the trial is included in the primary clinical trial outcome manuscript, then the data must be made available in the controlled-access CIDC for sharing with requestors from the general research community simultaneously with that publication. The Embargo Period may be extended on PACT Collaborator request to PACT JSC.

iii. During the Embargo Period, Clinical Data from PACT-Funded Trials 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 Embargo 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-Funded CIMAC Data or PACT Results in a manuscript, the CIMAC-CIDC investigators may perform additional analyses of the PACT-Funded CIMAC Data or PACT Results with approval from the relevant Clinical Trial Team(s)/Clinical Trial Network and PACT

Collaborator(s). These additional analyses will require submission of a proposal to NCI for review and approval describing the proposed analyses.

vi. Any analyses of data, including Cross-Trial Analyses, and any use of the Clinical Data, PACT-Funded CIMAC Data, or PACT Results, that are planned for publication, including via manuscripts and abstracts, will be submitted for approval by PACT JSC, and will be subject to the same terms as other Research Projects.

d. Use of data by PACT Collaborator

i. PACT Collaborators have the right to use 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 3h, below).

ii. As appropriate, CIDC team or Provider will share Clinical Data, PACT-Funded CIMAC Data, and PACT Results with PACT Collaborator.

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 Supplementary Biomarker Analysis Team, and notification to the PACT JSC.

e. Data Ownership

i. The CIMAC and Provider will jointly own the PACT Results, as well as the PACT-Funded CIMAC Data generated from the Research Project. The CIMAC(s) will own the data they generate that do not relate to a Research Project.

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

f. Intra-CIMAC-CIDC network sharing of PACT-Funded Trial data

Confidential, internal sharing of data across trials among CIMAC-CIDC investigators for activities described in the PACT JSC-approved Proposal Intake Forms, or for evaluation of assay and biomarker performance, including validation of clinical utility of biomarkers, is permitted. However, CIMAC-CIDC investigators must not publicly disclose (via abstract, manuscript, etc.) any resulting data, or data from a meta-analysis across PACT-Funded Trials, without the express, written approval of the PACT JSC and the PACT Collaborator(s) until the Research Project is completed, and the PACT Results have been published.

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 objectives of study projects. In receiving Non-CIMAC Data, the CIMAC-CIDC would be required to comply with the terms of the agreement(s) associated with the non-CIMAC Data (terms of the agreement would be specific to the situation / source of the data). 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 inventions created using data from PACT-Funded CIMAC Data or PACT Results will adhere to the PACT Intellectual Property Policy ratified within the PACT Research Plan and detailed below.

No PACT partner (defined above as "PACT Donor") or other PACT participant, including a CIMAC-CIDC Network grantee, is obligated to contribute pre-existing intellectual property owned or controlled by it (IP) to the PACT. If a PACT partner or other PACT participant chooses to have their pre-existing IP used in the PACT project, the PACT partner will permit such use, with the limitation that such use is solely for the PACT Project only, without charging a fee. Each PACT partner providing pre-existing IP will notify FNIH and the PACT partners via the PACT JSC if the IP is the subject of a pending patent application(s), an issued patent(s), or is copyright protected.

If a PACT partner or other PACT participant elects to contribute pre-existing IP to the Project, each such PACT partner or other PACT participant will notify FNIH, who will notify the PACT JSC, NCI, and the CIMAC-CIDC network of pending patent applications or issued patents, which the PACT partner owns or has a license to, that may impair the access and free use of PACT-Funded CIMAC Data and PACT Results in the CIDC by the general research community as soon as such PACT partner becomes aware of such pending patent application or issued patent.

PACT partners and CIMAC-CIDC Network grantees agree not to file a patent application(s) claiming inventions that are conceived or reduced to practice in the performance of the Research Project using PACT-Funded CIMAC Data or PACT Results that are not publicly available (a "PACT Invention") except in the rare instance when a consensus of FNIH, PACT JSC, and PACT EC agree that it is in the best interests of the goals of the PACT to do so. If, following this consensus, a PACT partner or CIMAC-CIDC Network grantee files a patent application(s) on a PACT Invention, such PACT partner or CIMAC-CIDC Network grantee shall grant the PACT partners and all CIMAC-CIDC network grantees a fully paid up, royalty free, perpetual, irrevocable, non-exclusive license, without possibility to sub-license, to manufacture, make, have made, produce, reproduce, copy, and use the PACT Invention for their own internal research purposes or for submission to a regulatory authority when seeking marketing authorization of the PACT Invention, and/or on a product insert or other promotional material regarding the PACT Invention after having obtained marketing authorization from a regulatory authority.

The permitted access and use of biospecimens and data created during the PACT project are addressed under the PACT Data Use and Sharing Policies ratified within the PACT Research Plan and further delineated for the purpose of clarification in the preceding sections of this document.

As noted in the PACT Data Use and Sharing Policies, all pre-existing CRADA and/or collaborative clinical trial agreements for use of trial data will be honored ahead of this PACT IP Policy. One example of this would be a NCI/CTEP-sponsored clinical trial that also becomes a PACT-Funded Trial will honor the NCI CTEP IP Option (described 3i).

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.**

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 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) and will be shared with NCI CTEP for review and approval by both the PACT and the NCI prior to release.

Note: PACT Collaborator comments are not binding, authors must make all reasonable efforts to 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-Publication

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 Embargo Period, the PACT-Funded CIMAC Data, Clinical Data, and PACT Results will be available in the controlled-access CIDC for sharing with requestors from the general research community. Each requestor will submit a proposal that will be shared with the relevant PACT/NCI Collaborator(s) for trials being requested for a review and comment period of four (4) weeks. Requestors will be required to sign NCI's 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.

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

c. 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