CTEP IP Option – FAQ

1. **What is the scope of the new option? To what studies will it apply?**

The updated IP option will apply to all inventions reported or filed from active studies as of April 1st 2011. We define an active clinical study as any study that is still enrolling and treating patients. We define the end of treatment as the point at which CTEP (or the Collaborator, in certain cases) is no longer shipping drug for that study. Active correlative studies would be those in which the analysis is ongoing.

The new IP option will not apply to studies where accrual and treatment are finished. The option will not apply retroactively to studies that have already been concluded. It will also not apply to inventions on current studies that have already had an invention report filed prior to April 1st.

1. **What is the intent of the requirement that the invention “claim the use and/or composition of the Agent”? 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 that were developed pursuant to the clinical study that use, incorporate or embody the agent, or could not be practiced but for the presence of the agent. Examples of these types of inventions would be: new indications 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 company would be offered Section A rights on embodiments that claim the use and/or composition of their agent, but not extending to embodiments that do not include their agent (although they would retain Section B rights on those embodiments).

1. **What is the intent of right to sublicense non-exclusive commercial license for “development” purposes?**

The intent of “development purposes” of the sublicensability clause is to enable a company to perform commercial activities related to the agent with commercial partners, but not to completely destroy all value of the patent for the inventor. In general we consider “development” activities to include: manufacture, marketing, sales and any other use related directly to the commercialization of the agent. The license would not extend to non-affiliates where the purpose of the sublicense is not directly related to the collaborators commercial interests in the Agent.

1. **What confidentiality protection is provided for CTEP-approved studies?**

Confidentiality provisions are covered in the funding agreements or material transfer agreements that document the transfer of material to third parties and in the initial collaborative agreement between the NCI and the Collaborator. Cooperative group confidentiality guidelines for these studies may be found at: <http://ctep.cancer.gov/industryCollaborations2/guidelines.htm>. These same terms are included in the phase 1 and 2 funding agreements. They address the use of unpublished data and raw data and the rights of the investigators to publish.

1. **Will currently active correlative studies have to go back to companies for review and comment?**

All studies activated under the old IP option/review process will continue as approved. The only change will be that the new IP option will be in force in the event of an invention, if the approved study had an active status as of April 1, 2011.

1. **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 agent treated samples 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 and agent treated samples. Investigators should submit a proposal that would go to the relevant collaborator/collaborators 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 groups be open to discussion with company to address any concerns raised in their review. Final decision regarding study design remains with group in the event that there is a conflict.

In regards to data and inventions generated from such studies:

The Collaborator would be granted a non-exclusive research use license to any invention and a commercial label license (specific to the agent) to any invention required for marketing. The Collaborator would have the right (a cNERF) to use any data generated in such studies for regulatory filings related to the agent as well.

1. **If a University 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 cNERF?**

In general CTEP feels 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 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 company would be responsible for patent costs in the US but not Japan in this instance.