NATIONAL CANCER INSTITUTE
Division of Cancer Treatment & Diagnosis

CTEP IP Option FAQ

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(Capitalized terms used herein and not otherwise defined will have the meanings given such terms in the CTEP IP Option)

1. What is the scope of the CTEP IP Option? To what studies does it apply?

The IP option applies to all inventions reported or filed from NCI-supported clinical studies, including those under a CTEP IND, a network group IND, or a network group study with a company IND (those studies required to apply the IP Option as a term and condition of their grant received from NCI. The IP Option also applies to inventions reported or filed from NCI-supported non-clinical studies using either investigational agent(s) provided by Collaborator(s) or secondary research using any biospecimens or data generated from such clinical studies using Collaborator(s) investigational agent(s).

2. What is "CTEP-provided Agent" in the IP Option?

For the application of the IP Option, a CTEP-provided Agent can be any investigational agent supplied free of charge by a pharmaceutical company or biotechnology company under a collaborative type of agreement, which may be shipped to CTEP for further distribution or directly to a NCI funded extramural clinical network group for conducting any CTEP-supported clinical studies and/or non-clinical studies.

Note that Agent can be broadly interpreted as drug compounds, assays, or other proprietary materials provided for the NCI supported clinical trials under collaborative agreements.

3. What types of studies may generate an invention that is subject to Section A of the Option?

Any NCI supported clinical studies (including protocol research and protocol-related research) or non-clinical studies using investigational agent(s) provided by Collaborator(s) under a collaborative agreement.

4. What is the intent of the requirement that the inventions "claim the use and/or composition of the Agent" under Section A of the Option? What if the invention reads on a broad class of agents?

The intent of the "claim the use and/or composition" language is to cover inventions developed pursuant to the NCI supported clinical study or non-clinical study, which as shown

in at least one patent claim for such invention uses, incorporates, or embodies the CTEP - provided Agent, or could not be practiced but for the presence of the Agent. Examples of these types of inventions could be new indications for the use of the Agent or an assay that includes the proprietary Agent itself. In the case of broad class inventions, the licensing rights would extend only so far as the Agent itself, i.e., the Collaborator would be offered Section A rights on the invention that is represented by one or a set of claims, which asserts the use and/or composition of its Agent, but Section A rights will not extend to other inventions that do not claim Collaborator's Agent (although Collaborator would retain Section B rights on such inventions).

5. Are the licensing rights under CTEP IP Option all sub-licensable?

A license granted under the CTEP IP Option is not sublicensable unless it is explicitly stated to be sublicensable in the Option (e.g., the commercial, non-exclusive, royalty-free (NERF) license under Section A (i) and (ii)). However, at the time of negotiation the Institution and Collaborator are free to negotiate for such additional rights.

6. What is the intent of the right to sublicense a non-exclusive commercial license for "development purposes" under Section A (i)? Does the reference to "research purposes" under Section B(i) include the development of Collaborator's Agent?

The intent of "development purposes" of the sublicensing clause in Section A(i) is to enable the licensee Collaborator to perform its development and commercialization activities related to its Agent with its development or commercialization partners, manufacturing contractors, and affiliates without undermining the value of the patent(s) owned and reserved by the licensor Institution. In general, we consider "development" activities to include the following: manufacture, marketing, sales, and any other uses related directly to the commercialization of the Collaborator's Agent. The aforementioned sublicensing right would not extend to Collaborator's non-affiliates where the purpose of the sublicense is not directly related to the Collaborator's commercial interests in the Agent.

Similarly, "research purposes" under Section B(i**)** can be interpreted as "research and development purposes" but does not include rights to commercialize the applicable invention.

7. Can diagnostic companies become the Collaborator and enjoy the CTEP IP Option rights?

Yes, a diagnostic company may become a Collaborator ("Assay Collaborator") by providing its proprietary diagnostic product free of charge (other conditions may apply depending on the need of related clinical studies). They're welcome to discuss with NCI CTEP Agreement Coordination Group (ACG) for details of collaboration and agreement mechanisms.

8. What rights in data and inventions would flow back to the Collaborator as the result of an investigator's partnership with a diagnostic company that utilizes the Collaborator's Agent-treated biospecimens and non-publicly disclosed clinical data? What rights of review/approval would Collaborators/CTEP have in such studies?

In regards to review:

CTEP must approve of any studies utilizing data generated from trials using Collaborator's Agent and Agent-treated biospecimen from such trials must be reviewed by Collaborators as well. Investigators should submit a study proposal that would go to the relevant Collaborator(s) for their review and comment. The Collaborators will have 30 days to review and comment. Prior to final CTEP approval of the proposal, the group would have to address any comments raised by the company, it is recommended that such proposing investigator be open to discussion with Collaborator(s) to address any concerns raised in their review. Final decision regarding study design remains with the investigator in the event that there is a conflict.

CTEP must also review and approve any agreement with any third party utilizing biospecimens or data from a NCI supported clinical trial (or a CTEP approved study).

In regards to data and inventions generated from such CTEP approved studies:

The Collaborator will be granted the rights described in the appropriate section of the IP Option by the inventing Institution. The license granted may only extend to the regulatory filings and development of the Collaborator's agent.

9. For a CTEP-approved study, if one Collaborator supplying an investigational agent ("Agent Collaborator") and another Collaborator supplying an investigational, diagnostic assay ("Assay Collaborator") are both involved in a CTEP-approved clinical study, how will the multi-party data and CTEP IP Option rights be exercised among them?

The rights of Assay Collaborator and Agent Collaborator to access and use such multi-party data from a CTEP-approved study will be co-exclusive and reciprocal. Both Collaborators can exclusively or co-exclusively exercise their rights under the Option to inventions made from such study solely for the research and development of their own investigational agent (or assay) involved in the study.

10. What rights under the Option will a diagnostic company who is not an Assay Collaborator but conducts the testing for a correlative study under the protocol of a CTEP-approved study have to provide to the relevant Collaborator? Can the exercise of such licensing rights by Collaborator possibly cause competition with the assay products of the diagnostic company or even block the company from developing its assay products?

Section B rights to the inventions made by a diagnostic company under such correlative studies will be available to the relevant Collaborator, but only for the needs and purposes of developing the Collaborator's own investigational agent. Thus, the Agent Collaborator cannot exercise such rights for developing a competitive diagnostic product.

11. Can the Collaborator negotiate with the Institution (the invention/patent owner) for rights beyond what's described in CTEP IP Option under those licenses?

Yes, but only after the invention arises from and is reported to the NCI. Likewise, in Q13, under a license described in the IP Option Collaborator can enter a good-faith negotiation with the inventing/owning Institution for rights in addition to those provided in the Option, such as the right to sublicense, the right to lead patent prosecution etc.

12. What would be the procedures that Institution follows for the Collaborator to exercise its rights under the CTEP IP Option?

Unless otherwise provided in the Option, each inventing Institution will follow its own institutional polices and standard patenting and licensing procedures when implementing the Option.

Please also note that the IP Option obligates the inventing Institution to report inventions but does not obligate it to file a patent application. However, the Collaborator as the potential licensee can always discuss an acceptable patenting strategy in the interest of both parties with the inventing Institution.

13. If a University (or Institution) decides to seek patent protection in a large number of jurisdictions, will the Collaborator be responsible for paying patent costs in all jurisdictions in order to obtain the commercial NERF ("cNERF")?

In general, it is up to the Collaborator and the Institution to agree on the specific details of any licensing arrangements as long as such arrangements conform to the language promulgated in the CTEP IP Option. In this case, CTEP believes this language may be interpreted as requiring Collaborators to pay patent costs for any jurisdiction in which they seek to exercise their right to a cNERF. This does not, however, obligate the Collaborator to pay for licensing costs in every jurisdiction if they do not wish to exercise their right to a cNERF

in a particular jurisdiction. For example, a university may seek patent protection on an invention in the US and Japan. A Collaborator may elect the cNERF in the US, but not elect the cNERF in Japan. The Collaborator would be responsible for patent costs in the US but not Japan in this instance.